

Basic RHC Compliance For Kentucky



Today's Objectives



Learn the basics of RHC regulations.

Understand the CMS interpretation of the regulations.

Learn what the regulations look like in your clinic.

§ 42 CFR 491.1 through 491.12



<https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-491>

Regulatory Requirements

CFR Title 42, Chapter IV, Subchapter G

Standards and Certification

Part 491 Cert of Certain Health Facilities

Subpart A—Rural Health Clinics: Conditions for Certification;

- § 491.1 Purpose and scope.
- § 491.2 Definitions.
- § 491.3 Certification procedures.
- § 491.4 Compliance with Federal, State and local laws.
- § 491.5 Location of clinic.
- § 491.6 Physical plant and environment.
- § 491.7 Organizational structure.
- § 491.8 Staffing and staff responsibilities.
- § 491.9 Provision of services.
- § 491.10 Patient health records.
- § 491.11 Program evaluation.
- § 491.12 Emergency preparedness.

§ 42 CFR 491.1 through 491.4



491.1 Purpose and scope

491.2 Definitions

491.3 Certification procedures

491.4: Compliance with Federal, State and local laws

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

- **Licensure of clinic.** The clinic or is licensed pursuant to applicable State and local law.
- **Licensure, certification or registration of personnel.** Staff of the clinic are licensed, certified or registered in accordance with applicable State and local laws.

§ 42 CFR 491.5 Location of Clinic



An RHC is located in a rural area that is designated as a shortage area.

Your present location is grandfathered in

Never move your certified clinic without checking the HPSA of the new location

HRSA offers a tool to help you determine if you are rural at:

<https://data.hrsa.gov/tools/shortage-area/by-address>.

Check Rural Health Information Hub for Population at
AM I Rural

<https://www.ruralhealthinfo.org/am-i-rural>

§ 42 CFR 491.5 Location of Clinic



May be permanent or mobile units.

- **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.
- **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, schedule locations.
- **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.

§ 491.6 Physical Plant and Environment

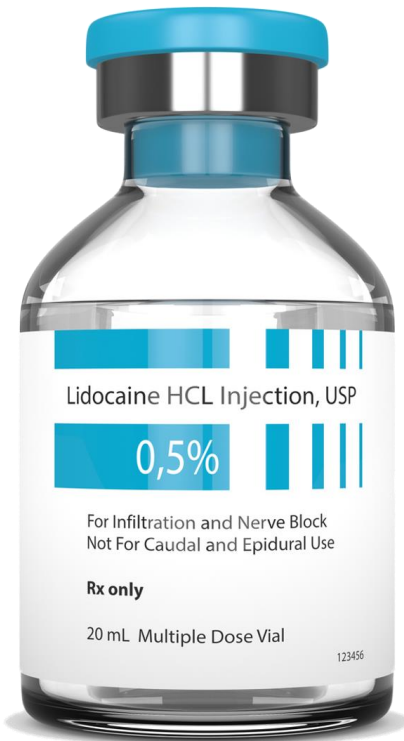


Construction. The clinic is constructed, arranged, and maintained to ensure access to and safety of patients, and provides adequate space for the provision of direct services.

Maintenance. The clinic 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.

Survey Issue: Vials



Single Dose Vials

Multi Dose Vials



28 Days

§ 491.7 Organizational Structure



Basic requirements.

- The clinic is under the medical direction of a physician and has a health care staff that meets the requirements of 491.8. The organization's policies and its lines of authority and responsibilities are clearly set forth in writing.
- The organization's policies and its lines of authority and responsibilities are clearly set forth in writing.

Disclosure. The clinic discloses:

- Its owners
- The person principally responsible for directing the operation of the clinic.
- The person responsible for medical direction.

§ 491.8 Staffing and Staff Responsibilities



Staffing

- Staff includes one or more physicians and one or more NPs or PAs.
- The physician may be the owner, an employee of the clinic, or under agreement..
- The PA or NP, Nurse-Midwife, Clinical Social Worker or Clinical Psychologist may be the owner or an employee.
- RHCs must have at least one PA or NP who is an employee.
- A Physician, NP, PA, Certified Nurse-Midwife, Clinical Social Worker, or Clinical Psychologist is available to furnish patient care services at all times the clinic operates.

