

(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.

(c) Have an agreement with the Secretary to be reimbursed under Medicare for the procurement of covered organs.

(d) Document that it has a defined service area that meets the requirements of § 486.307.

(e) Have a director and such other staff, including an organ donation coordinator and an organ procurement specialist, necessary to obtain organs effectively from donors in its service area.

(f) Have a board of directors or an advisory board that has the authority to recommend policies relating to the donation, procurement, and distribution of organs. While an OPO may have more than one board, the members specified in paragraphs (f)(1) through (f)(5) of this section must be members of a single board. The board of directors or advisory board must be composed of the following:

(1) Members who represent hospital administrators, tissue banks, voluntary health associations in its service area and either intensive care or emergency room personnel.

(2) Members who represent the public residing in that area.

(3) A physician with knowledge, experience, or skill in the field of human histocompatibility, or an individual with a doctorate degree in a biological science and with knowledge, experience, or skills in the field of human histocompatibility.

(4) A neurosurgeon or another physician with knowledge or skills in the field of neurology.

(5) A transplant surgeon from each transplant center in its service area with which the OPO has arrangements to coordinate its activities.

(g) To identify potential organ donors, have documented evidence that—

(1) It has a working relationship with at least 75 percent of the hospitals that participate in the Medicare and Medicaid programs in its service area and that have an operating room and the equipment and personnel for retrieving organs; and

(2) It conducts systematic efforts intended to acquire all usable organs from potential donors.

(h) Arrange for the appropriate tissue typing of donated organs.

(i) Have a system to equitably allocate donated organs among transplant patients that is consistent with—

(1) “Guidelines for Preventing Transmission of Human Immunodeficiency Virus Through Transplantation of Human Tissue and Organs” issued by the Centers for Disease Control and Prevention (CDC) that are appended to this subpart; and

(2) Rules of the Organ Procurement and Transplantation Network (OPTN), see § 486.308.

(j) Provide or arrange for the transportation of donated organs to transplant centers.

(k) Have arrangements to coordinate its activities with transplant centers in the area.

(l) Have arrangements to cooperate with tissue banks for the retrieval, processing, preservation, storage and distribution of tissues as may be appropriate to assure that all usable tissues are obtained from potential donors.

(m) Maintain and make available upon request of the Secretary, the Comptroller General, or their designees data that relate to the performance standards.

(n) Maintain data in a format that can be readily used by a successor OPO and agree to turn over to the Secretary copies of all records and data necessary to assure uninterrupted service by a successor OPO newly designated by CMS.

(o) Have a procedure for ensuring the confidentiality of patient records. Information from or copies of records may be released only to authorized individuals and the OPO must ensure that unauthorized individuals cannot gain access to or alter patient records. Original medical records may be released by the OPO only in accordance with Federal or State laws, court orders, or subpoenas.

(p) Conduct and participate in professional education concerning organ procurement.

(q) Ensure that appropriate donor screening and infection tests, consistent with OPTN standards and the CDC guidelines that are appended to this subpart, are performed by a laboratory that is certified in the appropriate specialty or subspecialty of service in accordance with part 493 of this

chapter, including tests to prevent the acquisition of organs that are infected with the etiologic agent for acquired immune deficiency syndrome.

(r) Assist hospitals in establishing and implementing protocols for making routine inquiries about organ donations by potential donors.

(s) Ensure that donors are tested for human immunodeficiency viral markers consistent with OPTN rules and the CDC guidelines appended to this subpart for solid organ donation.

(t) Submit accurate data to CMS within 15 days following the end of a calendar year (unless otherwise notified) giving information on the following:

- (1) Population of designated service area based on the most recent U.S. Bureau of the Census data.
- (2) Number of actual donors.
- (3) Number of kidneys procured.
- (4) Number of kidneys transplanted.
- (5) Number of extrarenal organs by type procured.
- (6) Number of extrarenal organs by type transplanted.

[53 FR 6550, March 1, 1988; 53 FR 9172, March 21, 1988; 53 FR 18987, May 26, 1988; 57 FR 7137, Feb. 28, 1992; 59 FR 46515, Sept. 8, 1994. Redesignated and amended at 60 FR 50447, 50448, Sept. 29, 1995; 61 FR 19743, May 2, 1996]

§ 486.307 OPO service area size designation and documentation requirements.

(a) *General documentation requirement.* An OPO must make available to CMS documentation verifying that the OPO meets the requirements of paragraphs (b) through (d) of this section at the time of application and throughout the period of its designation.

(b) *Boundary designation.* The defined service area either includes an entire Metropolitan Statistical Area or a New England County Metropolitan Area as specified by the Director of the Office of Management and Budget or does not include any part of such an area.

(c) *Service area location and characteristics.* An OPO must precisely define and document a proposed service area's location through the following information:

- (1) The names of counties (or parishes in Louisiana) served or, if the service

area includes an entire State, the name of the State.

(2) Geographic boundaries of the service area for which U.S. population statistics are available.

(3) Total population in service area.

(4) The number of and the names of acute care hospitals in the service area with an operating room and the equipment and personnel to retrieve organs.

(d) *Sufficient size requirements.* (1) Before January 1, 1996, an OPO must demonstrate that it can procure organs from at least 50 potential donors per calendar year or that its service area comprises an entire State.

(2) Beginning January 1, 1996, an OPO must meet at least one of the following requirements:

(i) Its service area must include an entire State or official U.S. territory.

(ii) It must either procure organs from an average of at least 24 donors per calendar year in the 2 years before the year of redesignation or request and be granted an exception to this requirement under paragraph (d)(3) or (d)(4) of this section.

(iii) In the case of an OPO operating exclusively in a noncontiguous U.S. State, a U.S. territory, or a U.S. commonwealth, such as Hawaii or Puerto Rico, it must procure organs at the rate of 50 percent of the national average of all OPOs for kidney procurement per million population and for kidney transplantation per million population.

(iv) If it is an entity that has not been previously designated as an OPO, it must demonstrate that it can procure organs from at least 50 potential donors per calendar year.

(3) CMS may grant an OPO an exception to paragraph (d)(2)(ii) of this section if the OPO can demonstrate that—

(i) It failed to meet the requirement because of unusual circumstances beyond its control;

(ii) It has historically maintained a service area of sufficient size to meet the criterion in paragraph (d)(2)(ii) of this section; and

(iii) It has a specific plan to meet the size criterion in paragraph (d)(2)(ii) of this section in the future.