

Designation or *redesignation* means CMS approval of an OPO for Medicare and Medicaid payment purposes under section 1138(b)(1)(F) of the Act. The terms are used interchangeably except when otherwise specifically indicated.

Entire standard metropolitan statistical area means a metropolitan statistical area, a consolidated metropolitan statistical area, or a primary statistical area listed in the State and Metropolitan Area Data Book published by the U.S. Bureau of the Census.

Open area means a service area for which CMS has notified the public that it is accepting applications for designation.

Organ means a human kidney, liver, heart, lung, pancreas, or intestines (or multivisceral organs).

Organ procurement organization means an organization that performs or coordinates the performance of retrieving, preserving and transporting organs and maintains a system of locating prospective recipients for available organs.

Potential donor means a person who dies in circumstances (causes and conditions of death, and age at death) that are generally acceptable for donation of at least one solid organ if the donor can be identified timely and permission for donation can be obtained.

Service area means a geographical area of sufficient size to assure maximum effectiveness in the procurement and equitable distribution of organs and that either includes an entire standard metropolitan statistical area or does not include any part of such an area and that meets the standards of this subpart.

Transplant center means a hospital certified by Medicare to furnish directly, for a specific organ(s), transplant and other medical and surgical specialty services required for the care of transplant patients.

[53 FR 6549, Mar. 1, 1988, as amended at 59 FR 46514, Sept. 8, 1994. Redesignated and amended at 60 FR 50447, 50448, Sept. 29, 1995; 66 FR 39938, Aug. 1, 2001]

§ 486.304 General requirements.

(a) *Designation—a condition for payment.* Payment may be made under the Medicare and Medicaid programs for organ procurement costs attributable

to payments made by an OPO only if the organization has been designated by the Secretary as an OPO, payment to which may be treated as organ procurement costs for reimbursement of hospitals under Medicare and Medicaid.

(b) *Requirements for designated status.* To be the designated OPO for a service area, an entity must do the following:

(1) Submit to CMS a written application for designation, using the application form prescribed by CMS.

(2) Be certified as a qualified OPO.

(3) Participate in the Organ Procurement and Transplantation Network as specified in § 486.308.

(4) Enter into an agreement with CMS that meets the requirements set forth in paragraph (c) of this section.

(5) Upon its initial designation, meet the requirements at § 486.310(a)(3) or § 486.310(b)(4), as appropriate, concerning working relationships with hospitals or transplant centers. During the initial designation period, the OPO is not required to demonstrate compliance with §§ 486.310(a)(1) and (a)(2) or § 486.310(b)(1), which set forth performance standards for OPOs.

(6) To be redesignated after an initial designation period, comply with all the requirements of this subpart, including those at § 486.310, which set forth performance standards for OPOs.

(7) Obtain CMS approval before entering into any change of ownership, merger, consolidation, or change in its service area (see § 486.318, which sets forth requirements concerning approval for changes in ownership and service area). Failure to do so could result in termination.

(8) Enter into a working relationship with any hospitals, including transplant centers, in the OPO's service area that request a working relationship.

(c) *Agreement with CMS.* An OPO must enter into an agreement with CMS. The agreement is effective upon submission by the OPO and acceptance by CMS, but may be terminated by either party. If an OPO agreement is terminated, payment for organ procurement services attributable to that OPO will not be made for services furnished on or after the effective date of termination. In the agreement, the OPO must agree to do the following:

(1) Maintain compliance with the requirements of titles XVIII and XIX of the Act, section 1138 of the Act, and applicable regulations, including the conditions set forth in this subpart, and the regulations of the OPTN approved and issued by the Secretary, and to report promptly to the Secretary any failure to do so.

(2) File a cost report in accordance with § 413.24(f) of this chapter within 3 months after the end of each fiscal year.

(3) Permit CMS to designate an intermediary to determine the interim payment rate payable to the transplant hospitals for services provided by the OPO and to make a determination of reasonable cost based on the cost report it files.

(4) Provide budget or cost projection information as may be required to establish an initial interim payment rate.

(5) Pay to CMS amounts that have been paid by CMS to transplant hospitals as Medicare payment for organ recovery fees and that are determined to be in excess of the reasonable cost of the services provided by the OPO.

(6) Not charge an individual for items or services for which that individual is entitled to have payment made under the Medicare program.

(7) Maintain and make available to CMS, the Comptroller General, or their designees data that show the number of organs procured and transplanted.

(8) Maintain data in a format that can be readily continued by a successor OPO and turn over to CMS copies of all records, data, and software necessary to ensure uninterrupted service by a successor OPO that may be designated for all or part of its service area. Records and data subject to this requirement include records on individual donors (including identifying data and data on organs retrieved), records on transplant candidates (including identifying data and data on immune system and other medical indications), and procedural manuals and other materials used in conducting OPO operations. Donor records must include at least information identifying the donor (for example, name, address, date of birth, social security number), the organs and tissues (when

applicable) retrieved, date of the organ retrieval, and test results.

(d) *When OPOs may apply for designation.* Entities may apply for designation whenever a service area becomes an open area.

(e) *Designation periods—(1) General.* An OPO is normally designated for 2 years. A designation period may not exceed 2 years but may be shorter.

(2) *Redesignation.* Redesignation must occur at least every 2 years and be completed before the end of an existing designation period.

(3) *Interim designation.* CMS may designate an organization for an interim designation period if the period is needed in order for CMS to make a final designation determination.

(i) The interim designee may be either the OPO previously designated for the service area or another organization.

(ii) The interim designation period does not exceed 180 days after the normal designation period has expired.

(iii) The interim designee must meet all requirements of section 371(b) of the Public Health Service Act (42 U.S.C. 273(b)) regarding qualified OPOs and must not be out of compliance with the requirements of section 1138(b)(1) (B) through (E) of the Act regarding requirements for payment of organ procurement costs under title XVIII or title XIX of the Act.

[53 FR 6549, Mar. 1, 1988, as amended at 59 FR 46514, Sept. 8, 1994 Redesignated and amended at 60 FR 50447, 50448, Sept. 29, 1995; 60 FR 53877, Oct. 18, 1995; 61 FR 19743, May 2, 1996]

§ 486.306 Qualifications for designation as an OPO.

To be designated as the OPO for a service area, an organization must, at the time of application and throughout the period of its designation, meet the following requirements:

(a) Be a nonprofit entity that is exempt from Federal income taxation under section 501 of the Internal Revenue Code of 1986.

(b) Have accounting and other fiscal procedures necessary to assure the fiscal stability of the organization, including procedures to obtain payment for kidneys and non-renal organs provided to transplant centers.