

## § 491.6

(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

care services at all times the clinic or center operates. In addition, for RHCs, a nurse practitioner, physician assistant, or certified nurse midwife is available to furnish patient care services at least 50 percent of the time the RHC operates.

(b) *Physician responsibilities.* (1) The physician:

(i) Except for services furnished by a clinical psychologist in an FQHC, which State law permits to be provided without physician supervision, provides medical direction for the clinic's or center's health care activities and consultation for, and medical supervision of, the health care staff.

(ii) In conjunction with the physician's assistant and/or nurse practitioner member(s), participates in developing, executing, and periodically reviewing the clinic's or center's written policies and the services provided to Federal program patients; and

(iii) Periodically reviews the clinic's or center's patient records, provides medical orders, and provides medical care services to the patients of the clinic or center.

(2) A physician is present for sufficient periods of time, at least once in every 2 week period (except in extraordinary circumstances), to provide the medical direction, medical care services, consultation and supervision described in paragraph (b)(1) of this section and is available through direct telecommunication for consultation, assistance with medical emergencies, or patient referral. The extraordinary circumstances are documented in the records of the clinic or center.

(c) *Physician assistant and nurse practitioner responsibilities.* (1) The physician assistant and the nurse practitioner members of the clinic's or center's staff:

(i) Participate in the development, execution and periodic review of the written policies governing the services the clinic or center furnishes;

(ii) Participate with a physician in a periodic review of the patients' health records.

(2) The physician assistant or nurse practitioner performs the following functions, to the extent they are not being performed by a physician:

(i) Provides services in accordance with the clinic's or center's policies;

(ii) Arranges for, or refers patients to, needed services that cannot be provided at the clinic or center; and

(iii) Assures that adequate patient health records are maintained and transferred as required when patients are referred.

(d) *Temporary staffing waiver.* (1) CMS may grant a temporary waiver of the RHC staffing requirements in paragraphs (a)(1) and (a)(6) of this section for a 1-year period to a qualified RHC, if the RHC requests a waiver and demonstrates that it has been unable, despite reasonable efforts in the previous 90-day period, to hire a nurse midwife, nurse practitioner, or physician assistant to furnish services at least 50 percent of the time the RHC operates.

(2) CMS terminates the RHC from participation in the Medicare program, if the RHC is not in compliance with the provisions waived under paragraphs (a)(1) and (a)(6) of this section at the expiration of the waiver.

(3) The RHC may submit its request for an additional waiver of staffing requirements under this paragraph no earlier than 6 months after the expiration of the previous waiver.

[57 FR 24983, June 12, 1992, as amended at 61 FR 14658, Apr. 3, 1996; 68 FR 74817, Dec. 24, 2003]

#### § 491.9 Provision of services.

(a) *Basic requirements.* (1) All services offered by the clinic or center are furnished in accordance with applicable Federal, State, and local laws; and

(2) The clinic or center is primarily engaged in providing outpatient health services and meets all other conditions of this subpart.

(3) The laboratory requirements in paragraph (c)(2) of this section apply to RHCs, but do not apply to FQHCs.

(b) *Patient care policies.* (1) The clinic's or center's health care services are furnished in accordance with appropriate written policies which are consistent with applicable State law.

(2) The policies are developed with the advice of a group of professional personnel that includes one or more physicians and one or more physician assistants or nurse practitioners. At