

OPTN Membership Application for Liver Transplant Programs

CERTIFICATION

The undersigned, a duly authorized representative of the applicant, does hereby certify that the answers and attachments to this application are true, correct and complete, to the best of his or her knowledge after investigation. I understand that the intentional submission of false data to the OPTN may result in action by the Secretary of the Department of Health and Human Services, and/or civil or criminal penalties. By submitting this application to the OPTN, the applicant agrees: (i) to be bound by OPTN Obligations, including amendments thereto, if the applicant is granted membership and (ii) to be bound by the terms, thereof, including amendments thereto, in all matters relating to consideration of the application without regard to whether or not the applicant is granted membership.

If you have any questions, please call the UNOS Membership Team at 833-577-9469 or email MembershipRequests@unos.org.

OPTN Representative

| | | |
|---------------------|-----------------------|----------------------|
| Printed Name | Signature | Email Address |
| | Position _____ | |
| Printed Name | Signature | Email Address |
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Position _____

Printed Name **Signature** **Email Address**

Part 1: General Information

Name of Transplant Hospital: _____

OPTN Member Code (4 Letters): _____

Transplant Hospital Address (where transplants occur)

Street: _____ Ste: _____ Phone #: _____

City: _____ ST: _____ Zip: _____ Fax #: _____

Name of Person Completing Form: _____ Title: _____

Email Address of Person Completing Form: _____

Date Form is submitted to OPTN Contractor: _____

Part 2: Program Director(s)

A liver transplant program must identify at least one designated staff member to act as the transplant program director. The director must be a physician or surgeon who is a member of the transplant hospital staff.

| Name of Program Director(s) (list all): | New | Existing |
|---|--------------------------|--------------------------|
| _____ | <input type="checkbox"/> | <input type="checkbox"/> |
| _____ | <input type="checkbox"/> | <input type="checkbox"/> |
| _____ | <input type="checkbox"/> | <input type="checkbox"/> |
| _____ | <input type="checkbox"/> | <input type="checkbox"/> |

Include the resume/CV of each new individual listed.

Part 3: Primary Program Administrator

A primary program administrator is the identified administrative lead for the transplant program.

Complete this section only if you are updating the Primary Program Administrator position for the program.

Name of Primary Program Administrator:

Credentials:

Title at Hospital:

Phone Number:

Email:

Part 4: Primary Data Coordinator

A primary data coordinator is the identified data lead for the transplant program.

Complete this section only if you are updating the Primary Data Coordinator position for the program.

Name of Primary Data Coordinator:

Credentials:

Title at Hospital:

Phone Number:

Email:

Part 5: Primary Liver Transplant Surgeon Requirements

1. Name of Proposed Primary Liver Transplant Surgeon (as indicated in Certificate of Assessment):

| Name | NPI # |
|------|-------|
|------|-------|

2. Check yes or no for each of the following. Provide documentation where applicable:

Yes No

- 2a. Does the surgeon 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?
Provide a copy of the surgeon's resume/CV.
- 2b. Has the surgeon been accepted onto the hospital's medical staff, and is practicing on site at this hospital? **Provide documentation from the hospital credentialing committee that it has verified the surgeon's state license, board certification, training, and transplant continuing medical education, and that the surgeon is currently a member in good standing of the hospital's medical staff.**

3. Certification. Check one and provide corresponding documentation:

- 3a. The surgeon is currently certified by the American Board of Surgery, the American Board of Urology, the American Board of Osteopathic Surgery, or the Royal College of Physicians and Surgeons of Canada.
Provide a copy of the surgeon's current board certification.
- 3b. The surgeon has just completed training and is pending certification by the American Board of Urology. Therefore, the surgeon is requesting conditional approval for 16 months to allow time to complete board certification, with the possibility of renewal for one additional 16-month period.
Provide documentation supporting that training has been completed and certification is pending, which must include the anticipated date of board certification and where the surgeon is in the process to be certified.
- 3c. The surgeon is without American Board of Surgery, the American Board of Urology, the American Board of Osteopathic Surgery, or the Royal College of Physicians and Surgeons of Canada or pending certification by the American Board of Urology.
If this option is selected:
- The surgeon must be ineligible for American board certification. Provide an explanation why the individual is ineligible:**

- **Provide a plan for continuing education that is comparable to American board maintenance of certification; and**
- **Provide at least 2 two letters of recommendation from directors of designated transplant programs not employed by the applying hospital that address**
 - **why an exception is reasonable,**
 - **the individual's overall qualifications to act as a primary liver transplant surgeon,**
 - **the individual's personal integrity and honesty,**
 - **the individual's familiarity with and experience in adhering to OPTN obligations and compliance protocols, and**
 - **any other matters judged appropriate.**

4. Summarize the surgeon's training and experience in transplant:

| Training and Experience | Approved Fellowship Programs? Y/N | Date (MM/DD/YY) | | Transplant Hospital | Program Director | # Liver Transplants as Primary | # Liver Transplants as 1st Assistant | # of Liver Procurements as Primary or 1 st Assistant |
|------------------------------|--------------------------------------|-----------------|-----|---------------------|------------------|--------------------------------|--------------------------------------|---|
| | | Start | End | | | | | |
| Fellowship Training | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| Experience Post - Fellowship | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |

5. Which of the following pathways is the proposed primary surgeon applying (check one, and complete the corresponding pathway section below):

- The **fellowship pathway**, as described in *Section 5A: Formal 2-year Transplant Fellowship Pathway* below.
- The **clinical experience pathway**, as described in *Section 5B: Clinical Experience Pathway* below.

5A. Formal 2-year Transplant Fellowship Pathway

Surgeons can meet the training requirements for primary liver transplant surgeon by completing a formal 2-year surgical transplant fellowship if the following conditions are met:

1. *The surgeon performed **at least 45** liver transplants as primary surgeon or first assistant during the 2-year fellowship period.*
This experience must be documented on a log that includes the date of transplant, the role of the surgeon, the medical record number or other unique identifier, and the fellowship director's signature.

2. *The surgeon performed **at least 20** liver procurements as primary surgeon or first assistant.* These procurements must have been performed anytime during the surgeon's fellowship and the two years immediately following fellowship completion.
This experience must be documented on a log that includes the date of procurement and Donor ID.

