

State Operations Manual

Appendix G - Guidance to Surveyors: Rural Health Clinics (RHCs)

Table of Contents
(Rev. 137, 04-01-15)

[Transmittals for Appendix G](#)

INDEX

§491.4 Condition of Coverage: Compliance With Federal, State, and Local Laws

§491.5 Condition of Coverage: Location of Clinic

§491.6 Condition of Coverage: Physical Plant and Environment

§491.7 Condition of Coverage: Organizational Structure

§491.8 Condition *for Certification*: Staffing and Staff Responsibilities

§491.9 Condition of Coverage: Provision of Services

§491.10 Condition of Coverage: Patient Health Records

§491.11 Condition of Coverage: Program Evaluation

Table A - Publications of the Bureau of the Census - Maps Displaying Urbanized Areas

Table B - Contacts in the Bureau of the Census Regional Offices

Table C - Cities With Boundaries Extending to Rural Populations

§491.4 Condition of Coverage: Compliance With Federal, State, and Local Laws

The RHC and its staff are in compliance with applicable Federal, State, and local laws and regulations.

A - Federal Laws and Regulations

The Federal regulations governing the certification of RHCs were published in the “Federal Register” on July 14, 1978, 43 FR 136. Conditions for certification under those regulations are the subject of these guidelines.

B - State Laws and Regulations

All States have practice acts that govern the activities of health professionals. While there is considerable variation in the States' practice acts concerning physician assistants, nurse practitioners and certified nurse-midwives, there is a broad mandate in the medical practice acts of all States giving physicians authority to diagnose and treat medical conditions. The extent to which the physician may delegate these responsibilities and to whom, and under what conditions, varies in the States. Some States have updated their practice acts since the advent of the physician assistant, nurse practitioner and certified nurse-midwife health care professionals. In some instances, these updated practice acts have included definitions and specific references to permitted/prohibited activities, supervision/guidance required by a physician, and location/situations in which nurse practitioners, certified nurse-midwives and physician assistants may function. In some States where nurse practice acts have not been significantly updated, some functions of the nurse practitioner are viewed as an extension of the traditional nursing role as being covered by the existing nurse practice act.

Rural health clinics can be certified only if the State permits - that is, does not explicitly prohibit the delivery of primary health care by a nurse practitioner, certified nurse-midwife or a physician assistant. The surveyor will encounter wide variations in the wording, interpretation, and application of States' practice acts as they affect the physician assistant, nurse practitioner and certified nurse-midwife in the RHC setting.

In situations where the State law is silent, or where the State law does not specifically prohibit the functioning of a physician assistant, nurse practitioner or certified nurse-midwife with medical direction by a physician and with the degree of supervision, guidance, and consultation required by the RHC regulations, the surveyor may consider this condition as being met. Interpretations needed on specific aspects of the State's practice act should be sought through the State regulatory agency or board(s) dealing with the practice and profession.

§491.5 Condition of Coverage: Location of Clinic

Consult with the RO to preliminarily ascertain that a clinic meets the basic requirement of location prior to scheduling a survey. The clinic must be located in a rural area that is designated as a shortage area. Applicants determined not qualified under this requirement should be sent a letter (see Exhibit 27) with the appropriate notation.

A - Rural Area Location

The law requires the clinic to be located in an area "that is not an urbanized area as defined by the Bureau of the Census." The Bureau has published both a narrative definition of an urbanized area and maps displaying the land area of urbanized areas. Lists and maps of the urbanized areas are contained in the "number of inhabitants" census volume for that State (census of population series PC-80-1-A). Note that this

definition is different from that of a metropolitan statistical area (MSA). Contact the Bureau of the Census ROs or the CMS ROs for a determination on whether the clinic is located in a nonurbanized area.

B - Shortage Area Designation

After it has been ascertained that the clinic is located in a nonurbanized area, the CMS RO will certify whether or not the clinic is located in a designated shortage area. The CMS RO, after consulting with PHS RO staff, promptly responds in writing to the request for a determination. This information may be given by telephone as long as it is followed by a written response. This consultation explores designation:

- As an area with a shortage of personal health services under §330(b)(3) or 1302(7) of the PHS Act;
- As a health manpower shortage area described in §332(a)(1)(A) of the PHS Act;
- As an area which includes a population group which the Secretary determines has a health manpower shortage under §332(a)(1)(B) of the PHS Act;
- As a high migrant impact area described in §329(a)(5) of the PHS Act; or
- As an area designated by the chief executive officer of the State and certified by the Secretary as an area with a shortage of personal health services.

