

**§ 486.312**

**42 CFR Ch. IV (10–1–06 Edition)**

(1) If CMS finds that the OPO has changed to such an extent that it no longer satisfies the requirements for OPO designation, CMS may de-certify the OPO and declare the OPO's service area to be an open area. An OPO may appeal such a de-certification as set forth in § 486.314. The OPO's service area is not opened for competition until the conclusion of the administrative appeals process.

(2) If CMS finds that the changed OPO continues to satisfy the requirements for OPO designation, the period of designation of the changed OPO is the remaining portion of the 4-year term of the OPO that was reorganized. If more than one designated OPO is involved in the reorganization, the remaining designation term is the longest of the remaining periods unless CMS determines that a shorter period is in the best interest of the Medicare and Medicaid programs. The changed OPO must continue to meet the requirements for certification at § 486.303 throughout the remaining period.

**RE-CERTIFICATION AND DE-CERTIFICATION**

**§ 486.312 De-certification.**

(a) *Voluntary termination of agreement.* If an OPO wishes to terminate its agreement, the OPO must send CMS written notice of its intention to terminate its agreement and the proposed effective date. 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 effective date if it determines that a different date would not disrupt services to the service area. 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. CMS will de-certify the OPO as of the effective date of the voluntary termination.

(b) *Involuntary termination of agreement.* During the term of the agreement, CMS may terminate an agreement with an OPO if the OPO no longer meets the requirements for certification at § 486.303. CMS may also termi-

nate an agreement immediately in cases of urgent need, such as the discovery of unsound medical practices. CMS will de-certify the OPO as of the effective date of the involuntary termination.

(c) *Non-renewal of agreement.* CMS will not voluntarily renew its agreement with an OPO if the OPO fails to meet the requirements for certification at § 486.318, based on findings from the most recent re-certification cycle, or the other requirements for certification at § 486.303. CMS will de-certify the OPO as of the ending date of the agreement.

(d) *Notice to OPO.* Except in cases of urgent need, CMS gives written notice of de-certification to an OPO at least 90 days before the effective date of the de-certification. In cases of urgent need, CMS gives written notice of de-certification to an OPO at least 3 calendar days prior to the effective date of the de-certification. The notice of de-certification states the reasons for de-certification and the effective date.

(e) *Public notice.* Once CMS approves the date for a voluntary termination, the OPO must provide prompt public notice of the date of de-certification and such other information as CMS may require through publication in local newspapers in the service area. In the case of involuntary termination or non-renewal of an agreement, CMS provides public notice of the date of de-certification through publication in local newspapers in the service area. No payment under titles XVIII or XIX of the Act will be made with respect to organ procurement costs attributable to the OPO on or after the effective date of de-certification.

**§ 486.314 Appeals.**

If an OPO's de-certification is due to involuntary termination or non-renewal of its agreement with CMS, the OPO may appeal the de-certification on substantive and procedural grounds.

(a) *Notice of initial determination.* CMS mails notice to the OPO of an initial de-certification determination. The notice contains the reasons for the determination, the effect of the determination, and the OPO's right to seek reconsideration.