

§ 491.7

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§ 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 rural health clinics, a nurse practitioner or a physician assistant is available to furnish patient care services at least 60 percent of the time the clinic 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

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transferred as required when patients are referred.

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§ 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 least one member is not a member of the clinic or center staff.

(3) The policies include:

(i) A description of the services the clinic or center furnishes directly and those furnished through agreement or arrangement.

(ii) Guidelines for the medical management of health problems which include the conditions requiring medical consultation and/or patient referral, the maintenance of health care records, and procedures for the periodic review and evaluation of the services furnished by the clinic or center.

(iii) Rules for the storage, handling, and administration of drugs and biologicals.

(4) These policies are reviewed at least annually by the group of professional personnel required under paragraph (b)(2) of this section and reviewed as necessary by the clinic or center.

(c) *Direct services*—(1) *General.* The clinic or center staff furnishes those diagnostic and therapeutic services and supplies that are commonly furnished in a physician's office or at the entry point into the health care delivery system. These include medical history,

physical examination, assessment of health status, and treatment for a variety of medical conditions.

(2) *Laboratory.* These requirements apply to RHCs but not to FQHCs. The RHC provides laboratory services in accordance with part 493 of this chapter, which implements the provisions of section 353 of the Public Health Service Act. The RHC provides basic laboratory services essential to the immediate diagnosis and treatment of the patient, including:

(i) Chemical examinations of urine by stick or tablet method or both (including urine ketones);

(ii) Hemoglobin or hematocrit;

(iii) Blood glucose;

(iv) Examination of stool specimens for occult blood;

(v) Pregnancy tests; and

(vi) Primary culturing for transmittal to a certified laboratory.

(3) *Emergency.* The clinic or center provides medical emergency procedures as a first response to common life-threatening injuries and acute illness and has available the drugs and biologicals commonly used in life saving procedures, such as analgesics, anesthetics (local), antibiotics, anticonvulsants, antidotes and emetics, serums and toxoids.

(d) *Services provided through agreements or arrangements.* (1) The clinic or center has agreements or arrangements with one or more providers or suppliers participating under Medicare or Medicaid to furnish other services to its patients, including:

(i) Inpatient hospital care;

(ii) Physician(s) services (whether furnished in the hospital, the office, the patient's home, a skilled nursing facility, or elsewhere); and

(iii) Additional and specialized diagnostic and laboratory services that are not available at the clinic or center.

(2) If the agreements are not in writing, there is evidence that patients referred by the clinic or center are being accepted and treated.

[57 FR 24983, June 12, 1992, as amended at 58 FR 63536, Dec. 2, 1993]