The PHS Bureau of Health Care Delivery and Assistance publishes these designations periodically in the Federal Register. Designation under any section qualifies a RHC location. The designation process is a continuing process, with additions of newly designated areas and deletions of previously designated areas occurring daily.

C - Mobile Units

A mobile unit must meet the Conditions for Certification for it to qualify as a RHC. In addition, it should be ascertained that the mobile unit has fixed scheduled locations, each of which meet the rural and shortage area requirements.

Since the mobile unit is a clinic, it is expected that the RHC services are provided in the unit and not in a permanent structure, with the unit serving only as a mobile repository for the equipment, supplies, and records. The only exception would be if the RHC services were furnished off the clinic's premises (away from the unit) to homebound patients.

Where a facility offers RHC services at a permanent structure as well as in a mobile unit, each facility must be certified separately as a RHC. This is differentiated from the situation where a permanent structure provides RHC services off the premises, e.g., to

homebound patients, with the use of a vehicle to transport supplies, equipment, records, and staff.

D - Exceptions to the Location Requirement

There are two grandfather provisions applicable to the certification process.

1 - Loss of Location Eligibility

This grandfather provision applies to the annual recertification process. It should be used as a “yes” response to item J11 and on the Form CMS-30 when a facility which was previously certified as being located in a nonurbanized and designated shortage area subsequently loses either or both of these characteristics. When this occurs, the facility does not lose its eligibility for continued participation in the program because it does not meet the location requirement. If J11 is marked “yes,” mark J17 and J18 “N/A.”

2 - Clinics Operating on July 1, 1977

Potential applicants under this grandfather provision still have to meet the rural location requirement. The other requirement under this provision is that the Secretary has determined that the area served has an insufficient supply of primary care physicians. Facilities providing services on July 1, 1977, in a nonurbanized area that is determined to have unmet needs for primary health care but which is not a designated shortage area are potential applicants. Therefore, the facility may be primarily serving a designated area but not located in a designated shortage area. It must be determined whether the location of the clinic is an appropriate part of a service area that includes areas or populations that have been designated either as having a health manpower shortage, or as being medically underserved. Aiding this determination will be previous PHS decisions made on behalf of the Secretary. The answer to question V on Form CMS-29 is an important indicator. Several PHS programs provide or have provided grant support to enable the facility to provide health care to designated areas. These programs do not require that the facility be located in a designated shortage area. Many of these facilities were operating with PHS grant support prior to enactment of the Rural Health Clinic Services Act of 1977 (P.L. 95-210) and may constitute certifiable RHC applicants. Some examples of these PHS programs are National Health Service Corps (NHSC), Migrant Health, Health Underserved Rural Areas (HURA), and Rural Health Initiative (RHI).

Prior to P.L. 95-210, a number of States had programs to assist their rural areas with greater access to primary care. The location of the facilities developed by these programs was determined by valid criteria established by the State, although location in a designated shortage area may not have been one of them. These facilities are also potential applicants under this grandfather provision.

When it is determined that an applicant clinic not located in a designated shortage area may be a potential applicant under this grandfather provision, develop the following information and submit it to the CMS RO for a determination as to whether the facility meets the requirements of this grandfather provision:

- A description of the geographic boundaries of the facility's service area;
- Information developed through consultation with the PHS RO staff about whether the area, or any portion of the area, had ever been reviewed for designation under any of the applicable sections of the PHS Act;
- Identification of any designated population group or institution in the facility's service area;
- Information secured from the appropriate Health Systems Agency and the State Health Planning and Development Agency about the primary care resources available in the facility's service area;
- Information about any planning, developmental, or operating funds awarded to the facility by the county, State, or Federal Government to assist in providing greater access to health care in the area;
- Information about the factors considered in determining where the facility was to be located; and
- Any additional information the SA or RO feels is relevant.

§491.6 Condition of Coverage: Physical Plant and Environment

A - Physical Plant Safety

To insure the safety of patients, personnel, and the public, the physical plant should be maintained consistent with appropriate State and local building, fire, and safety codes. Reports prepared by State and local personnel responsible for insuring that the appropriate codes are met should be available for review. Determine whether the clinic has safe access and is free from hazards that may affect the safety of patients, personnel, and the public.

