

# 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.

## OPTN Representative

_____	_____	_____
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: \_\_\_\_\_ Suite: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_

Liver Transplant Program Phone #: \_\_\_\_\_

Name of Person Completing Form: \_\_\_\_\_ Title: \_\_\_\_\_

Email Address of Person Completing Form: \_\_\_\_\_

Date Form is submitted to OPTN Contractor: \_\_\_\_\_

## Part 2: Certificate of Assessment

The hospital must conduct an assessment of all transplant program surgeons and physicians for any involvement in prior transgressions of OPTN obligations and plans to ensure compliance.

The **primary surgeon** and **primary physician** are responsible for ensuring the operation and compliance of the program according to OPTN requirements. The transplant hospital must notify the OPTN Contractor immediately if at any time the program does not meet these requirements. The individuals reported to the OPTN Contractor as the program's primary surgeon and primary physician should be the same as those reported to the Center for Medicaid and Medicare Services (CMS).

**Additional Transplant Surgeons** must be credentialed by the transplant hospital to provide transplant services and be able to independently manage the care of transplant patients, including performing the transplant operations and organ procurement procedures.

**Additional Transplant Physicians** must be credentialed by the transplant hospital to provide transplant services and be able to independently manage the care of transplant patients.

A surgeon or physician employed by the transplant hospital that does not independently manage the care of transplant patients may be listed as **other**.

This information is subject to medical peer review confidentiality requirements and must be submitted according to the guidelines provided in the application.

### Instructions:

*On the next page, list all surgeons and physicians involved in the transplant program.*

- *Use the checkboxes to indicate if the individual is part of the main program, living donor component of the program, and/or the pediatric component of the program. Multiple boxes may be checked.*
- *For any surgeon or physician indicated as 'Primary' that isn't already the approved primary surgeon or primary physician for the program, complete the relevant sections of the application below.*
- *For each surgeon or physician that is newly designated as 'Additional', provide a credentialing letter with this application.*
- *For each surgeon or physician listed as 'Other', no further action is needed.*
- *If you have answered 'yes' to any surgeon or physician having prior transgressions with the OPTN, please explain in the blank space provided below the table.*

<i>Name</i>	<i>NPI# (optional)</i>	<i>Surgeon or Physician</i>	<i>Primary, Additional, or Other</i>	<i>Main Program</i>	<i>Living Donor Component</i>	<i>Pediatric Component</i>
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Do any of the individuals listed above have OPTN transgressions? ☐ Yes ☐ No  
If yes, provide the name of the individual(s) and the program's plan to ensure compliance:

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## Part 3: Program Coverage Plan

The program director, along with the primary surgeon and physician, must submit a detailed **Program Coverage Plan** to the OPTN Contactor. The Program Coverage Plan must describe how continuous medical and surgical coverage is provided by transplant surgeons and physicians who have been credentialed by the transplant hospital to provide transplant services to the program.

A transplant program must inform its patients if it is staffed by a single surgeon or physician and acknowledge the potential unavailability of these individuals, which could affect patient care, including the ability to accept organ offers, procurement, and transplantation.

### Instructions:

*Complete the questions below and provide documentation where applicable.*

## Transplant Surgeon and Physician Coverage

### Surgeons

Yes No

☐ ☐ Is this a single surgeon program?

*If yes, provide a copy of the patient notice or protocol for providing patient notification.*

☐ ☐ Does the transplant program have transplant surgeons available 365 days a year, 24 hours a day, 7 days a week to provide program coverage?

*If the answer is no, provide a written explanation in the Program Coverage Plan that justifies the current level of coverage.*

☐ ☐ Is a transplant surgeon readily available in a timely manner to facilitate organ acceptance, procurement, and transplantation?

☐ ☐ Will any of the transplant surgeons be on call simultaneously at two transplant programs more than 30 miles apart?

*If the answer is yes, the program must request an exemption from the MPSC to operate as a transplant program sharing primary personnel with another transplant hospital, without additional transplant staff.*

☐ ☐ Is the **primary** transplant surgeon designated as the primary transplant surgeon at more than one transplant hospital?

