OPTN | UNOS Public Comment Proposal

OPTN/UNOS Pediatric Transplantation Committee

Proposal to Establish Pediatric Training and Experience Requirements in the Bylaws

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Executive Summary

The National Organ Transplant Act (NOTA) requires that the OPTN "recognize the differences in health and in organ transplantation issues between children and adults throughout the system and adopt criteria, policies, and procedures that address the unique health care needs of children."[1] Although pediatric transplantation is an accepted subspecialty within the field of transplantation, the current OPTN Bylaws do not include any requirements in order for programs to be approved to perform pediatric transplants.

As early as 1993, the Membership and Professional Standards Committee (MPSC) has sought guidance from the Pediatric Transplantation Committee in establishing pediatric requirements so it could better assess key personnel applications. 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. By establishing pediatric membership requirements, this proposal contributes to the OPTN Strategic Goals of improving transplant outcomes and promoting patient safety, while protecting access to transplantation.[2]

[1] 42 USC Sec. 274 (b)(2)(M).

[2] http://optn.transplant.hrsa.gov/governance/strategic-plan/

Proposal to Establish Pediatric Training and Experience Requirements in the Bylaws

Affected Policies: 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

Sponsoring Committee: Pediatric Transplantation Committee

Public Comment Period: August 14 – October 14, 2015

What problem will this proposal solve?

The National Organ Transplant Act (NOTA) requires that the OPTN "recognize the differences in health and in organ transplantation issues between children and adults throughout the system and adopt criteria, policies, and procedures that address the unique health care needs of children."[3] For the purposes of this requirement, it provides that "the term 'children' refers to individuals who are under the age of 18."[4] Pediatric transplantation is an accepted subspecialty within the field of transplantation, not unlike the 19 pediatric subspecialties recognized in other areas of medicine. [5] Yet, the current OPTN Bylaws do not include any requirements in order for programs to be approved to perform pediatric transplants. As early as 1993, the Membership and Professional Standards Committee (MPSC) has sought guidance from the Pediatric Transplantation Committee (hereafter, the Committee) in establishing pediatric requirements so it could better assess key personnel applications.

After an intensive two and a half year effort, the Committee first presented the OPTN/UNOS Board of Directors with a proposal on June 1, 2015 (Exhibit A). Although the proposal failed to pass by a majority of the Directors (19-Yes, 16-No, 3-Abstain), the Committee achieved consensus on the need to recognize pediatric transplantation as a subspecialty through pediatric membership requirements. The Board directed the Committee to work with interested stakeholders to revise the proposal to include stratified case volume requirements and submit it for public comment in August 2015.

A surgical case volume requirement is the number of pediatric transplants a surgeon must perform in order to qualify as a primary transplant surgeon. Rather than simply requiring a caseload in patients less than 18 years old, stratifying the case volume requirement means that the surgeon must perform a minimal number of transplants in younger pediatric patients in order to qualify as a primary transplant surgeon.

The proposed key personnel requirements only apply to individuals applying to be the primary transplant surgeon or the primary transplant physician at a designated program that will perform transplants in

[3] 42 USC Sec. 274 (b)(2)(M)
[4] 42 USC Sec. 274 (b)(2)(O)
[5] "Descriptions of Pediatric Subspecialties," Council of Pediatric Subspecialties, accessed January 5, 2015, http://www. pedsubs.org.

patients less than 18 years old. These requirements do not apply to all surgeons that perform pediatric transplants or physicians that care for pediatric transplant patients.

Why should you support this proposal?

This proposal fulfills a longstanding need to define pediatrics as a subspeciality within the field of transplantation. It has been developed through strong clinical consensus involving multiple stakeholders and strikes an appropriate balance between the competing interests of quality of care and access to transplantation. If we assume center volume is an adequate proxy for primary surgeon volume,[6] an estimated 93% of all pediatric transplants from January 1, 2010 to December 31, 2014 were performed at programs that would meet these more robust requirements today (Exhibit B).

The Committee proposes that a designated transplant program must have an approved pediatric component in order to register and perform kidney, liver, heart, and lung 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 organ-specific as follows:

Table 1. Pediatric Kidney Key Personnel Requirements

	Proposed Requirements
Primary Pediatric Kidney Surgeon	• Must meet the requirements for the Primary Kidney Transplant Surgeon in the current OPTN Bylaws, Appendix E.2[7] • Must have performed at least 10 kidney transplants in patients less than 18 years old, including 3 transplants in patients less than 6 years old or weighing less than 25 kilograms at the time of transplant • 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	Must meet the requirements for the Primary Kidney Transplant Physician in the current OPTN Bylaws, Appendix E.3,[8] and have completed at least one of the following training or experience pathways: • 3-year Pediatric Nephrology Fellowship Pathway • 12-month Pediatric Transplant Nephrology Fellowship Pathway • Combined Pediatric Nephrology Training and Experience Pathway

[6] Due to the limitations of OPTN data
[7] Appendix E.2: Primary Kidney Transplant Surgeon Requirements, Organ Procurement and Transplantation Network Bylaws.
[8] Appendix E.3: Primary Kidney Transplant Physician Requirements, Organ Procurement and Transplantation Network Bylaws.

Table 2. Pediatric Liver Key Personnel Requirements

	Proposed Requirements
Primary Pediatric Liver Surgeon	• Must meet the requirements for the Primary Liver Transplant Surgeon in the current OPTN Bylaws, Appendix F.2[9] • Must have performed at least 15 liver transplants in patients less than 18 years old, including 8 transplants in patients less than 6 years old or weighing less than 25 kilograms at the time of transplant • 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	Must meet the requirements for the Primary Liver Transplant Physician in the current OPTN Bylaws, Appendix F.3,[10] and have completed at least one of the following training or experience pathways: • 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

	Proposed Requirements
Primary Pediatric Heart Surgeon	• Must meet the requirements for the Primary Heart Transplant Surgeon in the current OPTN Bylaws, Appendix H.2[11] • Must have performed at least 8 heart transplants in patients less than 18 years old, including 4 transplants in patients less than 6 years old or weighing less than 25 kilograms at the time of transplant • 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	• Must meet the requirements for the Primary Heart Transplant Physician in the current OPTN Bylaws, Appendix H.3[12] • 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, including 4 transplants in patients less than 6 years old or weighing less than 25 kilograms • 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

[9] Appendix F.2: Primary Liver Transplant Surgeon Requirements, Organ Procurement and Transplantation Network Bylaws.
[10] Appendix F.3: Primary Liver Transplant Physician Requirements, Organ Procurement and Transplantation Network Bylaws.
[11] Appendix H.2: Primary Heart Transplant Surgeon Requirements, Organ Procurement and Transplantation Network Bylaws.
[12] Appendix H.3: Primary Heart Transplant Physician Requirements, Organ Procurement and Transplantation Network Bylaws.

Table 4. Pediatric Lung Key Personnel Requirements

	Proposed Requirements
Primary Pediatric Lung Surgeon	• Must meet the requirements for the Primary Lung Transplant Surgeon in the current OPTN Bylaws, Appendix I.2[13] • Must have performed at least 4 lung transplants in patients less than 18 years old, including 1 transplant in a patient less than 12 years old or weighing less than 40 kilograms at the time of transplant • 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	• Must meet the requirements for Primary Lung Transplant Physician in the current OPTN Bylaws, Appendix I.3[14] • Must have current certification in pediatric pulmonary medicine by the American Board of Pediatrics • Must have been directly involved in the primary care of at least 4 lung transplant patients less than 18 years old, including 1 transplant in a patient less than 12 years old or weighing less than 40 kilograms at the time of transplant • 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

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 example, designated liver programs will still be able to perform abdominal multivisceral transplants without separate pancreas transplant program approval.[15]

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 it determines 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.

How was this proposal developed?

The MPSC, the Pediatric Transplantation Committee, and others have attempted to define a pediatric program. For 20 years, efforts have failed because of an inability to reach consensus on proposed 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 (including the American Society of Transplantation (AST), the American Society of Transplant Suregons (ASTS), and the International Society for Heart and Lung Transplantation (ISHLT)), and the community.

In June 2015, the Board directed the Committee to work with interested stakeholders to revise its proposal to include stratified case volume requirements (see "What problem will this proposal solve?"). In

[13] Appendix I.2: Primary Lung Transplant Surgeon Requirements, Organ Procurement and Transplantation Network Bylaws.
[14] Appendix I.3: Primary Lung Transplant Physician Requirements, Organ Procurement and Transplantation Network Bylaws.
[15] Appendix D.2: Designated Transplant Program Requirement, Organ Procurement and Transplantation Network Bylaws.

response, the Committee Chair convened a joint OPTN-ASTS working group to develop stratified case volume requirements for the primary pediatric kidney and liver surgeons. Both groups independently developed criteria, which were very similar. The group quickly reached consensus on surgical case volume requirements in patients less than 18 years old, which would then be stratified to require a caseload of patients less than 6 years old or weighing less than 25 kilograms at the time of transplant. The surgeon 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).

Members of the Pediatric Transplantation Committee who participated in the joint working group reached out to colleagues in the thoracic community to develop the stratified case volume requirements for pediatric heart and lung key personnel. Unlike primary kidney and liver physicians, pediatric fellowship or training and experience pathways do not exist in the current Bylaws for primary heart and lung physicians. Working with these stakeholders, the Committee developed organ-specific, stratified case volume requirements for the primary pediatric thoracic surgeons and physicians. The stratification for lung patients was set at less than 12 years old or 40 kilograms to protect access to transplantation, since only an estimated 79% of pediatric transplants were performed at programs that met a stratified caseload of at least one patient less than 6 years old or 25 kilograms (versus 89% under the proposed requirements). Thoracic key personnel can also 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).

Pediatric key personnel must meet the current Bylaw requirements for key personnel in addition to pediatric subspeciality requirements. Some professionals expressed concern that key personnel at predominantly pediatric programs with low volumes may have difficulty meeting the current primary lung caseload requirements. These key personnel currently have the option of pursuing approval under the alternative pathway for predominantly pediatric programs, which these proposed pediatric Bylaws will replace. The Committee discussed this concern in the spring of 2014 when developing its initial proposal. Since 2003, the alternative pathway has been used 20 times across all organ programs, the majority of which were heart. After considering the infrequent use of this pathway, and in the interest of maintaining a consistent standard for pediatric primary surgeons and physicians, the Committee decided not to amend the requirements. However, the Committee plans to solicit additional feedback on these proposed requirements from the MPSC, thoracic transplant professionals, and professional organizations during public comment.

On July 15, 2015, the Pediatric Transplantation Committee voted to approve the proposal for public comment (14-Yes, 0-No, 0-Abstain).

Earlier History of Stratified Case Volume Requirements

This is not the first time in the history of this project that the Committee has considered stratified case volume requirements. In the fall of 2013, the Committee presented initial requirements that included stratified case volumes at the regional meetings. These requirements were far more restrictive than the current proposal. For example, the primary pediatric kidney surgeon had to perform 6 kidney transplants in patients weighing 20 kilograms or less at time of transplant, and the primary pediatric liver surgeon had to perform 9 liver transplants in patients less than 12 years old and five technical variants, including split, reduced, or living donor liver transplants. The surgeons also had to achieve the required caseloads within a recent five-year period. Those initial requirements were met with overwhelming concern for access to transplantation for pediatric patients. In response to community feedback, the Committee made significant modifications to the proposal to protect access for pediatric patients, including removing the stratified caseloads.

Although the current proposal reintroduces stratified caseload requirements, this proposal strikes a more appropriate balance between quality of care and access to transplantation. The proposed case volumes by organ are lower overall than those considered in 2013 and are roughly proportionate to the frequency of transplant in these age groups. 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). Programs may still 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 primary pediatric liver surgeon also does not have to perform a required number of technical variant liver transplants, including reduced, split, and living donor transplants. The work group consider including technical variant requirements, but decided against it after learning of several large pediatric programs that perform few technical variant liver transplants due to adequate access to size-matched, deceased donor organs.

How well does this proposal address the problem statement?

Historically the required number of transplants the primary surgeon must perform in order to demonstrate pediatric experience has been 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.[16,17,18,19] 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 all OPTN membership requirements involving case volume, these pediatric component requirements have been developed through clinical consensus. By stratifying the case volume requirements for key personnel, this proposal better reflects the training and experience necessary to provide care for younger pediatric patients. Through consensus, this stratification was set at less than 6 years old or an associated weight of less than 25 kilograms. This age and weight stratification encompasses a group of younger pediatric patients with medical complexities and psychosocial needs requiring specialized training and experience. This stratification was increased to less than 12 years old or less than 40 kilograms for lung patients to protect access to transplantation.

The purpose of these requirements is to establish criteria for membership. Experienced key personnel are one of many contributors to a successful transplant program, and these requirements do not have to be associated with improved transplant program outcomes to serve their purpose. However, in an effort to build consensus, the Committee investigated outcomes data. A descriptive analysis of OPTN data of pediatric transplants performed during 2002-2011 showed significantly better unadjusted Kaplan-Meier graft and patient survival within five years of transplant for kidney and liver transplants and significantly better patient survival within five years for lung transplants at centers meeting the proposed pediatric case volume requirements compared to transplants performed at centers not meeting the proposed pediatric case volume requirements. While pediatric heart transplants performed at centers meeting the proposed pediatric case volume requirements also had better patient survival, the difference was not statistically significant. Although these analyses were performed based on transplant program volumes as opposed to primary surgeon volumes, the results suggest that higher volume is associated with better post-transplant outcomes. (Exhibit C)

The Committee is also satisfied that the current proposal better balances the competing interests of quality of care and access to transplantation. From January 1, 2010 through December 31, 2014, 93% of pediatric transplants were performed at programs that would have met the proposed pediatric volume

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[16] 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.
[17] 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.
[18] 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.
[19] 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.

criteria (Exhibit B).[20] 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 (Exhibit D).

Which populations are impacted by this proposal?

By establishing pediatric training and experience requirements for key personnel, this proposal seeks to promote safety and quality of care for all pediatric candidates and recipients. It achieves this without adversely affecting pediatric access to transplantation (Exhibits B and D).

This proposal impacts any designated transplant program that performs kidney, liver, heart, or lung transplants in patients less than 18 years old. To be approved for a pediatric component, the program must identify a qualified primary pediatric surgeon and a qualified primary pediatric physician to serve as key personnel. The proposed requirements only apply to these individuals applying to be key personnel. These requirements do not apply to all surgeons that perform pediatric transplants or physicians that care for pediatric transplant patients.

How does this proposal support the OPTN Strategic Plan?

