

# RHC REGULATIONS AND COMPLIANCE

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*Promoting Access to Health Care*

# OBJECTIVES

- Attendees will gain an understanding of key items surveyors require to see documentation in regards to compliance.
- Attendees will gain an understanding of preparing an operating RHC manual to assist with managing the RHC
- Attendees will gain an understanding of maintaining this operating RHC manual



# COMPLIANCE

- New RHC applicants are expected to have all RHC requirements implemented at the time the surveyor presents at the clinic as a standard of practice.
- Established RHC clinics are expected to follow and maintain RHC regulations as a standard of practice.



# COMPLIANCE TOOLS

- Basic tools to be utilized to better understand RHC Compliance.....
  - 42 CFR 491..... \*review the electronic version
  - CMS Form 30
  - State Operating Manual
  - Federal & State OSHA Guidelines
  - Deeming entity Guidelines
  - Appendix G



## CONDITION VS STANDARD

- Subpart A of 42 CFR 491 sets forth the conditions that RHCs must meet in order to qualify for certification under Medicare and Medicaid.
- Standards are the clinic operating processes. You may receive deficiencies in Standards such as expired medications, etc.
- Conditions are severe deficiencies. You may receive deficiencies in Conditions such as not having a midlevel 50%, policies are not current or no Medical Director. No current annual meeting.



# CERTIFICATION/RECERTIFICATION

- Certification is the initial application process to become a RHC.
- Recertification is the continual review of compliance that the clinic is functioning under federal regulations as a RHC.
- Both visits are unannounced.



# SURVEY ENTITIES

- The RHC Survey for new certification is always considered a Tier IV.
- If a clinic is already a certified RHC, then the State will continue to conduct recertification surveys.
- Many States no longer complete initial certification surveys and the clinic must utilize a deeming entity.
  - The Compliance Team
  - AAAASF



42 CFR 491.5

## **Location of the Clinic**





# RHC REGULATIONS

## § 491.5 Location of Clinic

§ 491.5(d) The **facility meets the shortage area** requirements under one of the following criteria.



## HAVE AVAILABLE

- Ownership page
- Copy of current HPSA
- Copy of CMS initial/final tie-in notice
- Copy of last survey document (if available)



42 CFR 491.6

# Physical Plant and Environment



# RHC REGULATIONS

## § 491.6 Physical plant and environment.

- (a) *Construction.* The clinic or center is constructed, arranged, and maintained to **ensure 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:



# RHC REGULATIONS

- (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**.



## HAVE AVAILABLE

- ANNUAL preventive maintenance log/documentation, calibration, etc.
- Policies on annual check, how to handle new items, broken items, disposal of items
- Cleaning/Disinfecting policies/logs/Contract
- Spore check reports/Radiation reports
- Policies for drugs/biologicals
  - Storage, disposal, handling, power outage



## HAVE AVAILABLE

- Training documentation
  - Fire, tornado, inclement weather, emergency evacuation, biohazard, Safety, etc. AED
- Floor plan of clinic/identify routes of escape
- SDS sheets
- Policy for sanitation/cleaning of instruments that are not disposable.
- Evidence of current BLS certificates



## HAVE AVAILABLE

- Policy for Samples (if needed) and template of sample distribution log.
- Sample template of refrigerator temp log.
- Evidence of proficiency testing
- Equipment manuals
- Control logs





# ADDITIONAL HELPS

## ○ ADDITIONAL HELPS

- Refrigerators labeled.
  - Food Only
  - Meds Only
  - Labs Only
- DO NOT UNPLUG signs for refrigerators.
- Notice on how to handle medications during power outage.
- \*\*Copy of policy available regarding handling medications during power outage. Also recommend to place copy of policy of front of medication refrigerator

42 CFR 491.7 & 491.8

# **Organizational Structure and Staffing Responsibilities**



# RHC REGULATIONS

## § 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.



# RHC REGULATIONS

## (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]



# RHC REGULATIONS

## § 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.
- 

## RHC REGULATIONS

- (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. (has been changed to 50%)



# RHC REGULATIONS

## (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.



## RHC REGULATIONS

- (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.**





## RHC REGULATIONS

(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.

**This has changed to State specific requirements.**



# RHC REGULATIONS

- The Medical Director **MUST** be able to fulfill all of the other requirements listed.



## RHC REGULATIONS

(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.**



## RHC REGULATIONS

(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]



# HAVE AVAILABLE

- Ownership Page
- Current Organizational Chart
  - Be sure it reflects and includes the position of Medical Director
- Job Descriptions for ALL positions reflected in the Organizational chart.
- Current license/certifications for providers and required staff.
- If the physician is unavailable, there should be a written plan for remote consultation and transfer of patients who require further evaluation and treatment.
- Posted clinic hours/provider hours



## HAVE AVAILABLE

- Documentation to evidence participation in policy review.
- Documentation to evidence chart review and fulfillment of oversight requirements.
- Copies of completed/signed collaboration agreements, waivers, contracts, guidelines of practice limitations.
- Referral and tracking policies/ forms/logs, etc
- Policy on assuring provider is licensed, approved (credentialing--this is not insurance)
- MOA's



42 CFR 491.9

# Provision of Services



# RHC REGULATIONS

## § 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.





# RHC REGULATIONS

## (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.**



# RHC REGULATIONS

(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.**



## RHC REGULATIONS

(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.



## RHC REGULATIONS

(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.



# RHC REGULATIONS

(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.



## WHAT TO HAVE

- Policy stating all services rendered within the clinic, list all labs offered, and list name of outside lab.
- Policy for handling emergencies, maintaining emergency medications, handling Schedule II medications (if needed).
- Agreements with outside labs, hospitals, etc. for services not rendered within the clinic setting.
- Have a copy of the CLIA certificate and Waste Management agreement.



## WHAT TO HAVE

- Signatures on policies—with policy manual
  - Minimum, Medical Director, Non Physician providers and Community Member.
- Be sure chart contains required evidence of patient care
  - Also, consent to treat and informed consent. (copy of forms in the manual)
  - Continuity of care



CFR 42 491.10

# Medical Records Requirements





# RHC REGULATIONS

## § 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.



## RHC REGULATIONS

(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.**



# RHC REGULATIONS

(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]



# WHAT TO HAVE

- Various Medical Records Policies/Forms used
  - Contents of information within the chart
  - Person responsible for Medical Records
  - Confidentiality of record
  - Protection of record
  - Use and Removal of record
  - Release of information
  - Storage of record/Retention
  - Minimum necessary Use
  - Complaints
  - Fax and email (forms)



42 CFR 491.11

# Annual Program Evaluation



# RHC REGULATIONS

## § 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.**



# RHC REGULATIONS

(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]



## WHAT TO HAVE

- Policy for conducting Annual meeting
  - Sample of agenda
- Policy for review of policies
- Policy for review of active and inactive records
- QA PI program
- Copy of Annual meeting minutes
- Copy of your compliance plan