B - Preventive Maintenance

A program of preventive maintenance should be followed by the clinic. This includes inspection of all clinic equipment at least yearly, or as the type, use, and condition of equipment dictates; the safe storage of drugs and biologicals (see 42 CFR 491.6(b)(2)) and inspection of the facility to assure that services are rendered in a clean and orderly

environment. Inspection schedules and reports should be available for review by the surveyor.

C - Non-Medical Emergencies

Review written documentation and interview clinic personnel to determine what instructions for non-medical emergency procedures have been provided and whether clinic personnel are familiar with appropriate procedures. Non-medical emergency procedures may not necessarily be the same for each clinic.

§491.7 Condition of Coverage: Organizational Structure

A - Basic Requirements

Ascertain that the clinic is under the medical direction of a physician(s), has a staff that meets the requirements of §491.8, and has adequate written material covering organization policies, including lines of authority and responsibilities.

B - Written Policies

Written policies should consist of both administrative and patient care policies. Patient care policies are discussed under 42 CFR 491.9(b). In addition to including lines of authority and responsibilities, administrative policies may cover topics such as personnel, fiscal, purchasing, and maintenance of building and equipment. Topics covered by written policies may have been influenced by requirements of the founders of the clinic, as well as agencies that have participated in supporting the clinic's operation.

C - Disclosure of Names and Addresses

The clinic discloses names and addresses of the owner, person responsible for directing the clinic's operation, and physician(s) responsible for medical direction.

Any entity may organize itself as an owner of a RHC. The types of organizations being referred to are described in answers to question IV on the Request to Establish Eligibility. These range from:

- A physician in a private general practice located in a shortage area who employs either a nurse practitioner, certified nurse-midwife or a physician assistant;
- A nurse practitioner, certified nurse-midwife or a physician assistant in solo practice in a shortage area who develops the required relationship with a physician for medical direction; to
- Organizations either for profit or not for profit who own primary care clinics located in shortage areas.

Any change in ownership or physician(s) responsible for the clinic's medical direction requires prompt notice to the RO. Neither of these changes requires resurvey or recertification if the change can otherwise be adequately verified. Notice of any change in the physician(s) responsible for providing the clinic's medical direction should include evidence that the physician(s) is licensed to practice in the State.

§491.8 Condition for Certification: Staffing and Staff Responsibilities
(Rev. 137, Issued: 04-01-15, Effective: 03-27-15, Implementation: 03-27-15)

(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 clinic or center. In the case of a clinic, at least one physician assistant or nurse practitioner must be an employee of the clinic.

(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, certified 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. The physician performs the following:

(1) 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.

(2) 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.

(3) 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.

(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.

In accordance with §491.2, “Physician means the following:

(1) As it pertains to the supervision, collaboration, and oversight requirements in sections 1861(aa)(2)(B) and (aa)(3) of the Act, a doctor of medicine or osteopathy legally authorized to practice medicine or surgery in the State in which the function is performed; and

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

A - Sufficient Staffing

The staffing described in 42 CFR 491.8(a) is the minimum-staffing requirement. However, you also determine whether the clinic is sufficiently staffed to provide services essential to its operation. Because clinics are located in areas that have been designated as having shortages of health manpower or personnel health services, they frequently are not able to employ what would be considered sufficient health care staffs. When *staffing meets the minimum requirement but appears insufficient for the services the RHC provides*, explain, with reasonable detail, the circumstances (and *RHC's* efforts to overcome them) that make employment of additional needed staff not possible.

Should the loss of a physician reduce the clinic's staff below the required minimum, the clinic should be afforded a reasonable time to comply with the staffing requirement. The clinic must provide documentation showing its good faith effort to obtain *the services of a physician on a permanent basis, as well as arrangements it has made for immediate*

temporary physician services to perform the required physician responsibilities. The clinic should inform the State of all actions taken to recruit a replacement and expected outcome. Follow these situations closely and make recommendations about approvals pending correction of deficiencies, compliance, or decertification.

The regulation requires that at least one physician assistant, or nurse practitioner is an employee of the clinic. However, if the clinic has more than one non-physician practitioner on staff, the other practitioners may furnish services under contract to the clinic instead of being employees.

If a currently certified RHC loses its non-physician practitioner(s) and is unable to meet the requirement for a minimum 50 percent availability of such practitioners during the RHC's operating hours, it may request a temporary staffing waiver. The RHC must demonstrate its inability to recruit a replacement within the 90-day period prior to its application for a waiver. Only currently certified RHCs may request a waiver. CMS may not approve any waiver request submitted less than six months after the expiration of a previous waiver. Eligible waiver requests are deemed granted unless denied by the CMS regional office within 60 days of receipt.

