

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, CMS 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 CMS 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 CMS 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 CMS approval. In the case of a service area change that results from a change of ownership due to merger or consolidation, the entities must submit anew the information required in an application for designation, or other written documentation CMS determines to be necessary for designation.

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

(2) If CMS 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. CMS 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 CMS.

(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 CMS. CMS 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 CMS 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 CMS.

(2) *Involuntary termination.* CMS may terminate an agreement if it finds that an OPO no longer meets the conditions for coverage in this subpart, or is not in substantial compliance with any other applicable Federal regulations or provisions of titles XI, XVIII, or title XIX of the Act. CMS may also terminate an agreement immediately in cases of urgent need, such as the discovery of unsound medical practices.

(b) *Notice to OPO.* CMS gives notice of termination to an OPO at least 90 days before the effective date stated in the notice.