

(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