*If yes, answer the question below.*

Yes No

☐ ☐ Do you have additional surgeons listed with the program? **If the answer is no, the program must request an exemption from the MPSC to operate as a transplant program sharing primary personnel with another transplant hospital, without additional transplant staff.**

- ☐ ☐ Is the **primary** transplant surgeon **onsite** full-time at this transplant hospital?  
**If the answer is no, please describe in detail the onsite arrangements:**

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- ☐ ☐ Does the **primary** transplant surgeon have **on-call responsibilities** at more than one transplant hospital at the same time? **If the answer is yes, please explain below:**

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## Physicians

### Yes No

- ☐ ☐ Is this a single physician program?  
**If yes, provide a copy of the patient notice or protocol for providing patient notification.**

- ☐ ☐ Does the transplant program have transplant physicians available 365 days a year, 24 hours a day, 7 days a week to provide program coverage?  
**If the answer is no, provide a written explanation that justifies the current level of coverage.**

- ☐ ☐ Will any of the transplant physicians be on call simultaneously for two transplant programs more than 30 miles apart?  
**If the answer is yes, the program must request an exemption from the MPSC to operate as a transplant program sharing primary personnel with another transplant hospital, without additional transplant staff.**

- ☐ ☐ Is the primary transplant physician designated as the primary transplant physician at more than one transplant hospital?  
**If yes, answer the question below.**

### Yes No

- ☐ ☐ Do you have additional physicians listed with the program?  
**If the answer is no, the program must request an exemption from the MPSC to operate as a transplant program sharing primary personnel with another transplant hospital, without additional transplant staff.**

- ☐ ☐ Is the **primary** transplant physician **onsite** full-time at this transplant hospital?  
**If the answer is no, please describe in detail the onsite arrangements:**

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- ☐ ☐ Does the **primary** transplant physician have **on-call responsibilities** at more than one transplant hospital at the same time?

**If the answer is yes, please explain below:**

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## Patient Notification

**Check the box below to attest to the following:**

- ☐ The transplant program provides patients with a written summary of the Program Coverage Plan when placed on the waiting list and when there are any substantial changes in the program or its personnel.

**Attach a copy of the Program Coverage Plan to the application.**



## Part 4: 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.

**Program Director(s) (list all):**

Name	Credentials
Name	Credentials
Name	Credentials
Name	Credentials

## Part 5: Primary Liver Transplant Surgeon Requirements

1. Name of applicant (as indicated in Part 2: Certificate of Assessment):

Name	NPI # (optional)
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- ☐ The applicant is being proposed as the Primary Liver Transplant Surgeon
- ☐ The applicant is being proposed as the Primary Pediatric Liver Transplant Surgeon
- ☐ The applicant is being proposed as a Primary Living Donor Liver Surgeon

2. Check to attest to each of the following. Provide documentation where applicable:

- ☐ The surgeon has 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 medical license and resume/CV/documentation of education to show proof of this requirement.**
- ☐ The surgeon has 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:

- ☐ 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.**
- ☐ The surgeon has just completed training and is pending board certification. 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.**
- ☐ The surgeon is without certification 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 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:**

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- **Provide a plan for continuing education that is comparable to American board maintenance of certification. This plan must at least require that:**
    - o **The surgeon obtains 60 hours of Category I continuing medical education (CME) credits.**
    - o **The surgeon performs a self-assessment that is relevant to the individual's practice every three years, with a score of 75% or higher. Self-assessment is defined as a written or electronic question-and-answer exercise that assesses understanding of the material in the CME program.**
    - o **The transplant hospital document completion of this continuing education.**
  - **Provide at least 2 two letters of recommendation from directors of designated transplant programs not employed by the applying hospital that address:**
    - o **Why an exception is reasonable.**
    - o **The surgeon's overall qualifications to act as a primary liver transplant surgeon. The surgeon's personal integrity and honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.**
    - o **Any other matters judged appropriate.**

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

Training and Experience	Date (MM/DD/YY)		Transplant Hospital	Program Director
	Start	End		
Fellowship				
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 55A. *Formal 2-year Transplant Fellowship Pathway* below.
- ☐ The **clinical experience pathway**, as described in Section 5 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.

**These transplants must be documented in the surgeon's fellowship operative log. 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 that can be verified by the OPTN, 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.

**These procurements must be documented in the surgeon's fellowship operative log. 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.

- ☐ 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.

4. **Check to attest to the following**

- ☐ This training was completed at a hospital with a liver transplant training program approved by the American Society of Transplant Surgeons, the Royal College of Physicians and Surgeons of Canada, or another recognized fellowship training program accepted by the OPTN as described in OPTN membership requirements.

