Form Approved
OMB No. 0938-0512

INSTRUCTIONS FOR COMPLETING ORGAN PROCUREMENT ORGANIZATION (OPO) REQUEST FOR DESIGNATIONS AS AN OPO UNDER §1138 OF THE SOCIAL SECURITY ACT

STATEMENT CONCERNING INFORMATION COLLECTION REQUIREMENTS AND USES

Submission of this form will initiate the process of obtaining a decision as to whether the Conditions for Coverage: OPOs, are met. The form provides information and data about the OPO that is necessary to determine compliance with the Conditions and provides a data base necessary for responding to questions frequently asked by Congress, Federal agencies, and interested members of the public.

Answer all questions as of the current date. Return the original form and the signed agreement to the regional office serving your area and make a copy for your files. Failure to return this form may result in termination for the service area. The name, address and service areas of the regional offices are attached.

Detailed instructions are given for questions other than those considered self-explanatory.

Item I - Identifying Information

- Medicare provider number – Insert the facility's six digit Provider Number. Leave blank on initial request for designation.
- State/County and State Regional Codes – Leave blank. The Centers for Medicare & Medicaid Services Regional Office will complete.
- Related provider number – If the OPO is affiliated with any other Medicare provider, insert the related facility's six digit Medicare provider number.

Item II - Type of Control

Check the category(ies) that is most descriptive of the type of organization operating the facility. Check “nonprofit under §501” if the organization is exempt from Federal income taxation under §501 or the Internal Revenue Code of 1986.

Item III - Administrative and Staffing

Give the name and title of members of the Board of Directors, Advisory Board and staff members.

Item IV - Narrative

Please answer the questions in this section completely and concisely. Failure to do so may hinder consideration. Attach supporting documentation, such as agreements, statistical data, etc. The documentation should explain the OPO's plans or systematic efforts to provide its organ procurement services. The preferable documentation is a copy of the written agreements with the various hospitals and transplant centers in the service area that list the OPO's responsibilities and functions. If an organization seeking designation as an OPO does not have a written agreement with a given facility, we will accept a letter of intent from a hospital or transplant center that it will enter into such agreement within not more than 12 months after the OPO's designation. If an organization does not have either a written agreement or letter of intent, it must submit other documentation of its working relationship.

Item V - Performance

Specify the number of actual donors, number of kidneys transplanted, number of kidneys recovered, number of extrarenal organs recovered, number of extrarenal organs transplanted and the average number of organs retrieved per donor. This information is to be submitted 15 days following the end of each calendar year.

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ORGAN PROCUREMENT ORGANIZATION (OPO) REQUEST FOR DESIGNATION AS AN OPO UNDER §1138 OF THE SOCIAL SECURITY ACT

(READ INSTRUCTIONS AND INFORMATION COLLECTION STATEMENT ON COVER SHEET PRIOR TO COMPLETION)

CMS REGIONAL OFFICE USE ONLY

MEDICARE NUMBER	MEDICARE HOSPITAL NUMBER	DHHS REGIONAL OFFICE	
DATE OF SA RECEIPT	DATE OF RO RECEIPT	STATE/REG.	STATE/COUNTY CODE

RELATED PROVIDER NUMBER	STATE/COUNTY CODE	STATE/REGION CODE	FY ENDING DATE	MEDICARE PROVIDER NUMBER

I. IDENTIFYING INFORMATION

NAME OF FACILITY	STREET ADDRESS	
CITY, COUNTY AND STATE	ZIP CODE	TELEPHONE NO. *(Include Area Code)*
NAME OF CHIEF EXECUTIVE		

SERVICE AREA *(Attach separate sheet if necessary)*

A. LIST COUNTRIES SERVED *(or State if the service includes the entire State)*

B. GEOGRAPHIC BOUNDARIES

C. TOTAL POPULATION

D. LIST ALL ACUTE CARE HOSPITALS WITH AN OPERATING ROOM AND THE EQUIPMENT AND PERSONNEL TO RETRIEVE ORGAN

II. TYPE OF CONTROL *(Check all the apply)*

❑ INDEPENDENT ❑ INDIVIDUAL ❑ CORPORATION ❑ PARTNERSHIP ❑ STATE GOVERNMENT
❑ HOSPITAL-BASED ❑ PROFIT ❑ NONPROFIT UNDER §501 ❑ FEDERAL GOVERNMENT

