DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Baltimore, Maryland 21244-1850

Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-09-14

DATE: **November 21, 2008**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Interim Guidance Regarding the Survey and Certification of Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

Memorandum Summary

- The regulations at 42 CFR Part 405, Subpart X, Section 2401 and 42 CFR Part 491, Subpart A, governing RHC and FQHC participation in Medicare, have undergone major changes in recent years and are now proposed for further changes.
- This memorandum provides an overview of previous changes and clarifies the current RHC and FQHC regulatory requirements.

The purpose of this memorandum is to provide guidance regarding the regulatory requirements located at 42 CFR Part 405, Subpart X, Section 2401 and 42 CFR Part 491, Subpart A, applying to RHCs and FQHCs.

Overview of Regulatory Actions:

On December 24, 2003, the Centers for Medicare & Medicaid Services (CMS) published a final rule which revised certification and payment requirements for RHCs and FQHCs. Many of the amendments in that published rule were required by the Balanced Budget Act (BBA) of 1997 or the Omnibus Budget Reconciliation Act of 1989 (OBRA 89).

CMS later determined that this final rule was subject to Section 902 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003, which requires adoption of a final rule no later than 3 years after publication of the initial rule proposal. The RHC/FQHC rule published in December 2003 exceeded the 3-year statutory timeframe. Therefore, on September 22, 2006, CMS published an interim final rule that suspended the effectiveness of the amendments adopted

in 2003 and restored the previous version of the rule (71 FR 55341). However, we noted in the preamble to the 2006 rule that any statutory self-implementing provisions (that is, provisions which do not require any additional discretionary activity on the part of the Secretary) on which CMS had previously issued guidance continue in effect. This is the case even when the regulatory language that was reinstated differs from the self-implementing provisions of the law.

Finally, CMS proposed on June 27, 2008 amendments to 42 CFR Part 405, Subpart X and 42 CFR Part 491, Subpart A that would restore much of the December 2003 regulatory text (73 FR 36696).

Current Regulatory Requirements:

Attachment A contains the current regulatory text. It reflects changes from the December, 2003 version of the regulation in the following areas:

- 42 CFR 405.2401 – Scope and definitions of Services for FQHCs and RHCs
- 42 CFR 491.2 - Definitions
- 42 CFR 491.3 - Certification procedures
- 42 CFR 491.5 - Location of [rural health] clinic
- 42 CFR 491.8(a)(6) - Staffing [mid-level practitioner requirement for RHCs]
- 42 CFR 491.8(d) - Temporary staffing waiver [the waiver provision was eliminated]
- 42 CFR 491.11 - Program evaluation [replacing QAPI]

Despite the current regulatory text (as restored by the 2006 interim final rule), the following self-implementing statutory provisions are still in effect:

- **Staffing and Staffing Responsibilities**

  (1) Section 6213(a)(3) of OBRA 89 reduced the requirement for the minimum amount of time a mid-level practitioner is available to furnish patient care services in an RHC from 60% to 50% of the time the RHC operates (see section 1861(aa)(2)(J) of the Act). This provision was effective October 1, 1989. Although the December 24, 2003 final rule was suspended, this provision is self-implementing and is also being enforced via program memorandum issued February 6, 1998. (Attachment B)

  (2) Section 4205(c) of the BBA (codified at section 1861(aa)(7)(B) of the Act) modified waiver provisions for the mid-level staffing requirement as well as eliminating the availability of such waivers for new RHCs. Pursuant to the program memorandum cited above, issued February 6, 1998, RHCs that entered the Medicare program on or after January 1, 1998 are not eligible for a mid-level staffing waiver. RHCs that participated in the Medicare program prior to that date may submit a waiver request to CMS for a waiver of up to one year, if they can demonstrate that they have been unable, despite reasonable efforts, to hire a nurse practitioner, physician's assistant or certified nurse midwife in the prior 90 days. CMS may not approve any waiver request submitted less than six months after expiration of a previous waiver request. Eligible waiver requests are deemed granted unless denied by CMS within 60 days of receipt.

- **Location Requirements – Disqualifying Existing RHCs.**

Section 4205(d)(1) of the BBA amended section 1861(aa)(2) of the Act by applying shortage area requirements to existing as well as new RHCs. CMS previously issued guidance (S&C-04-42) on August 12, 2004 indicating that no action would be taken to disqualify, i.e., remove the certification of, currently approved Medicare participating RHCs that no longer met basic location requirements. This 2004 guidance remains in effect. (Attachment C)

Appendix G of the State Operations Manual is generally consistent with the September, 2006 reversion to the rule that was in effect before December 2003. However, it is important that surveyors review the self-implementing statutory provisions discussed above (and the guidance issued pursuant to those provisions). Surveyors may not cite an RHC for deficiencies when they are in compliance with the statutory provisions and guidance described above.