5. **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:
  - o The surgeon's overall qualifications to act as primary transplant surgeon.
  - o The surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations.
  - o 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 that can be verified by the OPTN. This log should be signed by the program director, division chief, or department chair from the program where the experience was gained.***

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 to attest to the following***

- ☐ *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 dysfunction in the allograft recipient.*
- ☐ *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.*

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 surgeon's overall qualifications to act as primary transplant surgeon.
  - The surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations.
  - 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 applicant (as indicated in Part 2: Certificate of Assessment):

Name	NPI # (optional)
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- ☐ The applicant is being proposed as the Primary Liver Transplant Physician
- ☐ The applicant is being proposed as the Primary Pediatric Liver Transplant Physician

2. Check to attest to each of the following. Provide documentation where applicable:

- ☐ The physician has 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 medical license and resume/CV/documentation of education to show proof of this requirement.**
- ☐ The physician has 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:

- ☐ The physician is currently board certified in gastroenterology, transplant hepatology, or has current pediatric transplant hepatology certification of added qualification 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.**
- ☐ 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:**  
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  - 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.**



- o The physician performs a self-assessment that is relevant to the individual's practice every three years, with a score of 75% or higher. Self-assessment is defined as a written or electronic question-and-answer exercise that assesses understanding of the material in the CME program.*
  - o The transplant hospital document completion of this continuing education.*
- *Provide at least 2 two letters of recommendation from directors of designated transplant programs not employed by the applying hospital that address:*
  - o Why an exception is reasonable.*
  - o The physician's overall qualifications to act as a primary liver transplant physician.*
  - o The physician's personal integrity and honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.*
  - o 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
	Start	End		
Fellowship				
Experience Post Fellowship				

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 5* below.
- ☐ The **clinical experience pathway**, as described in *Section 5* below.
- ☐ The **3-year pediatric gastroenterology fellowship pathway**, as described in *Section 5* below.
- ☐ The **pediatric transplant hepatology fellowship pathway**, as described in *Section 5* below.
- ☐ The **combined pediatric gastroenterology/transplant hepatology training and experience pathway**, as described in *Section 5* below.
- ☐ The **conditional approval pathway**, as described in *Section 5F: Conditional Approval for Primary Transplant Physician* below.

**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. Check to attest to the following**

- ☐ *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 that can be verified by the OPTN, 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 to attest to the following**

- ☐ *The physician has experience managing patients with end stage liver disease.*
- ☐ *The physician has experience managing patients with 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.*

- 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 that can be verified by the OPTN.***
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 physician's overall qualifications to act as primary transplant physician.
    - The physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations.
    - 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 that can be verified by the OPTN. This log should be signed by the program director, division chief, or department chair from the 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 within the last 2 years.*

***Check to attest to the following***

- ☐ *The physician has experience managing patients with end stage liver disease.*
- ☐ *The physician has experience managing patients with 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 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 that can be verified by the OPTN.***

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:
  - o The physician's overall qualifications to act as primary transplant physician.
  - o The physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations.
  - o 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:

***Check to attest to the following***

☐ *This physician's training meets the requirements described above.*

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 that can be verified by the OPTN, and the signature of the training program director or the transplant program's primary transplant physician.***

3. ***Check to attest to the following***

☐ *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 that can be verified by the OPTN.***

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 to attest to the following***

- ☐ *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.*

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:*
  - o *The physician's overall qualifications to act as primary transplant physician.*
  - o *The physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.*
  - o *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. **Check to attest to the following**

- ☐ *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 to attest to the following**

- ☐ *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.*
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 that can be verified by the OPTN.***
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 physician's overall qualifications to act as primary transplant physician.
    - The physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations.
    - 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. ***Check to attest to the following***

- ☐ *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 that can be verified by the OPTN, 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 to attest to the following***

- ☐ *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.*
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 that can be verified by the OPTN.***
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 physician's overall qualifications to act as primary transplant physician.
    - The individual's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations.
    - 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 that can be verified by the OPTN, 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 to attest to the following***

- ☐ *The physician has experience managing patients with end stage liver disease.*
- ☐ *The physician has experience managing patients with 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. ***Check to attest to the following***

- ☐ *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 that can be verified by the OPTN.***
6. *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 physician's overall qualifications to act as primary transplant physician.
    - The physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.
    - 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

### 1. Name of Director of Liver Transplant Anesthesia:

Name	NPI # (optional)
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### 2. The director of liver transplant anesthesia must have one of the following (check one, and provide the relevant documentation):

- ☐ The proposed director of liver transplant anesthesia is a Diplomate of the American Board of Anesthesiology.  
**Provide a copy of the certification.**
- ☐ The proposed director of liver transplant anesthesia is **not** a Diplomate of 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 in place of current certification by the American Board of Anesthesiology.** 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.