It is the responsibility of the clinic to promptly advise the State Survey Agency of any changes in staffing which would affect its certification status.

B - Staffing Availability

A physician, nurse practitioner, certified nurse-midwife (meeting the definition in 42 CFR 405.2401(b) or physician assistant must be available to furnish patient care services *on the clinic's premises (including a mobile unit)* at all times the clinic operates. Only the scheduled operating hours the clinic is offering RHC services are to be considered (as distinguished from other ambulatory services or related health activities).

A nurse practitioner, certified nurse-midwife or physician assistant must be available to furnish patient care services at least 50 percent of the operating hours during which RHC services are offered, even *when* a physician is *also* present in the clinic. *All time present in the clinic during the clinic's operating hours, even if not actually providing RHC services to patients, may be counted toward the 50 percent requirement. In addition, when RHC services are furnished to clinic patients outside of the clinic (e.g. in the patient's home, in a SNF or other residential facility.), the time spent providing RHC services outside the clinic may be counted towards the 50 percent requirement.*

For any portion of the RHC's schedule when neither a physician assistant, nor a certified nurse-midwife, nor a nurse practitioner is available, a physician must be available on-site to provide needed services in order for the RHC to be open and operating.

The following are examples of how determinations regarding these requirements may be made. A clinic *offers* RHC services from 10 to 5 Tuesday through Friday, 28 hours a week. A physician, nurse practitioner, certified nurse-midwife, or a physician assistant

must be available to furnish patient care services *during all* 28 hours. Of these 28 hours, a nurse practitioner, certified nurse-midwife or physician assistant must be available *on-site at the clinic (including in a mobile unit) or providing RHC services in the patient's residence* at least 14 hours (50 percent of 28 hours) to furnish patient care services.

In some cases, the clinic's weekly schedule may not be a *reasonable* period of time on which to base these determinations, and consideration of the biweekly or even a monthly schedule may be more appropriate. Such a situation may occur when *its* schedule offering RHC services is *very limited*. An example would be a clinic *where* RHC services are offered every other Tuesday from 10 to 4, and one Friday a month from 10 to 4 (18 hours a month). Of these 18 hours, a nurse practitioner, certified nurse-midwife or physician assistant must be available *on-site at the clinic (including in a mobile unit) or providing RHC services in the patient's residence* at least 9 hours to furnish patient care services. *This requirement would be met if a nurse practitioner, certified nurse-midwife or physician assistant was on-site on one Tuesday for 3 hours and on the Friday for 6 hours, or through some other schedule that results in their availability 9 hours/month.*

C - Staff Responsibilities

The requirement that a physician, physician assistant, certified nurse-midwife, and/or nurse practitioner participate jointly in the development of the clinic's written policies does not require the development of new policies in the event of changes in these staff members. Nevertheless, each staff member must review, agree with, and adhere to, or propose amendments to the clinic's policies. Compliance with this requirement has a special relationship to the clinic's written patient care guidelines. There should be sufficient written documentation that this requirement is appropriately carried out. There should be some mechanism to ensure that new clinic personnel are completely familiar with these policies.

1 - Physician Responsibilities

In accordance with §491.8(b), the physician performs the following:

- *Provides medical direction for the clinic's or center's health care activities and consultation for, and medical supervision of, the health care staff, except for services furnished by a clinical psychologist in an FQHC, if State law permits them to be provided without physician supervision.*
- *Together with the physician assistant and/or nurse practitioner member(s), participates in developing, executing, and periodically reviewing the clinic's or center's written policies and procedures governing the clinic's patient care services.*
- *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.*

A physician member *must* perform the duties and responsibilities described in 42 CFR 491.8(b)(1), (2), and (3), *but does not need to be on-site in order to perform all of these duties, unless there are times during the RHC's operating hours when no nurse practitioner, certified nurse-midwife or physician assistant is present at the RHC. With the development of technology that facilitates telemedicine, a physician has the flexibility to use a variety of ways and timeframes to provide medical direction, consultation, supervision, and medical care services, including being on-site at the facility. The regulation allows for use of team-based care while still requiring the physician to be on-site, as appropriate, to ensure the delivery of quality care. A State or the RHC itself is not precluded from establishing requirements for physician supervision of non-physician practitioners that are more stringent, but these requirements are not enforced through the Federal Medicare certification process.*

