

Department of Health and Human Services
Health Resources and Services Administration

OMB
No. 0915-0184
Expiration Date:
xx/xx/xxxx

**APPLICATION FOR
ORGAN PROCUREMENT ORGANIZATION (OPO) MEMBERSHIP
ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK
(OPTN)**

**UNOS
700 North 4th Street
Richmond, VA 23219
Main Phone: 804-782-4800**

Name of OPO:	
OPO Address:	
City, State, & Zip Code:	
Contact Person/Title:	
Phone Number:	Email:

PUBLIC BURDEN STATEMENT: 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 project is 0915-0184. Public reporting burden for this collection of information is estimated to average 4 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 14N-39, Rockville, Maryland 20857.

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.

Date:	Signature:
Print Name:	Title:
OPTN Member Code:	

ORGAN PROCUREMENT ORGANIZATION (OPO) APPLICATION

OPTN Membership Application Type

	Check One
Independent Organ Procurement Organization*	
Hospital Based Organ Procurement Organization	
Name of member/applicant hospital if OPO will be hospital-based:	

* An independent OPO is defined as having a distinct governing body separate from any transplant hospital or commonly controlled groups of hospitals it serves.

Provide the full name of the OPO and the CMS provider identification number.

OPO Name:	
CMS Provider Number and Date Approved:	

Part 1: Section A - Personnel, Administrative Director

1. Identify the primary administrative director (Executive Director/CEO/President) who is responsible for organization operations, including effective organ recovery and placement. Attach curriculum vitae (C.V.)/resume.

Name	Mailing Address, Phone Number, & Email Address	Effective date of appointment

2. If this appointment is for an interim period, when will a permanent director be hired? Describe recruitment plan.

[Insert detailed response here. Table will expand automatically]

Part 1: Section B - Personnel, Medical Director(s)

1. Identify the primary medical director who is ultimately responsible for the medical and clinical activities of the OPO. Attach C.V.

Name	Mailing Address, Phone Number, & Email Address	Effective date of appointment

2. Is this appointment for an interim period, a specific term, or not term limited?

If the appointment is interim or for a specific term, indicate term beginning and end dates (mm/dd/yy) and explain the recruitment plan, including timeline.

[Insert detailed response here. Table will expand automatically]

3. Medical directors must be licensed in at least one of the states in the OPO's DSA. Indicate the state(s) in which the medical director is licensed.

[Insert detailed response here. Table will expand automatically]

4. Is more than one person named as a medical director? If yes, please provide the following information for each additional director.

Name	Mailing Address, Phone Number, & Email Address	Term of appointment MM/DD/YY	State(s) where licensed

Part 1: Section C - Personnel, Other Staff

1. List the personnel who will be responsible for data collection and submission. Indicate their background in this area and the percentage of their time that will be dedicated to data collection and submission.

Name	Background	% of Time Dedicated to Data Collection & Submission

2. In Table 1, list all personnel (by position) employed by this OPO.

Part 2: Organizational Information

1. Describe the role of each medical or advisory board if a description is not included in the OPO's charter and bylaws.

Attach a copy of charter and bylaws.

[Insert detailed response here. Table will expand automatically]

2. Attach organizational chart for the OPO staff and for all Boards.
3. Attach list of names and positions of the Board of Directors and/or Advisory Board.
4. Attach a copy of non-profit status notification documenting that the OPO has nonprofit status as an organization exempt from federal income taxation under section 501 of the Internal Revenue Code of 1986.
5. If available, attach a copy of the organization's most recent annual report.
6. Provide evidence that the OPO is currently insured for professional liability for at least one million dollars with an insurer that is licensed for approval by the insurance regulatory agency of the state where the OPO's principal office is located.

If the OPO has a funded self-insurance program, provide proof of coverage and documentation that the fund provides equivalent coverage.

7. Describe the OPO's defined Donation Service Area (DSA) in terms of geographic region.
 - a) Names of counties or parishes served or the state if an entire state is served.

[Insert detailed response here or reference attachment. Table will expand automatically]

- b) Total population in the DSA base (most recent official census as well as the latest data estimate of the US Census Bureau performed between censuses).

[Insert detailed response here. Table will expand automatically]

- c) The number and name of acute care hospitals in the DSA that have operating rooms, equipment and personnel to retrieve organs.

[Insert detailed response here or reference attachment. Table will expand automatically]

- d) Indicate to what extent your defined service area is exclusive. For any non-exclusive service areas served, what other OPOs are involved.

[Insert detailed response here or reference attachment. Table will expand automatically]

Part 3: Process and Procedures

1. Data Collection and Submission: In accordance with the OPTN Policies, members must submit data on candidates, recipients, and donors.

a) Describe the methods that will be used to collect, verify, and submit data on a timely basis.

[Insert detailed response here. Table will expand automatically]

b) Describe the training/orientation for the data coordinator(s). Include details regarding competencies measured as part of the training.

[Insert detailed response here. Table will expand automatically]

2. Describe the procedures that will be in place to ensure the confidentiality of all organ donors.

<Type here or reference attachment>

3. Describe in detail the OPO's quality assurance/performance improvement protocol or process and how it will review its performance. Please indicate the method, frequency of reviews, and participants (by title). Expand or duplicate table as needed.

Individuals Involved: (name & title)	
Methods:	
Frequency of reviews:	
Metrics/Data Tracked:	
Detailed response:	

4. Public Education Plan: Provide summary of education plans that includes activities for public education about organ donation, including how donor families, transplant candidates, and recipients will participate.

[Insert detailed response here. Table will expand automatically]

Attach a copy of the plan for conducting or participating in professional education about organ and tissue procurement.

5. Organ Allocation Plans: The OPO must have procedures and technology to communicate information to distribute organs to transplant candidates at transplant hospitals within and beyond its service area. Describe how this OPO will meet or exceed this requirement including the arrangements for recovery and distribution of renal and non-renal organs

and tissues, and the arrangement for recovery and distribution of tissue (eye, bone, skin, etc.).

- Attach agreements with tissue and eye banks within area.

[Insert detailed response here. Table will expand automatically]

6. Describe the process for ensuring compliance with OPTN obligations. Include who is responsible (name and title/position).

Name/Title:
[Insert detailed response here. Table will expand automatically]

7. Attach a copy of the OPO's plan for addressing multi-cultural and diversity issues.
8. Patient Safety Contact: Describe process for identifying a patient safety contact for receiving potential disease transmission notifications and related communications as described in OPTN Policies. List contacts in Table 1.

[Insert detailed response here. Table will expand automatically]

9. Donation after Circulatory Death (DCD) Protocols. OPOs must develop, and once developed must comply, with protocols to facilitate the recovery of organs from DCD donors. OPO DCD recovery protocols must address the requirements set forth in the OPTN Policies.

Certification Statement
The undersigned, as the duly authorized Chief Executive Officer, hereby certifies after investigation that to the best of his or her knowledge, a Donation after Circulatory Death (DCD) organ recovery protocol has been developed, adopted and implemented in accordance with OPTN Bylaws; and that the DCD organ recovery protocol addresses the requirements.
This OPO has written agreements with all donor hospitals regarding participation in DCD recovery.
Signature:
Name:
Date:

Part 4: Contracts and Agreements

1. Attach documentation that demonstrates that this organization has been either:
 - a) designated as an organ procurement organization by the Secretary of the U.S. Department of Health and Human Services (HHS) under Section 1138(b) of the Social Security Act; or
 - b) is an organization that meets all requirements under Section 1138(b), except for OPTN membership.

If the OPO does not have current Medicare approval for reimbursement, submit evidence that an application has been submitted to Medicare.

2. List below the names and addresses of clinical transplant hospitals that this OPO will serve within its Donation Service Area (DSA). Include the type of transplant programs that it will serve for each transplant hospital (i.e. kidney, heart, lung, liver, pancreas, pancreas islet cell, VCA).

Attach copies of the written contracts/agreements with each transplant hospital.

Transplant Hospital Name & Address	Type of Programs

Expand rows as needed.

3. Describe any regional transplant agreements below.

[Insert detailed response here. Table will expand automatically]

4. Name below and provide a copy of an agreement with a Clinical Laboratory Improvement Amendment (CLIA) certified laboratory(ies) that meets OPTN standards to provide donor screening for transmissible disease, including Human Immunodeficiency Virus (HIV).

[Insert detailed response here. Table will expand automatically]

5. Name below and attach a copy of the agreement with OPTN approved histocompatibility laboratory(ies) to perform the necessary tissue typing of donated organs. The agreement must include all of the elements required in the OPTN Bylaws.

[Insert detailed response here. Table will expand automatically]

6. Attach a list of donor hospitals served and provide a current copy of each agreement.

7. List below tissue banks with which the OPO has written agreements for referral, recovery, processing, preservation, storage, and distribution of tissue from donors. Attach copies of the agreements.

[Insert detailed response here. Table will expand automatically]

Table 1: OPTN Staffing Report

Organ Procurement Organization

Member Code:	Name of OPO:		
Main OPO Phone Number:	Main OPO Fax Number:	OPO website URL: <u>http://www</u>	
Toll Free Phone number:			

List all staff affiliated with the OPO (insert additional rows as needed).

Name	Title	Mailing Address	Phone	Email