

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(2) RHCs with outdated shortage area designations will have 120 days, from the date CMS notifies the facility that its designation is no longer current, to submit an application to update its medically underserved designation.

(3) RHCs located in service areas with outdated shortage area designations will be protected, for 120 days, from RHC disqualification while their applications for updating the medically underserved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

than one location, each unit is independently considered for approval as a rural health clinic or for approval as an FQHC.

(b) *Exceptions.* CMS will not disqualify an RHC approved for Medicare participation located in an area that no longer meets the definition of a shortage or rural area, if it determines that the RHC has established that it is essential to the delivery of primary care services that otherwise are not available in the geographic area served by the RHC. An RHC no longer located in a rural area must have a valid shortage area designation (underserved area or population) and meet the criteria set forth in paragraphs (b)(2)(i), (b)(2)(ii), or (b)(2)(iii) of this section. The RHC that is no longer located in a rural area must also establish that it is essential to the delivery of primary care for patients residing in a rural area by demonstrating that at least 51 percent of the clinic's patients reside in an adjacent nonurbanized area.

(1) *Essential provider exception criteria.* In order to make the final decision to grant an exception as an essential provider under this section, CMS will:

(i) Grant an exception to one or more RHCs in a given service area if CMS determines the clinics each meet the criteria set forth in paragraphs (b)(2)(ii) or (b)(2)(iii) of this section.

(ii) Use the following criteria in determining distances corresponding to 30 minutes travel time:

(A) Under normal conditions with primary roads available within 20 miles.

(B) In areas with only secondary roads available within 15 miles.

(C) In flat terrain or in areas connected by interstate highways within 25 miles.

(2) *Conditions for exception.* To receive an exception, the RHC must meet one of the following conditions:

(i) *Sole community provider.* The RHC is the only participating primary care provider within 30 minutes travel time. For purposes of this exception, a participating primary care provider means an RHC, an FQHC, or a physician practicing in either general practice, family practice, or general internal medicine that is actively accepting and treating Medicare beneficiaries and

low-income patients (Medicaid beneficiaries and the uninsured, regardless of their ability to pay).

(ii) *Major community provider.* The RHC has Medicare and low-income patient (Medicaid and uninsured) utilization rates equal to or above 51 percent or low-income patient utilization rates equal to or above 31 percent. The RHC is also actively accepting and treating a major share of Medicare, Medicaid, and uninsured patients (regardless of their ability to pay) compared to other participating RHCs that are within 30 minutes travel time; or, if the clinic is the only participating RHC within 30 minutes travel, the RHC is actively accepting and treating a major share of Medicare, Medicaid, and uninsured patients (regardless of their ability to pay) compared to other participating primary care providers.

(iii) *Specialty clinic.* The RHC (located within 30 minutes travel time) is the sole or major source of pediatric or OB/GYN services for Medicare (where applicable), Medicaid, and uninsured patients (regardless of their ability to pay) and is actively accepting and treating these patients. Only clinics that exclusively provide pediatric or OB/GYN services can receive an exception under this test. A specialty clinic is also an RHC that is the sole source of mental health services, as defined in § 405.2450. For purposes of meeting this test, mental health services must be furnished onsite to clinic patients. Clinics applying as a major source of pediatric or OB/GYN services must have low-income patient (Medicaid and uninsured) utilization rates equal to or above 31 percent.

(iv) *Extremely rural community provider.* The RHC is actively accepting and treating Medicare, Medicaid, and uninsured patients (regardless of their ability to pay) and is located in a frontier county (less than six persons per square mile) or in a level 8 or level 9 nonmetropolitan county using urban influence codes as defined by the U.S. Department of Agriculture.

(c) *Criteria for designation of rural areas.* (1) Rural areas are areas not delineated as urbanized areas in the last census conducted by the Census Bureau.

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(2) Excluded from the rural area classification are:

(i) Central cities of 50,000 inhabitants or more;

(ii) Cities with at least 25,000 inhabitants which, together with contiguous areas having stipulated population density, have combined populations of 50,000 and constitute, for general economic and social purposes, single communities;

(iii) Closely settled territories surrounding cities and specifically designated by the Census Bureau as urban.

(3) Included in the rural area classification are those portions of extended cities that the Census Bureau has determined to be rural.

(d) *Requirements specific to FQHCs.* An FQHC approved for participation in Medicare must meet one of the following criteria:

(1) Furnish services to a medically underserved population.

(2) Be located in a medically underserved area, as demonstrated by an application approved by PHS.

CROSS REFERENCE: See 42 CFR 110.203(g) (41 FR 45718, Oct. 15, 1976) and 42 CFR Part 5 (42 FR 1586, Jan. 10, 1978).

[43 FR 5375, Feb. 8, 1978. Redesignated at 50 FR 33034, Aug. 16, 1985, and amended at 57 FR 24982, June 12, 1992; 61 FR 14658, Apr. 3, 1996; 68 FR 74816, Dec. 24, 2003]

## § 491.6 Physical plant and environment.

(a) *Construction.* The clinic or center is constructed, arranged, and maintained to insure access to and safety of patients, and provides adequate space for the provision of direct services.

(b) *Maintenance.* The clinic or center has a preventive maintenance program to ensure that:

(1) All essential mechanical, electrical and patient-care equipment is maintained in safe operating condition;

(2) Drugs and biologicals are appropriately stored; and

(3) The premises are clean and orderly.

(c) *Emergency procedures.* The clinic or center assures the safety of patients in case of non-medical emergencies by:

(1) Training staff in handling emergencies;

(2) Placing exit signs in appropriate locations; and

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(3) Taking other appropriate measures that are consistent with the particular conditions of the area in which the clinic or center is located.

[57 FR 24983, June 12, 1992]

## § 491.7 Organizational structure.

(a) *Basic requirements.* (1) The clinic or center is under the medical direction of a physician, and has a health care staff that meets the requirements of § 491.8.

(2) The organization's policies and its lines of authority and responsibilities are clearly set forth in writing.

(b) *Disclosure.* The clinic or center discloses the names and addresses of:

(1) Its owners, in accordance with section 1124 of the Social Security Act (42 U.S.C. 132 A-3);

(2) The person principally responsible for directing the operation of the clinic or center; and

(3) The person responsible for medical direction.

[57 FR 24983, June 12, 1992]

## § 491.8 Staffing and staff responsibilities.

(a) *Staffing.* (1) The clinic or center has a health care staff that includes one or more physicians. Rural health clinic staffs must also include one or more physician's assistants or nurse practitioners.

(2) The physician member of the staff may be the owner of the rural health clinic, an employee of the clinic or center, or under agreement with the clinic or center to carry out the responsibilities required under this section.

(3) The physician assistant, nurse practitioner, nurse-midwife, clinical social worker, or clinical psychologist member of the staff may be the owner or an employee of the clinic or center, or may furnish services under contract to the center.

(4) The staff may also include ancillary personnel who are supervised by the professional staff.

(5) The staff is sufficient to provide the services essential to the operation of the clinic or center.

(6) A physician, nurse practitioner, physician assistant, nurse-midwife, clinical social worker, or clinical psychologist is available to furnish patient