When CMS adopts a final rule concerning the amendments proposed in June 2008, we will issue guidance on its interpretation and enforcement.

If you have additional questions or concerns, please contact Shonté Carter at (410) 786-3532 or via email at shonte.carter@cms.hhs.gov.

Effective Date: Immediately. Please ensure that all appropriate staff are fully informed within 30 days of the date of this memorandum.

Training: The information contained in this letter should be shared with all survey and certification staff, their managers, and the State/RO training coordinators.

/s/
Thomas E. Hamilton

Attachments: (3)

cc: Survey and Certification Regional Office Management

Attachment A – Current Regulatory Text

Subpart X—Rural Health Clinic and Federally Qualified Health Center Services

* * *

§ 405.2401 Scope and definitions.

(a) *Scope.* This subpart establishes the requirements for coverage and reimbursement of rural health clinic and Federally qualified health center services under Medicare.

(b) *Definitions.* As used in this subpart, unless the context indicates otherwise:

Act means the Social Security Act.

Allowable costs means costs that are incurred by a clinic or center and are reasonable in amount and proper and necessary for the efficient delivery of rural health clinic and Federally qualified health center services.

Beneficiary means an individual enrolled in the Supplementary Medical Insurance program for the Aged and Disabled (part of title XVIII of the Act).

Coinsurance means that portion of the clinic's charge for covered services for which the beneficiary is liable in addition to the deductible.

Carrier means an organization that has a contract with the Secretary to administer the benefits covered by this subpart.

Covered services means items or services for which the beneficiary is entitled to have payment made on his or her behalf under this subpart.

Deductible means:

(1) The first $100 of expenses incurred by the beneficiary during any calendar year for items and services covered under Part B of title XVIII; and

(2) The expenses incurred for the first 3 pints of blood or 3 units of packed red blood cells furnished to a beneficiary during any calendar year. (See §§410.160 and 410.161 of this chapter for greater detail.)

Federally qualified health center (FQHC) means an entity that has entered into an agreement with CMS to meet Medicare program requirements under §§405.2434 and—

(1) Is receiving a grant under section 329, 330, or 340 of the Public Health Service Act, or is receiving funding from such a grant under a contract with the recipient of such a grant and meets the requirements to receive a grant under section 329, 330 or 340 of the Public Health Service Act;

(2) Based on the recommendation of the PHS, is determined by CMS to meet the requirements for receiving such a grant;

(3) Was treated by CMS, for purposes of part B, as a comprehensive federally funded health center (FFHC) as of January 1, 1990; or

(4) Is an outpatient health program or facility operated by a tribe or tribal organizations under the Indian Self-Determination Act or by an Urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act

CMS stands for Centers for Medicare & Medicaid Services.

Intermittent nursing care means a medically predictable need for nursing care from time to time, but usually not less frequently than once every 60 days.

Nurse-midwife means a registered professional nurse who meets the following requirements:

(1) Is currently licensed to practice in the State as a registered professional nurse.

(2) Is legally authorized under State law or regulations to practice as a nurse-midwife.

(3) Except as provided in paragraph (b)(10)(iv) of this section, has completed a program of study and clinical experience for nurse-midwives, as specified by the State.

(4) If the State does not specify a program of study and clinical experience that nurse-midwives must complete to practice in that State, meets one of the following conditions:

(i) Is currently certified as a nurse-midwife by the American College of Nurse-Midwives.

(ii) Has satisfactorily completed a formal education program (of at least one academic year) that, upon completion, qualifies the nurse to take the certification examination offered by the American College of Nurse-Midwives.

(iii) Has successfully completed a formal educational program for preparing registered nurses to furnish gynecological and obstetrical care to women during pregnancy, delivery, and the postpartum period, and care to normal newborns, and was practicing as a nurse-midwife for a total of 12 months during any 18-month period from August 8, 1976 to July 16, 1982.

Nurse practitioner and *physician assistant* means individuals who meet the applicable education, training experience and other requirements of §491.2 of this chapter.

Part-time nursing care means nursing care that is required on less than a full-time basis, that is, less than 8 hours a day or 40 hours a week.