This means no patients getting blood draws, weight or BP checks without a provider in the clinic.

- The staff is sufficient to provide the services essential of the clinic.
- An NP, PA, or Certified Nurse-Midwife Is available to furnish patient care services at least 50 percent of the time the RHC operates.

§ 491.8 Staffing and Staff Responsibilities



Physician responsibilities.

The physician performs the following:

- Provides medical direction for the clinic's health care activities and consultation for, and medical supervision of the health care staff
- In conjunction with the PA or NP participates in developing, executing, and periodically reviewing the clinic's written policies and the services provided to Federal program patients
- Periodically reviews the clinic's patient records, provides medical orders, and provides medical care services to the patients of the clinic

What does your physician oversight policy say?

How many charts per month or quarter per NP or PA?

What does your state say?

§ 491.8 Staffing and Staff Responsibilities



Physician assistant and nurse practitioner responsibilities.

The PA or NP members of the clinic's staff:

- Participate in the development, execution and periodic review of the written policies governing the services of the clinic;
- Participate with a physician in a periodic review of the patients' health records.

The PA or NP performs the following functions, to the extent they are not being performed by a physician:

- Provides services in accordance with the clinic's policies;
- Arranges for, or refers patients to, needed services that cannot be provided at the clinic.
- Assures that adequate patient health records are maintained and transferred as required when patients are referred..

§ 491.8(d) Vaccine Mandate Summary



COVID-19 vaccination of staff:

The RHC must develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID-19.

Staff are considered fully vaccinated if it has been 2 weeks or more since they completed a primary vaccination series for COVID-19. The completion of a primary vaccination series for COVID-19 is defined here as the administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine.

- 1) Regardless of clinical responsibility or patient contact, the policies and procedures must apply to the following clinic staff, who provide any care, treatment, or other services for the clinic and its patients:
 - RHC employees;
 - Licensed practitioners;
 - Students, trainees, and volunteers; and
 - Individuals who provide care, treatment, or other services for the clinic and/or its patients, under contract or by other arrangement.

§ 491.8(d) Vaccine Mandate Summary



- 2) The policies and procedures of this section do not apply to the following clinic staff:
- Staff who exclusively provide telehealth or telemedicine services outside of the clinic setting and who do not have any direct contact with patients and other staff.
 - Staff who provide support services for the clinic that are performed exclusively outside of the clinic setting and who do not have any direct contact with patients and other staff.

NO LONGER SURVEYABLE

§ 491.8(d) Vaccine Mandate Summary



3) The policies and procedures must include, at a minimum, the following components:

- A process for ensuring all staff specified in paragraph (d)(1) of this section *(except for those staff who have pending requests for, or who have been granted, exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations)* have received, at a minimum:
 - A single-dose COVID-19 vaccine, or the first dose of the primary vaccination series for a multi-dose COVID-19 vaccine prior to staff providing any care, treatment, or other services for the clinic and its patients;
 - A process for ensuring that all staff specified in paragraph (d)(1) of this section are fully vaccinated for COVID-19, *(except for those staff who have been granted exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations)*

NO LONGER SURVEYABLE

§ 491.9 Provision of Services



Basic requirements.

- All services are furnished in accordance with applicable Federal, State, and local laws
- The clinic is primarily engaged in providing outpatient health services

Primarily engaged is 51% RHC service

- Clinic complies with the laboratory requirements

Patient care policies.

- The clinic's health care services are furnished in accordance written policies which are consistent with applicable State law.
- The policies are developed with the advice of a group of professional personnel;
 - one or more physicians
 - one or more PAs or NPs.
 - one member is not a member of the clinic staff.

§ 491.9 Provision of Services



The policies include:

- A description of the services the clinic furnishes directly and those furnished through agreement or arrangement.
- 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.
- Rules for the storage, handling, and administration of drugs and biologicals

These policies are reviewed by MD, NP or PA and one outside person every two years.

§ 491.9 Provision of Services



Direct Services

- The clinic 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.

§ 491.9 Provision of Services



Laboratory

The RHC provides basic laboratory services essential to the **immediate** diagnosis and treatment of the patient, including:

- Chemical examinations of urine by stick or tablet method or both (including urine ketones);
- Hemoglobin or hematocrit
- Blood glucose
- Examination of stool specimens for occult blood
- Pregnancy tests
- Primary culturing for transmittal to a certified laboratory

§ 491.9 Provision of Services: Emergency



Emergency.

