# 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.

	<b>OPTN Representative</b>	
Printed Name	Signature	Email Address

# **Part 1: General Information**

Name of Transplant Hospital:				
OPTN Member Code:	_			
Transplant Hospital Address (when	re transplants	occur)		
Street:		Suite:		
City:	_ State:	Zip:		
Liver Transplant Program Phone #	:			
Liver Transplant Program Fax #:				
Name of Person Completing Form	:		Title:	
Email Address of Person Completi	ng Form:			
Date Form is submitted to OPTN C	ontractor:			

OMB No. 0915-0184

Expiration Date: 12/31/2025

#### 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 the requirements set forth in the OPTN Bylaws. 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.

## Department of Health and Human Services Health Resources and Services Administration

OMB No. 0915-0184 Expiration Date: 12/31/2025

Name (	NPI# Surgeon or optional) Physician	Primary, Additional, or Other  Program	Living Donor Component	Pediatric Component
--------	--	--	---------------------------	------------------------

#### Department of Health and Human Services Health Resources and Services Administration

OMB No. 0915-0184 Expiration Date: 12/31/2025

Do any of the individuals list If yes, provide the name of t			iance:	

OMB No. 0915-0184

Expiration Date: 12/31/2025

## **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**

Surge	eons
Yes N	o
	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 <b>primary</b> transplant surgeon designated as the primary transplant surgeon at more than one transplant hospital?  If yes, answer the question below.
	Yes No

Department of Health and Human Services Health Resources and Services Administration	OMB No. 0915-0184 Expiration Date: 12/31/2025
$\square$ $\square$ Do you have additional surgeons listed with the must request an exemption from the MPSC to optimary personnel with another transplant hospital.	pperate as a transplant program sharing
□ □ Is the <b>primary</b> transplant surgeon <b>onsite</b> full-time at this If the answer is no, please describe in detail the onsi	ite arrangements: 
□ □ Does the <b>primary</b> transplant surgeon have <b>on-call re</b> hospital at the same time? <b>If the answer is yes, pleas</b>	esponsibilities at more than one transplant se explain below:
Physicians Yes No □ □ Is this a single physician program?	
If yes, provide a copy of the patient notice or protoco	l for providing patient notification.
<ul> <li>□ □ Does the transplant program have transplant physician</li> <li>7 days a week to provide program coverage?</li> <li>If the answer is no, provide a written explanation that</li> </ul>	
☐ ☐ Will any of the transplant physicians be on call simulton than 30 miles apart?  If the answer is yes, the program must request an expression transplant program sharing primary personnel wandditional transplant staff.	exemption from the MPSC to operate as a
<ul> <li>□ □ Is the primary transplant physician designated as the one transplant hospital?</li> <li>If yes, answer the question below.</li> <li>Yes No</li> <li>□ □ Do you have additional physicians listed with the If the answer is no, the program must request and transplant program sharing primary personnel wanditional transplant staff.</li> </ul>	e program? exemption from the MPSC to operate as a
$\square$ Is the <b>primary</b> transplant physician <b>onsite</b> full-time at the <b>If the answer is no, please describe in detail the onsite</b>	· · · · · · · · · · · · · · · · · · ·

Department of Health and Human Services Health Resources and Services Administration	OMB No. 0915-0184 Expiration Date: 12/31/2025		
□ □ Does the <b>primary</b> transplant physician have <b>on-call re</b> s hospital at the same time? <b>If the answer is yes, please explain below:</b>	sponsibilities at more than one transplant		
Patient Notification			
Check the box below to attest to the following:			
☐ The transplant program provides patients with a written when placed on the waiting list and when there are any personnel.			