3. *The surgeon has maintained a current working knowledge of liver transplantation, defined as direct involvement in liver transplant patient care within the last 2 years. Check all that apply:*
 - The surgeon has experience managing patients with end stage liver disease.*
 - The surgeon has experience with the selection of appropriate recipients for transplantation.*
 - The surgeon has experience with donor selection.*
 - The surgeon has experience with histocompatibility and tissue typing.*
 - The surgeon has experience with performing the transplant operation.*
 - The surgeon has experience with immediate postoperative and continuing inpatient care.*
 - The surgeon has experience with the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression.*
 - The surgeon has experience with differential diagnosis of liver allograft dysfunction.*
 - The surgeon has experience with histologic interpretation of allograft biopsies.*
 - The surgeon has experience with interpretation of ancillary tests for liver dysfunction.*
 - The surgeon has experience with long term outpatient care.*

If a box is not checked, please provide an explanation:

4. Provide the following letters with the application:

- A letter from the director of the training program verifying that the surgeon has met the above requirements, and is qualified to direct a liver transplant program.

- A letter of recommendation from the fellowship training program's primary surgeon and transplant program director outlining
 - the individual's overall qualifications to act as primary transplant surgeon,
 - the individual's personal integrity and honesty,
 - the individual's 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 surgeon, at its discretion.
- A letter from the surgeon that details his or her training and experience in liver transplantation.

5B. Clinical Experience Pathway

Surgeons can meet the requirements for primary liver transplant surgeon through clinical experience gained post-fellowship, if the following conditions are met:

1. *The surgeon has performed **60 or more** liver transplants over a 2 to 5-year period as primary surgeon, co-surgeon, or first assistant at a designated liver transplant program. Of these 60 liver transplants, 30 or more must have been performed as primary surgeon or co-surgeon. Each year of the surgeon's experience must be substantive and relevant and include pre-operative assessment of liver transplant candidates, transplants performed as primary surgeon or first assistant, and post-operative management of liver recipients.
This experience must be documented on a log that includes the date of transplant, the role of the surgeon, and medical record number or other unique identifier.*
2. *The surgeon has performed **at least 30** liver procurements as primary surgeon, co-surgeon, or first assistant. Of these 30 liver procurements, at least 15 must have been performed as primary surgeon or co-surgeon.
This experience must be documented on a log that includes the date of procurement, Donor ID, and role of the surgeon.*
3. *The surgeon has maintained a current working knowledge of liver transplantation, defined as direct involvement in liver transplant patient care within the last 2 years.*

Check all that apply

- The surgeon has experience managing patients with end stage liver disease.*
- The surgeon has with the selection of appropriate recipients for transplantation.*
- The surgeon has experience with donor selection.*
- The surgeon has experience with histocompatibility and tissue typing.*
- The surgeon has experience with performing the transplant operation.*
- The surgeon has experience with immediate postoperative and continuing inpatient care.*
- The surgeon has experience with the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression.*
- The surgeon has experience with differential diagnosis of liver allograft dysfunction.*
- The surgeon has experience with histologic interpretation of allograft biopsies.*
- The surgeon has experience with interpretation of ancillary tests for liver dysfunction.*
- The surgeon has experience with long term outpatient care.*

If a box is not checked, please provide an explanation:

4. ***Provide the following letters with the application:***

- A letter from the director of the transplant program and chairman of the department or hospital credentialing committee verifying that the surgeon has met the above requirements, and is qualified to direct a liver transplant program.
- A letter of recommendation from the primary surgeon and transplant program director at the transplant program last served by the surgeon outlining
 - the individual's overall qualifications to act as primary transplant surgeon,
 - the individual's personal integrity and honesty,
 - the individual's 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 surgeon, at its discretion.
- A letter from the surgeon that details the training and experience the surgeon gained in liver transplantation.

Part 6: Primary Liver Transplant Physician Requirements

1. Name of Proposed Primary Liver Transplant Physician (as indicated in Certificate of Assessment):

| Name | NPI # |
|------|-------|
|------|-------|

2. Check yes or no for each of the following. Provide documentation where applicable:

Yes No

- 2a. Does the physician 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?

Provide a copy of the physician's resume/CV.

- 2b. Has the physician been accepted onto the hospital's medical staff, and is practicing on site at this hospital?

Provide 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.

3. Certification. Check one and provide corresponding documentation:

- 3a. The physician is currently certified in gastroenterology or transplant hepatology or certification of added qualification for pediatric transplant hepatology by the American Board of Internal Medicine, the American Board of Pediatrics, of the Royal College of Physicians and Surgeons of Canada.

Provide a copy of the physician's current board certification.

- 3b. The physician is without certification 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 be ineligible for American board certification. Provide an explanation why the individual is ineligible:**

-
- **Provide a plan for continuing education that is comparable to American board maintenance of certification**
 - **Provide at least 2 two letters of recommendation from directors of designated transplant programs not employed by the applying hospital that address**
 - **why an exception is reasonable,**
 - **the individual's overall qualifications to act as a primary liver transplant physician,**
 - **the individual's personal integrity and honesty,**
 - **the individual's familiarity with and experience in adhering to OPTN obligations and compliance protocols, and**

- *any other matters judged appropriate.*

4. Summarize the physician’s training and experience in transplant:

| Training and Experience | Date (MM/DD/YY) | | Transplant Hospital | Program Director | #LI Patients Followed | | |
|----------------------------|-----------------|-----|---------------------|------------------|-----------------------|------|------|
| | Start | End | | | Pre | Peri | Post |
| Experience Post Fellowship | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| Fellowship Training | | | | | | | |
| | | | | | | | |
| | | | | | | | |

5. Which of the following pathways is the proposed primary physician applying (check one, and complete the corresponding pathway section below):

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

5A. 12-month Transplant Hepatology Fellowship Pathway

Physicians can meet the training requirements for a primary liver transplant physician during a separate 12-month transplant hepatology fellowship if the following conditions are met:

1. *The physician completed **12 consecutive months** of specialized training in transplantation under the direct supervision of a qualified liver transplant physician and in conjunction with a liver transplant surgeon at a liver transplant program. The training must have included at least 3 months of clinical transplant service. The remaining time must have consisted of transplant-related experience, such as experience in a tissue typing laboratory, on another solid organ transplant service, or conducting basic or clinical transplant research.*

2. *During the fellowship period, the physician was directly involved in the primary care of **30 or more** newly transplanted liver recipients, and continued to follow these recipients for a minimum of 3 months from the time of transplant.*

This experience must be documented on a log that includes the date of transplant, medical record number or other unique identifier, and the signature of the director of the training program or the transplant program's primary transplant physician.