The clinic 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.

- While each category of drugs and biologicals must be considered, all are not required.
- An RHC must have those drugs and biologicals that are necessary to provide emergency care for common life-threatening injuries and acute illnesses.
- The RHC should have written policies and procedures for determining what drugs/biologicals are stored to for emergency care.
- MD and NP/PA sign off on the policy
- They should also be able to provide a complete list of which drugs/biologicals are stored and in what quantities.
- Policy should reflect how refrigerated drugs are managed during a power outage.

§ 491.9 Provision of Services: Emergency



Services provided through agreements or arrangements.

The clinic has agreements or arrangements with one or more providers or suppliers participating under Medicare or Medicaid to furnish other services to its patients, including:

- Inpatient hospital care;
- Physician services (whether furnished in the hospital, the office, the patient's home, a skilled nursing facility, or elsewhere)
- Additional and specialized diagnostic and laboratory services that are not available at the clinic

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

§ 491.10 Patient Health Records



Records System.

The clinic or center maintains a clinical record system in accordance with written policies and procedures.

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



§ 491.10 Patient Health Records



A complete record includes, as applicable:

- Identification and social data
- Evidence of consent forms
- Pertinent medical history
- Assessment of the health status and health care needs of the patient
- A brief summary of the episode, disposition
- Instructions to the patient
- Reports of physical examinations, diagnostic and laboratory test results, and consultative findings
- All physician's orders, reports of treatments and medications, and other pertinent information necessary to monitor the patient's progress
- Signatures of the physician or other health care professional

§ 491.10 Patient Health Records



Protection of record information:

- The clinic maintains the confidentiality of record information and provides safeguards against loss, destruction or unauthorized use.
- Written policies and procedures govern the use and removal of records from the clinic and the conditions for release of information.
- The patient's written consent is required for release of information not authorized to be released without such consent.

Retention of records.

- The records are retained for at least 6 years from date of last entry, and longer if required by State statute.

Survey Issue: Incomplete Charts



42 CFR § 491.10 - Patient health records

- 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
- Reports of physical examinations, diagnostic and laboratory test results, and consultative findings;
- All physician's orders, reports of treatments and medications, and other pertinent information necessary to monitor the patient's progress;
- Signatures of the physician or other health care professional.

§ 491.10 Patient Health Records



| Medical Record Audit Tool Insert "Y" (YES) if evidence is found, "N" (NO) if evidence of is missing, or "NA" if not applicable. Insert an "M" next the patient number if the patient is a minor child. | | | | | | | | |
|---|--------------------------|--------------------------|-----------------|--------------------------------------|--------------------------------|---------------------------------|--|------------------------------|
| Patient | Patient ID & Social Data | Written Consent to Treat | Medical History | Health Status & Patient Health Needs | Summary & Patient Instructions | Labs Diagnostics & Consult Info | Physicians' Orders & Treatments & Medications (includes allergies) | Signature of Provider & Date |
| 1. | | | | | | | | |
| 2. | | | | | | | | |
| 3. | | | | | | | | |
| 3' | | | | | | | | |
| 5' | | | | | | | | |

§ 491.11 Program Evaluation



The clinic carries out, or arranges for, a biennial evaluation of its total program.

The evaluation includes review of:

- The utilization of clinic services, including at least the number of patients served and the volume of services
- A representative sample of both active and closed clinical records
- The clinic's health care policies

The purpose of the evaluation is to determine whether:

- The utilization of services was appropriate;
- The established policies were followed
- Any changes are needed

The clinic staff considers the findings of the evaluation and takes corrective action if necessary.

§ 491.12 Emergency Preparedness



§ 491.12 Emergency Preparedness



Emergency plan. The RHC must develop and maintain an emergency preparedness plan that must be reviewed and updated at least every 2 years. The plan must do all of the following:

- 1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.
- 2) Include strategies for addressing emergency events identified by the risk assessment.
- 3) Address patient population, including, but not limited to, the type of services the RHC has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.
- 4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or an emergency situation.

§ 491.12 Emergency Preparedness



Policies and procedures. The clinic must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth at least every 2 years.