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

OMB No. 0915-0184

Expiration Date: 12/31/2025

# 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			

# **Part 5: Primary Liver Transplant Surgeon Requirements**

OMB No. 0915-0184

Expiration Date: 12/31/2025

	Name	NPI # (optional)	
Che	eck to attest to each of the following. Provide d	ocumentation where applicable:	
	The surgeon has an M.D., D.O., or equivalent of license to practice medicine in the hospital's sto	, ,	ent
	Provide a copy of the surgeon's medical education to show proof of this requirement.	license and resume/CV/documentation	of
<u> </u>	The surgeon has been accepted onto the hospit this hospital.	al's medical staff, and is practicing on site	e at
	Provide documentation from the hospital creasurgeon's state license, board certification, and education, and that the surgeon is currently a medical staff.	raining, and transplant continuing med	ical
Cer	tification. Check one and provide correspondin	g documentation:	
	The surgeon is currently certified by the American Board of Osteopathic St. Surgeons of Canada.	· ·	
	Provide a copy of the surgeon's current board	certification.	
	The surgeon has just completed training and surgeon is requesting conditional approval for certification, with the possibility of renewal for	16 months to allow time to complete bo	
	Provide documentation supporting that train pending, which must include the anticipated		
	surgeon is in the process to be certified.	date of board certification and where	uie
	The surgeon is without certification by the Amel Urology, the American Board of Osteopathic Surgeons of Canada or pending certification by If this option is selected:	urgery, or the Royal College of Physicians o	

explanation why the individual is ineligible:

OMB No. 0915-0184 Health Resources and Services Administration Expiration Date: 12/31/2025

\_\_\_\_\_

- 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.
  - o 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	<b>D</b> a (MM/[		Transplant Hospital	Program Director
Experience	Start	End	Transplant Hospital	i rogiam birector
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):
	<ul> <li>☐ The fellowship pathway, as described in Section 5 below.</li> <li>☐ The clinical experience pathway, as described in Section 5 below.</li> </ul>

#### 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.
	$\Box$ The surgeon has experience managing patients with end stage liver disease.
	☐ The surgeon has experience with the selection of appropriate recipients for transplantation.
	$\square$ The surgeon has experience with donor selection.
	$\square$ The surgeon has experience with histocompatibility and tissue typing.
	$\square$ The surgeon has experience with performing the transplant operation.
	$\hfill\Box$ 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.
	$\ \square$ The surgeon has experience with interpretation of ancillary tests for liver dysfunction.
	$\square$ 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 Section F.6: Approved Liver Surgeon Transplant Fellowship Programs in the OPTN bylaws.

#### 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:
  - 0 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.

OMB No. 0915-0184

Expiration Date: 12/31/2025

#### 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 preoperative 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.

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
$\square$ The surgeon has experience managing patients with end stage liver disease.
$\square$ The surgeon has experience with the selection of appropriate recipients for
transplantation.
$\square$ The surgeon has experience with donor selection.
$\square$ The surgeon has experience with histocompatibility and tissue typing.
$\square$ The surgeon has experience with performing the transplant operation.
$\ \square$ The surgeon has experience with immediate postoperative and continuing inpatient care.
$\hfill\square$ The surgeon has experience with the use of immunosuppressive therapy including side
effects of the drugs and complications of immunosuppression.
$\ \square$ The surgeon has experience with differential diagnosis of liver dysfunction in the allograft
recipient.
$\square$ The surgeon has experience with histologic interpretation of allograft biopsies.
$\Box$ 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:
  - 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 the training and experience the surgeon gained in liver transplantation.

# **Part 6: Primary Liver Transplant Physician Requirements**

OMB No. 0915-0184

Expiration Date: 12/31/2025

	Name	NPI # (optional)
Che	eck to attest to each of the following. Provid	de documentation where applicable:
	The physician has an M.D., D.O., or equival license to practice medicine in the hospital's	ent degree from another country, with a current s state or jurisdiction.
	Provide a copy of the physician's medieducation to show proof of this requirement	ical license and resume/CV/documentation of nt.
	The physician has been accepted onto the ho this hospital.	ospital's medical staff, and is practicing on site at
	physician's state license, board certification	credentialing committee that it has verified the on, training, and transplant continuing medical atly a member in good standing of the hospital's
Cer	tification. Check one and provide correspor	nding documentation:
	current pediatric transplant hepatology ce	n gastroenterology, transplant hepatology, or has rtification of added qualification by the American In Board of Pediatrics, of the Royal College of
	Provide a copy of the physician's current l	poard certification.
	<ul> <li>American Board of Pediatrics, or the Royal</li> <li>The physician must be ineligible for Alexander</li> <li>explanation why the individual is ineligible</li> </ul>	
	Provide a plan for continuing educe maintenance of certification. This plan	cation that is comparable to American boar

practice every three years, with a score of 75% or higher. Self-assessment is

5.

defined as a written or electronic question-and-answer exercise that assesses understanding of the material in the CME program.