3. *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. Check all that apply:*

- The physician has experience managing patients with end stage liver disease.*
- The physician has experience acute liver failure.*
- The physician has experience with the selection of appropriate recipients for transplantation.*
- The physician has experience with donor selection.*
- The physician has experience with histocompatibility and tissue typing.*
- The physician has experience with immediate post-operative patient care.*
- The physician has experience with the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression.*
- The physician has experience with differential diagnosis of liver allograft dysfunction.*
- The physician has experience with histologic interpretation of allograft biopsies.*
- The physician has experience with interpretation of ancillary tests for liver dysfunction.*
- The physician has experience with long term outpatient care.*

If a box is not checked, please provide an explanation:

4. *The physician has observed **at least 3** liver procurements. The physician must have observed the evaluation, donation process, and management of these donors.*

This experience must be documented on a log that includes the date of procurement and Donor ID.

5. *The physician has observed at least 3 liver transplants.*

This experience must be documented on a log that includes transplant date, donor type, and medical record number or other unique identifier.

6. ***Provide the following letters with the application:***

- A letter from the director of the training program and the supervising liver transplant physician verifying that the physician has met the above requirements and is qualified to direct a liver transplant program.
- A letter of recommendation from the fellowship training program's primary physician and transplant program director outlining
 - the individual's overall qualifications to act as primary transplant physician,
 - the individual's personal integrity and honesty,
 - the individual's 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.
- A letter from the physician that details the training and experience the physician gained in liver transplantation.

The training requirements outlined above are in addition to other clinical requirements for general gastroenterology training.

5B. Clinical Experience Pathway

A physician can meet the requirements for a primary liver transplant physician through acquired clinical experience if the following conditions are met:

1. *The physician has been directly involved in the primary care of **50 or more** newly transplanted liver recipients and continued to follow these recipients for a minimum of 3 months from the time of transplant. This patient care must have been provided over a 2 to 5-year period on an active liver transplant service as the primary liver transplant physician or under the direct supervision of a qualified liver transplant physician and in conjunction with a liver transplant surgeon at a designated liver transplant program.*
This experience must be documented on a log that includes the date of transplant and the medical record number or other unique identifier.

2. *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.*

Check all that apply

- The physician has experience managing patients with end stage liver disease.*
- The physician has experience acute liver failure.*
- The physician has experience with the selection of appropriate recipients for transplantation.*
- The physician has experience with donor selection.*
- The physician has experience with histocompatibility and tissue typing.*
- The physician has experience with immediate post-operative patient care.*
- The physician has experience with the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression.*
- The physician has experience with differential diagnosis of liver allograft dysfunction.*
- The physician has experience with histologic interpretation of allograft biopsies.*
- The physician has experience with interpretation of ancillary tests for liver dysfunction.*
- The physician has experience with long term outpatient care.*

If a box is not checked, please provide an explanation:

3. *The physician has observed **at least 3** liver procurements. The physician must have observed the evaluation, donation process, and management of these donors.*

This experience must be documented on a log that includes the date of procurement and Donor ID.

4. *The physician has observed **at least 3** liver transplants.*

This experience must be documented on a log that includes transplant date, donor type, and medical record number or other unique identifier.

5. ***Provide the following letters with the application:***

- A letter from the qualified transplant physician or the liver transplant surgeon who has been directly involved with the proposed physician documenting the physician's experience and competence.
- A letter of recommendation from the primary physician and transplant program director at the transplant program last served by the physician outlining
 - the individual's overall qualifications to act as primary transplant physician,
 - the individual's personal integrity and honesty,
 - the individual's 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.
- A letter from the physician that details the training and experience the physician gained in liver transplantation.

5C. 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 is currently board certified 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.*
Provide a copy of the physician's current board certification.
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 experience must be documented on a log that includes the date of transplant, medical record number or other unique identifier, and the signature of 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 has observed **at least 3** liver procurements. The physician must have observed the evaluation, donation process, and management of these donors.*
This experience must be documented on a log that includes the date of procurement and Donor ID.
5. *The physician has observed **at least 3** liver transplants.*
This experience must be documented on a log that includes transplant date, donor type, and medical record number or other unique identifier.
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.*
Check all that apply

- The physician has experience managing pediatric patients with end-stage liver disease.*
- The physician has experience managing pediatric patients with acute liver failure.*
- The physician has experience with the selection of appropriate pediatric recipients for transplantation.*
- The physician has experience with donor selection.*
- The physician has experience with histocompatibility and tissue typing.*
- The physician has experience with immediate postoperative care including those issues of management unique to the pediatric recipient.*
- The physician has experience with fluid and electrolyte management.*
- The physician has experience with the use of immunosuppressive therapy in the pediatric recipient including side-effects of drugs and complications of immunosuppression.*
- The physician has experience with the effects of transplantation and immunosuppressive agents on growth and development?*
- Does the physician have experience with differential diagnosis of liver dysfunction in the allograft recipient?*
- Does the physician have experience with manifestation of rejection in the pediatric patient?*
- Does the physician have experience with histological interpretation of allograft biopsies?*
- Does the physician have experience with interpretation of ancillary tests for liver dysfunction?*
- Does the physician have experience with long-term outpatient care of pediatric allograft recipients including management of hypertension, nutritional support, and drug dosage, including antibiotics, in the pediatric patient.*

If a box is not checked, please provide an explanation:

7. Provide the following letters with the application:

- 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.
- A letter of recommendation from the fellowship training program's primary physician and transplant program director outlining
 - the individual's overall qualifications to act as primary transplant physician,
 - the individual's personal integrity and honesty,

- the individual's 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.
- A letter from the physician that details the training and experience the physician gained in liver transplantation.

