Centers for Medicare & Medicaid Services, HHS

§ 486.308

(a) CMS designates only one OPO per service area. A service area is open for competition when the OPO for the service area is de-certified and all administrative appeals under § 486.314 are exhausted.

(b) Designation periods—
   (1) General. An OPO is normally designated for a 4-year agreement cycle. The period may be shorter, for example, if an OPO has voluntarily terminated its agreement with CMS and CMS selects a successor OPO for the balance of the 4-year agreement cycle. In rare situations, a designation period may be longer, for example, a designation may be extended if additional time is needed to select a successor OPO to an OPO that has been de-certified.
   (2) Re-Certification. Re-certification must occur not more frequently than once every 4 years.

(c) Unless CMS has granted a hospital a waiver under paragraphs

(d) If CMS 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.

(e) A hospital may request and CMS 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 CMS establishing that—
   (1) The waiver is expected to increase organ donations; and
   (2) The waiver will ensure equitable treatment of patients listed 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, CMS considers—
   (1) Cost effectiveness;
   (2) Improvements in quality;
   (3) Changes in a hospital’s designated OPO due to changes in the definitions of metropolitan statistical areas, 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