1. *Increase the number of transplants:* Since access to transplantation is protected, it follows that the overall number of transplants performed will not be negatively impacted (Exhibits B and D).

2. *Improve equity in access to transplants:* The Committee made significant modifications to the proposed case volume requirements in an effort to protect access to transplantation for pediatric patients. An estimated 93% of all pediatric transplants from January 1, 2010 to December 31, 2014 were performed at programs that would meet the proposed pediatric volume criteria today (Exhibit B). In general, programs that do not currently meet the case volume requirement are located near those that do, ensuring equitable access geographically to pediatric transplantation (Exhibit D).

3. *Improve waitlisted patient, living donor, and transplant recipient outcomes:* A descriptive analysis of OPTN data of pediatric transplants performed during 2002-2011 showed significantly better unadjusted Kaplan-Meier graft and patient survival within five years of transplant for kidney and liver transplants and significantly better patient survival within five years for lung transplants at centers meeting the proposed pediatric case volume requirements compared to transplants performed at centers not meeting the proposed pediatric case volume requirements. While pediatric heart transplants performed at centers meeting the proposed pediatric case volume requirements also had better patient survival, the difference was not statistically significant. Although these analyses were performed based on transplant program volumes as opposed to primary surgeon volumes, the results suggest that higher volume is associated with better post-transplant outcomes. (Exhibit C)

4. *Promote living donor and transplant recipient safety:* Although pediatric transplantation is an accepted subspecialty within the field of transplantation, the current OPTN Bylaws do not include any requirements in order for programs to be approved to perform pediatric transplants. In 2012, the Board included developing separate program requirements for pediatric programs as a key patient safety initiative in the OPTN/UNOS Strategic Plan. As early as 1993, the MPSC has sought guidance from the Pediatric Transplantation Committee so it could better assess key personnel applications. This proposal addresses this need by removing the current alternative pathways for predominantly pediatric programs from the Bylaws and creating well-defined pediatric requirements.

[20] Due to the limitations of OPTN data, center volume must be used as a proxy for primary surgeon volume.

5. *Promote the efficient management of the OPTN:* No expected impact on this goal.

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

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.

How will the OPTN implement this proposal?

If approved by the OPTN/UNOS Board of Directors, 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 Board's adoption of these proposed changes. During this time, the OPTN 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 UNet^{SM} and the UNOS membership database. The OPTN must also submit the pediatric component application forms to the Office of Management and Budget (OMB) for approval. Upon completion of programming and OMB-approval of the application forms, there will be a 90-day period for members to submit OPTN transplant program pediatric component applications. The proposed Bylaws will be slated for implementation 18 months after the conclusion of the 90-day pediatric component application submission period. During these 18 months, the OPTN 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. The OPTN 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 IT provides cost estimates for each public comment proposal that will require programming to implement. The estimates can be small (108-419 hrs.), medium (420-749 hrs.), large (750-1,649 hrs.), very large (1,650-3,999), or enterprise (4,000-8,000). The IT estimate for this proposal is large.

How will members implement this proposal?

The OPTN 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. 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 the OPTN. 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.

Will this proposal require members to submit additional data?

To be approved for a pediatric component, a designated transplant program must submit an application. The form will be similar to existing transplant program applications. New information collection will be limited to the training and experience qualifications of the pediatric key personnel, as detailed in this proposal. Consistent with the OPTN Principles of Data Collection, additional data collection will be limited to only that which is necessary to "determine if institutional members are complying with policy."

How will members be evaluated for compliance with this proposal?

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 UNet^{SM} may be subject to OPTN review, and members are required to provide documentation as requested.

Policy or Bylaw Language

Proposed new language is underlined and (example) and language that is proposed for removal is struck through (~~example~~).

Appendix E: Membership and Personnel Requirements for Kidney Transplant Programs

E.2 Primary Kidney Transplant Surgeon Requirements

~~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 Recipients Less than 18 Years Old

A designated kidney transplant program that performs transplants in recipients less than 18 years old at the time of transplant 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 10 kidney transplants, as the primary surgeon or first assistant, in recipients less than 18 years old at the time of transplant. At least 3 of these kidney transplants must have been in recipients less than 6 years old or weighing less than 25 kilograms at the time of transplant. 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 recipient's date of birth, the recipient's weight at transplant if less than 25 kilograms, 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 within the last 2 years. This includes the management of pediatric patients with end stage renal disease, the selection of appropriate pediatric recipients for transplantation, donor selection, 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:

- 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

b. The surgeon has performed at least 5 kidney transplants, as the primary surgeon or first assistant, in recipients less than 18 years old at the time of transplant. At least 1 of these kidney transplants must have been in recipients less than 6 years old or weighing less than 25 kilograms at the time of transplant. 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 recipient's date of birth, the recipient's weight at transplant if less than 25 kilograms, 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 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, 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.~~5~~6 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 Recipients Less than 18 Years Old

A designated liver transplant program that performs transplants in recipients less than 18 years old at the time of transplant 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 15 liver transplants, as the primary surgeon or first assistant, in recipients less than 18 years old at the time of transplant. At least 8 of these liver transplants must have been in recipients less than 6 years old or weighing less than 25 kilograms at the time of transplant. 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 recipient's date of birth, the recipient's weight at transplant if less than 25 kilograms, 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:

- The formal 2-year transplant fellowship pathway as described in SectionF.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

b. The surgeon has performed at least 7 liver transplants, as the primary surgeon or first assistant, in recipients less than 18 years old at the time of transplant. At least 2 of these liver transplants must have been in recipients less than 6 years old or weighing less than 25 kilograms at the time of transplant. 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 recipient's date of birth, the recipient's weight at transplant if less than 25 kilograms, 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 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.~~6~~7 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 Recipients Less than 18 Years Old

A designated pancreas transplant program that performs transplants in recipients less than 18 years old at the time of transplant 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 Recipients Less than 18 Years Old

A designated heart transplant program that performs transplants in recipients less than 18 years old at the time of transplant 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 recipients less than 18 years old at the time of transplant. At least 4 of these heart transplants must have been in recipients less than 6 years old or weighing less than 25 kilograms at the time of transplant. 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 recipient's date of birth, the recipient's weight at transplant if less than 25 kilograms, 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 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 recipients less than 18 years old at the time of transplant. At least 4 of these heart transplants must have been in recipients less than 6 years old or weighing less than 25 kilograms at the time of transplant. 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, the recipient's date of birth, the recipient's weight at transplant if less than 25 kilograms, and medical record number or other unique identifier that can be verified by the OPTN Contractor.
3. The physician has maintained a current working knowledge of pediatric heart transplantation, defined as direct involvement in pediatric heart transplant patient care within the last 2 years. This includes the care of acute and chronic heart failure, donor selection, the use of mechanical circulatory support devices, recipient selection, pre- and post-operative hemodynamic care, post-operative immunosuppressive therapy, histological interpretation and grading of myocardial biopsies for rejection, and long-term outpatient follow up.

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:
        - The formal cardiothoracic surgery residency pathway, as described in Section H.2.A: Cardiothoracic Surgery Residency Pathway
        - The 12-month heart transplant fellowship pathway, as described in Section H.2.B: Twelve-month Heart Transplant Fellowship Pathway
        - 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 recipients less than 18 years old at the time of transplant. At least 1 of these heart transplants must have been in recipients less than 6 years old or weighing less than 25 kilograms at the time of transplant. 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 recipient's date of birth, the recipient's weight at transplant if less than 25 kilograms, 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 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 recipients less than 18 years old at the time of transplant. At least 1 of these heart transplants must have been in recipients less than 6 years old or weighing less than 25 kilograms at the time of transplant. 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, the recipient's date of birth, the recipient's weight at transplant if less than 25 kilograms, and medical record number or other unique identifier that can be verified by the OPTN Contractor.
    c. The physician has maintained a current working knowledge of pediatric heart transplantation, defined as direct involvement in pediatric heart transplant patient care within the last 2 years. This includes the care of acute and chronic heart failure, donor selection, the use of mechanical circulatory support devices, recipient selection, pre- and post-operative hemodynamic care, post-operative immunosuppressive therapy, histological interpretation and grading of myocardial biopsies for rejection, and long-term outpatient follow up.

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 I.2.A* through *I.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 I.3.A* and *I.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 Recipients Less than 18 Years Old

A designated lung transplant program that performs transplants in recipients less than 18 years old at the time of transplant 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 recipients less than 18 years old at the time of transplant. At least one of these lung transplants must have been in a recipient less than 12 years old or weighing less than 40 kilograms at the time of transplant. 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 recipient's date of birth, the recipient's weight at transplant if less than 40 kilograms, 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 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 following requirements:

1. The physician meets *all* of the requirements described in *Section I.3: Primary Lung Transplant Physician Requirements* and individual must have current board certification in pediatric pulmonary medicine by the American Board of Pediatrics.

2. The physician has been directly involved in the primary care of at least 4 lung transplant recipients less than 18 years old at the time of transplant. At least one of these lung transplants must have been in a recipient less than 12 years old or weighing less than 40 kilograms at the time of transplant. 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, the recipient's date of birth, the recipient's weight at transplant if less than 40 kilograms, and medical record number or other unique identifier that can be verified by the OPTN Contractor.
3. The physician has maintained a current working knowledge of pediatric lung transplantation, defined as a 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, recipient selection, pre- and postoperative ventilator care, postoperative immunosuppressive therapy, histological interpretation and grading of lung biopsies for rejection, and long-term outpatient follow up.

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 recipients less than 18 years old at the time of transplant. 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 recipient's date of birth, 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 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 following requirements:
   a. The physician meets *all* of the requirements described in *Section I.3: Primary Lung Transplant Physician Requirements* and has current board certification in pediatric pulmonary medicine by the American Board of Pediatrics.
   b. The physician has been directly involved in the primary care of at least 2 lung transplant recipients less than 18 years old at the time of transplant. 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, the recipient's date of birth, and medical record number or other unique identifier that can be verified by the OPTN Contractor.
   c. The physician has maintained a current working knowledge of pediatric lung transplantation, defined as a 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, recipient selection, pre- and postoperative ventilator care, postoperative immunosuppressive therapy, histological interpretation and grading of lung biopsies for rejection, and long-term outpatient follow up.

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 lung 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 I.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*.

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BRIEFING PAPER **OPTN/UNOS**

Proposal to Establish Pediatric Training and Experience Requirements in the Bylaws

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BRIEFING PAPER **OPTN/UNOS**

Title: Proposal to Establish Pediatric Training and Experience Requirements in the Bylaws

Sponsoring Committee: Pediatric Transplantation Committee

Summary and Goals of the Proposal

The National Organ Transplant Act (NOTA) requires that the OPTN "recognize the differences in health and in organ transplantation issues between children and adults throughout the system and adopt criteria, policies, and procedures that address the unique health care needs of children."[1] Although pediatric transplantation is an accepted subspecialty within the field of transplantation, the current OPTN Bylaws do not include any requirements in order for programs to be approved to perform pediatric transplants. As early as 1993, the Membership and Professional Standards Committee (MPSC) has sought guidance from the Pediatric Transplantation Committee in establishing pediatric requirements so it could better assess key personnel applications. 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

NOTA requires that the OPTN "recognize the differences in health and in organ transplantation issues between children and adults throughout the system and adopt criteria, policies, and procedures that address the unique health care needs of children."[1] It also provides for the purposes of this requirements that "the term 'children' refers to individuals who are under the age of 18."[2] Pediatric transplantation is an accepted subspecialty within the field of transplantation, not unlike the 19 pediatric subspecialties recognized in other areas of medicine.[3] Yet, the current OPTN Bylaws do not include any requirements in order for programs to be approved to perform pediatric transplants. As early as 1993, the MPSC has sought guidance from the Pediatric Transplantation Committee (hereafter, the Committee) in establishing pediatric requirements so it could better assess key personnel applications.

The Proposal

The Committee proposes that a designated transplant program must have an approved pediatric component in order to register and 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:

[1] 42 USC Sec. 274 (b)(2)(M).
[2] 42 USC Sec. 274 (b)(2)(O).
[3] "Descriptions of Pediatric Subspecialties," Council of Pediatric Subspecialties, accessed January 5, 2015, http://www. pedsubs.org.

Table 1. Pediatric Kidney Key Personnel Requirements

Primary Pediatric Kidney Surgeon	• 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	Must meet current Bylaws for Primary Kidney Physician and have completed at least one of the following training or experience pathways: • 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	• 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	Must meet current Bylaws for Primary Liver Physician and have completed at least one of the following training or experience pathways: • 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	• 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	• Must meet current Bylaws for Primary Heart Physician • 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

Table 4. Pediatric Lung Key Personnel Requirements

Primary Pediatric Lung Surgeon	• 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	• 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.[4]

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 it determines 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 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 proposed 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 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

[4] Appendix D.2: Designated Transplant Program Requirement, Organ Procurement and Transplantation Network Bylaws

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 from the professional societies, 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. Most attendees requested that the Committee consider modifications to the proposed requirements to preserve access to pediatric transplantation. 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 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 input from the Thoracic Organ Transplantation Committee, thoracic caseloads have been reduced to accommodate the smaller frequency of pediatric heart and lung transplantation. In the spring of 2014, the Committee shared the modified requirements in an update at the regional meetings.

While these provisions were made in the interest of access, the Committee decided not to restrict the pediatric component requirements to programs that perform transplants in young pediatric and infant patients. NOTA specifically states that for the purposes of addressing the unique health care needs of children though the transplantation system, “the term ‘children’ refers to individuals who are under the age of 18.”[5] Defining a pediatric patient as less than 18 years old is also consistent with the Centers for Medicare and Medicaid Services and the American Academy of Pediatrics. The Committee is also concerned that any alternative to the definition of a pediatric patients as less than 18 years old in the Bylaws could have implications for allocation policy, where currently most candidates registered prior to 18 years old receive pediatric priority.

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

[5] 42 USC Sec. 274 (b)(2)(O).

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 the months prior to public comment in January 2015, the Committee 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 task force also suggested that the Committee not pursue pediatric membership requirements until the ASTS fellowship training committee completes pediatric requirements for abdominal transplantation, but acknowledged that these requirements would not be available in the short term.

The Committee considered the ASTS task force's feedback and decided to advance the project. The MPSC has asked for guidance from the Pediatric Committee in establishing pediatric requirements so it could better assess key personnel applications. The proposed requirements for the primary pediatric surgeon represent an experience, not a fellowship, pathway. Once the ASTS has finalized its pediatric fellowship training requirements for abdominal transplantation, the Pediatric Committee has expressed interest in adopting them into the OPTN Bylaws.