Physician means the following:

(1) A doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which the function is performed.

(2) Within limitations as to the specific services furnished, a doctor of dentistry or dental or oral surgery, a doctor of optometry, a doctor of podiatry or surgical chiropody or a chiropractor. (See section 1861(r) of the Act for specific limitations.)

(3) A resident (including residents as defined in §415.152 of this chapter who meet the requirements in §415.206(b) of this chapter for payment under the physician fee schedule).

Reporting period means a period of 12 consecutive months specified by the intermediary as the period for which a clinic or center must report its costs and utilization. The first and last reporting periods may be less than 12 months.

Rural health clinic means a facility that:

(1) Has been determined by the Secretary to meet the requirements of section 1861(aa)(2) of the Act and part 491 of this chapter; and

(2) Has filed an agreement with the Secretary in order to provide rural health clinic services under Medicare. (See §405.2402.)

Secretary means the Secretary of Health and Human Services or his delegate.

Visiting nurse services means part-time or intermittent nursing care and related medical supplies (other than drugs or biologicals) furnished by a registered nurse or licensed practical nurse to a homebound patient.

(Secs. 1102, 1833, 1861(aa), 1871, 1902(a)(13), Social Security Act; 49 Stat. 647, 79 Stat. 302, 322, and 331, 91 Stat. 1485 (42 U.S.C. 1302, 1395 *l,* 1395hh, 1395x(aa), and 1396(a)(13))

[43 FR 8261, Mar. 1, 1978, as amended at 43 FR 30526, July 14, 1978; 47 FR 21049, May 17, 1982; 47 FR 23448, May 28, 1982; 51 FR 41351, Nov. 14, 1986; 57 FR 24975, June 12, 1992; 59 FR 26958, May 25, 1994; 60 FR 63176, Dec. 8, 1995; 61 FR 14657, Apr. 3, 1996; 69 FR 74815, Dec. 24, 2003; 71 FR 55345, Sept. 22, 2006]

* * *

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 Definitions.

As used in this subpart, unless the context indicates otherwise:

Direct services means services provided by the clinic's staff.

FQHC means an entity as defined in §405.2401(b).

Nurse practitioner means a registered professional nurse who is currently licensed to practice in the State, who meets the State's requirements governing the qualifications of nurse practitioners, and who meets one of the following conditions:

(1) Is currently certified as a primary care nurse practitioner by the American Nurses' Association or by the National Board of Pediatric Nurse Practitioners and Associates; or

(2) Has satisfactorily completed a formal 1 academic year educational program that:

(i) Prepares registered nurses to perform an expanded role in the delivery of primary care;

(ii) Includes at least 4 months (in the aggregate) of classroom instruction and a component of supervised clinical practice; and

(iii) Awards a degree, diploma, or certificate to persons who successfully complete the program; or

(3) Has successfully completed a formal educational program (for preparing registered nurses to perform an expanded role in the delivery of primary care) that does not meet the requirements of paragraph (2) of this definition, and has been performing an expanded role in the delivery of primary care for a total of 12 months during the 18-month period immediately preceding the effective date of this subpart.

Physician means a doctor of medicine or osteopathy legally authorized to practice medicine or surgery in the State.

Physician assistant means a person who meets the applicable State requirements governing the qualifications for assistants to primary care physicians, and who meets at least one of the following conditions:

(1) Is currently certified by the National Commission on Certification of Physician Assistants to assist primary care physicians; or

(2) Has satisfactorily completed a program for preparing physician's assistants that:

(i) Was at least 1 academic year in length;

(ii) Consisted of supervised clinical practice and at least 4 months (in the aggregate) of classroom instruction directed toward preparing students to deliver health care; and

(iii) Was accredited by the American Medical Association's Committee on Allied Health Education and Accreditation; or

(3) Has satisfactorily completed a formal educational program (for preparing physician assistants) that does not meet the requirements of paragraph (2) of this definition and assisted primary care physicians for a total of 12 months during the 18-month period that ended on December 31, 1986.

Rural area means an area that is not delineated as an urbanized area by the Bureau of the Census.

Rural health clinic or clinic means a clinic that is located in a rural area designated as a shortage area, is not a rehabilitation agency or a facility primarily for the care and treatment of mental diseases, and meets all other requirements of this subpart.

Shortage area means a defined geographic area designated by the Department as having either a shortage of personal health services (under section 1302(7) of the Public Health Service Act) or a shortage of primary medical care manpower (under section 332 of that Act).

