

(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

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submits an acceptable corrective action plan in accordance with paragraph (d) of this section.

(3) *Exception for 1996 transition period.* During the 1996 designation period only, CMS may continue to designate for a service area an OPO that does not meet the standards under paragraph (b) of this section if the OPO:

(i) Meets three of the criteria in paragraphs (b)(1) through (b)(5) of this section; and

(ii) Submits an acceptable corrective action plan in accordance with paragraph (d) of this section.

(d) *Corrective action plans and corrected information—(1) Corrective action plans.* (i) If a designated OPO does not meet the standards of paragraph (a) of this section, it may submit to the appropriate CMS regional office a corrective action plan explaining why it failed to meet them and specifying the actions it will take to ensure it meets those standards in the future.

(ii) CMS will not accept corrective action plans from an OPO for failure to meet the standards specified in paragraph (b) of this section unless the OPO continues to be designated under paragraph (c)(2) or (c)(3) of this section.

(2) *Corrected information.* An OPO may request correction of the information required by § 486.306(e) from CMS throughout the two-year designation period. CMS will evaluate the OPO's request and may seek input from other sources, such as hospital personnel, neighboring OPOs, the OPTN contractor, and the Census Bureau as necessary to verify the OPO's information before making the changes requested by the OPO. In addition, CMS will notify an OPO if it does not meet the performance standards based on the information reported. Any OPO so notified may provide corrected information for consideration within 30 days of receipt of a notice of failure to meet the standards.

[59 FR 46516, Sept. 8, 1994. Redesignated and amended at 60 FR 50447, 50448, Sept. 29, 1995; 61 FR 19744, May 2, 1996]

§ 486.314 Effect of failure to meet requirements.

Failure to continue to meet any of the requirements in §§ 486.306 and 486.308 or to meet the performance

standards in § 486.310 may result in termination of the OPO's agreement with CMS.

[59 FR 46517, Sept. 8, 1994. Redesignated and amended at 60 FR 50447, 50448, Sept. 29, 1995; 61 FR 19745, May 2, 1996]

§ 486.316 Designation of one OPO for each service area.

(a) CMS designates only one OPO per service area. Applications for designation are accepted only during a period when the service area is an open area. A service area is open for competition once the existing designation period has expired, when the existing designated status of the OPO for that service area has been terminated, or when no OPO has been designated for the area. CMS may also declare the service area open in the event an OPO ceases to operate or CMS has reasonable ground for anticipating it will cease to operate. In cases of urgent need (such as evidence of medically or ethically unsound practices), CMS may terminate its agreement with an OPO immediately. The service area remains open until an OPO is designated for it. If more than one organization applies and substantially meets the requirements of § 486.306 in a given service area, CMS considers other factors in reaching a decision concerning which organization to designate. These factors follow:

(1) Prior performance, including the previous year's experience in terms of the number of organs retrieved and wasted and the average cost per organ;

(2) Actual number of donors compared to the number of potential donors;

(3) The nature of relationships and degree of involvement with hospitals in the organization's service area;

(4) Bed capacity associated with the hospitals with which the organizations have a working relationship;

(5) Willingness and ability to place organs within the service area; and

(6) Proximity of the organization to the donor hospitals.

(b) An organization that applies to CMS to be the designated OPO for its service area and that is not designated may appeal its nondesignation under part 498 of this chapter.