OPTN | UNOS Briefing Paper

# Subspecialty Board Certification for Primary Liver and Heart Transplant Physicians

***OPTN/UNOS Membership and Professional Standards Committee***

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# Subspecialty Board Certification for Primary Liver and Heart Transplant Physicians

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| *Sponsoring Committee:* | *Membership and Professional Standards* |
| *Public Comment Period:* | *August 15, 2016 – October 15, 2016* |

## Executive Summary

OPTN Bylaws require that a designated liver transplant program's primary liver transplant physician must have "current board certification in gastroenterology." The OPTN/UNOS Membership and Professional Standards Committee (MPSC) is increasingly receiving liver program key personnel applications that propose a primary transplant physician who meets all the Bylaws' requirements except they have current board certification in transplant hepatology, with lapsed gastroenterology board certification. The MPSC generally feels that these individuals meet the intent of the key personnel Bylaws and that they are qualified to serve as a liver program's primary transplant physician; however, it ultimately rejects these applications because the individual does not fulfill the explicit requirements in the Bylaws. Although not presented as frequently, the MPSC is also aware of a subspecialty board certification created for cardiologists by the American Board of Internal Medicine- advanced heart failure and transplant cardiology. This proposal modifies the board certification requirement for primary liver transplant physician applicants to include current board certification in transplant hepatology or current pediatric transplant hepatology certification of added qualification as acceptable options. Similarly, this proposal also modifies the board certification requirement for primary heart transplant physician applicants to also include current board certification in advanced heart failure and transplant cardiology as an acceptable option. Requiring board certification for a transplant program's primary physician that entails more transplant-specific training stands to improve outcomes and promote patient safety for candidates on the waiting list, living donors, and transplant recipients. Additionally, modifying OPTN Bylaws to reflect current practice helps promote the efficient management of the OPTN.

# What problem will this proposal solve?

OPTN/UNOS Bylaws require that a designated liver transplant program's primary liver transplant physician must have "current board certification in gastroenterology." The OPTN/UNOS Membership and Professional Standards Committee (MPSC) is increasingly receiving liver program key personnel applications that propose a primary transplant physician who meets all the Bylaws' requirements except they have current board certification in transplant hepatology, with lapsed gastroenterology board certification. The MPSC generally feels that these individuals meet the intent of the key personnel Bylaws and that they are qualified to serve as a liver program's primary transplant physician; however, it ultimately rejects these applications because the individual does not fulfill the explicit requirements in the Bylaws. Although not presented as frequently to the MPSC, the subspecialty board certification created for cardiologists by the American Board of Internal Medicine- advanced heart failure and transplant cardiology presents a similar problem.

# Why should you support this proposal?

The changes presented in this proposal stem directly from recommendations developed by a Joint Societies Working Group (JSWG), and are representative of a collaborative effort between the American Society of Transplantation (AST), the American Society of Transplant Surgeons (ASTS), the North American Transplant Coordinators Organization (NATCO), and the MPSC. The proposed changes update the Bylaws to reflect current practice regarding the subspecialty board certification that is more commonly held by transplant physicians at liver and heart transplant programs.

# How was this proposal developed?

In 2013, the MPSC created a working group to address a number of aspects in the Bylaws key personnel requirements that had repeatedly been noted as ambiguous, unenforceable, or regularly yielding questions from members or the MPSC. Included in the topics assigned to this working group was the consideration of subspecialty board certifications. While the MPSC Working Group began addressing the list of topics it had been assigned, the Joint Societies Policy Steering Committee met in May 2014 and opted for the formation of a Joint Societies Working Group (JSWG) to address the key personnel Bylaws projects being worked on by the MPSC.

The JSWG acknowledged it is not uncommon for transplant hepatologists to maintain their transplant hepatology board certification, while letting their gastroenterology board certification lapse. Considering the first transplant hepatology examination occurred in 2006, the JSWG indicated that transplant hepatology board certification is now common for physicians who are involved with a hospital's liver transplant program.

