

# ***Establishing Pediatric Training and Experience Requirements in the Bylaws***

**Sponsoring Committee:** Pediatric Transplantation

**Policy/Bylaws Affected:** OPTN Bylaws appendices E.2: Primary Kidney Transplant Surgeon Requirements, E.3: Primary Kidney Transplant Physician Requirements, E.5: Kidney Transplant Programs that Register Candidates Less than 18 Years Old, F.3: Primary Liver Transplant Surgeon Requirements, F.4: Primary Liver Transplant Physician Requirements, Appendix F.7: Liver Transplant Programs that Register Candidates Less than 18 Years Old, G.8: Pancreas Transplant Programs that Register Candidates Less than 18 Years Old, H.2: Primary Heart Transplant Surgeon Requirements, H.3: Primary Heart Transplant Physician Requirements, H.4: Heart Transplant Programs that Register Candidates Less than 18 Years Old, I.4: Lung Transplant Programs that Register Candidates Less than 18 Years Old, L.17: Interviews, and L.18: Hearings

**Public Comment:** January 2015 and August 2015

**Effective Date:** Upon implementation and notice to OPTN members

---

## **Problem Statement**

The National Organ Transplant Act (NOTA) requires that the OPTN “recognize the differences in health and in organ transplantation issues between children [less than 18 years old] and adults throughout the system and adopt criteria, policies, and procedures that address the unique health care needs of children.”<sup>1</sup> 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.

## **Summary of Changes**

The Bylaws will require that a designated transplant program have an approved pediatric component in order to perform kidney, liver, and heart 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 who will serve as key personnel.

## **What Members Need to Do**

UNOS will distribute a pediatric component application to any member transplant program that has had at least one pediatric patient on its waiting list in the last five years. If you do not automatically receive an application based on this criteria, contact the UNOS Membership Analyst for your region to request one. If

---

<sup>1</sup> 42 USC Sec. 274 (b)(2)(M).

you receive an application but don't intend to apply, please document your intention and submit it to UNOS.

Your program must complete and submit your application to UNOS within 90 days in order to guarantee that we process them before the Bylaws are implemented. UNOS and the MPSC will process each application over the next 18 months. We will notify you of the status of your application before the Bylaws are implemented.

Once the Bylaws are implemented, if your program has pediatric patients on the waiting list and you don't have approval for a pediatric component, you must follow the transition plan described in Appendix K.5: *Transition Plan during Long-term Inactivity, Termination, or Withdrawal*.

If your liver or heart transplant program does not have a pediatric component, you may register a patient less than 18 years old on the waiting list if you believe the transplant would prevent a serious or imminent threat to your patient's health or safety and if the patient qualifies as pediatric liver or heart Status 1A. Your program must submit a pediatric membership exception request to UNOS within 72 hours of the candidate's registration. The MPSC will retrospectively consult with the Pediatric Transplantation Committee to determine whether an emergency was present and that it was medically inadvisable or commercially impractical to transport the patient to a program with a pediatric component. If the MPSC denies an emergency exception request, that candidate's registration will be in violation of OPTN obligations and result in punitive action. Approval of an exception is limited to the individual case and does not mean that your program has been approved for a pediatric component.

### **Affected Policy/Bylaw Language:**

New language is underlined and language that will be deleted is ~~struck through~~.

## ***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 Register Candidates Less than 18 Years Old**

A designated kidney transplant program that registers candidates 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 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.56 Kidney Transplant Programs that Perform Living Donor Recovery**

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

### **F.3 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.4 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.7 Liver Transplant Programs that Register Candidates Less than 18 Years Old**

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

#### **A. Primary Pediatric Liver Transplant Surgeon Requirements**

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

1. The surgeon meets *all* of the requirements described in *Section F.2: Primary Liver Transplant Surgeon Requirements*, including completion of at least *one* of the following training or experience pathways:
  - The formal 2-year transplant fellowship pathway as described in *Section F.2.A: Formal 2-year Transplant Fellowship Pathway*
  - The liver transplant program clinical experience pathway, as described in *Section F.2.B: Clinical Experience Pathway*
2. The surgeon has performed at least 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 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
  - 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*.

#### **E. Emergency Pediatric Membership Exceptions**

A designated liver transplant program that does not have a pediatric component may register a patient less than 18 years old on the waiting list if *all* the following conditions are met:

1. The transplant program believes it must transplant the pediatric patient to prevent a serious and imminent threat to the patient's health or safety
2. The patient is pediatric Status 1A according to *Policy 9: Allocation of Livers and Liver-Intestines*.

