OPTN/UNOS Policy Notice - Subspecialty Board Certification for Primary Liver and Heart Transplant Physicians

Sponsoring Committee:	**Membership and Professional Standards**
Bylaws Affected:	**OPTN 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)**
Public Comment:	**August – October 2016**
Effective Date:	**March 1, 2017**

Problem Statement

OPTN/UNOS Bylaws require a liver transplant program's designated primary physician applicants to be board certified in gastroenterology. The OPTN/UNOS Membership and Professional Standards Committee (MPSC) is increasingly receiving key personnel applications from liver programs where a proposed primary transplant physician meets all the Bylaws' requirements but is board certified in transplant hepatology and their gastroenterology board certification has lapsed. Although all other requirements are met, because these individuals do not fulfill the requirements in the Bylaws the MPSC is obligated to reject these applications. The MPSC is also aware of a subspecialty board certification for cardiologists- advanced heart failure and transplant cardiology. When this subspecialty board certification becomes more prevalent in the community, it will create a similar problem for primary heart transplant physician applicants if the current Bylaws are not modified.

Summary of Changes

The Bylaws now include the following additional options for board certification for the liver and heart primary transplant physicians:

- Primary liver transplant physician – can hold current board certification in either gastroenterology or transplant hepatology.
- Primary heart transplant physician – can have current certification in adult or pediatric cardiology or advanced heart failure and transplant cardiology.

What Members Need to Do

No immediate action will be required of members upon the implementation of when we implement these changes. From the implementation date forward, however, we will evaluate all primary liver physician and primary heart physician membership applications based on the new requirements.

Affected Policy Language:

New language is underlined (example) and language that is removed is struck through (~~example~~).

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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