OPTN Membership Application for Intestine Transplant

OMB No. 0915-0184

Expiration Date: 12/31/2025

Programs

CERTIFICATION

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

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

	OPTN Representative	
Printed Name		Email Address

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Part 1: General Information

Name of Transplant Hospital:				
OPTN Member Code (4 Letters): _				
Transplant Hospital Address (whe	ere transplants	s occur)		
Street:		Suite:		
City:	State:	Zip:		
Intestine Transplant Program Pho	one #:			
Intestine Transplant Program Fax	#:			
Name of Person Completing Form	n:		Title:	
Email Address of Person Complet	ing Form:			
Date Form is submitted to OPTN (Contractor:			

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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 these 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.

- 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.

ı	Name	NPI# (optional)	Surgeon or Physician	Primary, Additional, or Other
of the individuals liste rovide the name of the				

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 No	0
	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

\square 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:
□ □ 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:
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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\square Does the primary transplant physician have on-call resp	oonsibilities at more than one transplant
hospital at the same time?	
If the answer is yes, please explain below:	
Patient Notification	
Check the box below to attest to the following:	
\Box The transplant program provides patients with a written s	summary of the Program Coverage Plan
when placed on the waiting list and when there are any supersonnel.	
Attach a copy of the Program Coverage Plan to the application	1.

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Part 4: Program Director(s)

An intestine transplant program must identify at least one designated staff member to act as the transplant program director. The director must be a surgeon or physician 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 Intestine Transplant Surgeon Requirements

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ck to attest to each of the following. Provide do	
-	lagrae from another country with a current
license to practice medicine in the hospital's stat	_
Provide a copy of the surgeon's medical leeducation to show proof of this requirement.	icense and resume/CV/documentation of
-	nedical staff and is practicing on site at this
surgeon's state license, board certification, tr	aining, and transplant continuing medical
cification. Check one and provide corresponding	documentation:
Osteopathic Surgery, or the Royal College of Phy	sicians and Surgeons of Canada.
of Osteopathic Surgery, or the Royal College of I If this option is selected:	Physicians and Surgeons of Canada.
	The surgeon been accepted onto the hospital's rehospital. Provide documentation from the hospital credesurgeon's state license, board certification, treducation, and that the surgeon is currently a medical staff. Effication. Check one and provide corresponding. The surgeon is currently certified by the Americal Osteopathic Surgery, or the Royal College of Physical Provide a copy of the surgeon's current board of Osteopathic Surgery, or the Royal College of the Surgeon is without certification by the Americal Osteopathic Surgery, or the Royal College of the Surgeon is without certification by the Americal Osteopathic Surgery, or the Royal College of the Surgeon is without certification by the Americal Osteopathic Surgery, or the Royal College of the Surgery.

o the transplant hospital document completion of this continuing education.

the material in the CME program.

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- 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 intestine 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	Date (MM/DD/YY)		Transplant Hospital	Program Director	
Experience	Start	End	Transplant Hospital	Program Director	
Fellowship					
Experience Post Fellowship					

5.	5. Which of the following pathways is the proposed primary surgeon applying (check one, and complete the corresponding pathway section below):				
		The full approval pathway , as described in <i>Section 5</i> Error: Reference source not found below.			
		The conditional pathway , as described in <i>Section 5B</i> : Conditional Intestine Surgeon Approval Pathway below.			

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5A: Full Intestine Surgeon Approval Pathway

Surgeons can be fully approved as a primary intestine transplant surgeon by completing a formal surgical transplant fellowship or by completing clinical experience at an intestine transplant program if *all* of the following conditions are met:

- 1. The surgeon performed **7 or more** intestine transplants at a designated intestine transplant program, to include the isolated bowel and composite grafts, as primary surgeon or first assistant within the last 10 years.
 - This experience must be documented on a log that includes the date of transplant, the role of the surgeon, medical record number or other unique identifier that can be verified by the OPTN. This log must be signed by the program director, division chief, or department chair from the program where the experience or training was gained.
- 2. The surgeon performed 3 or more intestine procurements as primary surgeon or first assistant. These procurements must include 1 or more organ recovery that includes a liver. This experience must be documented on a log that includes the date of procurement and Donor ID. This log must be signed by the program director, division chief, or department chair from the program where the experience or training was gained.

3. The surgeon must maintain a current working knowledge of intestine transplantation,

	defined as direct involvement in intestine transplant patient care within the last 5 years.
	Check to attest to the following
	☐ The surgeon has experience managing patients with short bowel syndrome or intestinal failure.
	\square The surgeon has experience with recipient selection.
	\square The surgeon has experience with donor selection.
	\Box The surgeon has experience with histocompatibility and tissue typing.
	\Box 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 intestine allograft dysfunction.
	 □ The surgeon has experience with histologic interpretation of allograft biopsies. □ The surgeon has experience with interpretation of ancillary tests for intestine dysfunction. □ The surgeon has experience with long term outpatient care.
4.	The training was completed at a hospital with an intestinal transplant training program approved by the American Society of Transplant Surgeons or the Royal College of Physicians and Surgeons of Canada, or another recognized fellowship training program accepted by the OPTN. This program must meet all of the below criteria. Check to attest to the following
	☐ The program is at a transplant hospital that transplants two or more organs, including liver and intestines.
	 □ The program is at an institution that has ACGME approved training in general surgery. □ The program performs at least 10 intestine transplants during each year of the fellowship training.

5. Provide the following letters with the application:

- A letter from the qualified intestine transplant physician and surgeon who have been directly involved with the surgeon documenting the surgeon's experience and competence.
- A letter of recommendation from the primary surgeon and transplant program director at the fellowship training program or transplant program last served by the surgeon outlining:
 - o the surgeon's overall qualifications to act as a 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 surgeon, primary physician surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.

• A letter from the surgeon that details the training and experience the surgeon gained in intestine transplantation.

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5B: Conditional Intestine Surgeon Approval Pathway

Surgeons can meet the requirements for conditional approval as primary intestine transplant surgeon through experience gained during or post-fellowship, if *all* of the following conditions are met:

1. The surgeon has performed **at least 4** intestine transplants that include the isolated bowel and composite grafts and must perform **3 or more** intestine transplants over the next 3 consecutive years as primary surgeon or first assistant at a designated intestine transplant program.

This experience must be documented on a log that includes the date of transplant, the role of the surgeon, medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair from the program where the experience or training was gained.

<u>Note</u>: Each year of the surgeon's experience must be substantive and relevant and include pre-operative assessment of intestine transplant candidates, transplants performed as primary surgeon or first assistant and post-operative management of intestine recipients.

2. The surgeon has performed **at least 3** intestine procurements as primary surgeon or first assistant. These procurements must include **at least 1** procurement of a graft that includes a liver.

3. The surgeon has maintained a current working knowledge of intestine transplantation,

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

defined as direct involvement in intestine transplant patient care within the last 5 years.
Check to attest to the following
\Box The surgeon has experience with managing patients with short bowel syndrome.
\Box The surgeon has experience with managing patients with intestinal failure.
\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.
$\ \square$ 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 intestine dysfunction in the
allograft recipient.
☐ The surgeon has experience with histologic interpretation of allograft biopsies.
\square The surgeon has experience with interpretation of ancillary tests for intestine
dysfunction.
\square The surgeon has experience with long term outpatient care.

4. The surgeon develops a formal mentor relationship with a primary intestine transplant surgeon at another approved intestine transplant program. The mentor will discuss program

requirements, patient and donor selection, recipient management, and be available for consultation as required until full approval conditions are all met.

Check to attest to the following:

☐ The surgeon has developed a formal mentor relationship with a primary intestine transplant surgeon at another approved intestine transplant program.

5. Provide the following letters with the application:

- A letter from the director of the transplant program and chair of the department or hospital credentialing committee verifying that the surgeon has met the above requirements and is qualified to direct an intestine 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 surgeon, primary physician, 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 intestine transplantation as well as detailing the plan for obtaining full approval within the 3-year conditional approval period.
- A letter of commitment from the surgeon's mentor supporting the detailed plan developed by the surgeon to obtain full approval.

Part 6: Primary Intestine Transplant Physician Requirements

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	Name	NPI # (optional)
Check to a	attest to each of the following. Provide do	ocumentation where applicable:
	cian has an M.D., D.O., or equivalent d practice medicine in the hospital's state o	egree from another country with a current
	copy of the physician's medical license a roof of this requirement.	nd resume/CV/documentation of education
Γhe physionospital.	cian has been accepted onto the hospital's	medical staff and is practicing on site at this
ohysician	s state license, board certification, tro , and that the physician is currently a	ntialing committee that it has verified the nining, and transplant continuing medical member in good standing of the hospital's
Certificati	on. Check one and provide corresponding	g documentation:
Fl	•	rology by the American Board of Internal
	the American Board of Pediatrics, or the	Royal College of Thysicians and Surgeons of
Medicine, Canada.	the American Board of Pediatrics, or the copy of the physician's current board cer	
Medicine, Canada. Provide a The physi	copy of the physician's current board cer	

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.

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- 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 intestine 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	Date (MM/DD/YY)		Transplant Hospital	Program Director
Experience	Start	End	панурын поэрцы	Program Director
Fellowship				
Experience Post Fellowship				

5. Pediatric-specific physician requirement for programs that serve predominantly pediatric patients:

Any physician who meets the criteria as a primary intestine transplant physician can function as the primary intestine transplant physician for a program that serves predominantly pediatric patients, if a pediatric gastroenterologist is also involved in the care of the transplant recipients.

Che	ck ye	es or no
Yes	No	
		Does this program serve predominantly pediatric patients?
		If yes, check to attest to the following
		☐ There is a pediatric gastroenterologist involved in the care of the pediatric transplant recipients at this intestine program.

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

 The primary intestine transplant physician full approval pathway, as described in Section 6A: Full Intestine Physician Approval Pathway below.

 The primary intestine transplant physician conditional pathway, as described in Section 6B: Conditional Intestine Physician Approval Pathway below.

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6A. Full Intestine Physician Approval Pathway

Physicians can meet the requirements for a primary intestine transplant physician during the physician's adult gastroenterology fellowship, pediatric gastroenterology fellowship, or through acquired clinical experience (including accumulated training during any fellowships) if all of the following conditions are met:

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1. The physician has been directly involved within the last 10 years in the primary care of **7 or more** newly transplanted intestine recipients and continued to follow these recipients for a minimum of 3 months from the time of transplant. This clinical experience must be gained as the primary intestine transplant physician or under the direct supervision of an intestine transplant physician and in conjunction with an intestine transplant surgeon at a designated intestine transplant program.

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. This log must be signed by the program director, division chief, or department chair from the program where the experience or training was gained.

2.	The physician has maintained a current working knowledge of intestine transplantation, defined as direct involvement in intestine transplant patient care within the last 5 years.
	Check to attest to the following
	☐ The physician has experience with managing patients with intestinal 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.
	\Box The physician has experience with immediate postoperative 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 intestine allograft dysfunction.
	\Box The physician has experience with histologic interpretation of allograft biopsies.
	☐ The physician has experience with interpretation of ancillary tests for intestine dysfunction.
	☐ The physician has experience with long term outpatient care.
3.	The physician has observed at least 1 isolated intestine transplant and at least 1 combined

4. Provide the following letters with the application:

liver-intestine or multi-visceral transplant.

above.

• A letter from the transplant program director documenting the physician's experience and training.

This experience must be documented either on a log or the table in Part 6, Question 4

- 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:
 - o 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.
- 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 intestine transplantation.

6B. Conditional Intestine Physician Approval Pathway

Physicians can meet the requirements for approval as primary intestine transplant physician through a conditional approval pathway if *all* of the following conditions are met:

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1. The physician has been involved in the primary care of **at least 4** newly transplanted intestine recipients, and has followed these patients for at least 3 months from the time of their transplant. Additionally, the physician must become involved in the care of **3 or more** intestine recipients over the next 3 consecutive years. This clinical experience must be gained as the primary intestine transplant physician or under the direct supervision of an intestine transplant physician and in conjunction with an intestine transplant surgeon at a designated intestine transplant program.

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. This log must be signed by the program director, division chief, or department chair from the program where the experience or training was gained.

2.	The physician has maintained a current working knowledge of intestine transplantation,
	defined as direct involvement in intestine transplant patient care within the last 5 years.
	Check to attest to the following
	☐ The physician has experience with managing patients with intestinal failure.
	\square 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 postoperative patient care.
	$\ \square$ 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 intestine allograft dysfunction.
	\square The physician has experience with histologic interpretation of allograft biopsies.
	\square The physician has experience with interpretation of ancillary tests for intestine
	dysfunction.
	☐ The physician has experience with long term outpatient care.
2	The physician developed a formal menter relationship with a primary intesting transplant
3.	The physician developed a formal mentor relationship with a primary intestine transplant physician at another approved designated intestine transplant program. The mentor will
	discuss program requirements, patient and donor selection, recipient management, and be
	available for consultation as required.
	Check to attest to the following:
	Check to ditest to the joilowing.
	☐ The physician has developed a formal mentor relationship with a primary intestine
	transplant physician at another approved intestine transplant program.

 A letter from the qualified intestine 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 an intestine transplant program.

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- 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 a 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 intestine transplantation as well as a detailed plan for obtaining full approval.
- A letter of commitment from the physician's mentor supporting the detailed plan developed by the physician to obtain full approval.

PUBLIC BURDEN STATEMENT

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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 11 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.