5D. 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 is currently board certified in pediatric gastroenterology or has 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.*

Provide a copy of the physician's current board certification or documentation of the approval 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 experience must be documented on a log that includes the date of transplant, medical record number or other unique identifier, and the signature of the training program director or the transplant program's 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.*

Check all that apply

- The physician has experience managing pediatric patients with end-stage liver disease*
- The physician has experience managing pediatric patients with acute liver failure.*
- The physician has experience with the selection of appropriate pediatric recipients for transplantation.*
- The physician has experience with donor selection.*
- The physician has experience with histocompatibility and tissue typing.*
- The physician has experience with immediate postoperative care including those issues of management unique to the pediatric recipient.*
- The physician has experience with fluid and electrolyte management.*

- The physician has experience with the use of immunosuppressive therapy in the pediatric recipient including side-effects of drugs and complications of immunosuppression.*
- The physician has experience with the effects of transplantation and immunosuppressive agents on growth and development.*
- The physician has experience with differential diagnosis of liver dysfunction in the allograft recipient.*
- The physician has experience with manifestation of rejection in the pediatric patient.*
- The physician has experience with histological interpretation of allograft biopsies.*
- The physician has experience with interpretation of ancillary tests for liver dysfunction.*
- The physician has experience with long-term outpatient care of pediatric allograft recipients including management of hypertension, nutritional support, and drug dosage, including antibiotics, in the pediatric patient.*

If a box is not checked, please provide an explanation:

5. *The physician has observed **at least 3** liver procurements.* The physician must have observed the evaluation, donation process, and management of these donors.
This experience must be documented on a log that includes the date of procurement and Donor ID.
6. *The physician has observed **at least 3** liver transplants.*
This experience must be documented on a log that includes transplant date, donor type, and medical record number or other unique identifier.
7. ***Provide the following letters with the application:***
 - 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.
 - A letter of recommendation from the fellowship training program's primary physician and transplant program director outlining
 - the individual's overall qualifications to act as primary transplant physician,
 - the individual's personal integrity and honesty,
 - the individual's 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.

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

5E. 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 is currently board certified in pediatric gastroenterology or has 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.*

Provide a copy of the physician's current board certification or documentation of approval 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 experience must be documented on a log that includes the date of transplant, medical record number or other unique identifier, and the signature of the training program director or the transplant program's primary transplant physician.

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.*

Check all that apply

- The physician has experience managing pediatric patients with end-stage liver disease.*
- The physician has experience managing pediatric patients with acute liver failure.*
- The physician has experience with the selection of appropriate pediatric recipients for transplantation.*
- The physician has experience with donor selection.*
- The physician has experience with histocompatibility and tissue typing.*
- The physician has experience with immediate postoperative care including those issues of management unique to the pediatric recipient.*
- The physician has experience with fluid and electrolyte management.*

- The physician has experience with the use of immunosuppressive therapy in the pediatric recipient including side-effects of drugs and complications of immunosuppression.*
- The physician has experience with the effects of transplantation and immunosuppressive agents on growth and development.*
- The physician has experience with differential diagnosis of liver dysfunction in the allograft recipient.*
- The physician has experience with manifestation of rejection in the pediatric patient.*
- The physician has experience with histological interpretation of allograft biopsies.*
- The physician has experience with interpretation of ancillary tests for liver dysfunction.*
- The physician has experience with long-term outpatient care of pediatric allograft recipients including management of hypertension, nutritional support, and drug dosage, including antibiotics, in the pediatric patient.*

If a box is not checked, please provide an explanation:

5. *The physician has observed **at least 3** liver procurements.* The physician must have observed the evaluation, the donation process, and the management of these donors.
This experience must be documented on a log that includes the date of procurement and Donor ID.

6. *The physician has observed **at least 3** liver transplants.*
This experience must be documented on a log that includes transplant date, donor type, and medical record number or other unique identifier.

7. ***Provide the following letters with the application:***
 - 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.
 - 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 individual's overall qualifications to act as primary transplant physician,
 - the individual's personal integrity and honesty,
 - the individual's 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.

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

5F. Conditional Approval for Primary Transplant Physician

If the primary liver transplant physician changes at an approved liver transplant program, a physician can serve as the primary liver transplant physician for a maximum of 12 months if the following conditions are met:

1. *The physician has been involved in the primary care of **25 or more** newly transplanted liver recipients, and has followed these patients for at least 3 months from the time of their transplant.*

This experience must be documented on a log that includes the date of transplant, medical record number or other unique identifier, and the signature of the program director, division chief, or department chair from the transplant program where the experience was gained.

2. *The physician has maintained a current working knowledge of liver transplantation, defined as direct involvement in liver transplant patient care during the last 2 years.*

Check all that apply

- The physician has experience managing patients with end stage liver disease.*
- The physician has experience acute liver failure.*
- The physician has experience with the selection of appropriate recipients for transplantation.*
- The physician has experience with donor selection.*
- The physician has experience with histocompatibility and tissue typing.*
- The physician has experience with immediate post-operative patient care.*
- The physician has experience with the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression.*
- The physician has experience with differential diagnosis of liver allograft dysfunction.*
- The physician has experience with histologic interpretation of allograft biopsies.*
- The physician has experience with interpretation of ancillary tests for liver dysfunction.*
- The physician has experience with long term outpatient care.*

3. *The physician has **12 months experience** on an active liver transplant service as the primary liver transplant physician or under the direct supervision of a qualified liver transplant physician along with a liver transplant surgeon at a designated liver transplant program.*

These 12 months of experience must be acquired within a 2-year period.

4. *The physician has observed **at least 3** liver procurements. The physician must have observed the evaluation, donation process, and management of these donors.*

This experience must be documented on a log that includes the date of procurement and Donor ID.