**For questions 3 through 5, check to attest that the program has put in place the following:**

### 3. Administrative Responsibilities

- ☐ The director of liver transplant anesthesia is a designated member of the transplant team and will be responsible for establishing internal policies for anesthesiology participation in the peri-operative care of liver transplant patients. These policies will be developed in the context of the institutional needs, transplant volume, and quality improvement initiatives.

### 4. Required Policies for Anesthesiology Participation

- ☐ The policy for anesthesiology participation has established a clear communication channel between the transplant anesthesiology service and services from other disciplines that participate in the care of liver transplant patients. The types of activities to consider include:
- ☐ Peri-operative consults
  - ☐ Participation in candidate selection
  - ☐ Participation in morbidity and mortality conferences (M&M Conferences)
  - ☐ Development of intra-operative guidelines based on existing and published knowledge

## 5. Clinical Responsibilities

- ☐ The director of liver transplant anesthesia has clinical responsibilities that include but are not limited to the following:
  - ☐ Pre-operative assessment of transplant candidates
  - ☐ Participation in candidate selection
  - ☐ Intra-operative management
  - ☐ Post-operative visits
  - ☐ Participation on the Selection Committee
  - ☐ Consultation pre-operatively with subspecialists as needed
  - ☐ Participation in morbidity and mortality (M&M) conferences

## 6. 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.  
***Provide a certificate of the fellowship, as well as a log documenting this experience.***
- ☐ 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.  
***Provide a log that documents this experience.***

## 7. 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. ***Provide documentation of CME credit obtained 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.

#### Instructions for Pediatric Component:

To propose a **primary pediatric liver surgeon**, complete section 8A of this application.

- If the surgeon is already the approved primary surgeon of the liver transplant program, complete numbers 1 and 3.
- If the surgeon is **NOT** already the approved primary surgeon of the liver transplant program, complete numbers 1, 2, and 3. To demonstrate that the proposed individual meets the OPTN requirements for both primary liver surgeon and primary pediatric liver surgeon, check the box in number 2 to identify the desired pathway and complete Part 5 of the application.

To propose a **primary pediatric liver physician**, complete section 8B of this application. Indicate the pathway in Number 2. To demonstrate that the proposed physician meets the OPTN requirements for both primary liver physician and primary pediatric liver physician, complete Part 6 of this application.

To apply for **conditional approval of a pediatric component**, complete section 8C of this application. For conditional approval, either the proposed primary surgeon or physician must be fully approved per OPTN requirements.

- Select **Option A** if the program has a qualified primary pediatric liver physician who meets all of the requirements but the **surgeon** is seeking conditional approval.
- Select **Option B** if the program has a qualified primary pediatric liver surgeon who meets all of the requirements but the **physician** is seeking conditional approval.

## Part 8A: Primary Pediatric Liver Transplant Surgeon Requirements

### 1. Name of Proposed Primary Pediatric Liver Transplant Surgeon (as indicated in Part 2: Certificate of Assessment):

Name	NPI # (optional)
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### 2. Which of the following pathways is the proposed primary pediatric surgeon applying (check one, and complete Part 5 of this application):

- ☐ The **fellowship pathway**, as described in Part 5, Section 55A. *Formal 2-year Transplant Fellowship Pathway* above.
- ☐ The **clinical experience pathway**, as described in Part 5, Section 5 above.

### 3. 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 to attest to the following**

- ☐ 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 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.

## Part 8B: Primary Pediatric Liver Transplant Physician Requirements

1. Name of Proposed Primary Pediatric Liver Transplant Physician (as indicated in Part 2: Certificate of Assessment):

Name	NPI # (optional)
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2. Which of the following pathways is the proposed primary pediatric physician applying (check one, and complete Part 6 of this application):

- ☐ The **3-year pediatric gastroenterology fellowship pathway**, as described in *Part 6, Section 6* above.
- ☐ The **pediatric transplant hepatology fellowship pathway**, as described in *Part 6, Section 6D Pediatric Transplant Hepatology Fellowship Pathway* above.
- ☐ The **combined pediatric gastroenterology or transplant hepatology training and experience pathway**, as described in *Part 6, Section 6* above.

## Part 8C: Conditional Approval for a Pediatric Component

**Instructions: Check Option A or Option B 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 described in **Part 8B: Primary Pediatric Liver Transplant Physician Requirements** above and a **surgeon** who meets *all* of the following requirements.