On December 10, 2014, the MPSC reviewed 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 considered. 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).

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 all OPTN membership requirements involving case volume, these pediatric component requirements have been developed through clinical consensus.

The purpose of these requirements is to establish criteria for membership; therefore, the Committee does not have to demonstrate improved outcomes associated with these requirements. However, in an effort to build consensus, the Committee investigated outcomes data. 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 B-D). 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 E). Additionally, adjusted analyses that were performed independently by UNOS showed that as a group, centers performing <18 pediatric liver transplants during 2000-2010 had an increased risk of graft loss and death within 5 years (i.e., worse outcomes) as compared to centers performing 18+ pediatric liver transplants during that period; and centers that performed <12 pediatric kidney transplants during 2000-2010 had an increased risk of graft loss and death within 5 years (i.e., worse outcomes) as compared to centers that performed 12+ pediatric kidney transplants during that period (Exhibit F-G).

The Committee is also satisfied that the current proposal better balances the competing interests of quality of care and access to transplantation. From January 1, 2005 through July 31, 2014, 97.7% of pediatric transplants were performed at programs that would have met the proposed pediatric volume criteria (Exhibit H).[10] 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 I-L).

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.

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.

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[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.
[10] Due to the limitations of OPTN data, center volume must be used as a proxy for primary surgeon volume.

Expected Impact on OPTN Key Goals 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. Based on the outcomes analysis performed, the Committee also has evidence that the proposal supports Goal 3, improving patient and graft survival for pediatric transplant recipients.

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 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 approved by the Board, 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 UNet^{SM} 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 inform members of any changes to the Bylaws through a standard Policy Notice. 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 UNet^{SM} may be subject to OPTN review, and members are required to provide documentation as requested.

Bylaw Proposal:

At a meeting of the OPTN/UNOS Board of Directors convened on June 1-2, 2015 in Atlanta, Georgia, the following resolution is offered.

A resolution to establish pediatric training and experience requirements in the Bylaws.

Sponsoring Committee: Pediatric Transplantation Committee

RESOLVED, that additions and changes to Appendix E.2 (Primary Kidney Transplant Surgeon Requirements), Appendix E.3 (Primary Kidney Transplant Physician Requirements), Appendix E.5 (Kidney Transplant Programs that Perform Transplants in Patients Less than 18 Years Old), Appendix F.2 (Primary Liver Transplant Surgeon Requirements), Appendix F.3 (Primary Liver Transplant Physician Requirements), Appendix F.6 (Liver Transplant Programs that Perform Transplants in Patients Less than 18 Years Old), Appendix G.2 (Primary Pancreas Transplant Surgeon Requirements), Appendix G.3 (Primary Pancreas Transplant Physician Requirements), Appendix G.8 (Pancreas Transplant Programs that Perform Transplants in Patients Less than 18 Years Old), Appendix H.2 (Primary Heart Transplant Surgeon Requirements), Appendix H.3 (Primary Heart Transplant Physician Requirements), Appendix H.4 (Heart Transplant Programs that Perform Transplants in Patients Less than 18 Years Old), Appendix I.2 (Primary Lung Transplant Surgeon Requirements), Appendix I.3 (Primary Lung Transplant Physician Requirements), and Appendix I.4 (Lung Transplant Programs that Perform Transplants in Patients Less than 18 Years Old), modified as set forth below, are hereby approved, effective pending implementation and notice to members.

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.~~5~~6 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 *SectionF.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 *SectionF.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.~~6~~7 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 I.2.A* through *I.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 I.3.A* and *I.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 lung 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 I.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*.

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Public Comment Responses

1. Public Comment Distribution

Date of distribution: January 27, 2015
Public comment end date: March 27, 2015

2. Primary Public Comment Concerns/Questions

The Committee received support for this proposal from pediatric specialists, including organizations such as the American Society of Nephrology (ASN), the American Society of Pediatric Nephrology (ASPN), the North American Pediatric Renal Trial and Collaborative Studies, the Studies of Pediatric Liver Transplantation (SPLIT), as well as parents and family members of pediatric transplant patients. Transplant professionals supportive of the proposal voiced appreciation for defining the widely-accepted subspecialty of pediatrics in the Bylaws, as well as for establishing a standard of quality and safety for all pediatric patients. Parents expressed an expectation that these quality and safety standards exist, as well as a desire for all children to receive care from highly-qualified individuals who understand their unique needs.

However, despite the Committee's efforts to build consensus for proposed requirements, many recurrent themes emerged from public comment. These include that the proposal:

- Lacks evidence of a patient safety concern
- Cannot define a pediatric patient as less than 18 years old
- Lacks evidence to support the proposed caseload requirements
- Limits access to transplantation for pediatric patients
- Needs to stratify caseload requirements by age, weight, and other clinical factors.

During its April 14, 2015 meeting in Chicago, the Committee considered all public comment feedback. Its responses to each of the themes follows.

The proposal lacks evidence of a patient safety concern.

The National Organ Transplant Act (NOTA) requires that the OPTN "recognize the differences in health and in organ transplantation issues between children and adults throughout the system and adopt criteria, policies, and procedures that address the unique health care needs of children." Pediatric membership requirements are the most fundamental of criteria the OPTN could adopt to recognize the unique needs of children in transplantation. As early as 1993, the MPSC has sought guidance from the Pediatric Committee in establishing pediatric requirements so it could better assess key personnel applications.

While centers not meeting the proposed criteria do not experience poor outcomes immediately post-transplant, long-term patient and graft survival is significantly better at centers that meet criteria. Some have suggested that this justifies excluding the surgeon from any pediatric requirements. However, the primary surgeon is integral to the leadership of a program and shares responsibility with the primary physician and medical director for its long-term outcomes.

The proposal cannot define a pediatric patient as less than 18 years old.

For the purposes of addressing the unique health care needs of children throughout the transplantation system, NOTA states that "the term 'children' refers to individuals who are under the age of 18." Defining a pediatric patient as less than 18 years old is also consistent with CMS and the American Academy of Pediatrics. Any alternative to the definition of a pediatric patient

as less than 18 years old in the Bylaws could have implications for allocation policy, where currently most candidates registered prior to 18 years old receive pediatric priority.

The proposal lacks evidence to support the proposed caseload requirements.

Many have asked the Committee to produce evidence to support the proposed case volume requirements for the primary pediatric surgeon. As with all OPTN membership requirements involving case volume, the proposed case volume requirements were developed through clinical consensus. None of the OPTN membership requirements, alone, are predictive of good program outcomes. Many factors contribute to the success of a program. However, qualified key personnel are important contributors to a program's success, and case volume is the most basic way a surgeon demonstrates requisite experience.

The purpose of these requirements is to establish criteria for membership; therefore, the Committee does not have to demonstrate improved outcomes associated with these requirements. However, in an effort to build consensus, the Committee investigated outcomes data. 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 B-D). 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 E). Additionally, adjusted analyses that were performed independently by UNOS showed that as a group, centers performing <18 pediatric liver transplants during 2000-2010 had an increased risk of graft loss and death within 5 years (i.e., worse outcomes) as compared to centers performing 18+ pediatric liver transplants during that period; and centers that performed <12 pediatric kidney transplants during 2000-2010 had an increased risk of graft loss and death within 5 years (i.e., worse outcomes) as compared to centers that performed 12+ pediatric kidney transplants during that period (Exhibit F-G).

The proposal limits access to transplantation for pediatric patients.

In response to feedback from the Regions, the Committee made major comprises in the development of these proposed Bylaws in the interest of access to transplantation for pediatric patients. The resulting proposal better balances the competing interests of quality of care, including patient safety, and access to transplantation for pediatric candidates. In fact, from January 1, 2005 through July 31, 2014, 97.7% of pediatric transplants were performed at centers that would have met the proposed pediatric volume criteria. Again, because of the limitations of OPTN data, center volume is being used as a proxy for primary surgeon volume. A low volume center could still be approved for a pediatric component so long as a surgeon that has performed the required number of pediatric surgeries over the history of his or her career can serve as key personnel. Programs may also take advantage of a 24-month conditional pathway to establish a new pediatric component or accommodate a change in key personnel.

The Committee continues to receive requests for an exception that would allow programs without a pediatric component to perform a pediatric transplant in an emergency, such as acute fulminant liver failure. The Committee has thoroughly considered and decided against proposing such an exception, which 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 instances, patients can be safely transported to qualified pediatric component program.

The proposal needs to stratify caseload requirements by age, weight, and other clinical factors.

At the Regional Meetings in the fall of 2013, the Committee presented initial requirements that were stratified by age, weight, and other relevant clinical factors in an effort to build consensus prior to public comment. Among the initial requirements, the primary pediatric kidney surgeon must have performed 6 transplants in patients weighing 20 kilograms or less at time of transplant, and the primary pediatric liver surgeon must have performed 9 transplants in patients less than 12 years old and 5 technical variants, including split, reduced, or living donor liver transplants. This experience had to be achieved over a recent five year period. As mentioned above, the Committee received overwhelming feedback to modify the requirements to preserve access to transplantation for pediatric patients. In response, the Committee eliminated stratifications from the pediatric caseload requirements and proposed that the requisite surgeries could be performed over an entire career, so long as the surgeon demonstrates currency of experience as currently defined in the Bylaws. Informed by the development process, the Committee knows it cannot achieve consensus for stratified caseload requirements and recognizes its responsibility to balance quality of care with access to transplantation for pediatric patients.

3. Regional Comments

Region 1 OPTN/UNOS

Regional Meeting Vote: 6 yes 5 no 2 abstentions Comments: The region generally supports the concept of the OPTN establishing pediatric program requirements. Below are comments made by those who opposed the proposal as written. The statement that low volume centers have worse outcomes than high volume centers is not backed up with data. It was noted during that meeting that this statement was generated by a statistically valid analysis of the SRTR data. • The committee should reexamine adding an exception clause for a very sick patient. • Looking at volume alone is not enough survival rates need to be part of the proposal. However UNOS has never used this as a standard for program approval. If used no new programs would ever be approved. Some concern regarding the number of transplants being proposed specifically for liver and kidney programs but it was noted that conditional approval is an option. The KM curves imply that surgical expertise is not the issue rather that medical care after one year is an issue.

Region 1 OPTN/UNOS

Regional Meeting Vote: 1 yes 16 no 7 abstentions Comments: Members requested that the committee confirm that all fellowship programs proposed in this proposal or in an existing bylaw are still relevant. Members were concerned that providing a pediatric certification to a center whose primary experience is with candidates/recipients age 10-17 year old inaccurately portrays them as a pediatric center Members urged the committee to develop a better definition of a pediatric patient prior to implementing any requirements. Members agreed that patients under 10 and especially under 5 should be cared for by a center who has demonstrated quality experience. They did are not convinced that this proposal meets that standard. Members questioned that if the proposed requirements are met by 98% of current centers - what is the purpose of the requirement?

Region 1 OPTN/UNOS

Regional Meeting Vote: 2 yes 14 no 1 abstention Comments: The data is limited and should be stratified by age group (e.g. 0 to 5 6 to 10 11 to 15 16 to 18). There should be an exception for the larger adolescent urgent cases. Concerns were raised about medical judgement being

removed out of the hands of the adult program. The committee should reconsider using weight as the criteria.

Region 2 OPTN/UNOS

Regional Meeting Vote: 19 yes 10 no 3 abstentions Comments: Access to care will be an issue for adolescent patients. The data doesn't show that adolescents are not being served well currently. Requirements will not improve patient safety for pediatrics • Requirements will only disadvantage programs transplanting the occasional teenager Programs should be allowed to submit an exception letter for cases that require clinical specialization only used at an adult center (i.e. bypass needed during re-transplant). In these cases the post-transplant care will still take place at the pediatric program. Data does not support rationale that pediatric programs have better outcomes Age cut-off should be lower.

Region 3 OPTN/UNOS

Regional Meeting Vote: 0 yes 21 no 1 abstention Comments: The proposal takes too hard of a stance and there should be a softer approach that address exceptions for adolescent patients. Ancillary services need to be confirmed. There is a correlation between ancillary support and survival. Access could be an issue since there would be states without a program. There are socioeconomic factors that limit the ability for a patient to travel. The committee should consider a regional analysis. It is unreasonable that the programs have 90 days to complete the application yet there is 18 months for processing and review of the applications. How many finishing fellows would be qualified under the proposed criteria?

Region 4 OPTN/UNOS

Regional Meeting Vote: 6 yes 18 no 2 abstentions Comments: The proposal restricts access to care for pediatric patients o The committee doesn't have compelling evidence that restricting access will improve outcomes for pediatric patients. The region doesn't think that low volume pediatric programs are better equipped to transplant a pediatric patient than a high volume center. The requirements should be based on age and weight – this would be more acceptable and less restrictive. The proposal must have an exception pathway for emergency situations. Transferring very sick patients is risky. The Kaplan-Meier survival data needs to be risk adjusted. The KM curves diverge between high and low volume centers only after a year which would imply that surgical expertise is not the driving factor in this difference.

Region 5 OPTN/UNOS

Regional Meeting Vote: 7 yes 19 no 1 abstention Vote with Amendment: 16 yes 5 no 0 abstentions Amendment: Pediatric patients should be considered those under 14 years of age Comments: Members requested that the committee consider adopting an exception pathway for adult centers who have an adolescent patient urgently admitted to their facility. The data used to develop the numerical qualifications is based on center not individual clinician data. Members were unclear how center date (which could include multiple providers) can be used to develop individual clinician requirements. The region strongly supports the sentiment that pediatric patients (under the age of 14) should be cared for in a pediatric center. In particular that the ancillary support (psychosocial adherence) provided to pediatric and adolescent patients is unique and necessary. They commented that a proposal that only includes primary surgeon and physician qualifications without outcome measures and no programmatic infrastructure requirements does not ensure that pediatric patients will receive “safer” care than they receive currently. There was concern that the OPTN is creating additional regulation when the data does not support the need to require this oversight. Members requested to review data that validates the assumption that pediatric patients are receiving sub-optimal care within the existing system. If there is not current outcome issues then what problem is the OPTN

addressing?