2 - Physician Assistant, Nurse Practitioner and Certified Nurse Midwife Responsibilities

The surveyor verifies through appropriate written documentation that the physician assistant, certified nurse-midwife and/or nurse practitioner is performing the necessary responsibilities *at 42 CFR 491.8(c)(1) and (2).*

§491.9 Condition of Coverage: Provision of Services

A - Basic Requirements

1 - State and Local Laws

Know the State's position, generally, with respect to implementing the Federal RHC requirements vis-à-vis the State's Medical Practice Act, Nurse Practice Act, the Pharmacy Act, and the Comprehensive Drug Abuse Prevention and Control Act of 1970 (P.L. 91- 513) and the general scope of practice permitted for nurse practitioners, certified nurse-midwives and physician assistants.

Some States may have legal impediments because applicable practice acts prohibit nurse practitioners, certified nurse-midwives and/or physician assistants from independent acts of medical diagnosis and treatment precluding the fullest implementation of the Federal RHC requirements.

This does not necessarily preclude participation by a RHC that provides RHC services (physician-type services) furnished by nurse practitioners, certified nurse-midwives and/or physician assistants under the direct supervision (as distinguished from indirect supervision) of a physician. Therefore, inquiries to State authorities about compliance with the Federal RHC requirements, as well as decisions concerning applicant RHCs, must be weighed against several determinations, including:

- The medical direction and supervision described in the regulations is the

minimum requirement; many participating RHCs operate with greater medical direction and supervision than these minimums.

- The word “supervision” does not automatically equate with direct, over the shoulder supervision. Many States requiring physician supervision of medical acts performed by a nurse practitioner or a physician assistant have held that performances of such medical acts under written patient care guidelines developed and/or approved by a licensed physician satisfy the requirement of supervision.

2 - Providing Rural Health Clinic Services

The law describes a RHC as a facility primarily engaged in providing RHC services as defined in this subpart. Under this definition, a facility may provide services in addition to RHC services; usually, related health care services such as the “other ambulatory services” covered by Medicaid State plans. Certification as a RHC applies to the facility as a whole and the total operating schedule of the facility (the hours it is open) is considered when determining if the facility is primarily engaged in providing RHC services. If onsite observation of services provided and discussion with the staff indicate that the majority of the services provided by the clinic are primary medical care (treatment of acute or chronic medical problems which usually bring a patient to a physician’s office), then the clinic may satisfy the “primarily engaged” requirement providing that RHC services are offered at least 51 percent of the total operating schedule. The time RHC services are offered may differ from the total operating schedule of the facility, but may not be less than 51 percent of this total operating schedule.

If there is a question about this condition, review a sample of patient health records covering a reasonable period of time to determine the majority of specific services actually furnished.

An example of a clinic schedule that combines RHC services and “other ambulatory services” would be a clinic in which primary medical care is offered from 9 to 4 Monday through Thursday, and dental services are offered from 9 to 4 on Friday.

B - Patient Care Policies Requirements

Review the clinic’s policies and ascertain who developed them. Where changes in clinic personnel and/or clinic administration make it impossible or not relevant to ascertain who developed the policies, it is necessary to ascertain that the current physician member(s) and the nurse practitioner, certified nurse-midwife, and/or physician assistant member(s) of the staff have an in-depth knowledge of the policies and have had the opportunity to discuss them, adopt them as is, or make any agreed- to written changes in them. If a clinic’s organizational structure includes a governing body, ascertain whether the governing body has ultimate authority in approving the patient care policies and, if so, when such approval was last given. While clinics frequently seek the participation of

other health care professionals in developing patient care policies (particularly the written guidelines for the medical management of health problems) the term “a group of professional personnel” is not restricted to health care professionals. In some cases, the clinic will have involved health care professional’s representatives to a hospital with which the clinic has an agreement for patient referral. In any event, one member of the group of three or more may not be a member of the clinic’s staff, and professions which are not directly related to health care delivery (attorneys, community planners, etc.) are potentially useful.