Secretary means the Secretary of Health and Human Services, or any official to whom he has delegated the pertinent authority.

[71 FR 55345, Sept. 22, 2006]

§ 491.3 Certification procedures.

A rural health clinic will be certified for participation in Medicare in accordance with subpart S of 42 CFR part 405. The Secretary will notify the State Medicaid agency whenever he has certified or denied certification under Medicare for a prospective rural health clinic in that State. A clinic certified under Medicare will be deemed to meet the standards for certification under Medicaid.

[71 FR 55346, Sept. 22, 2006]

§ 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.* (1) CMS does not disqualify an RHC approved under this subpart if the area in which it is located subsequently fails to meet the definition of a rural, shortage area.

(2) A private, nonprofit facility that meets all other conditions of this subpart except for location in a shortage area will be certified if, on July 1, 1977, it was operating in a rural area that is determined by the Secretary (on the basis of the ratio of primary care physicians to the general population) to have an insufficient supply of physicians to meet the needs of the area served.

(3) Determinations on these exceptions will be made by the Secretary upon application by the facility.

(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) *Criteria for designation of shortage areas.* (1) The criteria for determination of shortage of personal health services (under section 1302(7) of the Public Health Services Act), are:

(i) The ratio of primary care physicians practicing within the area to the resident population;

(ii) The infant mortality rate;

(iii) The percent of the population 65 years of age or older; and

(iv) The percent of the population with a family income below the poverty level.

(2) The criteria for determination of shortage of primary medical care manpower (under section 332(a)(1)(A) of the Public Health Services Act) are:

(i) The area served is a rational area for the delivery of primary medical care services;

(ii) The ratio of primary care physicians practicing within the area to the resident population; and

(iii) The primary medical care manpower in contiguous areas is overutilized, excessively distant, or inaccessible to the population in this area.

(e) *Medically underserved population.* A medically underserved population includes the following:

(1) A population of an urban or rural area that is designated by PHS as having a shortage of personal health services.

(2) A population group that is designated by PHS as having a shortage of personal health services.

(f) *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; 71 FR 55346, Sept. 22, 2006]

§ 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 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 transferred as required when patients are referred.

[57 FR 24983, June 12, 1992, as amended at 61 FR 14658, Apr. 3, 1996; 68 FR 74817, Dec. 24, 2003; 71 FR 55346, Sept. 22, 2006]

§ 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.

(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 Program evaluation.

(a) The clinic or center carries out, or arranges for, an annual evaluation of its total program.

(b) The evaluation includes review of:

(1) The utilization of clinic or center services, including at least the number of patients served and the volume of services;

(2) A representative sample of both active and closed clinical records; and

(3) The clinic's or center's health care policies.

(c) The purpose of the evaluation is to determine whether:

(1) The utilization of services was appropriate;

(2) The established policies were followed; and

(3) Any changes are needed.

(d) The clinic or center staff considers the findings of the evaluation and takes corrective action if necessary.

[71 FR 55346, Sept. 22, 2006]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Memorandum

DATE: February 6, 1998

FROM: Director
Center for Medicaid and State Operations

SUBJECT: Balanced Budget Act of 1997: Implementation of the Refinement of the Shortage Area Requirements and the Staffing Waiver Requirement – **ACTION**

TO: Associate Regional Administrators
Center for Medicaid and State Operations
Regions I-X

The purpose of this memorandum is to provide specific guidance in processing new applicants' requests to participate in the rural health clinic (RHC) program as required by two specific provisions of the 1997 Balanced Budget Act (BBA). The two relevant provisions are:

- § 4205(d): Refinement of the Shortage Area Requirements, and
- § 4205(c): Staffing Waiver Requirement

REFINEMENT OF THE SHORTAGE AREA REQUIREMENTS

Defining a Current Shortage Area Designation

As of January 1, 1998, per these instructions, new applicants requesting entrance into the Medicare and/or Medicaid programs as a RHC must be located in a health professional shortage area (HPSA), a medically underserved area (MUA), or a shortage area designated by a State Governor whose designation has been made or updated within the current year or one of the previous three calendar years. (For instance, if an application is received by the State agency in 1998, HCFA will consider all shortage designations made in 1997, 1996, or 1995 to be current regardless of the month the application was received.) Any shortage area designation made or last updated in a calendar year more than three years prior to the date of application receipt, is considered outdated and not timely for purposes of the RHC location requirement and, therefore, cannot be approved.