Region 6 OPTN/UNOS

Regional Meeting Vote: 16 yes 34 no 4 abstentions Comments: During the discussion the following issues were raised: If 98% of pediatric transplants are being done at programs that would qualify under the proposed requirements this change will not improve pediatric transplants. It will only ensure they stay the same. Improving results will require more stringent requirements. The age group covered in this proposal (under 18) is not reflective of the age group that requires pediatric surgical expertise. These requirements will not keep surgeons and physicians without pediatric experience from transplanting and caring for pediatric patients. Only the primary surgeon and physician must meet requirements. Adolescents do not need a surgeon with pediatric experience but probably do need a pediatric physician. Medical care for this age group requires more pediatric expertise. The committee should consider requiring a pediatric qualified physician but not a surgeon for adolescents. The committee should consider outcomes and not volume when developing requirements. Since some candidates over the age of 18 may do better in a pediatric program (emotionally or mentally challenged) and some adolescents may be better served by an adult program the decision about where the candidate would be served best should be left with the transplant team.

Region 7 OPTN/UNOS

Regional Meeting Vote: 6 yes 13 no 4 abstentions. Approved with an amendment: 12 yes 7 no 6 abstentions. Amendment: Surgical requirements should be equitable across all organs. The region selected 4 as the minimum surgeon requirement for all organs since this is the lowest number being proposed (lung). Comments: The data used to develop organ specific surgeon requirements is based on center volume data relative to graft survival. Members commented that center outcomes are the sum of all surgeons at a center and does not specifically show individual surgeon proficiencies. If individual surgeon data is not available to assess quality surgeons should be conditionally approved and have a period of time to meet defined outcomes measures before final approval is granted. The presentation stated that 98% of programs who care for pediatric patients meet the proposed requirement. Members questioned why there needed to be additional bylaw requirements given that implementation will incur expenses for both the OPTN and transplant centers and will only impact 2% of programs nationally. Although the proposal states safety and quality as goals members commented that the proposal contains only quantity not quality measures.

Region 8 OPTN/UNOS

Regional Meeting Vote: 19 yes 2 no 0 abstentions Comments: Some members opined that the requirements should be stratified by age/weight. There was support for including pediatric specific program requirements in the bylaws. In addition to the primary physician and surgeon there are other personnel and support needed to ensure that pediatric patients have quality care. The concern was that a surgeon and physician meeting the training and experience requirements could open a pediatric program without any of the additional support needed to care for pediatric patients.

Region 9 OPTN/UNOS

Regional Meeting Vote: 7 yes 10 no 2 abstentions Comments: The committee should reexamine adding an exception clause for a very sick patient. Access to care will be an issue for pediatric patients. The region is particularly concerned about the 14-18 year age group. The data doesn't show that adolescents are not being served well currently.

4. Committee Comments

Kidney Committee OPTN/UNOS

The Committee generally supports this proposal and would like to commend and thank the Pediatric Committee for the work they've done over the past few years to accommodate some of the concerns we've had. Particularly we appreciate that you've incorporated a conditional pathway and delayed implementation of the proposal. We do agree that pediatric patients are a unique transplant patient population not just in a surgical aspect but in their overall needs both pre and post-transplant. So we do agree that there is a need to ensure that the primary physician and surgeon caring for a pediatric transplant patient has the experience and expertise needed for this population. We do want to acknowledge that several of the regional representatives on the committee are still concerned that there may be pockets of the country with gaps in access to transplant for pediatric transplants should this proposal be approved. We request that the Pediatric Committee examine the geographic gaps in greater depth before moving forward with the proposal to ensure that pediatric kidney patients will have adequate support and access to transplant wherever they live.

Liver & Intestinal Organ Transplantation OPTN/UNOS

Although the Liver Committee is generally supportive of the concept of developing experience and training bylaws for the speciality of pediatric transplantation they are not supportive of the proposal as written. The policy as written does not adequately address the idea that children and adolescents require providers with special expertise. There were great concerns raised over classifying all candidates under the age of 18 as pediatric. Members felt that there is a significant difference in the training and experience required for a surgeon and a physician caring for an 18 month old as opposed to an 18 year old. The Committee suggests that the Pediatric Committee take a closer look at this factor by stratifying candidates and classifying them as infant pediatric adolescent & adult. The Committee also suggest that the Pediatric Committee entertain the idea of incorporating size or weight into the classification system but acknowledges that relying on these factors alone may be challenging on an independent candidate level. Outcomes were emphasized as another point to incorporate on a center by center level rather than focusing on the primary surgeon and primary physician. The Committee feels that ultimately outcomes determine whether a policy or bylaw is truly effective in regards to patient safety. The Committee also acknowledges that many pediatric candidates are currently traveling to programs outside of their local area but is concerned that this proposal may limit access for those candidates that do not have the means to travel. In conclusion the Committee would urge the Pediatric Committee to re-evaluate whether or not this proposal will actually lead to an increase in patient safety whether that increase in patient safety is worth the decrease in patient access and the continued resources that would be required to bring this concept to fruition. The Committee thanks the Pediatric Committee for their presentation and the opportunity to comment on this important issue.

Minority Affairs Committee OPTN/UNOS

The Minority Affairs Committee (hereafter referred to as the Committee) expressed concern in regards to two specific aspects of the proposal: 1) access and 2) definition of a pediatric patient. In regards to the former concern the Committee discussed disparities in access-not just the physical geography of where pediatric centers are located but socioeconomic factors that affect families. In regards to the proposal's definition of a pediatric patient while legally the age of < 18 is true in terms of transplantation other criteria might be more critical e.g. weight size. Members agreed that that smallest and youngest patients would indeed benefit from being cared for by

experienced pediatric specialists however there were concerns raised about the mandate to transfer older children to pediatric centers when admitted to adult centers (for eg. 17- yr old patient in acute liver failure). Given that 98% of programs already appear to be within the parameters of the proposed requirements it would behoove the MPSC to communicate with the 2% of programs that do not meet these requirements if indeed outcomes of pediatric patients transplanted at those centers are worse than expected. Members of the Committee also questioned that of the 2% of centers that do not meet standards are their outcomes significantly different than the other 98%?

Thoracic Organ Transplantation Committee OPTN/UNOS

After reviewing the proposal the Thoracic Committee voiced a number of concerns. First the experience for the heart and lung programs is disparate. The data show that 20 out of 42 lung transplant centers would not currently meet criteria. This is disconcerting because a number of these programs might be performing transplants for adolescent lung recipients. The Thoracic Committee therefore believes this policy might have a negative impact on adolescent candidates and decrease their access to transplant. One Thoracic Committee member did point out that the maps showing the number of centers that would qualify under the new bylaws are based on center volumes not surgeon volumes and that the bylaws for surgeon volumes will be much easier to meet. Some members of the Thoracic Committee also do not find the data showing the relationship between outcomes and experience to be compelling and argued that the data reveal a relationship between outcomes and volumes in infants not all pediatric patients less than 18. One member of the Committee explained that the data cannot show the relationship between outcomes and volumes for lungs because the number of cases is too small but the data showing the relationship between outcomes and volumes in other organs is convincing. Adolescents in particular have the highest risk of rejection non-compliance and shortest graft survival and they therefore require a transplant team that is experienced in handling adolescent cases. The bylaws should therefore focus more on center volume instead of surgeon volume. Another Thoracic Committee member expressed concern about the number of highly trained pediatric pulmonologists and the potential number of pediatric lung transplant programs. Centers will be required to hire a pediatric pulmonologist but there are insufficient pediatric pulmonologists trained in transplantation. Additionally there may be centers that would hire a pediatric pulmonologist that would only be performing adolescent not infant transplants anyway. While pediatric transplantation teams are very important it is also important that the patient is cared for by experienced surgeons and physicians. The Thoracic Committee suggested that the age cut-off of 18 is not appropriate. The Committee suggested there are ways to justify an age cut-off lower than 18 perhaps based on size/weight or the ability to perform certain technical procedures on the patient. Even if these bylaws apply to all programs treating all candidates less than 18 the Committee suggested including an exception in the bylaws albeit an exception with limited application so that it doesn't become the norm.

5. Individual Comments

Adriona Gaul, **Individual**

I believe that the primary pediatric physician should be trained and qualified to be the key personnel In assisting the pediatric surgeon. Everyone deserves the best care possible and that poses a big threat on the patients if the people assisting or performing it is not properly trained and fully qualified. Especially infants and toddlers. But I feel as though even teenagers and adults deserve well trained people.

Annalise Ennis, **Parent of a patient from Boston Childrens Hospital**

I've learn from my own first hand experience. As a mother of a child that has under gone a liver transplant and a granddaughter of a grandmother who has received a kidney transplant. That there is a world of difference between a child receiving a life saving organ than an adult. Not only in the basic make up of the body. But also in the over all environment that occurs before transplant and after transplant. A child especially a very young one doesn't understand that this event occur to save their life. Instead it seems scary strange and they question so much. The doctors treating them have to have a understanding about children in general. As the child progresses in life the doctors that are in charge of your child's care become a second family. You seem them so often that you know things about them as they do you. So you need someone that has not only the basic surgical/doctor skills need to graft the donated organ to function properly in the child's body. But you also need to have a doctor that understands the basic needs of a child. And the ability to get them through such a major ordeal with making them feel like they are more then just a body lying in a bed!! We need our specialist when it comes to childhood health care to actual understand children. To have study more then just the physical make up of a child but has understanding on what is developing at what time of a child's life. I think when it comes to childhood care when dealing with transplant you have to remember that they have entered into a life long relationship in medicine. From that point on they will be doing things with in the walls of hospitals for years to come. Its best to get them started on the right foot with having them be given a feeling of caring.

Anne McGinnis, **Children's Hospital of Pittsburgh of UPMC**

Children’s Hospital of Pittsburgh of UPMC strongly supports the establishment of training and experience requirements for pediatric patients. As providers dedicated to the health and well-being of children we believe these patients are best cared for by pediatric specialists. We would like to comment on the proposed requirements for the primary Lung physician. Under Full Approval the proposal states an individual must qualify by utilizing the current bylaw requirements. These requirements offer 2 pathways: 12-month transplant pulmonology fellowship or clinical experience. The volume requirements for primary and follow up care of recipients for these pathways are the same at 15 newly transplanted lung or heart/lung patients. Given the incidence of pediatric lung and heart/lung transplantation we would propose that these volumes be reduced. For all other programs the pediatric volume requirements for approval are less than what is currently required. In addition there are approximately 50 – 60 pediatric lung and heart/lung transplants per year compared to almost 2 000 per year in the adult population. To keep the requirements the same is not appropriate given the large difference in adult vs. pediatric transplants.

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Asha Moudgil, **Children National Health System**

Children deserve to be treated by experienced pediatric transplant personnel including surgeons and physicians. These are the minimum purposed standards.

Casey Bolton

The impact of this policy will be to improve the care of pediatric transplant candidates and recipients and the impact on access to care will be small. I support this.

Craig Langman MD, **Laurie Children's Hospital of Chicago**

It is mandatory that children 18years and younger have their transplant care from a qualified pediatric kidney physician and surgeon as noted in the proposed rules. The unique developmental aspects as well as the pharmacokinetics of this wide age range must be handled by someone experienced in this area which is satisfied as listed in the three pathways to becoming a pediatric transplant physician.

Daniel Shoskes, **American Urological Association**

The American Urological Association (AUA) commends the Pediatric Transplantation Committee for their work on this proposal. We echo the Committee's sentiments that designated transplant programs must have an approved pediatric component in order to perform transplants in pediatric patients. We also agree having a qualified primary pediatric surgeon and qualified pediatric physician serving as key personnel are vital to patient safety and quality of care. However recognizing that pediatric patients are unique and vary greatly in terms of biological and physical characteristics (e.g. height weight etc.) the AUA has concerns about the Committee's proposed simple definition of a pediatric patient (under 18 years of age) and would encourage the inclusion of separate tiered weight and age level criteria for the kidney transplant program requirements specifically relative to the number of kidney transplants required of the primary pediatric kidney surgeon. We understand it is extremely vital to the patient's safety and care that specialized surgical training and expertise is necessary for a pediatric kidney transplant surgeon to perform kidney transplants in infants and children; however we argue that performing a kidney transplant on a 16-year old is no different – neither surgically nor medically – than performing that surgery on a 22-year old and believe the new requirements should reflect this. We echo the concerns of many that the age cut-off of 18 years is arbitrary and would support a weight-based threshold in which special training is necessary. The AUA also asks the Committee to consider adding a requirement for a pediatric kidney transplant program that operates on infants or children to have an affiliation with a pediatric urology program. Given that many of these patients have underlying genitourinary tract abnormalities and some may have already undergone extensive genitourinary procedures (e.g. vesicoureteral reflux repair or even reconstruction) prior to their transplant it would be beneficial for these surgeons to be familiar with and again have the specialized training and expertise to know how to work within such specialized areas (such as reconstructed bladders etc.).

DAVID DIRUBBO, **D & D FINANCIAL ASSOCIATES INC**

It has to be made a priority to require physicians to have specific training to treat minor children who have transplants. The trauma that a little child would have could be 10 times worse if the Doctors did not specific know how to deal with the child.

David Rosenthal, **Stanford University**

The issue of pediatric training requirements has been very controversial in transplantation unlike every other branch of medical subspecialty where the principle is well-established and is a foundation of delivery of high quality care. The impact of this policy will be to improve the care of pediatric transplant candidates and recipients and the impact on access to care will be small. In

the tradeoff between regionalization and access to care this proposal strikes a reasonable balance that should have a strongly positive impact on overall outcomes and quality.

Dawn-Marie Buttafoco

I am a grandmother to a liver transplant patient. My grandson was 6 years old at the time of his surgery. Due to the expert team at Children's Hospital here in Boston using the best of knowledge available my grandson is now 11 years old and an example of a successful transplant. I feel strongly that any and all resources should be available to all the grandchildren that are unfortunate enough be in the situation that our family faced.

Ellen O'Brien

Please approve this critically important approval.

Emily Arnold, **American Nephrology Nurses' Association**

The American Nephrology Nurses' Association agrees with the concepts in this proposal but has concerns that it may decrease access to transplant by increasing distance between kids who need a transplant and a qualified pediatric transplant center.

ERIN LANGHORST

Support Required training for pediatric transplants.