OMB No. 0915-0184

- 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:

Fraining and Experience	Date (MM/DD/YY)		Transplant Hospital	Program Director		
	Start	End	Transplant Hospital	i iogiani birectoi		
Fellowship						
Experience Post Fellowship						

Which of the following pathways is the proposed primary physician applying? (check one, and complete the corresponding pathway section below):					
The <b>12-month transplant hepatology fellowship pathway</b> , as described in <i>Section 5</i> below.					
The clinical experience pathway, as described in Section 5 below.					
The <b>3-year pediatric gastroenterology fellowship pathway</b> , as described in <i>Section 5</i> below.					
The <b>pediatric transplant hepatology fellowship pathway</b> , as described in <i>Section 5</i> 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:

OMB No. 0915-0184

Expiration Date: 12/31/2025

#### 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 <u>within the last 2 years</u>.

#### Check to attest to the following

CII	eck to attest to the johowing
	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:
  - 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.

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

OMB No. 0915-0184

Expiration Date: 12/31/2025

#### 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
۷٠	as direct involvement in liver transplant patient care within the last 2 years.
	Check to attest to the following
	$\square$ The physician has experience managing patients with end stage liver disease.
	$\square$ The physician has experience managing patients with acute liver failure.
	$\square$ The physician has experience with the selection of appropriate recipients for
	transplantation.
	$\square$ The physician has experience with donor selection.
	$\square$ The physician has experience with histocompatibility and tissue typing.
	$\square$ The physician has experience with immediate post-operative patient care.
	$\Box$ The physician has experience with the use of immunosuppressive therapy including side
	effects of the drugs and complications of immunosuppression.
	$\Box$ The physician has experience with differential diagnosis of liver allograft dysfunction.
	$\Box$ The physician has experience with histologic interpretation of allograft biopsies.
	$\Box$ The physician has experience with interpretation of ancillary tests for liver dysfunction.

- 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.

☐ The physician has experience with long term outpatient care.

- 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:
  - 0 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:

OMB No. 0915-0184

Expiration Date: 12/31/2025

#### 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.

OMB No. 0915-0184 Health Resources and Services Administration Expiration Date: 12/31/2025

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
	$\Box$ The physician has experience managing pediatric patients with end-stage liver disease.
	$\square$ The physician has experience managing pediatric patients with acute liver failure.
	$\Box$ The physician has experience with the selection of appropriate pediatric recipients for transplantation.
	$\square$ The physician has experience with donor selection.
	$\square$ 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.
	$\square$ 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.
	$\Box$ The physician has experience with the effects of transplantation and immunosuppressive agents on growth and development.
	$\Box$ The physician has experience with differential diagnosis of liver dysfunction in the allograft recipient.
	$\square$ The physician has experience with manifestation of rejection in the pediatric patient.
	$\square$ The physician has experience with histological interpretation of allograft biopsies.
	$\ \square$ 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:
  - 0 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.

## Department of Health and Human Services Health Resources and Services Administration

OMB No. 0915-0184 Expiration Date: 12/31/2025

• 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 fol	lowing
٠.	Circuit to	accest to	,	

Ш	The exp	erience	e ii	n caring	for p	ediatric liv	er patients	occ	urred at	a liv	er transpl	lant
	program	with	а	qualified	liver	transplan	t physician	and	surgeon	that	performs	an
	average	of <b>at l</b> e	eas	<b>t 10</b> pedia	atric li	iver transpl	ants 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.

Ch	eck 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.

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:
  - 0 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.

# 5E. Combined Pediatric Gastroenterology/Transplant Hepatology Training and Experience Pathway

OMB No. 0915-0184

Expiration Date: 12/31/2025

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	fol	lowing

- ☐ 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 preoperative, 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.