The group considered whether transplant hepatology certification should be an option for primary liver physician applicants, or if it should replace the gastroenterology certification requirement. The JSWG noted that the training and experience reflected by transplant hepatology certification is more applicable to the regular duties performed by liver transplant physician, as compared to gastroenterology board certification. Additionally, the training and experience reflected by gastroenterology board certification would not be completely ignored by requiring transplant hepatology board certification, as an individual must have current board certification in gastroenterology to sit for the transplant hepatology board exam. Finally, the JSWG believes that relatively few liver programs' primary physicians were only gastroenterology certified and that transplant hepatology certification is prevalent among liver transplant programs. Considering these things, the JSWG agreed that the Bylaws should require that all primary liver transplant physicians are currently board certified in transplant hepatology.

Suggesting that transplant hepatology certification should replace the current requirement prompted members to consider how that may affect liver programs at children's hospitals. Pediatric transplant hepatologists on the OPTN/UNOS Pediatric Committee and the MPSC were consulted on this. The pediatric hepatologists consulted on this matter agreed that it would be appropriate to require that primary

transplant liver physicians possess current certification in transplant hepatology instead of requiring gastroenterology board certification. Along these same lines, and to accommodate key personnel at those programs that predominantly transplant pediatric patients, it was recommended that any Bylaws modifications should also allow a pediatric transplant hepatology certification of added qualification. Pediatric hepatologists familiar with this certification of added qualification indicated that they believed a sufficient number had been granted such that adding this new requirement should not create an undue burden on liver programs that primarily transplant pediatric patients.

With this confirmation, the JSWG felt comfortable recommending that the current primary liver transplant physician requirements should replace the current gastroenterology board certification requirement with a requirement that the individual must possess current board certification in transplant hepatology or a current pediatric transplant hepatology certification of added qualification.

The JSWG also discussed another subspecialty certification- advanced heart failure and transplant cardiology. The JSWG did not believe enough individuals in the transplant community possessed this certification at this time to justify including it in the Bylaws, but noted that this should be monitored for future revisions to the primary heart transplant physician requirements.

These recommendations were presented to the MPSC and Joint Societies Policy Steering Committee, respectively. Both groups endorsed these recommendations, with no concerns raised.

# How well does this proposal address the problem statement?

The Bylaws changes included in this proposal will effectively address the situation of primary liver transplant physician applicants who are seemingly qualified to serve in this role except they have current transplant hepatology board certification, while letting their gastroenterology board lapse. Likewise, adding the advanced heart failure and transplant cardiology subspecialty board certification as another option for primary heart transplant physicians will help prevent similar problems and better reflect current practice. The MPSC believes it is necessary to update the Bylaws to reflect the current standards that are now common at liver and heart transplant programs.

# Was this proposal changed in response to public comment?

Yes. In response to public comment feedback, the MPSC made two post-public comment modifications to the originally proposed Bylaws changes, and voted (36- support, 0- oppose, 0- abstentions) to send the modified proposal for the OPTN/UNOS Board of Directors consideration during its December 2016 meeting. The two post-public comment changes are:

1. *Include transplant hepatology board certification as another option for primary liver transplant physicians, in addition to the current gastroenterology board certification requirement.* The original proposal recommended *replacing* the current gastroenterology board certification requirement with a transplant hepatology board certification requirement for primary liver transplant physicians. This modification was a direct response to the primary concern with this proposal, which was raised repeatedly. In reviewing this feedback, the MPSC agreed that this was an appropriate and necessary change to make.