George Gialopsos

To Whom It may Concern I fully support a new bylaw requiring that a designated transplant program must have an approved pediatric component in order to perform transplants in patients less than 18 years old. Thank you for making this happen. Regards George Gialopsos

George Mallory, **Texas Children's Hospital**

I am a great believer that UNOS should avoid the role of policeman over organ transplantation. However I have been concerned for many years about adolescent and children undergoing lung transplantation in adult centers. I count many adult transplant pulmonologists as friends and role models but none have training in adolescent medicine. There is data to suggest that pediatric patients transplanted in adult centers have significantly shorter survival than those transplanted in pediatric centers for all organs but lung transplantation is fraught with the greatest propensity to serious complication. The requirement in the revision under consideration that each adult center should have a pediatric pulmonologist with board certification is a weak requirement easily prone to abuse. Pediatric pulmonologists without substantial lung transplant experience are not qualified to be lung transplant physicians and medical directors of pediatric programs by UNOS's own criteria. Why should a pediatric pulmonologist with no lung transplant experience whose name gets included on a long list of personnel lead to a certification of credentialing to an adult lung transplant center with no commitment to developing expertise in an area of transplantation which like all others requires volumes of experience. I am aware that the few pediatric lung transplant centers in the USA puts a geographic burden on families. In my opinion geographic proximity or convenience can never trump competence and commitment.

George Mazariegos MD, **Studies in Pediatric Liver Transplantation (SPLIT)**

Members of the Studies in Pediatric Liver Transplantation (SPLIT) Council strongly support the initiative being brought forth by the Pediatric Transplantation Committee for establishing minimum standards for pediatric training and experience for the primary surgeons and physicians of programs performing pediatric transplantation. SPLIT is a community of pediatric hepatologists transplant surgeons research coordinators nurse coordinators and other health professionals across the United States and Canada working together to advance knowledge in

pediatric liver transplantation. SPLIT was started in 1995 and has evolved from a research registry into a multifaceted organization focused on improving outcomes for children receiving liver transplantation. The UNOS/OPTN Pediatric Transplantation Committee has worked diligently to fulfill the charge of the Board of Directors to develop Bylaws that provide for pediatric training and experience standards for pediatric programs. We believe that the proposal as stated (http://optn.transplant.hrsa.gov/governance/public-comment/establish-pediatric-training-and-experience-bylaws-requirements) makes important progress in this regard. We advocate for approval of the policy while understanding that some modifications in regards to specifics of volume requirements and potential exemptions under emergency indications may be needed in the future. SPLIT looks forward to reviewing and commenting on any further policy revisions specifically in relation to pediatric liver transplant program requirements as this effort moves forward. George Mazariegos MD SPLIT Chair Simon Horslen MD SPLIT Vice Chair John Magee MD Vicky Ng MD Michelle Nadler RN PPCNP-BC Linda Book MD Nitika Gupta MD Evelyn Hsu MD Shikha Sundaram MD Vicki Fioravanti RN CCTC CCTN

James St.Louis, **Children's Mercy Hospital**

My name is Dr.James St.Louis and I am Director of Pediatric Cardiac Transplantation at Children's Mercy Hospital in Kansas City. I am in complete agreement with the acertian that the current regulations defining and qualifying those individuals leading current pediatric transplant program are insufficient. Although the current proposal falls short of establishing the strict guidelines needs to maintain the quality the public has come to expect. I would strongly support the statement with in guidelines for primary Surgeons for cardiac programs the need for board certification of congenital heart surgery currently mandated by the ABTS.. This must be added to ensure the premise that only qualified pediatric surgeons are performing this type of operation Thank you Sincerely Dr James St.Louis MD

Jeri Leonard

I am in favor if this proposal!!

Jim Gleason, **none**

I strongly support this proposal long overdue and now presented with good background research and logic developed over the years. Nice work committee.

john renz, **ILUC**

I believe this proposal is another example of the "haves" rigging the system against the "have-nots" and will decrease access of critically ill children to life-saving transplants. The minimal qualifications have no scientific merit and the age threshold of <18years is absurd. Does the committee really think a 16year old fulminant cannot be successfully managed by an adult liver transplant center? In fact they may be managed better due to a large volume adult program's experience with ALF. Does the committee think it is in the 16year old's interest to potentially undergo a long medical transport to get to an "approved" pediatric center? The answers are obvious. I would propose 1) lowering the age cut-off substantially - perhaps to pre-pubertal 7-9years 2) permitting "carve-outs" for ALF or beginning by limiting the recommendations to ESLD 3) change your criteria to recommendations not mandates The closed-minded thinking of committees dominated by largely political appointments from large centers is strangulating transplantation in the US. It is rare that game-changing discoveries originate from large corporations/establishments and the same is true in medicine - don't squash the little guy who often can increase access to care and spur innovation - two words that are becoming heresy at UNOS

John Williams, **Children's Hospital of Pittsburgh**

The old saying is trite but true that children are not little adults. There are unique biological aspects to pediatric transplant medicine that require specialized pediatric training. The developing immune system need for vaccinations normal growth and development and puberty are just a few aspects of pediatric health that differ substantially from adults and are significantly affected by transplant surgery and medications. The surgical approach differs in many cases as well and experience with pediatric transplant is associated with better clinical outcomes. In addition to the medical issues there are psychosocial behavioral and familial aspects of pediatric transplant medicine that strongly affect outcomes. Qualified pediatric experience is required for these issues as well to ensure optimal use of scarce organs and best outcomes.

jorge reyes, **University of Washington**

I am concerned that the definition of Pediatric as being patients "< 18 years of age" does not reflect the expertise needed in the patients of most concern (and which may reflect the cause for lower graft / patient survival) which are the newborns infants toddlers. Also for certain organs such as the Lung or Heart such care may only be available in adult centers which may not meet the volume requirement. Also I would want to have the differential outcome which has served as the basis for this proposal in the document since I am not aware of this data (and which have excluded the teenage age group).

Juli levine

Our son at 5 months old had a full cadaver liver transplant done at Boston Children's Hospital that saved his life. He is now 11 and thriving. We know that a huge part of his success was due to the fact that he had a pediatric transplant doctor - I can't imagine a non-pediatric-trained physician operating on our tiny tiny son. It is critical in our opinion that transplant doctors that are working on patients under the age of 18 should have pediatric training. Thank you for your time.

Julie Buttafoco

Our son Cole received a liver transplant 5 years ago when he was just 7 years old. We are fortunate to live close to Boston and have access to the best resources and hospitals the country has to offer. We were assigned a team of specialized personnel at Children's Hospital. Given all the unique circumstances of Cole's transplant: various medicines the size of his liver specific to the surgery and donor recipient to rejection to the psychological issues that needed addressing with the therapist the nurses that provided the hours of specialized care and attention and many other issues that were involved in his case we strongly feel it is imperative and necessary for there to be regulations requiring the transplant team to have pediatric training and standards in order to be qualified for transplantation. Thank you for this proposal and we hope to see it move forward and implemented. Warmest Regards Brian and Julie Buttafoco

Julie Kobold, **parent of pediatric transplant patient**

I support this proposal! All pediatric patients deserve a highly qualified transplant surgeon and physician to manage their care. Why is transplant the only area that does not require pediatric specialization? The care of an adolescent or infant goes well beyond the care of an adult. Transplant procedures medicines and research are not interchangeable. Dealing with caregivers and facilitating transitions to adulthood and independence are core elements of the pediatric patient. They are not just little adults. What may work for a 25 year old may be ineffective for a 17 year old. Transplant centers that want to expand their care should invest in training or recruiting highly qualified pediatric specialists. This should not be about denying access to pediatric patients but rather holding transplant centers to the highest standard.

Katherine Twombley, Medical University of South Carolina

I agree with everything that Dr. Harmon said. I think that our top priority should be the children and ensuring that the children are receiving the top quality outstanding care that they deserve. I too support this proposal and strongly recommend that the board approve it.

Kenneth Newell MD PhD, **American Society of Transplantation**

The AST agrees that minimum standards for qualification are desirable but we do not support this proposal as written. The premise of this proposal is sound but the proposal itself is not perfect. There were significant concerns by the AST constituency as follows: 1. The estimate of the number of programs that would no longer meet approval is unclear. We would like to see more granular data on the anticipated impact to geographical distribution of available transplant services for patients particularly in more sparsely populated areas where higher volumes are difficult to achieve based on population demographics. The proposed volume criteria for the pediatric programs set a high bar that we suspect will have a more detrimental effect to access to care than the offsetting benefit in improved outcomes from increasing the volume criteria to the extent noted. 2. The proposal does not acknowledge any differences in complexities between infant and adolescent surgery. 3. There may well be cases where experienced high-volume adult surgeons may be more appropriate to perform adolescent transplantations than a pediatric surgeon with a lower volume of transplants. However other aspects of the program infrastructure would need to be in place such as child life psychosocial support and nursing expertise. 4. The proposal also lacks detail in regard to the supporting staff and QI.

Kenny Laferriere, **New England Organ Bank**

Being a heart recipient myself and employed at the OPO in region 1 I support this proposal and strongly suggest to the Board they adopt this policy. The pediatric population requires specialized training and experience in order to become fluent when working with this group of patients. I was lucky enough to live near Boston and was able to go to

Children's Hospital Boston for my care and transplant. I understand this may put geographic limitations for some families but I feel that ensuring your child receives the best care possible from qualified transplant professionals trumps the geographic issues that may affect some families. I strongly support this proposal and would recommend that it be adopted into policy.

Kevin Daly, **Boston Children's Hospital**

Children deserve to receive care from doctors nurses social workers nutritionists pharmacists and other professionals who understand their unique needs. The diseases that lead to end stage organ failure are different and the understanding and role of the patient and family are unique to children. This is not a topic of debate but has been well recognized by the medical community. The question becomes where you draw the line between children and adults. Using the 18 y/o cutoff is imperfect but reasonable. The proposed policy strikes a reasonable compromise and the fact that no pediatric training is already required to care for pediatric transplant recipients is unacceptable. We have a responsibility to protect this vulnerable population by insuring access to the best care. Debates about patients on the margin of the policy (i.e. the 17 y/o with end stage organ failure) should not undermine the importance of the policy to the pediatric patient population as a whole. I fully support this proposal.

Loralei Lauranzano

My son has received three liver transplants (age 9 months age 6 age 8) and all of them were performed by pediatric transplant surgeons in a pediatric hospital. Operating on an infant can not possibly be the same as operating on a full sized adult. Also from my experience with both children and adults in my family pediatric care is completely different from adult care. Infants toddlers young children and adolescents are not mini adults. They require expert pediatric care

and rely on parents who must also be trained counseled and supported by experienced staff so they can provide for their child's medical needs and general wellness. This proposal is an excellent one and in my opinion it is long overdue.

Lori Loycano

My nephew received a transplant at the age of 6 and thanks to the expert care of Dr Heung Bae Kim MD of Boston children's hospital he has grown into a healthy 11 year old boy. I am grateful everyday that he had access to the amazing pediatric care that saved his life. Thank you.

Lynda S

Children have specialized needs and should have specialists addressing them. You don't have a mechanic look at a submarine and those are inanimate.

Marcus Groff, **Demandware**

I am writing to voice my support for the Committee's proposal to require that a designated transplant program have an approved pediatric component in order to perform transplants in patients under the age of 18. As the father of a child who received a kidney transplant at the age of two and weight of just over twenty pounds I have learned just how radically different the medical needs of a child (vs. an adult) are. Expertise with adolescents is a material concern. Sincerely Marcus Groff

Marissa Gialopsos

I have worked at Dana Farber in Boston for a couple years. I have seen the Jimmy Fund and know how important it is to have doctors specially trained in pediatrics. I feel that this is an important and necessary step for patient safety. Thank you

Mark Lukaszewski, **American Society of Nephrology (ASN)**

On behalf of the American Society of Nephrology (ASN) thank you for the opportunity to provide support and comments for the UNOS Proposal to Establish Pediatric Training and Experience Requirements in the Bylaws. ASN is the world’s leading organization of kidney health professionals representing over 15 000 physicians scientists nurses and health professionals who improve the lives of patients with kidney disease every day. ASN and the professionals it represents are committed to maintaining the integrity of the physician-patient relationship as well as simplifying patient access to optimal quality care regardless of socioeconomic status geographic location or demographic characteristics. ASN joins the American Society of Pediatric Nephrology (ASPN) in support of these requirements and submits the follow comments for your consideration. ASN supports ASPN’s detailed review of the proposal including the history that requirements for pediatric transplant have been in development since 1993. Most recently UNOS has outlined goals directed at pediatric transplant program requirements. Specifically in 2010 the UNOS Membership and

Professional Standards Committee set a goal to develop qualification criteria for pediatric organ transplant program approval and in 2012 the UNOS Board of Directors made the development of pediatric program requirements one of the key initiatives in its strategic plan to promote transplant patient safety. In the current UNOS bylaws there are no specific criteria to define pediatric expertise required for a program to perform pediatric transplants. This lack of requirements potentially allows for a surgeon or physician with no pediatric experience to perform and manage transplants in pediatric patients which ASN and ASPN believe should be rectified immediately. The UNOS proposed Pediatric Bylaws is a good first step in making that happen. ASN is concerned with the lack of established standards to ensure the quality of care delivered to our pediatric kidney transplant recipients defined in the proposal as children and adolescents less than 18 years old. ASN and ASPN believe it would be appropriate to include

children and adolescents up to age 18 years under the proposed Pediatric Bylaws and has always advocated for pediatric physicians to provide medical care to adolescent patients. However disagrees with classifying patients by size and lumping adolescents with adults for several reasons. Teenagers as well as younger children have pediatric diseases leading to end stage organ failure and the need for transplant and should be treated by pediatric personnel who are familiar with these diseases. For example pediatric end stage renal disease (ESRD) is caused by congenital anomalies acquired glomerulonephritis hereditary diseases and other rare kidney diseases whereas ESRD in adults is mostly due to diabetes primary hypertension and autosomal dominant polycystic kidney disease. In addition the adolescent population has not completed growth and development and teenagers are still dependent on parents or guardians for their livelihood and care. Finally less than 18 years of age is a well-accepted definition of pediatrics by the National Organ Transplant Act (NOTA) the Centers for Medicare and Medicaid Services (CMS) and the American Academy of Pediatrics. While advocating for pediatric expertise for quality of transplant care we also want to ensure that access to transplants for our pediatric patients is preserved. The UNOS Pediatric Committee has done an analysis of UNOS programs that performed at least 1 pediatric transplant between 1/1/05 and 7/31/14 and found that 98% www.aspneph.com; info@aspneph.com of pediatric (less than 18yo) transplants were performed in programs whose volume of pediatric transplants would meet the volume criteria by organ in this proposal. Based on this finding we are confident that the proposed Pediatric Bylaws will begin to ensure access to quality care for pediatric patients without restricting access of children and adolescents to transplant. We would like to point out that most regions and states have only a few transplant centers so adults as well as pediatric patients already must travel to a specialized transplant center to obtain their care. No one would suggest that an adult patient should be transplanted by a local surgeon and cared for by a nephrologist with no kidney transplant experience and current UNOS Bylaws would not allow that to happen for adults. It only follows that the same level of care should be provided to children and adolescents. In conclusion ASN believes that children and adolescents less than 18 years old who constitute the pediatric age group are a well-recognized special population of patients whose optimal care necessitates pediatric expertise of key transplant personnel. The proposed Pediatric Bylaws are long overdue and should be adopted as a minimum first step to promote patient safety and optimize outcomes for pediatric transplant recipients. Sincerely John R. Sedor MD FASN Chair ASN Public Policy Board