The requirements concerning written policies address four areas:

1 - Description of Services

A description of the services the clinic furnishes directly and those furnished through agreement or arrangement. The services furnished by the clinic should be described in a manner that informs potential patients of the types of health care available at the clinic, as well as setting the parameters of the scope of what services are furnished through referral. Such statements as the following sufficiently describe services: Taking complete medical histories, performing complete physical examinations, assessments of health status, routine lab tests, diagnosis and treatment for common acute and chronic health problems and medical conditions, immunization programs, family planning, complete dental care, emergency medical care. Statements such as “complete management of common acute and chronic health problems” standing alone, do not sufficiently describe services.

Additional services, furnished through referral, are sufficiently described in such statements as: Arrangements have been made with X hospital for clinic patients to receive the following services if required: specialized diagnostic and laboratory testing, specialized therapy, inpatient hospital care, physician services, outpatient and emergency care when clinic is not operating, referral for medical cause when clinic is operating.

2 - Guidelines for Medical Management

The clinic’s written guidelines for the medical management of health problems include a description of the scope of medical acts that may be undertaken by the physician assistant, certified nurse-midwife, and/or nurse practitioner. They represent an agreement between the physician providing the clinic’s medical direction and the clinic’s physician assistant, certified nurse-midwife, and/or nurse practitioner on the privileges and limits of those acts of medical diagnosis and treatment which may be undertaken without direct, over the shoulder physician supervision. They describe the regimens to be followed and stipulate the conditions in the illness or health care management at which consultation or referral is required.

Acceptable guidelines may follow various formats. Some guidelines are collections of general protocols, arranged by presenting symptoms; some are statements of medical directives arranged by the various systems of the body (such as disorders of the

gastrointestinal system); some are standing orders covering major categories such as health maintenance, chronic health problems, common acute self-limiting health problems, and medical emergencies.

The manner in which these guidelines describe the criteria for diagnosing and treating health conditions may also vary. Some guidelines will incorporate clinical assessment systems that include branching logic. Others may be in a more narrative format with major sections covering specific medical conditions in which such topics as the following are discussed: The definition of the condition, its etiology, its clinical features, recommended laboratory studies, differential diagnosis, treatment procedures, complications, consultation/referral required, and follow-up. Even though approaches to describing guidelines may vary, acceptable guidelines for the medical management of health problems must include the following essential elements. They:

- Are comprehensive enough to cover most health problems that patients usually see a physician about;
- Describe the medical procedures available to the nurse practitioner, certified nurse-midwife, and/or physician assistant;
- Describe the medical conditions, signs, or developments that require consultation or referral; and
- Are compatible with applicable State laws.

Members of the medical profession have published a number of patient care guidelines. Should a clinic choose to adopt such guidelines (or adopt them essentially with noted modifications), this would be acceptable if the guidelines include the essential elements described above.

3 - Drugs and Biologicals

Written policies cover at least the following elements:

- Requirements dealing with the storage of drugs and biologicals in original manufacturer's containers to assure that they maintain their proper labeling and packaging;
- Requirements dealing with outdated, deteriorated, or adulterated drugs and biologicals being stored separately so that they are not mistakenly used in patient care prior to their disposal in compliance with applicable laws;
- Requirements dealing with storage in a space that provides proper humidity, temperature, and light to maintain the quality of drugs and biologicals;

- Requirements for a securely constructed locked compartment for storing drugs classified under Schedule II of the Comprehensive Drug Abuse Prevention and Control Act of 1970;
- Requirements dealing with the maintenance of adequate records of receipt and distribution of controlled drugs that account for all drugs in Schedules II, III, IV, and V; with Schedule II drugs being accounted for separately;
- Requirements that containers used to dispense drugs and biologicals to patients conform to the Poison Prevention Packaging Act of 1970;
- Requirements dealing with the complete and legible labeling of containers used to dispense drugs and biologicals to patients;
- Requirements concerning the availability of current drug references and antidote information; and
- Requirements dealing with prescribing and dispensing drugs in compliance with applicable State laws.

4 - Review of Policies

The group of professional personnel, which can be the governing body acting as the group, is responsible for an annual review of patient care policies.

C - Direct Services

The purpose of the Rural Health Clinic Services Act is primarily to make available outpatient or ambulatory care of the nature typically provided in a physician's office or outpatient clinic and the like. The regulations specify the services that must be made available by the clinic, including specified types of diagnostic examination, laboratory services, and emergency treatments.

The clinic's laboratory is to be treated as a physician's office for the purpose of licensure and meeting health and safety standards. The listed laboratory services are considered essential for the immediate diagnosis and treatment of the patient. To the extent they can be provided under State and local law, the nine services listed in J61, [Form CMS-30](#), are considered the minimum the clinic should make available through use of its own resources.