At a minimum, the policies and procedures must address the following:

- Safe evacuation from the clinic, which includes appropriate placement of exit signs; staff responsibilities and needs of the patients.
- A means to shelter in place for patients, staff, and volunteers who remain in the facility.
- A system of medical documentation that preserves patient information, protects confidentiality of patient information, and secures and maintains the availability of records.
- The use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of State and Federally designated health care professionals to address surge needs during an emergency.

§ 491.12 Emergency Preparedness



Communication plan.

The communication plan must include all of the following:

- Names and contact information for the following:
 - Staff.
 - Entities providing services under arrangement.
 - Patients' physicians.
 - Other RRHC or FQHC
 - Volunteers.

Contact information for the following:

- Federal, State, tribal, regional, and local emergency preparedness staff.
- Other sources of assistance.

A means of providing information about the general condition and location of patients under the facility's care

A means of providing information about the RHC needs, and its ability to provide assistance, to the authority having jurisdiction or the Incident Command Center.

§ 491.12 Emergency Preparedness



Training and testing. The clinic must develop and maintain an emergency preparedness training and testing program that is based on its emergency plan.

Training program. The clinic must do all of the following:

- Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles;
 - Provide emergency preparedness training at least every 2 years.
 - Maintain documentation of the training.
 - Demonstrate staff knowledge of emergency procedures.
 - If the emergency preparedness policies and procedures are significantly updated, the clinic must conduct training on the updated policies and procedures.

§ 491.12 Emergency Preparedness



Testing. The clinic must conduct exercises to test the emergency plan at least annually.

The clinic must do the following:

- Participate in a full-scale exercise that is community-based every 2 years; or
- When a community-based exercise is not accessible, an individual, facility-based functional exercise every 2 years; or
- If the clinic experiences an actual natural or man-made emergency that requires activation of the emergency plan, the clinic is exempt from engaging in its next required full-scale community-based or individual, facility-based functional exercise following the onset of the emergency event.

§ 491.12 Emergency Preparedness



Conduct an additional exercise every 2 years, opposite the year the full-scale or functional exercise:

- A second full-scale exercise that is community-based or an individual, facility-based functional exercise; or
- A mock disaster drill; or
- A tabletop exercise or workshop that is led by a facilitator and includes a group discussion, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

Analyze the clinic's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the clinic's emergency plan, as needed.

§ 491.12 Emergency Preparedness



Integrated healthcare systems. If a clinic is part of a healthcare system consisting of multiple separately certified healthcare facilities that elects to have a unified and integrated emergency preparedness program, the RHC may choose to participate in the healthcare system's coordinated emergency preparedness program.

If elected, the unified and integrated emergency preparedness program must do all of the following:

- Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program.
- Be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered.
- Demonstrate that each separately certified facility is capable of actively using the unified and integrated emergency preparedness program and is in compliance with the program.

§ 491.12 Emergency Preparedness



Include a unified and integrated emergency plan that meets the requirements of paragraphs (a)(2),(3), and (4) of this section. The unified and integrated emergency plan must also be based on and include all of the following:

- A documented community-based risk assessment, utilizing an all-hazards approach
- A documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach
- Include integrated policies and procedures that meet the requirements set forth in paragraph (b) of this section, a coordinated communication plan, and training and testing programs that meet the requirements of paragraphs (c) and (d) of this section, respectively.

Appendix G



State Operations Manual Appendix G - Guidance for Surveyors: Rural Health Clinics (RHCs)

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(Rev. 200, 02-21-20)

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Rural Health Clinic Survey Protocol

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State Operations Manual (SOM) Appendix G –
(Guidance for Surveyors: Rural Health Clinics)
This document contains detailed interpretive
guidelines for RHC survey and certification than
the previous version

What to Expect on Survey Day



- RHC surveys are unannounced so be prepared!
- Managers share your knowledge with staff
- Most surveys take between 6 to 9 hours per clinic depending on the size and number of providers/staff. If multiple clinics are being surveyed at the same time, the surveyor or survey team will inform you upon arrival of the number of days they expect to be onsite.
- Remember that having easy access to policies, personnel records and medical records as they are requested will allow the surveyor to proceed without delay.
- Once complete, the surveyor will conduct an exit interview to discuss the survey findings.

QUESTIONS?

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