Mark Lukaszewski, **American Society of Nephrology (ASN)**

On behalf of the American Society of Nephrology (ASN) thank you for the opportunity to provide support and comments for the UNOS Proposal to Establish Pediatric Training and Experience Requirements in the Bylaws. ASN is the world’s leading organization of kidney health professionals representing over 15 000 physicians scientists nurses and health professionals who improve the lives of patients with kidney disease every day. ASN and the professionals it represents are committed to maintaining the integrity of the physician-patient relationship as well as simplifying patient access to optimal quality care regardless of socioeconomic status geographic location or demographic characteristics. ASN joins the American Society of Pediatric Nephrology (ASPN) in support of these requirements and submits the follow comments for your consideration. ASN supports ASPN’s detailed review of the proposal including the history that requirements for pediatric transplant have been in development since 1993. Most recently UNOS has outlined goals directed at pediatric transplant program requirements. Specifically in 2010 the UNOS Membership and Professional Standards Committee set a goal to develop qualification criteria for pediatric organ transplant program approval and in 2012 the UNOS Board of Directors made the development of pediatric program requirements one of the key initiatives in its strategic plan to promote transplant patient safety. In the current UNOS bylaws there are no specific criteria to define pediatric expertise required for a program to perform

pediatric transplants. This lack of requirements potentially allows for a surgeon or physician with no pediatric experience to perform and manage transplants in pediatric patients which ASN and ASPN believe should be rectified immediately. The UNOS proposed Pediatric Bylaws is a good first step in making that happen. ASN is concerned with the lack of established standards to ensure the quality of care delivered to our pediatric kidney transplant recipients defined in the proposal as children and adolescents less than 18 years old. ASN and ASPN believe it would be appropriate to include children and adolescents up to age 18 years under the proposed Pediatric Bylaws and has always advocated for pediatric physicians to provide medical care to adolescent patients. However disagrees with classifying patients by size and lumping adolescents with adults for several reasons. Teenagers as well as younger children have pediatric diseases leading to end stage organ failure and the need for transplant and should be treated by pediatric personnel who are familiar with these diseases. For example pediatric end stage renal disease (ESRD) is caused by congenital anomalies acquired glomerulonephritis hereditary diseases and other rare kidney diseases whereas ESRD in adults is mostly due to diabetes primary hypertension and autosomal dominant polycystic kidney disease. In addition the adolescent population has not completed growth and development and teenagers are still dependent on parents or guardians for their livelihood and care. Finally less than 18 years of age is a well-accepted definition of pediatrics by the National Organ Transplant Act (NOTA) the Centers for Medicare and Medicaid Services (CMS) and the American Academy of Pediatrics. While advocating for pediatric expertise for quality of transplant care we also want to ensure that access to transplants for our pediatric patients is preserved. The UNOS Pediatric Committee has done an analysis of UNOS programs that performed at least 1 pediatric transplant between 1/1/05 and 7/31/14 and found that 98% www.aspneph.com; info@aspneph.com of pediatric (less than 18yo) transplants were performed in programs whose volume of pediatric transplants would meet the volume criteria by organ in this proposal. Based on this finding we are confident that the proposed Pediatric Bylaws will begin to ensure access to quality care for pediatric patients without restricting access of children and adolescents to transplant. We would like to point out that most regions and states have only a few transplant centers so adults as well as pediatric patients already must travel to a specialized transplant center to obtain their care. No one would suggest that an adult patient should be transplanted by a local surgeon and cared for by a nephrologist with no kidney transplant experience and current UNOS Bylaws would not allow that to happen for adults. It only follows that the same level of care should be provided to children and adolescents. In conclusion ASN believes that children and adolescents less than 18 years old who constitute the pediatric age group are a well-recognized special population of patients whose optimal care necessitates pediatric expertise of key transplant personnel. The proposed Pediatric Bylaws are long overdue and should be adopted as a minimum first step to promote patient safety and optimize outcomes for pediatric transplant recipients. ‘ Sincerely John R. Sedor MD FASN Chair ASN Public Policy Board

Matthew Grinsell, **University of Utah**

As a member of the ASPN and a practicing pediatric nephrologist I support adoption of the proposal requiring pediatric medical and surgical expertise in programs transplanting children. The proposed Pediatric Bylaws are indeed long overdue and should be adopted as a minimum first step to promote patient safety and optimize outcomes for pediatric transplant recipients.

Megan Lo

I am always worried about new rules which require more checkboxes and oversight which may lose individual patients in the mix. It may be very easy for us to say that it is not unreasonable to transport a family to another center but some families may have to travel hours when a closer center could provide the care but does not quite meet qualifications. There is also always the risk of poor care in the handoff/transfer process to a team which has not been the primary one

following the patient all along. Number cutoffs are never appropriate. Team A which does one transplant a year may do better than Team B that does 20 if Team A pays meticulous attention to the needs of that specific patient and Team B shunts people through as a matter of course just as an example. I can also think of patients who may have died waiting or trying to get to another center. Some programs are also building joint transplant programs covering all solid organs and those should be taken into account. Therefore I recommend taking out the number limits or barring that to at least put those limits on an averaged rolling basis every 3 years. No program should go out and create transplant patients just to keep numbers up. Setting a number is too cut and dry for medicine. No number limit is an absolute cutoff when discussing real individual patients. Outcomes are the more important measure but harder to evaluate. I loathe the idea of yet another database to look at but this information can be pulled from Transplant QAPI rather than inventing yet another committee or form to fill out. There also should be an emergency clause for programs that already have transplant available. We want safe care but we should be improving access not creating more limits. Thank you.

Melissa Gould

My son was almost 17 years old when he had his liver transplant at Children's Hospital Boston. He is now almost 20. We travel 5 hours to each of his appointments both pre and post transplant and will continue to do so gladly due to the outstanding pediatric care that he receives. Even though he is an adult physically delays (such as puberty growth weight) makes the pediatric doctors and surgeons more experienced in his health care. CHB transplant team experience far exceeds the care he receives from his local doctors even his specialists here. Personally we would travel any distance for the care provided by the pediatric transplant teams.

Melvin Sperber, **Recepient**

I support that a pediatric trained component should be involved with the child transplant programs. Especially a program that can ensure correct and consistent care.

Michael Bowler

Pediatric patients should receive care from those that are specially trained for pediatric medicine and transplantation. Just as there are specialists in all areas of medicine there are those same specialists that have the additional training and practice for pediatric patients. Transplant surgeons that work with pediatric patients should have specialized training. The pediatric patient presents differently from the adult patient a pediatric surgeon would recognize those nuances in the care.

Michael Congoran

I support this proposal.

Michelle Rheault, **University of Minnesota Masonic Children's Hospital**

I am a pediatric nephrologist and medical director of dialysis at the University of Minnesota Masonic Children's Hospital. I firmly support the proposal that a transplant program must have an approved pediatric component in order to perform transplants in patients less than 18 years old including a qualified primary pediatric surgeon and a qualified primary pediatric physician to serve as key personnel. Children have unique medical and psychosocial needs that are not adequately met by treatment in an adult center. This is the right thing to do for children.

Page McDonald

Children are very different from adults and especially children with heart or other organ problems who may have

multiple special differences. A surgeon who performs transplants on our little ones needs to be

fully trained in

Paul Grimm, **Stanford University**

The reality is that quality is linked to volume. For a child to have an organ transplant should be a once in a lifetime event. Pediatric programs are trained to incorporate differences in the biology and cognitive development of children into their care. If a center is inexperienced in any procedure then the risks of poor outcome goes up. There should be a minimum standard. A perceived hardship because a child has to travel a longer distance should be mitigated by social and financial support not doing a once in a lifetime critical procedure in the nearest center that does adults without the finesse of a well oiled pediatric organization that is used to doing these procedures. We need to consider how doing the best transplant possible the first time will affect the rest of their life.

Paul Morrissey, **RIRH**

I have concerns with the Pediatric Transplantation Committee proposal for requirements for the qualifying surgeon in pediatric solid organ transplantation: specifically liver kidney and heart. I will confine my comments to kidney for the most part since that is what I do and where my experience lies. The proposal was discussed at the UNOS Region 1 meeting where it met with significant debate and a split decision (6-5-2) for approval. My center RIRH voted against.

The principle concern was the number of required cases for the surgeon to qualify for approval. By way of example permit me to describe the pediatric renal transplant at RIH a program that easily meets the current proposed standards but would not have qualified at its inception. We established our program in 1998 one year after establishing adult renal transplantation. Our program director had performed more than 1200 kidney transplants over 25 years in adults. None of the surgeons had any pediatric experience except for two cases I assisted on in fellowship. We had a freestanding Pediatric Hospital (Hasbro Children's) and at the time a pediatric nephrologist who had been practicing for over 30 years. Since then we have performed 39 pediatric transplants in children age 2-17 with great success. Two full-time pediatric nephrologists now staff the program at RIH/Hasbro Children's. To begin a similar program now we would have to hire a new transplant surgeon with experience in 6 pediatric transplants or obtain that experience for one of the existing surgeons and then have that surgeon participate in 6 additional pediatric transplants in the next 24 months. Of the three phases of transplantation (pre-transplant the surgical episode and in-hospital recovery post-transplantation) the aspects that are most unique and challenging do not involve the surgery and immediate recovery. In fact pediatric renal transplantations are often the most straightforward. There are some particular issues regarding volume management and blood pressure but these are easily addressed. The same is likely true for pediatric liver transplants with non-cirrhotic livers being more straightforward to explant. I cannot comment knowledgably about heart transplants. The numbers of transplants suggested (12 for kidney 18 for liver) are not evidence based. The figures included with the proposal show nearly identical results for low volume centers at one-year implying that the surgical phase per se is not affected even in the lowest volume centers (< 12 transplants in 15 years for kidney). Further the curves diverge in the post-transplant follow-up phase again indicating that longitudinal long-term follow-up is essential to maintaining excellent results not specific pediatric surgical experience. In terms of kidney I assume that most centers performing very small numbers of renal transplants in children are doing adolescent recipients – the most challenging group and the divergent results might be somewhat if not totally explained by this challenging population rather than the quality of the follow-up care. At our Regional Meeting the presenter and several seasoned pediatric nephrologists in the audience repeatedly cited issues of disease etiology pharmacokinetics adverse medication effects (growth hirsutism etc.) and adherence as issues requiring special expertise and attention in pediatric renal

transplantation. No concern regarding surgical quality was mentioned. Finally while many programs (nearly all) would be grandfathered in or qualify currently under the new rules many centers have a single surgeon performing their pediatric renal transplants. A well-established program with pediatric nephrologists would lose their center approval if that surgeon left the center. While a new surgeon with expertise could be recruited that remains challenging as most renal transplant fellows do not graduate with sufficient pediatric experience. The requirement then to begin with conditional approval and meet full approval over 24 possibly 48 months becomes an onerous task for the new surgeon based on a weak hypothesis and little actual evidence. I strongly endorse the need for pediatric expertise in the evaluation and on the long-term care of young solid organ recipients. This expert care can come from surgical transplant group pediatric transplant subspecialists or a combination. Long-term care solely by community practitioners does not seem appropriate for a complex lifelong medical condition. However in the absence of data to the contrary reasonable arguments at our UNOS Regional Meeting (there were none) and our experience at RIRH (Hasbro Children's Hospital) I strongly oppose the arbitrary requirement numbers to qualify as a capable pediatric transplant surgeon.

Peter Stock, **ASTS**

ASTS does not support this proposal. Over the past two years ASTS has participated in dialogue with the committee as it worked to develop training and experience requirements for pediatric programs. After careful review of the proposal set forth for public comment we are unable to support the recommendations as they fail to address key ASTS concerns that have been repeatedly shared with the committee. Specifically it remains unclear what "problem" the proposed bylaws are designed to address. Given OPTN's limited resources additional bylaws requirements should not be undertaken without clearly defined goals that address clearly identified problems. ASTS maintains that a survey of community is necessary to identify the current landscape of pediatric transplant care delivery. Additionally MPSC data related to pediatric program quality issues reported/reviewed and the frequency of such issues would help define the scope of the problem the proposal is designed to address. Greater clarity in this regard will help develop more nuanced and effective criteria. Furthermore ASTS remains concerned that size stratification was eliminated from the proposal. A simple numbers requirements for pediatric cases in patients less than 18 y/o fails to capture the important differences in the level of expertise required for smaller children. For example in pediatric kidney recipients a surgeon leading a pediatric kidney transplant program should have experience in transplanting children under 25 kg since this is the approximate cut-off at which the operation changes from an extraperitoneal operation to an intraperitoneal operation. The latter frequently involves cross clamping the abdominal aorta and inferior vena cava in turn changing the dynamics of the operation including the important interaction between experienced surgeons and pediatric anesthesiologists. For the liver and intestine the technical challenges of transplanting a baby less than 6 kg are vastly different from transplanting a 15-year-old though under current and proposed criteria both are "pediatric." ASTS suggests the committee consider specific experience for the designated surgical head of a pediatric liver transplant program represented by reasonable numbers in transplanting babies in each of 3 groups: from 0 – 1 year of age from 1 – 5 years of age and > 5 years (or 5 – 18). Additionally it is our strong opinion that demonstrated training and experience in performance of technical variant transplants and segmental grafts should be an essential component of "pediatric experience for program leadership." Given the small numbers of intestinal transplants being performed currently in a limited number of centers and given that close to 50% of current intestinal transplants occur as part of liver-containing grafts extending the liver criteria as a proxy for pediatric intestine criteria may be a reasonable expedient at the present time. ASTS recognizes that there must be a

minimum bar by which to judge programs. However it is insufficient for numbers to be the sole criteria. Important aspects such as selection processes and outcomes must be included. If the goal of the proposed policy is to judge competency then training experience numbers weights and outcomes are surrogates that must be considered en masse. As the leading medical specialty society advancing surgical care in transplantation with an established accreditation process ASTS is the body best suited to define new requirements for transplant surgeons involved in pediatric transplantation. In fact current OPTN policy already recognizes ASTS accredited fellowship training programs as the primary pathway for key personnel requirements. We would be pleased to expand accreditation requirements to address pediatric training requirements which could serve as the basis for expanded policy if these requirements are deemed to be necessary. We envision such requirements would address specific experience during training combined with post-training experience under supervision from an experienced pediatric transplant surgeon. This experience should be organ specific (i.e. split and living donor liver transplantation single lobe lung transplants in children kidney transplants in children <15 kg etc.) and define experience caring for infants as well as adolescents. In conclusion ASTS believes that there are key items that remain unaddressed with the proposal and therefore we strongly object to its adoption as policy.