2. *Similarly, add the advanced heart failure & transplant cardiology subspecialty board certification as another option for primary heart transplant physicians.* Changes to the primary heart transplant physician Bylaws were not originally included in this proposal, but the MPSC was motivated to make this change in response to feedback during public comment, in consideration of the amendment for primary liver transplant physicians, in anticipation of similar problems for subspecialty certified transplant cardiologists, and to gain some efficiencies in the policy development process. Although this specific consideration was not included in the original proposal, in anticipation of its public comment feedback review discussions, the MPSC requested that the OPTN/UNOS Thoracic Organ Transplantation Committee (the Thoracic Committee)

comment on this possible approach and amendment. The Thoracic Committee supported this possible amendment and did not express any concerns with this approach. This support further encouraged the MPSC to make this post-public comment modification.

This proposal received additional feedback that did not prompt post-public comment modifications. The MPSC's review of these comments yielded the following responses:

- *Support for the proposal.*
  - The MPSC appreciates the commenters' review and support of this proposal.
- *Region 4 and AST suggested including language that would accommodate individuals who are "board eligible" to take the transplant hepatology exam.*
  - The MPSC appreciates this feedback, but ultimately decided not to include "board eligible" language. The Committee felt this was somewhat redundant and unnecessary because current board certification in gastroenterology is a pre-requisite for the transplant hepatology exam, and considering the post-public comment modification, that gastroenterology board certification will be retained as an acceptable option for primary liver transplant physicians. Additionally, Committee members also supported not including "board eligible" indicating that some certifying bodies are moving away from the usage of this term due to some individuals who have had difficulty passing the exam taking advantage of this "board eligible" designation. This rationale similarly applies to the advanced heart failure and transplant cardiology post-public comment change.
- *Region 7 commented that the proposal should include a "grandfather" clause.*
  - The MPSC has historically been opposed to "grandfathering" transplant hospital key personnel for multiple reasons. First, some current key personnel may not currently meet all requirements upon submission of another application. For example, someone who currently serves as transplant program key personnel and has let their board certification lapse. Additionally, information provided within a hospital's application is ultimately the property of that applying hospital, and therefore it is not appropriate for the OPTN/MPSC to simply reference past hospital submissions to evaluate a separate hospital's application.

# Which populations are impacted by this proposal?

As primary liver and heart transplant physicians are required at every liver and heart program, and as these proposed changes address primary transplant physician requirements, this proposal has the potential to impact all liver and heart patients; however, the effect realized by any individual patient or group of patients is likely to be negligible as these changes are primarily operational in nature.

# How does this proposal impact the OPTN Strategic Plan?

1. *Increase the number of transplants:* There is no impact to this goal.
2. *Improve equity in access to transplants:* There is no impact to this goal.
3. *Improve waitlisted patient, living donor, and transplant recipient outcomes:* Allowing physicians with more transplant-specific training to serve as a transplant program's primary physician may improve waitlisted patient, living donor, and transplant recipient outcomes.
4. *Promote living donor and transplant recipient safety:* Allowing physicians with more transplant-specific training to serve as a transplant program's primary physician may improve living donor and transplant recipient safety.

5. *Promote the efficient management of the OPTN:* The MPSC receives primary liver transplant physician applications that indicate the applicant has current transplant hepatology boards and their gastroenterology boards have been allowed to lapse. Discussions with liver transplant physicians indicated that this approach is, and will continue to be, increasingly more common. Similarly, this problem is also likely to occur with the primary heart transplant physicians who obtain certification in advanced heart failure and transplant cardiology. Modifying OPTN Bylaws to reflect current practice helps promote the efficient management of the OPTN.

# How will the OPTN implement this proposal?

Assuming the Board adopts these changes, members will be alerted through a policy notice. All applications received on or after the March 1, 2017, implementation date, would be evaluated by the MPSC considering these new Bylaws.

# How will members implement this proposal?

No immediate action will be required of members upon the implementation of these proposed changes. Membership and key personnel change applications for liver programs submitted on or after the implementation of these proposed changes will be evaluated relative to these requirements.

## Transplant Hospitals

Upon the adoption and implementation of these changes, primary liver transplant physician applicants will have an additional option of transplant hepatology board certification or a pediatric transplant hepatology certification of added qualification. Primary heart transplant physicians will have the option of certification in advanced heart failure & transplant cardiology.

