

this section, it may submit to the appropriate HCFA 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) HCFA 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 HCFA throughout the two-year designation period. HCFA 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, HCFA 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 HCFA.

[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) HCFA 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. HCFA may also declare the service area open in the event an OPO ceases to operate or HCFA has reasonable ground for anticipating it will cease to operate. In cases of urgent need (such as evidence of medically or ethically unsound practices), HCFA 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, HCFA 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 HCFA to be the designated OPO for its service area and that is not designated may appeal its nondesignation under part 498 of this chapter.

(c) After January 1, 1996, a hospital must enter into an agreement only with the OPO designated to serve the area in which the hospital is located unless HCFA has granted the hospital a waiver under paragraphs (d) through (g) of this section to be serviced by another OPO.

(d) If HCFA changes the OPO designated for an area, hospitals located in that area must enter into agreements with the newly designated OPO or submit a request for a waiver in accordance with paragraph (e) of this section within 30 days of notice of the change in designation.

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(e) A hospital may request and HCFA may grant a waiver permitting the hospital to have an agreement with a designated OPO other than the OPO designated for the service area in which the hospital is located. To qualify for a waiver, the hospital must submit data to HCFA establishing that—

(1) The waiver is expected to increase organ donations; and

(2) The waiver will ensure equitable treatment of patients referred for transplants within the service area served by the hospital's designated OPO and within the service area served by the OPO with which the hospital seeks to enter into an agreement.

(f) In making a determination on waiver requests, HCFA considers:

(1) Cost effectiveness;

(2) Improvements in quality;

(3) Changes in a hospital's designated OPO due to changes in the metropolitan service area designations, if applicable; and

(4) The length and continuity of a hospital's relationship with an OPO other than the hospital's designated OPO.

(g) A hospital may continue to operate under its existing agreement with an out-of-area OPO while HCFA is processing the waiver request. If a waiver request is denied, a hospital must enter into an agreement with the designated OPO within 30 days of notification of the final determination.

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

§ 486.318 Changes in ownership or service area.

(a) *OPO requirements.* (1) A designated OPO considering a change in ownership or in its service area must notify HCFA before putting it into effect. This notification is required to ensure that the entity, as changed, will continue to satisfy Medicare and Medicaid requirements. A change in ownership takes place if there is the merger of one entity into another or the consolidation of one entity with another.

(2) A designated OPO considering a change in its service area must obtain prior HCFA approval. In the case of a service area change that results from a change of ownership due to merger or

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consolidation, the entities must submit anew the information required in an application for designation, or other written documentation HCFA determines to be necessary for designation.

(b) *HCFA requirements.* (1) If HCFA finds that the entity has changed to such an extent that it no longer satisfies the prerequisites for OPO designation, HCFA may terminate the OPO's agreement and declare the OPO's service area to be an open area.

(2) If HCFA finds that the changed entity continues to satisfy the prerequisites for OPO designation, the period of designation of the changed entity is the remaining designation term of the OPO that was reorganized. If more than one designated OPO is involved in the reorganization, the remaining designation term is ordinarily the longest of the remaining periods. HCFA may determine, however, that a shorter period applies if it decides that a shorter period is in the best interest of the Medicare and Medicaid programs. The performance standards of § 486.310 apply at the end of this remaining period.

[59 FR 46517, Sept. 8, 1994. Redesignated and amended at 60 FR 50447, 50448, Sept. 29, 1995]

§ 486.325 Terminations of agreement with HCFA.

(a) *Types—*(1) *Voluntary termination.* If an OPO wishes to terminate its agreement, it must send written notice of its intention with the proposed effective date to HCFA. HCFA may approve the proposed date, set a different date no later than 6 months after the proposed effective date, or set a date less than 6 months after the proposed date if it determines that it would not disrupt services to the service area or otherwise interfere with the effective and efficient administration of the Medicare and Medicaid programs. If HCFA determines that a designated OPO has ceased to furnish organ procurement services to its service area, the cessation of services is deemed to constitute a voluntary termination by the OPO, effective on a date determined by HCFA.

(2) *Involuntary termination.* HCFA may terminate an agreement if it finds that an OPO no longer meets the conditions for coverage in this subpart, or is