Russell Steele, **Ochsner Childrens Health Center and Tulane**

The transplant team should include a pediatric infectious disease specialist to manage pre-transplant immunizations assessment of previous exposure to potential pathogens (CMV EBV TB etc.) and to treat post transplant infections.

Scott Wenderfer, **Baylor College of Medicine**

As a board certified pediatric nephrologist and an Assistant Professor of Pediatrics I feel that the safest and most effective kidney transplant program for patients less than 18 years old must have a qualified primary pediatric surgeon and a qualified primary pediatric nephrologist serving as key personnel. I do not feel that this would create a undue burden to patients or families as nearly all pediatric and adolescent kidney transplants are already being performed in transplant centers located within proximity to pediatric nephrology practices.

sharon bartosh

agree

Shawnna Morrison-Downey, **Parent of a pediatric transplant recipient**

I am a mother of a pediatric transplant recipient as well as a current nursing student. Therefore I know the medical community is well aware of how vastly different adult and pediatric care is-which is why pediatrics is a specialty! With the medical community knowing this I was shocked to find out that there were no laws in place requiring a surgeon to be specialty trained in performing transplant surgeries on pediatric patients and centers not specialty trained either but allowed to provide follow-up care for these young patients. This day in age-with the advancements in medicine and the knowledge we hold this is truly unacceptable! UNOS needs to change this STAT! This is a very serious flaw in their current criteria and one that truly puts pediatric patients at risk! Transplantation is a very specialized field in itself now think about that while dealing with a pediatric patient. Forget about a transplanted organ being thrown into the mix because pediatric medicine alone requires extensive specialty training. You cannot have providers who are only trained in adult care caring for pediatric patients! That's just insane-you MUST have providers who are properly trained to care for these children! They too deserve the best medical care that can be achieved and the current criteria UNOS has in place leaves the end result lacking for our pediatric patients! Our children deserve better and UNOS has the ability to make it happen!

Simon Horslen, **Seattle Children's**

I endorse this proposal. Pediatric patients and families deserve expert age appropriate care not just in terms of the experience and technical skills of their surgeons but in the management of medical conditions developmental issues and infrastructure particular to infants children and adolescents.

Steven Alexander, **NAPRTCS - The North American Pediatric Renal**

The Children's Health Act of 2000 incorporated as an amendment to NOTA requires that the transplant community recognize the differences in health and organ transplantation issues between children (< 18 years of age) and adults throughout the system and adopt criteria policies and procedures that address the unique health care needs of children. In harmony with this requirement the OPTN has developed a common-sense proposal that requires that programs caring for children are led by physicians and surgeons who have demonstrated either training or experience in caring for them. This proposal is balanced and as the background documents clearly show its enactment will have little effect on a child's access to care. While we realize this proposal has sparked disagreement over using the number of pediatric transplant procedures or the number of pediatric patients whom a center's designated pediatric surgeon and physician have cared for as a basis for approval we note that similar disagreements have occurred with every previous sub-type of transplant that OPTN has recognized. OPTN has used specialized experience and training criteria as the basis for approval of all types of transplants and they now should do so for pediatric transplant programs by adopting this proposal. NAPRTCS fully supports this proposal and urges the OPTN Board of Directors to approve it. The North American Pediatric Renal Trials and Collaborative Studies (NAPRTCS) was founded in 1987 as a registry designed to collect information about children receiving kidney transplants. It has evolved into a CKD dialysis and transplant registry and into a multi-center clinical trials network that has collaborated with NIH and other sponsors to undertake critical studies in these children. The NAPRTCS currently collects data on pediatric kidney transplant recipients from over 50 North American pediatric centers. During its 28 years of continuous operation it has enrolled followed and reported on over 12 000 kidney transplants in 11 000 pediatric recipients. NAPRTCS results are freely available to the entire transplant community at its web site (http://spitfire.emmes.com/study/ped/). Over the life-time of NAPRTCS young children who receive kidney transplants have gone from being a very high-risk group to having the best long-term outcomes of any age group including all categories of adults (NEJM 2014;371:549-558). This remarkable turn-around has occurred only because of the dedication and skill of the programs that treat these vulnerable patients. For the NAPRTCS Board of Directors: Steven Alexander MD (Stanford); Mark Benfield MD (Birmingham); Richard Fine MD (Los Angeles); Stuart Goldstein MD (Cincinnati); William Harmon MD (Boston); Ruth McDonald MD (Seattle); Alicia Neu MD (Baltimore); Bradley Warady MD (Kansas City).

Susan Boensel

We have pediatric physicians pediatric dentists pediatric oncologists and the list goes on and on. It only makes sense in such life threatening/changing events such as an organ transplant that we should have highly trained specialists to perform such procedures. I would agree that there needs to be an approved pediatric component in order to perform transplants in our young children.

Susan Halbach, **Seattle Children's Hospital**

As stated by many others the medical and surgical issues involved in treating the pediatric transplant patient can be very different from those of adult patients. In this age of transparency in medicine it is imperative that families can be assured the transplant center its physicians

nurses and support staff have adequate experience in meeting the needs of this vulnerable population. This proposal seems like a good place to start.

Susan Ingraham

As has often been said children are not just small adults. A child's anatomy physiology response to therapies medical management requirements and psychosocial support needs are all distinct from those of an adult. It is imperative that

Thomas May, **Parent**

Being the parent of a heart recipient I'm in favor of setting uniform standards for transplants.

Thomas Simon

Absolutely agree--training should be required.

TRAIRONG THOMAS, **JINXIN Inc**

As a parent of a 2 yrs old child who did receive transplant care I fully support this initiative. While I fully appreciate that one solution does not necessarily apply to all situations I believe this is a step in the right direction. The experience and expertise that the pediatric surgeons brought to my child's case was the single most significant contributor in the success of her liver transplant surgery where a partial adult liver was used to replace a small child's liver. In this case experience and expertise in pediatric surgery was indispensable. If more people can be given specialized care without denying access to others then it should be done. Again not a perfect solution but a definite step in the right direction.

Uzma Shah, **MGH**

There are numerous issues with Pediatric training for liver transplantation with controversy in the need for a separate fellowship and Board certification. Whilst these issues remain iy would not be prudent to make sweeping changes such as these. Liver transplant and hepatology training is part of general Pediatric GI training as well and it is important to ensure that centers are that are providing good quality care continue to do so.

Victoria Norwood, **American Society of Pediatric Nephrology**

On behalf of the American Society of Pediatric Nephrology (ASPN) I welcome the opportunity to provide comments and support for the current UNOS proposal to establish pediatric training and experience requirements in its bylaws. Founded in 1969 ASPN is a professional society composed of pediatric nephrologists whose goal is to promoteoptimal care for children with kidney disease and to disseminate advances in the clinical practice and basic science of pediatric nephrology. The ASPN currently has over 700 members making it the primary representative of the pediatric nephrology community in North America. Our support is based on a detailed review of the proposal including the history that requirements for pediatric transplant have been in development since 1993. Most recently UNOS has outlined goals directed at pediatric transplant program requirements. Specifically in 2010 the UNOS Membership and Professional Standards Committee set a goal to develop qualification criteria for pediatric organ transplant program approval and in 2012 the UNOS Board of Directors made the development of pediatric program requirements one of the key initiatives in its strategic plan to promote transplant patient safety. In the current UNOS bylaws there are no specific criteria to define pediatric expertise required for a program to perform pediatric transplants. This lack of requirements potentially allows for a surgeon or physician with no pediatric experience to perform and manage transplants in pediatric patients which the ASPN believes should be rectified immediately. The UNOS proposed Pediatric Bylaws is a good first step in making that happen. As advocates for children and adolescents with end stage renal disease we are

concerned with the lack of established standards to ensure the quality of care delivered to our pediatric kidney transplant recipients defined in the proposal as children and adolescents less than 18 years old. ASPN believes it is appropriate to include children and adolescents up to age 18 years under the proposed Pediatric Bylaws and has always advocated for pediatric physicians to provide medical care to adolescent patients. ASPN disagrees with classifying patients by size and lumping adolescents with adults for several reasons. Teenagers as well as younger children have pediatric diseases leading to end stage organ failure and the need for transplant and should be treated by pediatric personnel who are familiar with these diseases. For example pediatric end stage renal disease (ESRD) is caused by congenital anomalies acquired glomerulonephritis hereditary diseases and other rare kidney diseases whereas ESRD in adults is mostly due to diabetes primary hypertension and autosomal dominant polycystic kidney disease. In addition the adolescent population has not completed growth and development and teenagers are still dependent on parents or guardians for their livelihood and care. Finally less than 18 years of age is a well-accepted definition of pediatrics by the National Organ Transplant Act (NOTA) the Centers for Medicare and Medicaid Services (CMS) and the American Academy of Pediatrics. While advocating for pediatric expertise for quality of transplant care we also want to ensure that access to transplants for our pediatric patients is preserved. The UNOS Pediatric Committee has done an analysis of UNOS programs that performed at least 1 pediatric transplant between 1/1/05 and 7/31/14 and found that 98% of pediatric (less than 18yo) transplants were performed in programs whose volume of pediatric transplants would meet the volume criteria by organ in this proposal. Based on this finding we are confident that the proposed Pediatric Bylaws will begin to ensure access to quality care for pediatric patients without restricting access of children and adolescents to transplant. We would like to point out that most regions and states have only a few transplant centers so adults as well as pediatric patients already must travel to a specialized transplant center to obtain their care. No one would suggest that an adult patient should be transplanted by a local surgeon and cared for by a nephrologist with no kidney transplant experience and current UNOS Bylaws would not allow that to happen for adults. It only follows that the same level of care should be provided to children and adolescents. In conclusion ASPN believes strongly that children and adolescents less than 18 years old who constitute the pediatric age group are a well-recognized special population of patients whose optimal care necessitates pediatric expertise of key transplant personnel. The proposed Pediatric Bylaws are long overdue and should be adopted as a minimum first step to promote patient safety and optimize outcomes for pediatric transplant recipients.

Wendy Bendle

Our daughter had a liver transplant when she was 5 months old. All of her care has been at a children's hospital with a pediatric liver transplant team. The medical care she received before during and after her transplant has been appropriate and specific for her age and physical size as a small baby (and now a growing toddler). What became clear to me in the months after her transplant was the follow up care focused on her needs that were specific to her being a baby--she had not yet developed antibodies to EBV her donor liver had and she developed PTLD a rare condition in pediatric transplant cases. Her pediatric transplant doctors were able to use their experience to guide us and provide care for her when she was so sick. I have profound respect for all transplant docs for it is all incredible lifesaving work but I am much much more comfortable having our child receive her care from doctors and clinicians who treat children all the time with these unusual childhood diseases and transplant issues. I am concerned about a one-size-fits-all approach to transplant surgery or medicine because the needs and potential complications for a child tx patient are different from an adult.

William Harmon, **Boston Children's Hospital**

Thank you for the opportunity to comment on this important and long-overdue proposal. OPTN has accomplished an important standard by assuring that transplant patients in the USA are treated by programs that are directed by well-educated and experienced professionals. With the introduction of new organ systems or procedures such as vascularized composite grafts or the use of living donors OPTN must decide whether there are significant enough differences from established programs that new requirements are necessary. In the case of pediatrics this question has been asked for over 2 decades and it is gratifying that OPTN has now proposed important program requirements. Some may question whether there are sufficient differences between pediatric and adult programs to warrant separate criteria. Certainly pediatric diseases leading to organ failure are more likely to be genetic or congenital the transplant procedures are frequently different some of the end-points such as growth and development are different pharmacokinetics are definitely different as are usual laboratory values and very importantly psychosocial treatments. Understanding the scope of these differences the requirement for specialized knowledge to care for this group of patients is both obvious and reasonable. The use of the 18th birthday to define the distinction between minor and adult is well established in custom and law. Some would argue that the proposed requirements are not rigorous enough while others suggest that any limitations place on recipient age are unnecessarily restrictive. The pediatric committee is to be congratulated for finding a reasonable compromise between these extremes. The committee has also shown that this proposal is unlikely to have much impact on access to care. Most of the programs that provide transplants for children have sufficient volume to allow a pediatric team member to qualify based on experience. Clearly the acceptance of these new standards will assure that children undergoing organ transplantation will receive the outstanding care that they deserve. I support this proposal and strongly recommend that the Board approve it.

Zoe Stewart, **Individual comment**

My concerns echo prior issues raised by ASTS and members of MPSC on review of the proposal. 1) The volume requirements seem arbitrary and as projected could propose significant hardship on families who will be forced to now travel great distances for evaluation transplant and post-transplant cares. In a time of trying to enhance geographic equity in organ access in other OPTN policies; this seems destined to do exactly the opposite for pediatric patients and families. There has been no risk:benefit analysis of the impact of how long travel may impact long-term graft outcomes (which is really what this is predicated on in the supporting appendices). 2) As noted by others comparing the transplantation of infants to adolescents is apples to oranges. If my teenager needed a kidney transplant and there is a transplant center in our town doing >50 transplants/year I cannot fathom someone mandating that I travel 5-6 hours to a "pediatric" transplant center". This will financially cripple many families and have unintended financial and social consequences.

Post Public Comment Consideration:

After carefully considering feedback received during public comment, and developing responses to the themes identified above, the Committee voted to approve the proposed Bylaws without modification (16-Support, 0-Oppose, 0-Abstain).