# Will this proposal require members to submit additional data?

This proposal does not require additional data collection.

# How will members be evaluated for compliance with this proposal?

All membership and key personnel applications proposing a primary liver transplant physician that are received by UNOS on or after the implementation date of these changes must propose an individual who is currently certified in gastroenterology, transplant hepatology, or have a pediatric transplant hepatology certificate of added qualification. In addition, all applications proposing a primary heart transplant physician must demonstrate current board certification in adult or pediatric cardiology or advanced heart failure and transplant cardiology.

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

The impact of these changes will be evaluated as the MPSC receives primary liver or heart transplant physician key personnel applications. The MPSC will assess primary liver and heart transplant physician board certification deficiencies, as well as the type and frequency of questions raised about this new requirement.

# Policy or Bylaws Language

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

**RESOLVED, that changes to Bylaws Appendices F.4 (Primary Liver Transplant Physician Requirements), F.4.C (Three-year Pediatric Gastroenterology Fellowship Pathway), F.4.D (Pediatric Transplant Hepatology Fellowship Pathway), F.4.E (Combined Pediatric Gastroenterology/Transplant Hepatology Training and Experience Pathway), and H.3 (Primary Heart Transplant Physician Requirements), as set forth below, are hereby approved, effective March 1, 2017.**

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

### F.4 Primary Liver Transplant Physician Requirements

A designated liver transplant program must have a primary physician who meets *all* the following requirements:

1. The physician must have an M.D., D.O., or equivalent degree from another country, with a current license to practice medicine in the hospital's state or jurisdiction.
2. The physician must be accepted onto the hospital's medical staff, and be on site at this hospital.
3. The physician must have documentation from the hospital credentialing committee that it has verified the physician's state license, board certification, training, and transplant continuing medical education and that the physician is currently a member in good standing of the hospital's medical staff.
4. The physician must have current board certification in gastroenterology, current board certification in transplant hepatology, or a current pediatric transplant hepatology certification of added qualification by the American Board of Internal Medicine, the American Board of Pediatrics, or the Royal College of Physicians and Surgeons of Canada.

   In place of current certification ~~in gastroenterology~~ by the American Board of Internal Medicine, the American Board of Pediatrics, or the Royal College of Physicians and Surgeons of Canada, the physician must:

   a. Be ineligible for American board certification.
   b. Provide a plan for continuing education that is comparable to American board maintenance of certification. This plan must at least require that the physician obtains 60 hours of Category I continuing medical education (CME) credits with self-assessment that are relevant to the individual's practice every three years. Self-assessment is defined as a written or electronic question-and-answer exercise that assesses understanding of the material in the CME program. A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve an acceptable self-assessment score are allowed. The transplant hospital must document completion of this continuing education.
   c. Provide to the OPTN Contractor two letters of recommendation from directors of designated transplant programs not employed by the applying hospital. These letters must address:

      i. Why an exception is reasonable.
      ii. The physician's overall qualifications to act as a primary liver transplant physician.
      iii. The physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.

iv. Any other matters judged appropriate.

If the physician has not adhered to the plan for maintaining continuing education or has not obtained the necessary CME credits with self-assessment, the transplant program will have a six-month grace period to address these deficiencies. If the physician has not fulfilled the requirements after the six-month grace period, and a key personnel change application has not been submitted, then the transplant program will be referred to the MPSC for appropriate action according to *Appendix L* of these Bylaws. If the OPTN Contractor becomes aware that a primary physician has not been compliant for 12 months or more and deficiencies still exist, then the transplant program will not be given any grace period and will be referred to the MPSC for appropriate action according to *Appendix L* of these Bylaws.