If any of these laboratory services cannot be provided at the clinic under State or local law, that laboratory service is not required for certification.

Some clinics are not able to furnish the nine services, even though they may be allowed to do so under State and local law, without involving an arrangement with a Medicare approved laboratory.

Those clinics unable to furnish all nine services directly when allowed to by State and local law should be given deficiencies. Such deficiencies should not be considered sufficiently significant to warrant termination if the clinic has an agreement or arrangement with an approved laboratory to furnish the basic laboratory service it does not furnish directly, especially if the clinic is making an effort to meet this requirement.

§491.10 Condition of Coverage: Patient Health Records

A - Records System

The clinic is to maintain patient health records in accordance with its written policies and procedures. These records are the responsibility of a designated member of the clinic's professional staff and should be maintained for each person receiving health care services. All records should be kept at the clinic site so that they are available when patients may need unscheduled medical care.

Examine a randomly selected sample of health records to determine if appropriate information, as related in J70 of the SRF and 42 CFR 491.10(a)(3), is included. This listing is the minimum requirement for record maintenance. If deficiencies are found while reviewing the records, review additional records to determine the prevalence of these deficiencies.

Record on the SRF the number of records reviewed and deficiencies found, if any, and as questions arise concerning the records, discuss them with the person responsible for record maintenance.

B - Protection of Record Information

The clinic must ensure the confidentiality of the patient's health records and provide safeguards against loss, destruction, or unauthorized use of record information. Ascertain that information regarding the use and removal of records from the clinic and the conditions for release of record information is in the clinic's written policies and procedures. The patient's written consent is necessary before any information not authorized by law may be released.

C - Retention of Records

Review the clinic policy pertaining to the retention of patient health records. This policy reflects the necessity of retaining records at least 6 years from the last entry date or longer if required by State statute.

§491.11 Condition of Coverage: Program Evaluation

An evaluation of a clinic's total operation including the overall organization, administration, policies and procedures covering personnel, fiscal and patient care areas must be done at least annually. This evaluation may be done by the clinic, the group of professional personnel required under 42 CFR 491.9(b)(2), or through arrangement with other appropriate professionals. The surveyor clarifies for the clinic that the State survey does not constitute any part of this program evaluation.

The total evaluation does not have to be done all at once or by the same individuals. It is acceptable to do parts of it throughout the year, and it is not necessary to have all parts of the evaluation done by the same personnel. However, if the evaluation is not done all at once, no more than a year should elapse between evaluating the same parts. For example, a clinic may have its organization, administration, and personnel and fiscal policies evaluated by a health care administrator(s) at the end of each fiscal year; and its utilization of clinic services, clinic records, and health care policies evaluated 6 months later by a group of health care professionals.

If the facility has been in operation for at least a year at the time of the initial survey and has not had an evaluation of its total program, report this as a deficiency. It is incorrect to consider this requirement as not applicable (N/A) in this case.

A facility operating less than a year or in the start-up phase may not have done a program evaluation. However, the clinic should have a written plan that specifies who is to do the evaluation, when and how it is to be done, and what will be covered in the evaluation. What will be covered should be consistent with the requirements of 42 CFR 491.11. Record this information under the explanatory statements on the SRF.

Review dated reports of recent program evaluations to verify that such items are included in these evaluations. When corrective action has been recommended to the clinic, verify that such action has been taken or that there is sufficient evidence indicating the clinic has initiated corrective action.

Table A - Publications of the Bureau of the Census - Maps Displaying Urbanized Areas

The following publications of the Bureau of the Census include maps displaying urbanized areas:

- Bureau of Census publication series (PC(1)A entitled “Characteristics of the Population 1970 Census.” This series is consecutively numbered paperback volumes dealing with individual States. The volumes may be purchased individually, and the following index shows the volume number relating to a specific State:

Parts 1-53 are bound separately; parts 54-58 are bound together in one book.