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:
  - 0 the physician's overall qualifications to act as primary transplant physician.
  - o the individual'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.

#### **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.

	γ Ο · · · · · · · · · · · · · · · · · ·
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 <b>12 months experience</b> 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

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:
    - 0 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.

# Part 7: Director of Liver Transplant Anesthesia Requirements

OMB No. 0915-0184

Name of Director of Liver Transplant Anesthesia:		
NPI # (optional)		
The director of liver transplant anesthesia must have one of the following (check one, and provide the relevant documentation):		
of the American Board of		
e of the American Board of er transplant anesthesia at member in place of current must address:		
liver transplant		
the following:		
of the transplant team and gy participation in the peri- eloped in the context of the atives.		
or communication channel om other disciplines that ies to consider include: erences)		
t t		

5. Clinical Responsibilities ☐ The director of liver transplant anesthesia has clinical responsibilities that include but are not limited to the following: O Pre-operative assessment of transplant candidates O Participation in candidate selection 0 Intra-operative management O Post-operative visits O Participation on the Selection Committee O Consultation pre-operatively with subspecialists as needed O 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.

OMB No. 0915-0184

Expiration Date: 12/31/2025

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.

OMB No. 0915-0184

Expiration Date: 12/31/2025

#### **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 bylaw 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 bylaw 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 the bylaws.

- 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

OMB No. 0915-0184

1.	Name of Proposed Primary Pediatric Liver Transplant Surgeon (as indicated in Part 2: Certificate of Assessment):			
		Name	NPI # (optional)	
2.	Which of the following pathways is the proposed primary pediatric surgeon applying (check one and complete Part 5 of this application):			
		e <b>fellowship pathway</b> , as described in <i>Part 5</i> , e <b>clinical experience pathway</b> , as described i		
3.	Pediat	ric-Specific Requirements		
	a.	The surgeon has performed at least 15 li assistant, in recipients less than 18 years of liver transplants must have been in recipier kilograms at the time of transplant. These after fellowship, or across both periods.  This experience must be documented on	ver transplants, as the primary surgeon or first old at the time of transplant. At least 8 of these ats less than 6 years old or weighing less than 25 transplants must have been performed during or a log that includes the date of transplant, the eight at transplant if less than 25 kilograms, the I number or other unique identifier.	
	b.	<ul> <li>defined as direct involvement in pediatric live.</li> <li>Check to attest to the following</li> <li>The surgeon has experience managing period of the surgeon has experience with the transplantation.</li> <li>The surgeon has experience with donor service of the surgeon has experience with histocorular of the surgeon has experience performing to the surgeon has experience with immediate of the surgeon has experience with the underfects of the drugs and complications of the drugs and complications.</li> </ul>	mpatibility and HLA typing.  the pediatric transplant operation.  iate postoperative and continuing inpatient care.  se of immunosuppressive therapy including side  f immunosuppression.  htial diagnosis of liver allograft dysfunction.	
		☐ The surgeon has experience with interpro ☐ The surgeon has experience with long te	etation of ancillary tests for liver dysfunction.	

# Part 8B: Primary Pediatric Liver Transplant Physician Requirements

OMB No. 0915-0184

1.	Name of Proposed Primary Pediatric Liver Transplant Physician (as indicated in Part 2: Certificate of Assessment):		
	Name	NPI # (optional)	
2.	Which of the following pathways is the proposed primary pediatric physician applying (check one, and complete Part 6 of this application):		
	☐ The <b>3-year pediatric gastroenterology fellowship pathway</b> , as described in <i>Part 6</i> , <i>Section 6</i> above.		
	☐ The <b>pediatric transplant hepatology fellowship</b> Pediatric Transplant Hepatology Fellowship Path		
	☐ The combined pediatric gastroenterology or train pathway, as described in Part 6, Section 6 above	nsplant hepatology training and experience	