5. The physician must have completed at least one of pathways listed below:
   a. The 12-month transplant hepatology fellowship pathway, as described in *Section F.4.A. 12-month Transplant Hepatology Fellowship Pathway* below.
   b. The clinical experience pathway, as described in *Section F.4.B. Clinical Experience Pathway* below.
   c. The 3-year pediatric gastroenterology fellowship pathway, as described in *Section F.4.C. Three-year Pediatric Gastroenterology Fellowship Pathway* below.
   d. The 12-month pediatric transplant hepatology fellowship pathway, as described in *Section F.4.D. Pediatric Transplant Hepatology Fellowship Pathway* below.
   e. The combined pediatric gastroenterology or transplant hepatology training and experience pathway, as described in *Section F.4.E. Combined Pediatric Gastroenterology/Transplant Hepatology Training and Experience Pathway* below.
   f. The conditional approval pathway, as described in *Section F.3.F. Conditional Approval for Primary Transplant Physician* below, if the primary liver transplant physician changes at an approved liver transplant program.

Pediatric liver transplant programs should have a board certified pediatrician who meets the criteria for primary liver transplant physician. If a qualified pediatric physician is not on staff at the program, a physician meeting the criteria as a primary liver transplant physician for adults can function as the primary liver transplant physician for the pediatric program, if a pediatric gastroenterologist is involved in the care of the pediatric liver transplant recipients.

### C. Three-year Pediatric Gastroenterology Fellowship Pathway

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

1. The physician has current board certification in pediatric gastroenterology or a pediatric transplant hepatology certification of added qualification by the American Board of Pediatrics~~,~~ or the Royal College of Physicians and Surgeons of Canada.
2. During the 3-year training period the physician was directly involved in the primary care of 10 or more newly transplanted pediatric liver recipients and followed 20 newly transplanted liver recipients for a minimum of 3 months from the time of transplant, under the direct supervision of a qualified liver transplant physician along with a qualified liver transplant surgeon. The physician was also directly involved in the preoperative, peri-operative and post-operative care of 10 or more liver transplants in pediatric patients. The pediatric gastroenterology program director may elect to have a portion of the transplant experience carried out at another transplant service, to meet these requirements. This care must be documented in a log that includes the date of transplant, the medical record number or other unique identifier

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

3. The experience caring for pediatric patients occurred at a liver transplant program with a qualified liver transplant physician and a qualified liver transplant surgeon that performs an average of at least 10 liver transplants on pediatric patients per year.
4. The physician must have observed at least 3 liver procurements. The physician must have observed the evaluation, donation process, and management of these donors. These observations must be documented in a log that includes the date of procurement, location of the donor and Donor ID.
5. The physician must have observed at least 3 liver transplants. The observation of these transplants must be documented in a log that includes the transplant date, donor type, and medical record number or other unique identifier that can be verified by the OPTN Contractor.
6. The physician has maintained a current working knowledge of liver transplantation, defined as direct involvement in liver transplant patient care within the last 2 years. This includes the management of pediatric patients with end-stage liver disease acute liver failure, the selection of appropriate pediatric recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate postoperative care including those issues of management unique to the pediatric recipient, fluid and electrolyte management, the use of immunosuppressive therapy in the pediatric recipient including side-effects of drugs and complications of immunosuppression, the effects of transplantation and immunosuppressive agents on growth and development, differential diagnosis of liver dysfunction in the allograft recipient, manifestation of rejection in the pediatric patient, histological interpretation of allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long-term outpatient care of pediatric allograft recipients including management of hypertension, nutritional support, and drug dosage, including antibiotics, in the pediatric patient.
7. The following letters are submitted directly to the OPTN Contractor:
    a. A letter from the director of the pediatric gastroenterology training program, and the qualified liver transplant physician and surgeon of the fellowship training program verifying that the physician has met the above requirements, and is qualified to act as a liver transplant physician and direct a liver transplant program.
    b. A letter of recommendation from the fellowship training program's primary physician and transplant program director outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
    c. A letter from the physician that details the training and experience the physician gained in liver transplantation.

