OMB No. 0915-0184
Expiration Date: xx/xx/20xx

OPTN Membership Application for Organ Procurement Organizations (OPOs)

CERTIFICATION

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

OPTN Representative

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

OMB No. 0915-0184
Expiration Date: xx/xx/20xx

Part 1: General Information

Name of OPO:_____

OPTN Member Code (4 Letters): _____ **CMS Provider #:** _____

Office Address

Street: _____ **Suite:** _____ **Phone #:** _____

City: _____ **State:** _____ **Zip:** _____

OPO Website Address: _____

Name of Person Completing Form: _____ **Title:** _____

Email Address of Person Completing Form: _____

Date Form is submitted to OPTN Contractor: _____

Is the OPO part of a hospital or independent? Check one

☐ Part of a Hospital

☐ Independent

Instructions: If you are applying for a new OPO, complete all parts of the application.

If you are naming a new **OPO Administrative Director**, only complete Part 4, Question 1.

If you are naming a new **Medical Director**, only complete Part 4, Question 2.

If this is an application for a change in key personnel, effective date of change: _____

Part 2: Facilities and Services

OPOs must have extensive facilities to be fully operational. OPOs must also provide a number of services as part of their daily operations. These required facilities and services are described in the sections that follow.

Transplant Hospital Relationship

1. ***Provide copies of written agreements with all transplant hospitals within its Donation Service Area (DSA) to coordinate its procurement activities, according to the Code of Federal Regulations.***

2. ***Provide copies of written agreements with donor hospitals that include arrangements for the identification, referral, and maintenance of potential organ donors. This also includes preservation and transportation of donated organs to transplant hospitals in its DSA.***

Laboratory Testing Services

1. ***Provide copies of written agreements with all Clinical Laboratory Improvement Amendment (CLIA) certified laboratories that meet OPTN standards to provide donor screening for transmissible disease, including Human Immunodeficiency Virus (HIV).***

2. ***Provide copies of written agreements with all OPTN approved histocompatibility laboratories to perform the necessary tissue typing of donated organs. The agreements must include all of the following:***

   <u>HLA Typing Requirements:</u>

   - Sample requirements
   - Loci and level of resolution typed
   - Process for verifying and reporting results to the OPO and the OPTN
   - Expected turnaround time from receipt of donor sample to reporting results to the OPO and process of notification if turnaround time is going to be exceeded
   - Process for resolving discrepancies and errors

   <u>Crossmatching Requirements:</u>

   - Sample requirements for both donors and recipients
   - If OPO-contracted laboratory performs crossmatching, methodology and criteria for physical crossmatching as well as interpretation and reporting of results.
   - Process for reporting of crossmatching results to the OPO or transplant hospital and verification of results, including verification if changes occur
   - Expected turnaround time from receipt of donor sample to reporting results to the OPO and process of notification if turnaround time is going to be exceeded

   <u>The length of time for which donor specimens are to be stored for repeat or future testing.</u>

Tissue Bank Services

1. ***Provide copies of written agreements with all tissue banks used.***

Education Plans

1. ***Provide written summaries of plans for activities for public education about organ donation, including how donor families, transplant candidates, and recipients will participate.***

2. ***Provide an education plan to conduct or participate in professional education about organ and tissue procurement.***

Organ Allocation Plans

1. ***Provide copies of the OPO's procedures to communicate information to distribute organs to transplant candidates at transplant hospitals within and beyond your service area.***

2. ***Provide the OPO's plan to equitably allocate donated organs among transplant patients.***

Part 3: Quality Assessment and Performance Improvement (QAPI) Requirement

Check the boxes below to attest to the following

☐ *The OPO has developed, implemented and maintained an ongoing, comprehensive and data-driven QAPI program designed to monitor and evaluate compliance with OPTN requirements and produce measurable process improvement initiatives.*

☐ *The OPO has documented implementation of all elements of the QAPI plan*

Provide QAPI plan documentation as an attachment to the application.

3.

