

#### § 491.4

specified in §§ 405.2402 through 405.2404 of this chapter, and with the applicable procedures in part 486 of this chapter.

(2) If CMS approves or disapproves the participation request of a prospective RHC, CMS notifies the State agency for that RHC.

(3) CMS deems an RHC that is approved for Medicare participation to meet the standards for certification under Medicaid.

(b) *Current designation.* (1) Participating RHCs and an applicant requesting entrance into the Medicare program as an RHC must be located in a current shortage area for which a designation is made or updated within the current year or within the previous 3 years.

(2) RHCs with outdated shortage area designations will have 120 days, from the date CMS notifies the facility that its designation is no longer current, to submit an application to update its medically underserved designation.

(3) RHCs located in service areas with outdated shortage area designations will be protected, for 120 days, from RHC disqualification while their applications for updating the medically underserved designations are under review by HRSA.

(c) *Exception process.* (1) An RHC's location fails to satisfy the definition of a shortage area if it is no longer designated by the Secretary or by the chief executive officer of the State as medically underserved, or if it is no longer designated as nonurbanized by the Census Bureau.

(2) An existing RHC may apply for an exception from disqualification by submitting a written request to a CMS regional office within 180 days from the date CMS notifies the RHC that it is no longer located in a shortage area. The request must contain all information necessary to establish whether an exception is warranted.

(3) The CMS regional office may grant a 3-year exception based on its review of an RHC request and other relevant information, if the CMS regional office determines that the RHC is essential to the delivery of primary care services that otherwise are not available in the geographic area served by the RHC as specified in § 491.5(b).

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(4) Clinics can renew their essential provider status by submitting written assurances to the CMS regional office that they continue to meet the conditions at § 491.5.

(5) CMS terminates an ineligible clinic from participation in the Medicare program as an RHC, effective the final day of the 6th month from the date CMS notifies the clinic of a final determination of ineligibility (including denial of any exception request submitted). CMS may terminate RHC status earlier based on noncompliance with other certification requirements.

[68 FR 74816, Dec. 24, 2003]

#### § 491.4 Compliance with Federal, State and local laws.

The rural health clinic or FQHC and its staff are in compliance with applicable Federal, State and local laws and regulations.

(a) *Licensure of clinic or center.* The clinic or center is licensed pursuant to applicable State and local law.

(b) *Licensure, certification or registration of personnel.* Staff of the clinic or center are licensed, certified or registered in accordance with applicable State and local laws.

[57 FR 24982, June 12, 1992]

#### § 491.5 Location of clinic.

(a) *Basic requirements.* (1) An RHC is located in a rural area that is designated as a shortage area.

(2) An FQHC is located in a rural or urban area that is designated as either a shortage area or an area that has a medically underserved population.

(3) Both the RHC and the FQHC may be permanent or mobile units.

(i) *Permanent unit.* The objects, equipment, and supplies necessary for the provision of the services furnished directly by the clinic or center are housed in a permanent structure.

(ii) *Mobile unit.* The objects, equipment, and supplies necessary for the provision of the services furnished directly by the clinic or center are housed in a mobile structure, which has fixed, scheduled location(s).

(iii) *Permanent unit in more than one location.* If clinic or center services are furnished at permanent units in more