1. **Name of proposed primary pediatric liver transplant surgeon who meets conditional requirements:**

Name	NPI # (optional)
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2. 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 5, Section 55A. Formal 2-year Transplant Fellowship Pathway* above.

☐ The **liver transplant program clinical experience pathway**, as described in application *Part 5, Section 5* above.

***If the surgeon is not the approved primary transplant surgeon of the liver program, complete Part 5 of this application.***

3. 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 that can be verified by the OPTN.***

4. 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 to attest to the following**

- ☐ 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.*
- ☐ **Option B.** The program has a qualified primary pediatric liver **surgeon** who meets *all* of the requirements described in **Part 8A: Primary Pediatric Liver Transplant Surgeon Requirements** above and a **physician** who meets *all* of the following requirements.

1. **Name of proposed primary pediatric liver transplant physician who meets conditional requirements:**

Name	NPI# (optional)
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2. 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.***

3. **Check to attest to the following:**

- ☐ The physician gained a **minimum of 2 years** of experience during or after fellowship, or accumulated during both periods, at a liver transplant program.

4. 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 that can be verified by the OPTN, and the signature of the training program director or the transplant program primary transplant physician.***

5. 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.

**Check to attest to the following**

- ☐ *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.*
6. 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 in a log that includes the date of procurement and Donor ID.***
7. ***Provide the following letters with the application:***
- o 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.
  - o 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.
    - The physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations.
    - 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.
  - o 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.

Liver recovery hospitals must meet all the requirements of a designated liver transplant program as outlined above, *and* must also have the following:

***For questions 1 and 2, check to attest that the program has adequate resources in place for living donor liver recovery:***

**1. Living Donor Medical Evaluations**

- ☐ The liver recovery hospital has the clinical resources available to assess the medical condition of and specific risks to the living donor.

**2. Living Donor Psychosocial Evaluation**

- ☐ The liver recovery hospital has the clinical resources to perform a psychosocial evaluation of the living donor.

**3. 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.

**Name of Independent Living Donor Advocate (ILDA):** \_\_\_\_\_

## Part 9A: Primary Living Donor Liver Surgeon

Name of Proposed Living Donor Surgeon (as indicated in Part 2: Certificate of Assessment):

Name	NPI # (optional)
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A liver recovery hospital must have on site at least 2 surgeons who meet the following criteria.

***Check to attest to the following and provide corresponding documentation***

- ☐ The proposed individual meets the primary liver transplant surgeon requirements as outlined in Part 5 of the application above.  
***If the surgeon is not the approved primary transplant surgeon of the liver program, complete Part 5 of the liver application.***
- ☐ The proposed individual has 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 that can be verified by the OPTN.***



## Part 9B: Primary Living Donor Liver Surgeon

If the second primary living donor surgeon will be seeking conditional approval, complete Part 9C for that individual instead of Part 9B.

Name of Proposed Living Donor Surgeon (as indicated in Part 2: Certificate of Assessment):

Name	NPI # (optional)
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A liver recovery hospital must have on site at least 2 surgeons who meet the following criteria.

***Check to attest to the following and provide corresponding documentation***

- ☐ The proposed individual meets the primary liver transplant surgeon requirements as outlined in Part 5 of the application above.  
***If the surgeon is not the approved primary transplant surgeon of the liver program, complete Part 5 of the liver application.***
- ☐ The proposed individual has 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 that can be verified by the OPTN.***

## Part 9C: Conditional Program Approval

If the program does not have a second surgeon on site who has performed at least 7 living donor liver recoveries within the past 5-years, the program may be eligible for conditional approval status.

Name of Living Donor Surgeon seeking conditional approval:

_____	_____
Name	NPI # (optional)

***Check to attest to the following and provide corresponding documentation***

- ☐ The proposed individual meets the primary liver transplant surgeon requirements as outlined in Part 5 of the application above.  
***If the surgeon is not the approved primary transplant surgeon of the liver program, complete Part 5 of the liver application.***
- ☐ The proposed individual has 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.  
***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 that can be verified by the OPTN.***

The transplant program may be granted one year to fully comply with applicable membership criteria with a possible one-year extension. During this period of conditional approval, both of the designated surgeons must be present at all living donor liver recoveries.

### **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 membership requirements; 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 xx/xx/20xx. 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 5.79 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 Information Collection Clearance Officer, 5600 Fishers Lane, Room 14N39, Rockville, Maryland, 20857 or [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov).