

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.

(4) During the 1996 redesignation process only, CMS may grant an exception to paragraph (d)(2)(ii) of this section to an OPO that can demonstrate that—

(i) It meets the performance criteria in § 486.310(b); and

(ii) It has a specific plan to meet the service area size criterion in paragraph (d)(2)(ii) of this section by the 1998 redesignation period.

[61 FR 19744, May 2, 1996]

§ 486.308 Condition: Participation in organ procurement and transplantation network.

In order to be designated as the OPO for its service area, and to continue to be the designated OPO once designated, an OPO must be a member of, have a written agreement with, and abide by the rules of the OPTN established and operated in accordance with section 372 of the Public Health Service (PHS) Act (42 U.S.C. 274). The term “rules of the OPTN” means those rules provided for in regulations issued by the Secretary in accordance with section 372 of the PHS Act. No OPO is considered to be out of compliance with section 1138(b)(1)(D) of the Act or this section unless the Secretary has given the OPTN formal notice that he or she approves the decision to exclude the entity from the OPTN and also has notified the entity in writing.

[59 FR 46516, Sept. 8, 1994. Redesignated and amended at 60 FR 50447, 50448, Sept. 29, 1995]

§ 486.309 Recertification from January 1, 2002 through December 31, 2005.

An OPO will be considered to be recertified for the period of January 1, 2002 through December 31, 2005 if an entity meets, or has met, the standards to be a qualified OPO within a four year period ending December 31, 2001 and has an agreement with the Secretary that was scheduled to terminate on July 31, 2002. Agreements based on this recertification will end on July 31, 2006.

[66 FR 67111, Dec. 28, 2001]

§ 486.310 Condition: Adherence to performance standards.

(a) *Standards before January 1, 1996.* Before January 1, 1996, OPOs must

meet the following performance standards:

(1) Each OPO must procure within its service area a minimum ratio of 23 cadaveric kidneys per million population of its service area for each 12-month period surveyed.

(2) Each OPO must provide a minimum ratio of cadaveric kidneys procured in its service area and transplanted (either locally or exported and transplanted) of 19 cadaveric kidneys per million population of its service area for each 12-month period surveyed.

(b) *Standards beginning on January 1, 1996.* Except as specified in paragraph (c) of this section, each OPO must achieve at least 75 percent of the national mean for four of the following five performance categories, averaged over the 2 calendar years before the year of redesignation:

(1) Number of actual donors per million population.

(2) Number of kidneys recovered per million population.

(3) Number of extrarenal organs recovered per million population.

(4) Number of kidneys transplanted per million population.

(5) Number of extrarenal organs transplanted per million population.

(c) *Exceptions and exemptions—(1) Exception based on location.* OPOs operating exclusively in a noncontiguous U.S. State, a U.S. territory, or a U.S. commonwealth, such as Hawaii or Puerto Rico, may be granted an exception from the performance standards of paragraph (b) of this section because of special geographically related characteristics, such as difficulty in transporting organs to the mainland, that impede satisfaction of the national rate of organ procurement. They must meet a standard of 50 percent of the national average of all OPOs for kidneys recovered and transplanted per million population.

(2) *Exception because of lack of competition for a service area.* CMS may continue to designate an OPO that does not meet the standards under paragraph (b) of this section for a service area if no OPO that meets the performance and qualification requirements is willing to accept responsibility for the service area and if the designated OPO