5. *The physician has observed at least 3 liver transplants.
This experience must be documented on a log that includes transplant date, donor type, and medical record number or other unique identifier.*

6. ***Provide documentation** that the transplant program will **submit activity reports** to the OPTN Contractor every 2 months describing the transplant activity, transplant outcomes, physician recruitment efforts, and other operating conditions as required by the MPSC to demonstrate the ongoing quality and efficient patient care at the program. The activity reports must also demonstrate that the physician is making sufficient progress to meet the required involvement in the primary care of 50 or more liver transplant recipients, or that the program is making sufficient progress in recruiting a physician who meets all requirements for primary liver transplant physician and who will be on site and approved by the MPSC to assume the role of primary physician by the end of the 12 month conditional approval period.*

7. ***Provide documentation** that the program has established and documented a **consulting relationship** with counterparts at another liver transplant program.*

8. ***Provide the following letters along with your application:***
 - A letter from the qualified liver transplant physician and surgeon who were directly involved with the physician verifying that the physician has satisfactorily met the above requirements to become the primary transplant physician of a liver transplant program.
 - A letter of recommendation from the primary physician and transplant program director at the transplant program last served by the physician outlining
 - the individual's overall qualifications to act as primary transplant physician,
 - the individual's personal integrity and honesty,
 - the individual's 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.

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

Part 7: Director of Liver Transplant Anesthesia Requirements

Liver transplant programs must designate a director of liver transplant anesthesia who has expertise in the area of peri-operative care of liver transplant patients and can serve as an advisor to other members of the team.

1. Name of Director of Liver Transplant Anesthesia:

| Name | NPI # |
|--|-------|
| <i>Include this individual's resume/CV with the application.</i> | |

2. Provide a copy of the certification that the director of liver transplant anesthesia is a *Diplomate of the American Board of Anesthesiology*.

- *In place of current certification by the American Board of Anesthesiology, provide two letters of recommendation from current directors of liver transplant anesthesia at a designated liver program who are not employed by the applying member. These letters must address:*
 - Why an exception is reasonable.
 - The anesthesiologist's overall qualifications to act as a director of liver transplant anesthesiology.
 - Any other matters judged appropriate.

3. The director of liver transplant anesthesia should have *one* of the following: **Check one**

- Fellowship training in Critical Care Medicine, Cardiac Anesthesiology, or a Liver Transplant Fellowship, that includes the peri-operative care of **at least 10** liver transplant recipients.
- Experience in the peri-operative care of **at least 20** liver transplant recipients in the operating room, within the last 5 years. Experience acquired during postgraduate residency training does not count for this purpose.

4. The director of Liver Transplant Anesthesia should also earn a **minimum of 8 hours** of credit in transplant related educational activities from the Accreditation Council for Continuing Medical Education (ACCME) Category I Continuing Medical Education (CME) within the most recent 3-year period.

Part 8: Pediatric Transplant Component

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.

Part 8A: Primary Pediatric Liver Transplant Surgeon Requirements

1. Name of Proposed Primary Pediatric Liver Transplant Surgeon (as indicated in Certificate of Assessment):

| Name | NPI # |
|------|-------|
|------|-------|

2. Check yes or no for each of the following. Provide documentation where applicable:

Yes No

- 2a. Does the surgeon 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?
Provide a copy of the surgeon's resume/CV.
- 2b. Has the surgeon been accepted onto the hospital's medical staff, and is practicing on site at this hospital? **Provide documentation from the hospital credentialing committee that it has verified the surgeon's state license, board certification, training, and transplant continuing medical education, and that the surgeon is currently a member in good standing of the hospital's medical staff.**

3. Certification. Check one and provide corresponding documentation:

- 3a. The surgeon is currently certified by the American Board of Surgery, the American Board of Urology, the American Board of Osteopathic Surgery, or the Royal College of Physicians and Surgeons of Canada.
Provide a copy of the surgeon's current board certification.
- 3b. The surgeon has just completed training and is pending certification by the American Board of Urology. Therefore, the surgeon is requesting conditional approval for 16 months to allow time to complete board certification, with the possibility of renewal for one additional 16-month period.
Provide documentation supporting that training has been completed and certification is pending, which must include the anticipated date of board certification and where the surgeon is in the process to be certified.
- 3c. The surgeon is without American Board of Surgery, the American Board of Urology, the American Board of Osteopathic Surgery, or the Royal College of Physicians and Surgeons of Canada or pending certification by the American Board of Urology.
If this option is selected:
- **The surgeon must be ineligible for American board certification. Provide an explanation why the individual is ineligible:**

- **Provide a plan for continuing education that is comparable to American board maintenance of certification; and**
- **Provide at least 2 two letters of recommendation from directors of designated transplant programs not employed by the applying hospital that address**
 - **why an exception is reasonable,**
 - **the individual's overall qualifications to act as a primary liver transplant surgeon,**
 - **the individual's personal integrity and honesty,**
 - **the individual's familiarity with and experience in adhering to OPTN obligations and compliance protocols, and**
 - **any other matters judged appropriate.**

4. Summarize the surgeon's training and experience in transplant:

| Training and Experience | Approved Fellowship Program? Y/N | Date (MM/DD/YY) | | Transplant Hospital | Program Director | # Liver Transplants as Primary | # Liver Transplants as 1st Assistant | # of Liver Procurements as Primary or 1st Assistant |
|------------------------------|-------------------------------------|-----------------|-----|---------------------|------------------|--------------------------------|--------------------------------------|---|
| | | Start | End | | | | | |
| Fellowship Training | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| Experience Post - Fellowship | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |

5. Which of the following pathways is the proposed primary surgeon applying (check one, and complete the corresponding pathway section below):

- The **fellowship pathway**, as described in *Section 5A: Formal 2-year Transplant Fellowship Pathway* below.
- The **clinical experience pathway**, as described in *Section 5B: Clinical Experience Pathway* below.

6. Pediatric-Specific Requirements

- a. *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.

This experience must be documented on 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, and the medical record number or other unique identifier.

- b. *The surgeon has maintained a current working knowledge of pediatric liver transplantation, defined as direct involvement in pediatric liver transplant patient care within the last 2 years.*

Check all that apply

- The surgeon has experience managing pediatric patients with end stage liver disease.*
- The surgeon has experience with the selection of appropriate pediatric recipients for transplantation.*
- The surgeon has experience with donor selection.*
- The surgeon has experience with histocompatibility and tissue typing.*
- The surgeon has experience performing the pediatric transplant operation.*
- The surgeon has experience with immediate postoperative and continuing inpatient care.*
- The surgeon has experience with the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression.*
- The surgeon has experience with differential diagnosis of liver allograft dysfunction.*
- The surgeon has experience with histologic interpretation of allograft biopsies.*
- The surgeon has experience with interpretation of ancillary tests for liver dysfunction.*
- The surgeon has experience with long term outpatient care.*

If a box is not checked, please provide an explanation:

5A. Formal 2-year Transplant Fellowship Pathway

Surgeons can meet the training requirements for primary liver transplant surgeon by completing a formal 2-year surgical transplant fellowship if the following conditions are met:

1. *The surgeon performed **at least 45** liver transplants as primary surgeon or first assistant during the 2-year fellowship period.*
This experience must be documented on a log that includes the date of transplant, the role of the surgeon, the medical record number or other unique identifier, and the fellowship director's signature.