Number of pediatric transplants at centers meeting the proposed pediatric volume criteria, 1/1/10-12/31/14

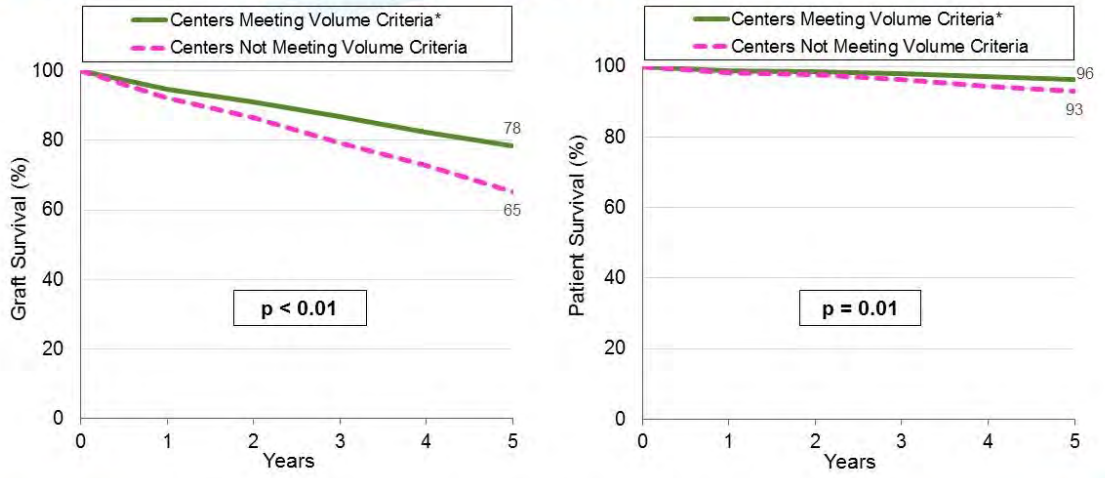
Organ Transplanted	Number of Pediatric Transplants	Number and Percent of Pediatric Transplants at Centers Meeting Volume Criteria*	
	N	N	%
Kidney	3,733	3,398	91
Liver	2,667	2,533	95
Heart	1,918	1,838	96
Lung	255	227	89
All Organs	8,573	7,996	93

Volume criteria:

- **Kidney**: 10+ transplants in recipients <18 years, and 3+ of these in recipients <6 years or <25 kg
- **Liver**: 15+ transplants in recipients <18 years, and 8+ of these in recipients <6 years or <25 kg
- **Heart**: 8+ transplants in recipients <18 years, and 4+ of these in recipients <6 years or <25 kg
- **Lung**: 4+ transplants in recipients <18 years, and 1+ of these in recipients <12 years or <40 kg

OPTN | UNOS

Unadjusted Kaplan-Meier Survival by Center Volume Category for Pediatric Kidney Transplants, 1/1/02-12/31/11

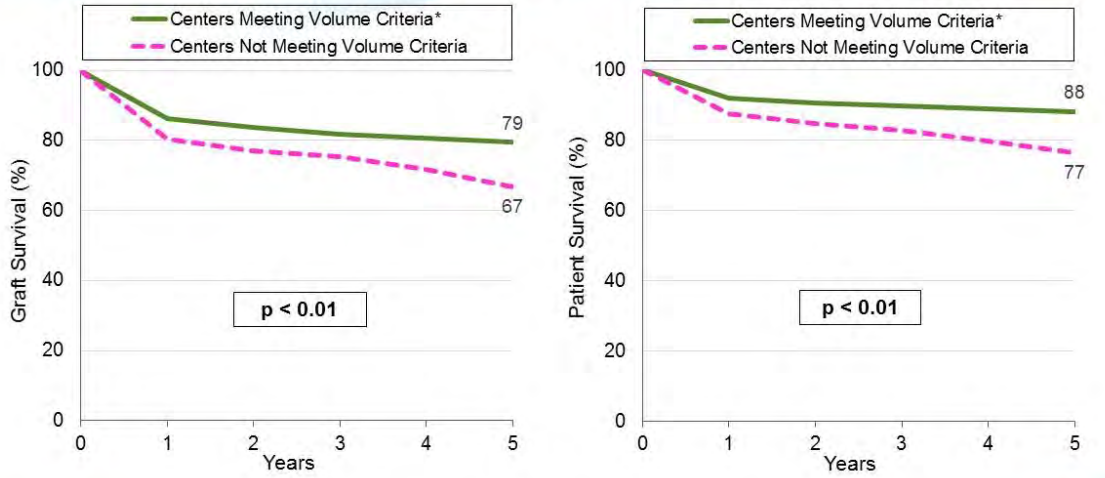


OPTN | UNOS

*Centers Meeting Volume Criteria: Centers with at least 10 transplants in recipients <18 years, including at least 3 transplants in recipients <6 years or <25 kg.

13

Unadjusted Kaplan-Meier Survival by Center Volume Category for Pediatric Liver Transplants, 1/1/02-12/31/11

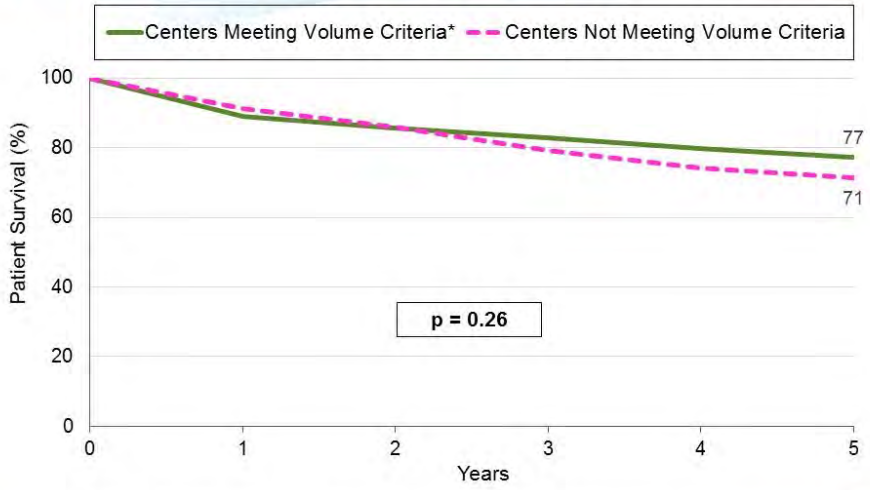


OPTN | UNOS

*Centers Meeting Volume Criteria: Centers with at least 15 transplants in recipients <18 years, including at least 8 transplants in recipients <6 years or <25 kg.

14

Unadjusted Kaplan-Meier Survival by Center Volume Category for Pediatric Heart Transplants, 1/1/02-12/31/11

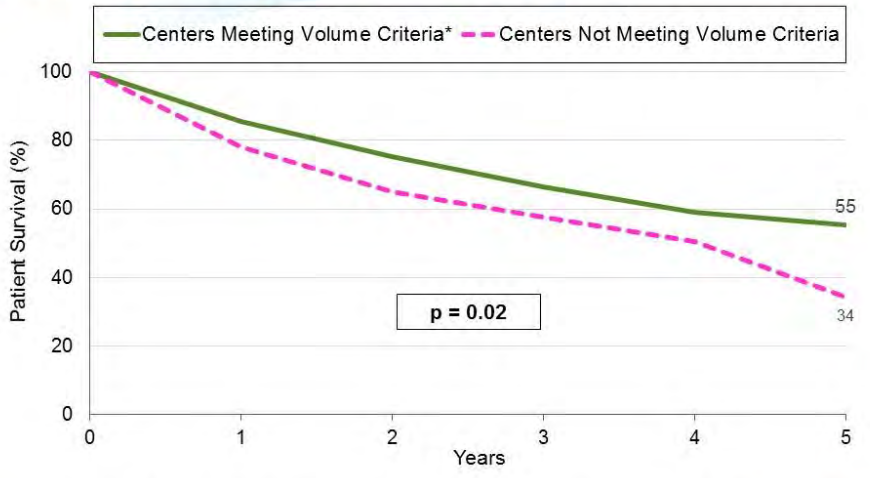


OPTN | UNOS

*Centers Meeting Volume Criteria: Centers with at least 8 transplants in recipients <18 years, including at least 4 transplants in recipients <6 years or <25 kg.

15

Unadjusted Kaplan-Meier Survival by Center Volume Category for Pediatric Lung Transplants, 1/1/02-12/31/11

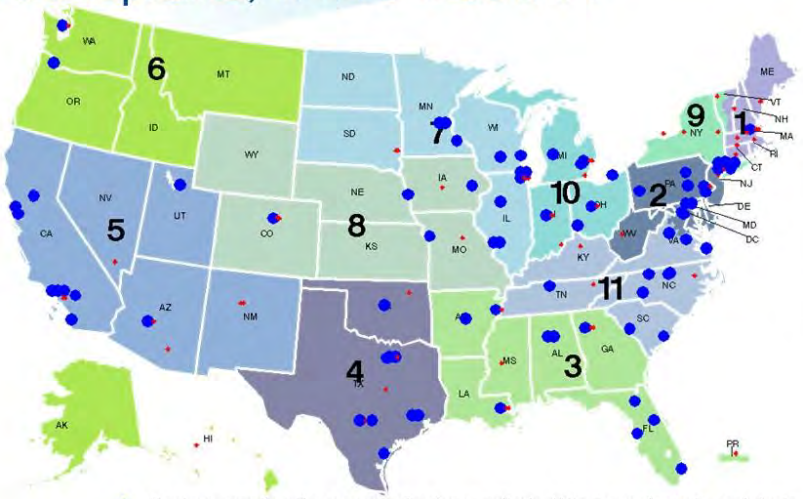


OPTN | UNOS

*Centers Meeting Volume Criteria: Centers with at least 4 transplants in recipients <18 years, including at least 1 transplant in recipients <12 years or <40 kg.

16

Geographic locations of centers performing pediatric kidney transplants, 1/1/10-12/31/14

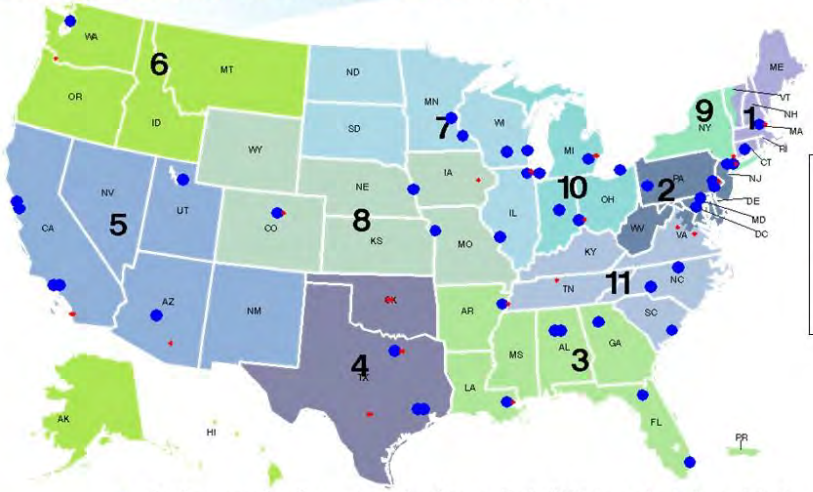


91% of pediatric transplants were performed at centers meeting the proposed volume criteria

- Centers meeting the proposed volume criteria (10+ transplants in recipients <18 years and 3+ of these in recipients <6 years or <25 kg)
- Centers not meeting the proposed volume criteria

OPTN | UNOS

Geographic locations of centers performing pediatric liver transplants, 1/1/10-12/31/14



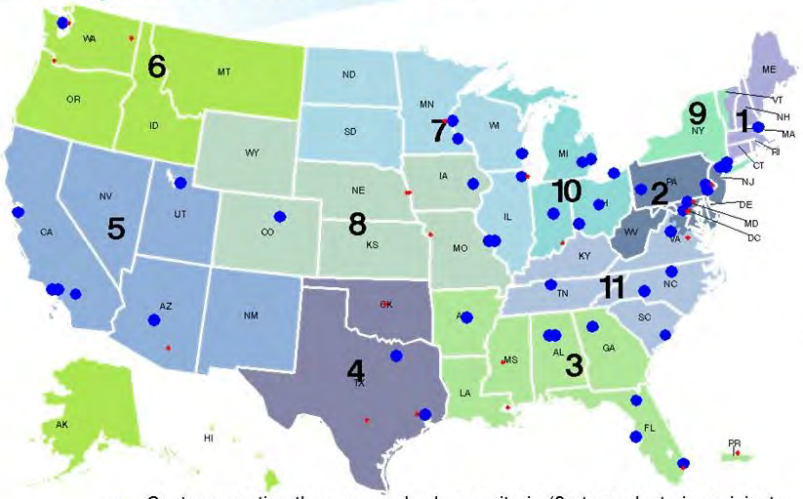
95% of pediatric transplants were performed at centers meeting the proposed volume criteria

- Centers meeting the proposed volume criteria (15+ transplants in recipients <18 years and 8+ of these in recipients <6 years or <25 kg)
- Centers not meeting the proposed volume criteria

OPTN | UNOS

2

Geographic locations of centers performing pediatric heart transplants, 1/1/10-12/31/14



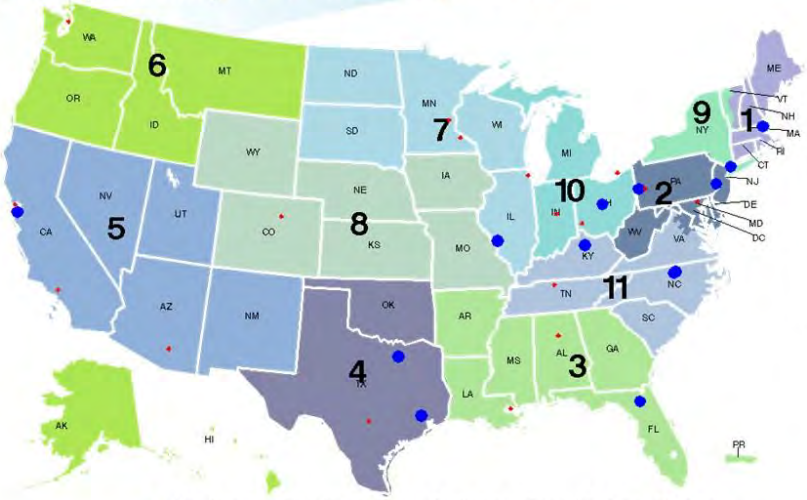
96% of pediatric transplants were performed at centers meeting the proposed volume criteria

- Centers meeting the proposed volume criteria (8+ transplants in recipients <18 years and 4+ of these in recipients <6 years or <25 kg)
- Centers not meeting the proposed volume criteria

OPTN | UNOS

3

Geographic locations of centers performing pediatric lung transplants, 1/1/10-12/31/14



89% of pediatric transplants were performed at centers meeting the proposed volume criteria

- Centers meeting the proposed volume criteria (4+ transplants in recipients <18 years, 1+ of these in recipients <12 years or <40 kg)
- Centers not meeting the proposed volume criteria

OPTN | UNOS

4