# Part 8C: Conditional Approval for a Pediatric Component

OMB No. 0915-0184

Instructions: Check Option A or Option B and complete the corresponding portions of the application. Provide supporting documentation where applicable:		
requ	ion A. The program has a qualified primary pediatric liver physician who meets all of the uirements described in Part 8B: Primary Pediatric Liver Transplant Physician Requirements we and a surgeon who meets all of the following requirements.	
1.	Name of proposed primary pediatric liver transplant surgeon who meets conditional bylaw requirements:	
	Name NPI # (optional)	
2.	The surgeon is the current primary transplant surgeon for the liver program or meets <i>all</i> of the requirements in one of the pathways listed below:	
	O The <b>formal 2-year transplant fellowship pathway</b> as described in application <i>Part 5</i> , <i>Section 5</i> above.	
	O 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 <b>at least 7</b> liver transplants, as the primary surgeon or first assistant, in recipients less than 18 years old at the time of transplant. <b>At least 2</b> 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.	
	$\square$ The surgeon has experience with histocompatibility and HLA typing.	
	☐ The surgeon has experience performing the transplant operation.	
	$\square$ The surgeon has experience with immediate post-operative and continuing inpatient care.	

Health Resources and Services Administration Expiration Date: 12/31/2025 ☐ 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.  $\square$  The surgeon has experience with histologic interpretation of allograft biopsies. ☐ The surgeon has experience with interpretation of ancillary tests for liver dysfunction.  $\square$  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) 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, perioperative 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.  $\square$  The physician has experience with donor selection.  $\square$  The physician has experience with histocompatibility and tissue typing.

OMB No. 0915-0184

Department of Health and Human Services

lealth Resources and Services Administration	Expiration Date: 12/31/2025
☐ The physician has experience with immediate pomanagement unique to the pediatric recipient.	ostoperative care including those issues of
$\ \square$ The physician has experience with fluid and electro	lyte management.
<ul> <li>The physician has experience with the use of im recipient including side-effects of drugs and compl</li> </ul>	
<ul> <li>The physician has experience with the effects o agents on growth and development.</li> </ul>	f transplantation and immunosuppressive
<ul> <li>The physician has experience with differential dia recipient.</li> </ul>	ngnosis of liver dysfunction in the allograft
$\square$ The physician has experience with manifestation of	frejection in the pediatric patient.
$\square$ The physician has experience with histological inte	rpretation of allograft biopsies.
$\square$ The physician has experience with interpretation of	f ancillary tests for liver dysfunction.
$\Box$ The physician has experience with long-term outp	atient care of pediatric allograft recipients

OMB No. 0915-0184

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.

including management of hypertension, nutritional support, and drug dosage, including

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

antibiotics, in the pediatric patient.

Department of Health and Human Services

- 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.

Department of Health and Human Services Health Resources and Services Administration

OMB No. 0915-0184 Expiration Date: 12/31/2025

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	
	$\Box$ 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 <i>Policy 14.2: Independent Living Donor Advocate (ILDA) Requirements</i> .	
	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): NPI # (optional) Name 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.

OMB No. 0915-0184

# OMB No. 0915-0184

Expiration Date: 12/31/2025

# 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)		
Αl	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 <b>at least 20</b> major liver resection surgeries, including living donor procedures, splits, reductions, and resections, within the past 5 years. Of these 20 major liver resection surgeries, <b>seven</b> must have been live donor procedures, and <b>at least 10</b> 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.		

OMB No. 0915-0184

Expiration Date: 12/31/2025

# 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.

Na	Name of Living Donor Surgeon seeking conditional approval:		
	Name	NPI # (optional)	
Che	eck to attest to the following and provide correspon	ding documentation	
	The proposed individual meets the primary liver transport 5 of the application above.  If the surgeon is not the approved primary transport 5 of the liver application.		
	The proposed individual has demonstrated experifirst assistant by completion of at least 20 major liprocedures, splits, reductions, and resections, with This experience must be documented on a log that the surgeon, and the medical record number or of the OPTN.	ver resection surgeries, including living donor n the past 5 years.  It includes the date of the surgery, the role of	
	The transplant program may be granted one year criteria with a possible one year extension. During the designated surgeons must be present at all living	this period of conditional approval, both of	

#### **PUBLIC BURDEN STATEMENT**

OMB No. 0915-0184

Expiration Date: 12/31/2025

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 12/31/2025. 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 13 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.