2. *The surgeon performed **at least 20** liver procurements as primary surgeon or first assistant. These procurements must have been performed anytime during the surgeon's fellowship and the two years immediately following fellowship completion.*
This experience must be documented on a log that includes the date of procurement and Donor ID.

3. *The surgeon has maintained a current working knowledge of liver transplantation, defined as direct involvement in liver transplant patient care within the last 2 years.*

Check all that apply

- The surgeon has experience managing patients with end stage liver disease.*
- The surgeon has experience with the selection of appropriate recipients for transplantation.*
- The surgeon has experience with donor selection.*
- The surgeon has experience with histocompatibility and tissue typing.*
- The surgeon has experience with performing the transplant operation.*
- The surgeon has experience with immediate postoperative and continuing inpatient care.*
- The surgeon has experience with the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression.*
- The surgeon has experience with differential diagnosis of liver allograft dysfunction.*
- The surgeon has experience with histologic interpretation of allograft biopsies.*
- The surgeon has experience with interpretation of ancillary tests for liver dysfunction.*
- The surgeon has experience with long term outpatient care.*

If a box is not checked, please provide an explanation:

4. ***Provide the following letters with the application:***

- A letter from the director of the training program verifying that the surgeon has met the above requirements, and is qualified to direct a liver transplant program.

- A letter of recommendation from the fellowship training program's primary surgeon and transplant program director outlining
 - the individual's overall qualifications to act as primary transplant surgeon,
 - the individual's personal integrity and honesty,
 - the individual's 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 surgeon, at its discretion.
- A letter from the surgeon that details his or her training and experience in liver transplantation.

5B. Clinical Experience Pathway

Surgeons can meet the requirements for primary liver transplant surgeon through clinical experience gained post-fellowship, if the following conditions are met:

1. *The surgeon has performed **60 or more** liver transplants over a 2 to 5-year period as primary surgeon, co-surgeon, or first assistant at a designated liver transplant program. Of these 60 liver transplants, 30 or more must have been performed as primary surgeon or co-surgeon. Each year of the surgeon's experience must be substantive and relevant and include pre-operative assessment of liver transplant candidates, transplants performed as primary surgeon or first assistant, and post-operative management of liver recipients.
This experience must be documented on a log that includes the date of transplant, the role of the surgeon, and medical record number or other unique identifier.*
2. *The surgeon has performed **at least 30** liver procurements as primary surgeon, co-surgeon, or first assistant. Of these 30 liver procurements, at least 15 must have been performed as primary surgeon or co-surgeon.
This experience must be documented on a log that includes the date of procurement, Donor ID, and role of the surgeon.*
3. *The surgeon has maintained a current working knowledge of liver transplantation, defined as direct involvement in liver transplant patient care within the last 2 years.*

Check all that apply

- The surgeon has experience managing patients with end stage liver disease.*
- The surgeon has experience with the selection of appropriate recipients for transplantation.*
- The surgeon has experience with donor selection.*
- The surgeon has experience with histocompatibility and tissue typing.*
- The surgeon has experience with performing the transplant operation.*
- The surgeon has experience with immediate postoperative and continuing inpatient care.*
- The surgeon has experience with the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression.*
- The surgeon has experience with differential diagnosis of liver allograft dysfunction.*
- The surgeon has experience with histologic interpretation of allograft biopsies.*
- The surgeon has experience with interpretation of ancillary tests for liver dysfunction.*
- The surgeon has experience with long term outpatient care.*

If a box is not checked, please provide an explanation:

4. ***Provide the following letters with the application:***

- A letter from the director of the transplant program and chairman of the department or hospital credentialing committee verifying that the surgeon has met the above requirements, and is qualified to direct a liver transplant program.
- A letter of recommendation from the primary surgeon and transplant program director at the transplant program last served by the surgeon outlining
 - the individual's overall qualifications to act as primary transplant surgeon,
 - the individual's personal integrity and honesty,
 - the individual's 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 surgeon, at its discretion.

- A letter from the surgeon that details the training and experience the surgeon gained in liver transplantation.

Part 8B: Primary Pediatric Liver Transplant Physician Requirements

1. Name of Proposed Primary Pediatric Liver Transplant Physician (as indicated in Certificate of Assessment):

| | |
|------|-------|
| Name | NPI # |
|------|-------|

2. Check yes or no for each of the following. Provide documentation where applicable:

Yes No

- 2a. Does the physician 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?

Provide a copy of the physician's resume/CV.

- 2b. Has the physician been accepted onto the hospital's medical staff, and is practicing on site at this hospital?

Provide 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.

3. Certification.

- The physician is currently certified in gastroenterology or transplant hepatology or certification of added qualification for pediatric transplant hepatology by the American Board of Internal Medicine, the American Board of Pediatrics, or the Royal College of Physicians and Surgeons of Canada.

Provide a copy of the physician's current board certification.

4. Summarize the physician's training and experience in transplant:

| Training and Experience | Date (MM/DD/YY) | | Transplant Hospital | Program Director | #LI Patients Followed | | |
|----------------------------|-----------------|-----|---------------------|------------------|-----------------------|------|------|
| | Start | End | | | Pre | Peri | Post |
| Experience Post Fellowship | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| Fellowship Training | | | | | | | |

| | | | | | | | |
|--|--|--|--|--|--|--|--|
| | | | | | | | |
| | | | | | | | |

5. Which of the following pathways is the proposed primary physician applying (check one, and complete the corresponding pathway section below):

- The **3-year pediatric gastroenterology fellowship pathway**, as described in *Section 5A: Three-year Pediatric Gastroenterology Fellowship Pathway* below.
- The **12-month pediatric transplant hepatology fellowship pathway**, as described in *Section 5B* below.
- The **combined pediatric gastroenterology or transplant hepatology training and experience pathway**, as described in *Section 5C: Combined Pediatric Gastroenterology/Transplant Hepatology Training and Experience Pathway* below.

5A. 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 is currently 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.*
Provide a copy of the physician's current board certification.
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 experience must be documented on a log that includes the date of transplant, medical record number or other unique identifier, and the signature of 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 has observed **at least 3** liver procurements. The physician must have observed the evaluation, donation process, and management of these donors.*
This experience must be documented on a log that includes the date of procurement and Donor ID.
5. *The physician has observed **at least 3** liver transplants.*
This experience must be documented on a log that includes transplant date, donor type, and medical record number or other unique identifier.
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.*
Check all that apply

- The physician has experience managing pediatric patients with end-stage liver disease.*
- The physician has experience managing pediatric patients with acute liver failure.*
- The physician has experience with the selection of appropriate pediatric recipients for transplantation.*
- The physician has experience with donor selection.*
- The physician has experience with histocompatibility and tissue typing.*
- The physician has experience with immediate postoperative care including those issues of management unique to the pediatric recipient.*
- The physician has experience with fluid and electrolyte management.*
- The physician has experience with the use of immunosuppressive therapy in the pediatric recipient including side-effects of drugs and complications of immunosuppression.*
- The physician has experience with the effects of transplantation and immunosuppressive agents on growth and development?*
- Does the physician have experience with differential diagnosis of liver dysfunction in the allograft recipient?*
- Does the physician have experience with manifestation of rejection in the pediatric patient?*
- Does the physician have experience with histological interpretation of allograft biopsies?*
- Does the physician have experience with interpretation of ancillary tests for liver dysfunction?*
- Does the physician have experience with long-term outpatient care of pediatric allograft recipients including management of hypertension, nutritional support, and drug dosage, including antibiotics, in the pediatric patient.*

If a box is not checked, please provide an explanation:

7. *Provide the following letters with the application:*

- 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.
- A letter of recommendation from the fellowship training program's primary physician and transplant program director outlining
 - the individual's overall qualifications to act as primary transplant physician,
 - the individual's personal integrity and honesty,

- the individual's 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.

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

5B. 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 is currently board certified pediatric gastroenterology or has 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.*

Provide a copy of the physician's current board certification or documentation of approval 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 experience must be documented on a log that includes the date of transplant, medical record number or other unique identifier, and the signature of the training program director or the transplant program's 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.*

Check all that apply

- The physician has experience managing pediatric patients with end-stage liver disease.*
- The physician has experience managing pediatric patients with acute liver failure.*
- The physician has experience with the selection of appropriate pediatric recipients for transplantation.*
- The physician has experience with donor selection.*
- The physician has experience with histocompatibility and tissue typing.*
- The physician has experience with immediate postoperative care including those issues of management unique to the pediatric recipient.*
- The physician has experience with fluid and electrolyte management.*

- The physician has experience with the use of immunosuppressive therapy in the pediatric recipient including side-effects of drugs and complications of immunosuppression.*
- The physician has experience with the effects of transplantation and immunosuppressive agents on growth and development.*
- The physician has experience with differential diagnosis of liver dysfunction in the allograft recipient.*
- The physician has experience with manifestation of rejection in the pediatric patient.*
- The physician has experience with histological interpretation of allograft biopsies.*
- The physician has experience with interpretation of ancillary tests for liver dysfunction.*
- The physician has experience with long-term outpatient care of pediatric allograft recipients including management of hypertension, nutritional support, and drug dosage, including antibiotics, in the pediatric patient.*

If a box is not checked, please provide an explanation:

5. *The physician has observed **at least 3** liver procurements.* The physician must have observed the evaluation, donation process, and management of these donors.
This experience must be documented on a log that includes the date of procurement and Donor ID.
6. *The physician has observed **at least 3** liver transplants.*
This experience must be documented on a log that includes transplant date, donor type, and medical record number or other unique identifier.
7. ***Provide the following letters with the application:***
 - 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.
 - A letter of recommendation from the fellowship training program's primary physician and transplant program director outlining
 - the individual's overall qualifications to act as primary transplant physician,
 - the individual's personal integrity and honesty,
 - the individual's 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.

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

5C. 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 is currently board certified 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.*

Provide a copy of the physician's current board certification or documentation of approval 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 experience must be documented on a log that includes the date of transplant, medical record number or other unique identifier, and the signature of the training program director or the transplant program's primary transplant physician.

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.*

Check all that apply

- The physician has experience managing pediatric patients with end-stage liver disease.*
- The physician has experience managing pediatric patients with acute liver failure.*
- The physician has experience with the selection of appropriate pediatric recipients for transplantation.*
- The physician has experience with donor selection.*
- The physician has experience with histocompatibility and tissue typing.*
- The physician has experience with immediate postoperative care including those issues of management unique to the pediatric recipient.*
- The physician has experience with fluid and electrolyte management.*

- The physician has experience with the use of immunosuppressive therapy in the pediatric recipient including side-effects of drugs and complications of immunosuppression.*
- The physician has experience with the effects of transplantation and immunosuppressive agents on growth and development.*
- The physician has experience with differential diagnosis of liver dysfunction in the allograft recipient.*
- The physician has experience with manifestation of rejection in the pediatric patient.*
- The physician has experience with histological interpretation of allograft biopsies.*
- The physician has experience with interpretation of ancillary tests for liver dysfunction.*
- The physician has experience with long-term outpatient care of pediatric allograft recipients including management of hypertension, nutritional support, and drug dosage, including antibiotics, in the pediatric patient.*

If a box is not checked, please provide an explanation:

5. *The physician has observed **at least 3** liver procurements.* The physician must have observed the evaluation, the donation process, and the management of these donors.
This experience must be documented on a log that includes the date of procurement and Donor ID.

6. *The physician has observed **at least 3** liver transplants.*
This experience must be documented on a log that includes transplant date, donor type, and medical record number or other unique identifier.

7. ***Provide the following letters with the application:***
 - 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.
 - 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 individual's overall qualifications to act as primary transplant physician,
 - the individual's personal integrity and honesty,
 - the individual's 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.