Part 4: Personnel

Each OPO must have personnel who are qualified to effectively recover organs from all donors in its DSA.

1. OPO Administrative Director

Each OPO must identify an individual that serves as the administrative director. The administrative director, together with other OPO staff, is responsible for effective organ recovery and placement according to OPTN obligations.

Name of Administrative Director: _____

Include this individual's resume/CV with the application.

2. Medical Director

The OPO medical director must be a physician licensed in at least one of the states within the OPO's DSA. The medical director is responsible for the medical and clinical activities of the OPO.

Name of Medical Director: _____

Include this individual's resume/CV with the application. Provide a copy of state license.

3. Board of Directors

Each OPO must have a board of directors or an advisory board with members selected according to the Code of Federal Regulations. The board of directors or advisory board has the authority to recommend policies that guide the donation, procurement, and equitable distribution of organs.

Provide a list of the organization's Board of Directors or Advisory Board with the application.

4. Additional Necessary Staff

Each OPO must have the necessary staff to recover and distribute organs according to OPTN obligations, including an organ donation coordinator and an organ procurement specialist.

Attach an organizational chart for the OPO to show adequate staffing.

Part 5: Additional Requirements

1. Liability

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.

2. Tax Exemption

Provide evidence of the OPO's nonprofit status as an organization exempt from federal income taxation under section 501 of the Internal Revenue Code of 1986.

3. Fiscal Procedures

Provide a copy of the OPO's policies and procedures to obtain payment for organs provided to transplant hospitals.

4. Medicare Reimbursement

Check one. Provide supporting documentation where applicable.

☐ *The organization is approved by Medicare to be reimbursed for the procurement and recovery of organs.*

☐ *The OPO does not have current Medicare approval for reimbursement.*

An application to the appropriate Medicare agency must be submitted and approved within 120 days of receiving membership in the OPTN.

5. Center for Medicare/Medicaid Services (CMS) Certification

Provide the OPO's CMS Provider number and date approved.

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

6. Donation Service Area

The organization must have a defined Donation Service Area (DSA), consistent with information submitted to CMS that includes the following information:

Provide documentation that illustrates the following:

- *Names of counties or parishes served, or the state if an entire state is served.*
- *Total population in the DSA, documented by the most recent official census as well as the latest data estimate of the U.S. Census Bureau performed between censuses, as required by CMS.*
- *The number and name of acute care hospitals in the DSA that have operating rooms, equipment and personnel to retrieve organs.*

7. Patient Confidentiality

Provide a copy of the OPO's documented policies and procedures in place for ensuring the confidentiality of all organ donors.

8. 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.

Check the boxes below to attest to the following

☐ *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 membership requirements; and that the DCD organ recovery protocol addresses the requirements.*

☐ *This OPO has written agreements with all donor hospitals regarding participation in DCD recovery.*

Provide a copy of the OPO's protocols to facilitate the recovery of organs from DCD donors.

OMB No. 0915-0184
Expiration Date: xx/xx/20xx

PUBLIC BURDEN STATEMENT

The private, non-profit Organ Procurement and Transplantation Network (OPTN) collects this information in order to perform the following OPTN functions: to assess whether applicants meet OPTN membership requirements; and to monitor compliance of member organizations with OPTN Obligations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0915-0184 and it is valid until xx/xx/20xx. This information collection is required to obtain or retain a benefit per 42 CFR §121.11(b)(2). All data collected will be subject to Privacy Act protection (Privacy Act System of Records #09-15-0055). Data collected by the private non-profit OPTN also are well protected by a number of the Contractor's security features. The Contractor's security system meets or exceeds the requirements as prescribed by OMB Circular A-130, Appendix III, Security of Federal Automated Information Systems, and the Departments Automated Information Systems Security Program Handbook. The public reporting burden for this collection of information is estimated to average 18.33 hours per response, including the time for reviewing instructions, searching existing data sources, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to HRSA Information Collection Clearance Officer, 5600 Fishers Lane, Room 14N39, Rockville, Maryland, 20857 or paperwork@hrsa.gov.