III. ADMINISTRATION AND STAFFING

BOARD OF DIRECTORS AND ADVISORY BOARD *(Give names and title of members who represent the following)*

1. HOSPITAL'S ADMINISTRATOR	5. TISSUE BANKS
2. INTENSIVE CARE OR EMERGENCY ROOM PERSONNEL	6. ORGAN PROCUREMENT SPECIALIST
3. DIRECTOR	7. VOLUNTARY HEALTH ASSOCIATIONS
4. DONATION COORDINATOR	

III. ADMINISTRATION AND STAFFING (continued)

8. PHYSICIAN WITH KNOWLEDGE, EXPERIENCE, OR SKILL IN THE FIELD OF HUMAN HISTOCOMPATIBILITY OR AN INDIVIDUAL WITH A DOCTORATE DEGREE IN BIOLOGICAL SCIENCE OR WHO HAS KNOWLEDGE, EXPERIENCE, OR SKILLS IN THE FIELD OF HUMAN HISTOCOMPATIBILITY

9. TRANSPLANT SURGEONS *(from each transplant hospital with an agreement in the service area)*

10. MEMBERS WHO REPRESENT THE PUBLIC RESIDING IN THE AREA

11. NEUROSURGEON OR ANOTHER PHYSICIAN WITH KNOWLEDGE OR SKILLS IN THE FIELD OF NEUROLOGY

IV. NARRATIVE

ANSWER THE FOLLOWING QUESTIONS AND ATTACH SUPPORTING DOCUMENTATION.

1. Attach documentation of working relationship that exists with facilities of the service area for harvesting organs. Specify percentage of hospitals in the service area that you have a working relationship with and specify bed capacity of associated hospitals.
2. Specify allocation plan for donated organs among transplant patients.
3. Discuss arrangements for tissue typing donated organs.
4. Discuss and document your accounting procedures and give name and address of accounting firm.
5. Submit quantifiable data showing service area, population and number of potential donors per year.
6. Document your affiliation with tissue banks for the retrieval, processing, preservation, storage and distribution of tissues to assure that all usable tissues from potential donors are obtained.
7. Discuss and document your procedures for testing for HIV reactivity to prevent the acquisition of organs infected with the etiologic agent for acquired immune deficiency syndrome.
8. Document your arrangements to coordinate activities with transplant centers in your service area.
9. Discuss and document your procedures for ensuring the confidentiality of patient records.
10. Discuss and document your activities relating to professional education concerning organ procurement.
11. Document your assistance with hospitals in establishing and implementing protocols for making routine inquires about organ donations by potential donors.
12. Discuss and document your procedures for allocating organs equitably among transplant patients consistent with OPTN criteria as approved by the Secretary.

V. PERFORMANCE

PROCUREMENT ACTIVITY *(the activity is for the 2 calendar years prior to the year of designation):*
NOTE: THIS INFORMATION MUST BE SUBMITTED 15 DAYS FOLLOWING THE END OF EACH CALENDAR YEAR.

	FIRST CALENDAR YEAR	SECOND CALENDAR YEAR
DATE OF CALENDAR YEAR	MM/DD/YY	MM/DD/YY
NUMBER OF ACTUAL DONORS		
NUMBER OF KIDNEYS TRANSPLANTED		
NUMBER OF KIDNEYS RECOVERED		
NUMBER OF EXTRARENAL ORGANS RECOVERED		
NUMBER OF EXTRARENAL ORGANS TRANSPLANTED		
AVERAGE NUMBER OF ORGANS PROCURED PER DONOR		

WHOEVER KNOWINGLY OR WILLFULLY MAKES OR CAUSES TO BE MADE A FALSE STATEMENT OR REPRESENTATION ON THIS STATEMENT, MAY BE PROSECUTED UNDER APPLICABLE FEDERAL OR STATE LAWS. IN ADDITION, KNOWINGLY AND WILLFULLY FAILING TO FULLY AND ACCURATELY DISCLOSE THE INFORMATION REQUESTED MAY RESULT IN DENIAL OF A REQUEST TO PARTICIPATE, OR WHERE THE ENTITY ALREADY PARTICIPATES, A TERMINATION OF ITS AGREEMENT OR CONTRACT WITH THE STATE AGENCY OR THE SECRETARY, AS APPROPRIATE.

SIGNATURE OF AUTHORIZED OFFICIAL *(Sign in ink)* | DATE