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

Part 8C: Conditional Approval for a Pediatric Component

1. Name of Proposed Primary Pediatric Liver Transplant Surgeon or Physician who fully meets the bylaw requirements:

| Name | Position |
|------|----------|
|------|----------|

2. Name of Proposed Primary Pediatric Liver Transplant Surgeon or Physician who is being proposed as conditional personnel:

| Name | Position |
|------|----------|
|------|----------|

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

Check one, and complete the corresponding portions of the application. Provide supporting documentation where applicable:

- Option A.** The program has a qualified primary pediatric liver **physician** who meets *all* of the requirements and a **surgeon** who meets *all* of the following requirements:
- The surgeon is the current primary transplant surgeon for the liver program or meets *all* of the requirements in one of the pathways listed below:
 - The **formal 2-year transplant fellowship pathway** as described in application *Part 3, Section 5A: Formal 2-year Transplant Fellowship Pathway*
 - The **liver transplant program clinical experience pathway**, as described in application *Part 3, Section 5B: Clinical Experience Pathway*
 - *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.*
This experience must be documented on 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, and the medical record number or other unique identifier.
 - *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 surgeon has experience managing pediatric patients with end stage liver disease.*

- The surgeon has experience with the selection of appropriate pediatric recipients for transplantation.*
- The surgeon has experience with donor selection.*
- The surgeon has experience with histocompatibility and HLA typing.*
- The surgeon has experience performing the transplant operation.*
- The surgeon has experience with immediate post-operative and continuing inpatient care.*
- The surgeon has experience with the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression.*
- The surgeon has experience with differential diagnosis of liver allograft dysfunction.*
- The surgeon has experience with histologic interpretation of allograft biopsies.*
- The surgeon has experience with interpretation of ancillary tests for liver dysfunction.*
- The surgeon has experience with long term outpatient care.*

If a box is not checked, please provide an explanation:

- Option B.** The program has a qualified primary pediatric liver **surgeon** who meets *all* of the requirements and a **physician** who meets *all* of the following requirements:
 - 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.
Provide a copy of the physician's current board certification or documentation of approval to take the certifying exam.
 - The physician gained a **minimum of 2 years** of experience during or after fellowship, or accumulated during both periods, at a liver transplant program.
 - 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 experience must be documented on a log that includes the date of transplant, medical record number or other unique identifier, and the signature of the training program director or the transplant program primary transplant physician.
- 8. 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 physician has experience managing pediatric patients with end-stage liver disease.*
- The physician has experience with the selection of appropriate pediatric recipients for transplantation.*
- The physician has experience with donor selection.*
- The physician has experience with histocompatibility and tissue typing.*
- The physician has experience with immediate postoperative care including those issues of management unique to the pediatric recipient.*
- The physician has experience with fluid and electrolyte management.*
- The physician has experience with the use of immunosuppressive therapy in the pediatric recipient including side-effects of drugs and complications of immunosuppression.*
- The physician has experience with the effects of transplantation and immunosuppressive agents on growth and development.*
- The physician has experience with differential diagnosis of liver dysfunction in the allograft recipient.*
- The physician has experience with manifestation of rejection in the pediatric patient.*
- The physician has experience with histological interpretation of allograft biopsies.*
- The physician has experience with interpretation of ancillary tests for liver dysfunction.*
- The physician has experience with long-term outpatient care of pediatric allograft recipients including management of hypertension, nutritional support, and drug dosage, including antibiotics, in the pediatric patient.*

If a box is not checked, please provide an explanation:

- The physician should have observed **at least 3** organ procurements and **at least 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.
This experience must be documented on the log provided.
- ***Provide the following letters with the application:***
 - 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.
 - 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 individual's overall qualifications to act as a primary transplant physician,
 - the individual's personal integrity and honesty,

- the individual's 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.

- 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.

Part 9: Liver Transplant Programs that Perform Living Donor Recovery

A liver recovery hospital is a designated liver transplant program that performs the surgery to recover livers for transplantation from living donors.

1. Living Donor Surgeon

A liver recovery hospital must have on site **at least 2** surgeons who:

- Meet the primary liver transplant surgeon requirements as outlined in Part 5 of the application above.

- Have demonstrated experience as the primary surgeon, co-surgeon, or first assistant by completion of **at least 20** major liver resection surgeries, including living donor procedures, splits, reductions, and resections, within the past 5 years. Of these 20 major liver resection surgeries, **seven** must have been live donor procedures, and **at least 10** must have been performed as the primary surgeon or co-surgeon.
This experience must be documented on a log that includes the date of the surgery, the role of the surgeon, and the medical record number or other unique identifier.

Name of Proposed Living Donor Surgeon(s):

| Name | NPI # |
|------|-------|
| | |
| | |

2. Independent Living Donor Advocate (ILDA)

The liver recovery hospital must have an independent living donor advocate (ILDA) who is not involved with the evaluation or treatment decisions of the potential recipient, and is a knowledgeable advocate for the living donor. The ILDA must be independent of the decision to transplant the potential recipient and follow the protocols that outline the duties and responsibilities of the ILDA according to OPTN *Policy 14.2: Independent Living Donor Advocate (ILDA) Requirements*.

Name of Independent Living Donor Advocate (ILDA):

PUBLIC BURDEN STATEMENT

The private, non-profit Organ Procurement and Transplantation Network (OPTN) collects this information in order to perform the following OPTN functions: to assess whether applicants meet OPTN Bylaw requirements for membership in the OPTN; and to monitor compliance of member organizations with OPTN Obligations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0915-0184 and it is valid until 08/31/2023. This information collection is required to obtain or retain a benefit per 42 CFR §121.11(b)(2). All data collected will be subject to Privacy Act protection (Privacy Act System of Records #09-15-0055). Data collected by the private non-profit OPTN also are well protected by a number of the Contractor's security features. The Contractor's security system meets or exceeds the requirements as prescribed by OMB Circular A-130, Appendix III, Security of Federal Automated Information Systems, and the Departments Automated Information Systems Security Program Handbook. The public reporting burden for this collection of information is estimated to average 3 hours per response, including the time for reviewing instructions, searching existing data sources, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to HRSA Reports Clearance Officer, 5600 Fishers Lane, Room 14N136B, Rockville, Maryland, 20857 or paperwork@hrsa.gov.