Applying Phase I

HCFA will use a two-tiered approach to implement the refinement of shortage area requirements to RHCs. During Phase I, the refinement of shortage area requirements will apply only to new

applicants seeking RHC status. HCFA will issue separate guidelines to implement Phase II. Phase II guidelines (which will take effect January 1, 1999) will apply to existing clinics located in areas that have lost their shortage area designation since their initial certification.

Phase I: Determining the Status of a Shortage Area Designation

On a quarterly basis (beginning December 31, 1997), the Health Resources and Services Administration (HRSA), the Department of Health and Human Services agency responsible for designating shortage areas, will send to HCFA central office, a current listing of the designation status of HPSAs and MUAs across the country and/or will make such lists available through a Website (http://www.hrsa.dhhs.gov). HCFA central office will forward regional data to each HCFA regional office. HCFA regional offices will send a State listing of current HPSAs and MUAs to each State's survey agency.

The States in your region may have, in addition to HPSAs and MUAs, shortage areas designated by the Governor for RHC purposes only. If the Governor's designation in a specific State is outdated, a request for review should be submitted to the Office of the Governor of that State. Please note, not all States have a Governor's designation.

Phase I: Processing New Applicants' Requests

The State survey agency should screen preliminary information to determine if the currency of designation requirement has been met before requiring the RHC candidate to complete a formal application. An application received by the State survey agency before January 1, 1998, may be processed under old criteria.

If an applicant requesting participation in the Medicare and/or Medicaid programs as a RHC is located in an outdated shortage area, the applicant should work with the State primary care office (PCO) to secure a current designation. The State PCO will tell the applicant what is required to complete a review. Once the required information is compiled by the applicant in consultation with the PCO, the request should be submitted to the Health Resources and Services Administration, Bureau of Primary Health Care, Division of Shortage Designation (DSD), 4350 East-West Highway, Rm 9-1D1, Bethesda, MD 20857. The DSD attempts to process complete applications (those which do not require additional information) within 90 days from the date of receipt. Attached for your information is a current list of State PCOs.

STAFFING WAIVER REQUIREMENT LIMITED TO CLINICS IN THE PROGRAM

Effective January 1, 1998, section 4205(c) of the BBA modifies and limits the existing staffing waiver. New applicants requesting RHC status will no longer qualify for a mid-level staffing waiver. Therefore, clinics entering the program on or after January 1, 1998, must follow the requirements of title XVIII of the Social Security Act (the Act) and have a mid-level practitioner on staff at least 50 percent of the time in order to receive RHC status. Do not approve RHC

applicants that fail to satisfy the mid-level staffing requirement in section 1861(aa)(2)(J) of the Act.

CONTACT PERSON

Following the distribution of this memorandum, we will schedule a teleconference with you to respond to your questions. In the meantime, if you have any immediate concerns, call Julie Radoslovich at (410) 786-9520 or email at Jradoslovich@hcfa.gov.

/s/
Sally K. Richardson
Director

Attachment

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-12-25
Baltimore, Maryland 21244-1850

Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-04-42

DATE: **August 12, 2004**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Status of the December 24, 2003 Final Rule: Rural Health Clinics

Letter Summary

- The Medicare Modernization Act (MMA) limits the authority of the Secretary to issue and enforce final rules that are issued more than three years after the proposed rule or interim final rule.
- These instructions clarify the status of the December 24, 2003 Final Rule.

The Centers for Medicare & Medicaid Services (CMS) has not yet implemented the changes to the Rural Health Clinic regulations that were published on December 24, 2003 (68 FR 74792). Therefore, until further notice, do not take any action to disqualify currently approved Medicare participating Rural Health Clinics that no longer meet basic location requirements. Please note that initial Rural Health Clinic applicants must meet existing rural and shortage area location requirements.

In addition, the Quality Assessment and Performance Improvement (QAPI) program requirements, cited at 42 CFR 491.11 in the December 24 publication, are not yet mandatory. However, any Rural Health Clinic that has implemented the QAPI program as specified should be considered to be in compliance with the existing Program Evaluation requirements at that site.

Effective Date: This guidance is effective immediately. Nothing in this Memorandum should be construed to require the rescheduling of a re-certification review. Please ensure distribution by August 31, 2004.

Training: The information contained in this announcement should be shared with all surveyors, survey and certification staff, their managers, and the state/RO training coordinators.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management (G-5)