The transplant program must submit a pediatric membership exception request to the OPTN Contractor within 72 hours of the candidate's registration on the waiting list.

The MPSC will retrospectively review pediatric membership exception requests. As part of this review, the MPSC will consult with the Pediatric Transplantation Committee. In submitting the pediatric membership exception request, the transplant program must demonstrate *all* the following:

1. That the transplant was necessary to prevent a serious and imminent threat to the patient's health or safety
2. That it was medically inadvisable or commercially impractical for the transplant program to transport the candidate to a designated liver transplant program with an approved pediatric component
3. The candidate was registered as pediatric Status 1A and remained pediatric Status 1A until the time of transplant

If the member fails to demonstrate the criteria for this emergency exception, any listing made thereunder will be a violation of OPTN obligations and will be referred to the MPSC.

Approval of an emergency pediatric membership exception request does not grant the transplant program approval of the pediatric component.

## **F.78 Liver Transplant Programs that Perform Living Donor Recovery**

*[Subsequent headings affected by the renumbering of this policy will also be changed as necessary.]*

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

## **G.8 Pancreas Transplant Programs that Register Candidates Less than 18 Years Old**

A designated pancreas transplant program that registers candidates 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 Register Candidates Less than 18 Years Old**

A designated heart transplant program that registers candidates 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 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*.

## **E. Emergency Pediatric Membership Exceptions**

A designated heart transplant program that does not have a pediatric component may register a patient less than 18 years old on the waiting list if all the following conditions are met:

1. The transplant program believes it must transplant the pediatric patient to prevent a serious and imminent threat to the patient's health or safety
2. The patient is pediatric Status 1A according to *Policy 6: Allocation of Heart and Heart-Lungs*

The transplant program must submit a pediatric membership exception request to the OPTN Contractor within 72 hours of the candidate's registration on the waiting list.

The MPSC will retrospectively review pediatric membership exception requests. As part of this review, the MPSC will consult with the Pediatric Transplantation Committee. In submitting the pediatric membership exception request, the transplant program must demonstrate all the following:

1. That the transplant was necessary to prevent a serious and imminent threat to the patient's health or safety
2. That it was medically inadvisable or commercially impractical for the transplant program to transport the candidate to a designated heart transplant program with an approved pediatric component
3. The candidate was registered as pediatric Status 1A and remained pediatric Status 1A until the time of transplant

If the member fails to demonstrate the criteria for this emergency exception, any listing made thereunder will be a violation of OPTN obligations and will be referred to the MPSC.

Approval of an emergency pediatric membership exception request does not grant the transplant program approval of the pediatric component.

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

## **I.4 Lung Transplant Programs that Register Candidates Less than 18 Years Old**

A designated lung transplant program that registers candidates 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 requirements described in *Section I.2: Primary Lung Transplant Surgeon Requirements*.

### **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.

## **Appendix L: Reviews, Actions, and Due Process**

### **L.17. Interviews**

An interview is not a hearing, is preliminary in nature, and is not conducted according to the procedural rules followed for hearings. The member will be informed of the reasons for the interview and may present any information it considers useful and relevant.

#### **A. Members' Right to an Interview**

The member will have the right to an interview when:

1. A Letter of Reprimand is recommended.
2. An adverse action is recommended.
3. A membership application or application for designated transplant program status is rejected.
4. A pediatric membership exception request is rejected.

However, a member has no right to an interview when a potential violation is being reviewed through the Imminent Threat Review pathway. After the interview is completed, the MPSC will promptly provide a summary of the interview to the member.

### **L.18. Hearings**

If the MPSC makes a recommendation for an adverse action, or the Board of Directors takes an adverse action without recommendation from the MPSC, the member is entitled to a hearing.

#### **A. Members' Right to a Hearing**

The member has a right to a hearing when an adverse action is:

1. Recommended by the MPSC.
2. Recommended by a subcommittee of the MPSC, if the action is the rejection of an initial membership application or application for designated transplant program status.
3. A result of a determination regarding a potential violation undergoing an Imminent Threat Review.
4. Taken by the Board of Directors or the Executive Committee notwithstanding a favorable recommendation by the MPSC or standing subcommittee of the MPSC under circumstances where no right to a hearing existed.
5. Taken by the Board of Directors or the Executive Committee on its own without a prior recommendation by the MPSC.

The member also has a right to a hearing when the MPSC or a subcommittee of the MPSC rejects a pediatric membership exception request.

If the Board of Directors determines, based on available evidence that a potential violation of OPTN Obligations may pose an urgent and severe risk to patient health or public safety, the Board may take action even if the member has not had the opportunity for a hearing.

#