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requirements specified in § 417.436 of this chapter.

(e) If an adult individual is incapacitated at the time of admission or at the start of care and is unable to receive information (due to the incapacitating conditions or a mental disorder) or articulate whether or not he or she has executed an advance directive, then the provider may give advance directive information to the individual's family or surrogate in the same manner that it issues other materials about policies and procedures to the family of the incapacitated individual or to a surrogate or other concerned persons in accordance with State law. The provider is not relieved of its obligation to provide this information to the individual once he or she is no longer incapacitated or unable to receive such information. Follow-up procedures must be in place to provide the information to the individual directly at the appropriate time.

[57 FR 8203, Mar. 6, 1992, as amended at 59 FR 45403, Sept. 1, 1994; 60 FR 33294, June 27, 1995; 62 FR 46037, Aug. 29, 1997; 64 FR 67052, Nov. 30, 1999; 68 FR 66720, Nov. 28, 2003]

§ 489.104 Effective dates.

These provisions apply to services furnished on or after December 1, 1991 payments made under section 1833(a)(1)(A) of the Act on or after December 1, 1991, and contracts effective on or after December 1, 1991.

PART 491—CERTIFICATION OF CERTAIN HEALTH FACILITIES

Subpart A—Rural Health Clinics: Conditions for Certification; and FQHCs Conditions for Coverage

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Subpart A—Rural Health Clinics: Conditions for Certification; and FQHCs Conditions for Coverage

§ 491.1 Purpose and scope.

This subpart sets forth the conditions that rural health clinics or FQHCs must meet in order to qualify for reimbursement under Medicare (title XVIII of the Social Security Act) and that rural health clinics must meet in order to qualify for reimbursement under Medicaid (title XIX of the Act).

[57 FR 24982, June 12, 1992]

§ 491.2 Definition of shortage area for RHC purposes.

Shortage area means a geographic area that meets one of the following criteria. It is—

- (a) Designated by the Secretary as an area with shortage of personal health services under section 330(b)(3) of the Public Health Service Act;
- (b) Designated by the Secretary as a health professional shortage area under section 332(a)(1)(A) of the public Health Service Act because of its shortage of primary medical care professionals;
- (c) Determined by the Secretary to contain a population group that has a health professional shortage under section 332(a)(1)(B) of that Act; or
- (d) Designated by the chief executive officer of the State and certified by the Secretary as an area with a shortage of personal health services.

[68 FR 74816, Dec. 24, 2003]

§ 491.3 RHC procedures.

- (a) *General.* (1) CMS processes Medicare participation matters for RHCs as 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).

(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.

(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

(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

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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 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]

§ 491.10 Patient health records.

(a) *Records system*. (1) The clinic or center maintains a clinical record system in accordance with written policies and procedures.

(2) A designated member of the professional staff is responsible for maintaining the records and for insuring that they are completely and accurately documented, readily accessible, and systematically organized.

(3) For each patient receiving health care services, the clinic or center maintains a record that includes, as applicable:

(i) Identification and social data, evidence of consent forms, pertinent medical history, assessment of the health status and health care needs of the patient, and a brief summary of the episode, disposition, and instructions to the patient;

(ii) Reports of physical examinations, diagnostic and laboratory test results, and consultative findings;

(iii) All physician's orders, reports of treatments and medications, and other pertinent information necessary to monitor the patient's progress;

(iv) Signatures of the physician or other health care professional.

(b) *Protection of record information*. (1) The clinic or center maintains the confidentiality of record information and provides safeguards against loss, destruction or unauthorized use.

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(2) Written policies and procedures govern the use and removal of records from the clinic or center and the conditions for release of information.

(3) The patient's written consent is required for release of information not authorized to be released without such consent.

(c) *Retention of records.* The records are retained for at least 6 years from date of last entry, and longer if required by State statute.

(Secs. 1102, 1833 and 1902(a)(13), Social Security Act; 49 Stat. 647, 91 Stat. 1485 (42 U.S.C. 1302, 13951 and 1396a(a)(13)))

[43 FR 30529, July 14, 1978. Redesignated at 50 FR 33034, Aug. 16, 1985, as amended at 57 FR 24984, June 12, 1992]

§ 491.11 Quality assessment and performance improvement.

The RHC must develop, implement, evaluate, and maintain an effective, ongoing, data-driven quality assessment and performance improvement (QAPI) program. The self-assessment and performance improvement program must be appropriate for the complexity of the RHC's organization and services and focus on maximizing outcomes by improving patient safety, quality of care, and patient satisfaction.

(a) *Standard: Components of a QAPI program.* The RHC's QAPI program must include, but not be limited to, the use of objective measures to evaluate the following:

(1) Organizational processes, functions, and services.

(2) Utilization of clinic services, including at least the number of patients served and the volume of services.

(b) *Standard: Program activities.* (1) For each of the areas listed in paragraph (a)(1) of this section, the RHC must do the following:

(i) Adopt or develop performance measures that reflect processes of care and RHC operation and is shown to be predictive of desired patient outcomes or be the outcomes themselves.

(ii) Use the measures to analyze and track its performance.

(2) The RHC must set priorities for performance improvement, considering either high-volume, high-risk services, the care of acute and chronic conditions, patient safety, coordination of

care, convenience and timeliness of available services, or grievances and complaints.

(3) The RHC must conduct distinct improvement projects; the number and frequency of distinct improvement projects conducted by the RHC must reflect the scope and complexity of the clinic's services and available resources.

(4) The RHC must maintain records on its QAPI program and quality improvement projects.

(5) An RHC may undertake a program to develop and implement an information technology system explicitly designed to improve patient safety and quality of care. This activity will be considered to fulfill the requirement for a project under this section.

(c) *Standard: Program responsibilities.* The RHC's professional staff, administrative officials, and governing body (if applicable) are responsible for the following:

(1) Ensuring that quality assessment and performance improvement efforts effectively address identified priorities.

(2) Identifying or approving those priorities and for the development, implementation, and evaluation of improvement actions.

[68 FR 74817, Dec. 24, 2003]

PART 493—LABORATORY REQUIREMENTS

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