## D. Pediatric Transplant Hepatology Fellowship Pathway

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

1. The physician has current board certification in pediatric gastroenterology or a current pediatric transplant hepatology certification of added qualification by the American Board of Pediatrics, the Royal College of Physicians and Surgeons of Canada, or is approved by the American Board of Pediatrics to take the certifying exam.

2. During the fellowship, the physician was directly involved in the primary care of 10 or more newly transplanted pediatric liver recipients and followed 20 newly transplanted liver recipients for at least 3 months from the time of transplant, under the direct supervision of a qualified liver transplant physician and in conjunction with a qualified liver transplant surgeon. The physician must have been directly involved in the pre-operative, peri-operative and post-operative care of 10 or more liver transplants in pediatric patients. The pediatric gastroenterology program director may elect to have a portion of the transplant experience completed at another liver transplant program in order to meet these requirements. This care must be documented in a log that includes the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log must be signed by the training program director or the transplant program primary transplant physician.
3. The experience in caring for pediatric liver patients occurred at a liver transplant program with a qualified liver transplant physician and surgeon that performs an average of at least 10 pediatric liver transplants a year.
4. The physician has maintained a current working knowledge of liver transplantation, defined as direct involvement in liver transplant patient care within the last 2 years. This includes the management of pediatric patients with end-stage liver disease, acute liver failure, the selection of appropriate pediatric recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate postoperative care including those issues of management unique to the pediatric recipient, fluid and electrolyte management, the use of immunosuppressive therapy in the pediatric recipient including side-effects of drugs and complications of immunosuppression, the effects of transplantation and immunosuppressive agents on growth and development, differential diagnosis of liver dysfunction in the allograft recipient, manifestation of rejection in the pediatric patient, histological interpretation of allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long-term outpatient care of pediatric allograft recipients including management of hypertension, nutritional support, and drug dosage, including antibiotics, in the pediatric patient.
5. The physician must have observed at least 3 liver procurements. The physician must have observed the evaluation, donation process, and management of these donors. These observations must be documented in a log that includes the date of procurement, location of the donor and Donor ID.
6. The physician must have observed at least 3 liver transplants. The observation of these transplants must be documented in a log that includes the transplant date, donor type, and medical record number or other unique identifier that can be verified by the OPTN Contractor.
7. The following letters are submitted directly to the OPTN Contractor:
    a. A letter from the director of the pediatric transplant hepatology training program, and the qualified liver transplant physician and surgeon of the fellowship training program verifying that the physician has met the above requirements, and is qualified to act as a liver transplant physician and direct a liver transplant program.
    b. A letter of recommendation from the fellowship training program's primary physician and transplant program director outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
    c. A letter from the physician that details the training and experience the physician gained in liver transplantation.

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

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

1. The physician has current board certification in pediatric gastroenterology or a current pediatric transplant hepatology certification of added qualification by the American Board of Pediatrics, the Royal College of Physicians and Surgeons of Canada, or is approved by the American Board of Pediatrics to take the certifying exam.
2. The physician gained a minimum of 2 years of experience during or after fellowship, or accumulated during both periods, at a liver transplant program.
3. During the 2 or more years of accumulated experience, the physician was directly involved in the primary care of 10 or more newly transplanted pediatric liver recipients and followed 20 newly transplanted liver recipients for a minimum of 6 months from the time of transplant, under the direct supervision of a qualified liver transplant physician and along with a qualified liver transplant surgeon. The physician must have been directly involved in the pre-operative, peri-operative and post-operative care of 10 or more pediatric liver transplants recipients. This care must be documented in a log that includes at the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log must be signed by the training program director or the transplant program primary transplant physician.
4. The individual has maintained a current working knowledge of liver transplantation, defined as direct involvement in liver transplant patient care within the last 2 years. This includes the management of pediatric patients with end-stage liver disease, the selection of appropriate pediatric recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative care including those issues of management unique to the pediatric recipient, fluid and electrolyte management, the use of immunosuppressive therapy in the pediatric recipient including side-effects of drugs and complications of immunosuppression, the effects of transplantation and immunosuppressive agents on growth and development, differential diagnosis of liver dysfunction in the allograft recipient, manifestation of rejection in the pediatric patient, histological interpretation of allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long-term outpatient care of pediatric allograft recipients including management of hypertension, nutritional support, and drug dosage, including antibiotics, in the pediatric patient.
5. The physician must have observed at least 3 liver procurements. The physician must have observed the evaluation, the donation process, and the management of these donors. These observations must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
6. The physician must have observed at least 3 liver transplants. The observation of these transplants must be documented in a log that includes the transplant date, donor type, and medical record number or other unique identifier that can be verified by the OPTN Contractor.
7. The following letters are submitted directly to the OPTN Contractor:
    a. A letter from the qualified liver transplant physician and surgeon who have been directly involved with the physician documenting the physician's experience and competence.
    b. A letter of recommendation from the primary physician and transplant program director at the fellowship training program or transplant program last served by the physician outlining the physician's overall qualifications to act as a primary transplant physician, as