1	U.S. Summary	30	Nevada
2	Alabama	31	New Hampshire
3	Alaska	32	New Jersey
4	Arizona	33	New Mexico
5	Arkansas	34	New York
6	California	35	North Carolina
7	Colorado	36	North Dakota
8	Connecticut	37	Ohio
9	Delaware	38	Oklahoma
10	District of Columbia	39	Oregon
11	Florida	40	Pennsylvania
12	Georgia	41	Rhode Island
13	Hawaii	42	South Carolina
14	Idaho	43	South Dakota
15	Illinois	44	Tennessee
16	Indiana	45	Texas
17	Iowa	46	Utah
18	Kansas	47	Vermont
19	Kentucky	48	Virginia
20	Louisiana	49	Washington
21	Maine	50	West Virginia
22	Maryland	51	Wisconsin
23	Massachusetts	52	Wyoming
24	Michigan	53	Puerto Rico
25	Minnesota	54	Guam
26	Mississippi	55	Virgin Islands
27	Missouri	56	American Samoa
28	Montana	57	Canal Zone

29 Nebraska

58 Trust Territory of the
Pacific Islands

- Bureau of the Census publication PC(S1)-106. This is a supplement to the above series. It includes the current definition of an urbanized area and displays maps of 27 additional urbanized areas that were identified under the current definition.
- Bureau of the Census publication PC(SI) -108 entitled "Population and Land Area of Urbanized Areas for the United States 1970 and 1960." This new publication lists all urbanized areas and displays the geographic boundaries of each urbanized area in shaded maps. The cost is \$6.00.

These publications may be ordered from the:

Subscriber Services Division
Bureau of the Census
Room 1121
Building 4
Washington, D.C. 20233.

Table B - Contacts in the Bureau of the Census Regional Offices

Atlanta	Wayne Hall	404-881-2274
Boston	Judith Cohen	617-223-0668
Charlotte, N.C.	Lawrence McNutt	704-372-0711 ext. 438
Chicago	Thomas Moss	312-353-0980
Dallas	Valerie McFarland	214-749-2394
Denver	Jerry O'Donnell	303-234-5825
Detroit	Timothy Jones	313-226-4675
Kansas City	Kenneth Wright	816-374-4601
Los Angeles	E. J. Steinfeld	213-824-7291
New York	James Hsiung	212-264-4730
Philadelphia	David Lewis	215-597-8314
Seattle	Lyle Larson	206-442-7080

Table C - Cities With Boundaries Extending to Rural Populations

The Bureau of the Census has determined that the boundaries of some cities are so extended that they include areas having rural populations. These cities have been identified as “extended cities” and the rural portion of them meets the definition of non-urbanized areas. The following is a listing of extended cities.

I.	Boston	
	Maine	- Auburn City
	Massachusetts	- Fall River city
II.	New York	
	New York	- Rome city
	New Jersey	- Millville city
		Ringwood borough
		Vineland city
III.	Philadelphia	
	Pennsylvania	- Archbald borough
	Virginia	- Chesapeake city
		Virginia Beach city
IV.	Atlanta	
	Alabama	- Madison town
	Florida	- Jacksonville city
		Miramar city
		West Palm Beach city
	South Carolina	- Columbia city
	Tennessee	- Memphis city
	Nashville	- Davidson city
V.	Chicago	
	Indiana	- Indianapolis city
	Minnesota	- Apple Valley village
		Blane city
		Cottage Grove village
		Eden Prairie village
		Inver Grove Heights village

Lake Elmo village
Lakeville village
Lino Lakes village
Maple Grove village
Medina village
Minnestrista village
Savage village
Woodbury village

Wisconsin

- Mequon city
- Muskego city

VI.

Dallas

Louisiana

Oklahoma

- New Orleans city
- Broken Arrow city
- Edmond city
- Jones town
- Moore city
- Norman city
- Oklahoma City city
- Tulsa city

Texas

- Houston city
- League city
- Texas City city
- Euless village

VII.

Kansas City

Iowa

Kansas

Missouri

- Davenport city
- Waterloo city
- Leawood city
- Overland Park city
- Kansas City city
- Lee's Summit city
- Liberty city

VIII. **Denver**

None

IX. **San Francisco**

Arizona

- Scottsdale city

California

- Fremont city

Hayward city

Palo Alto city

Roseville city

San Diego city

San Jose city

Union City city

X. **Seattle**

None

Transmittals Issued for this Appendix

Rev #	Issue Date	Subject	Impl Date	CR#
R137SOM	04/01/2015	Revisions to State Operations Manual (SOM) Appendices A, G, L and T related to Hospitals, Rural Health Clinics, Ambulatory Surgical Centers and Swing Beds	03/27/2015	N/A
R01SOM	05/21/2004	Initial Release of Pub 100-07	N/A	N/A