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

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

# *Appendix H: Membership and Personnel Requirements for Heart Transplant Programs*

## H.3 Primary Heart Transplant Physician Requirements

A designated heart transplant program must have a primary physician who meets *all* the following requirements:

1. The physician must have an M.D., D.O., or equivalent degree from another country, with a current license to practice medicine in the hospital's state or jurisdiction.
2. The physician must be accepted onto the hospital's medical staff, and be practicing on site at this hospital.
3. The physician must have documentation from the hospital credentialing committee that it has verified the physician's state license, board certification, training, and transplant continuing medical education and that the physician is currently a member in good standing of the hospital's medical staff.
4. The physician must have current certification in adult or pediatric cardiology or current board certification in advanced heart failure and transplant cardiology by the American Board of Internal Medicine, the American Board of Pediatrics, or the Royal College of Physicians and Surgeons of Canada.

   In place of current board certification ~~in adult or pediatric cardiology~~ by the American Board of Internal Medicine, the American Board of Pediatrics, or the Royal College of Physicians and Surgeons of Canada, the physician must:

   a. Be ineligible for American board certification.
   b. Provide a plan for continuing education that is comparable to American board maintenance of certification. This plan must at least require that the physician obtains 60 hours of Category I continuing medical education (CME) credits with self-assessment that are relevant to the individual's practice every three years. Self-assessment is defined as a written or electronic question-and-answer exercise that assesses understanding of the material in the CME program. A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve an acceptable self-assessment score are allowed. The transplant hospital must document completion of this continuing education.
   c. Provide to the OPTN Contractor two letters of recommendation from directors of designated transplant programs not employed by the applying hospital. These letters must address:
      i. Why an exception is reasonable.
      ii. The physician's overall qualifications to act as a primary heart transplant physician.
      iii. The physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.
      iv. Any other matters judged appropriate.

If the physician has not adhered to the plan for maintaining continuing education or has not obtained the necessary CME credits with self-assessment, the transplant program will have a six-month grace period to address these deficiencies. If the physician has not fulfilled the requirements after the six-month grace period, and a key personnel change application has not been submitted, then the transplant program will be referred to the MPSC for appropriate action according to *Appendix L* of these Bylaws. If the OPTN Contractor becomes aware that a primary physician has not been compliant for 12 months or more and deficiencies still exist, then the transplant program will not be given any grace period and will be referred to the MPSC for appropriate action according to *Appendix L* of these Bylaws.

5. The physician must have completed at least *one* of the pathways listed below:

    a. The 12-month transplant cardiology fellowship pathway, as described in *Section H.3.A.Twelve-month Transplant Cardiology* Fellowship Pathway below.
    b. The clinical experience pathway, as described *in Section H.3.B.Clinical Experience Pathway* below.
    c. The conditional approval pathway, as described in *Section H.3.C. Conditional Approval for Primary Transplant Physician* below, if the primary heart transplant physician changes at an approved heart transplant program.

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