
RHC PROGRAM EVALUATION 2021

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PRESENTATION TOPICS

- ✓ RHC Program Evaluation
- ✓ Differences between Surveying Agencies/Organizations
- ✓ What/Who/When/Why/How to do the Program Evaluation
- ✓ Compliance Components



THE RULES - 42 CFR 491

This is the Code of Federal Regulations (CFR) which stipulates Rural Health Clinics' conditions for certification.

http://www.cms.gov/Regulations-and-Guidance/Legislation/CFCsAndCoPs/RHC_FQHC.html



RURAL HEALTH CLINIC REQUIREMENTS

§491.1-3 Purpose-Scope; Definitions; Certification Procedures

§491.4 Compliance with Federal, State and local laws

§491.5 Condition for Certification: Location of clinic

§491.6 Condition for Certification: Physical plant and environment

§491.7 Condition for Certification: Organizational structure

§491.8 Condition for Certification: Staffing and staff responsibilities

§491.9 Condition for Certification: Provision of services

§491.10 Condition for Certification: Patient health records

§491.11 Condition for Certification: Program evaluation



WHO DOES RHC SURVEYS?

CMS interprets and enforces the federal RHC regulations. CMS approves or denies the state's recommendations. Most states now direct RHCs to Accreditation Organizations for initial survey.

Although an RHC may be accredited (e.g. through TCT/AAAASF), all RHCs are still subject to survey by the State Department of Health, CMS personnel (this would be bad), or the Postal Inspector (that is usually much worse).

A State Dept of Health survey for an Accredited RHC is a rarity, unless there is a complaint.



AAAASF AND COMPLIANCE TEAM

- ✓ Outside accreditation agencies approved by CMS to perform RHC survey and re-survey.
- ✓ There is an additional expense.
- ✓ An RHC has been “accredited” if one of these entities did the survey.
- ✓ An RHC is “certified” if the state does the survey.



COMPLIANCE STANDARDS

State surveyors may have slightly different standards or enforce interpretive guidelines differently than The Compliance Team or AAAASF surveyors. Examples where these may differ:

- ✓ Corporate Compliance Plans
- ✓ On-Site Physician and Medical Director Requirements
- ✓ Emergency Drug Requirements



RHC INSPECTION GUIDANCE

Social Security Act Section 1861(aa)(2)(K)

[42 CFR §405.2402](#) (Basic Requirements)

[42 CFR Part 491, Subpart A](#) (Conditions for Participation!)

[State Operations Manual](#) – Appendix G (Surveyor Guidance)

Accreditation Organization Standards:

[AAAASF](#)

[The Compliance Team](#)



STATE OPERATIONS MANUAL

The SOM is the surveyor's guide to an RHC inspection. It contains detailed explanation of requirements for each compliance component.

We have a new version effective 2.21.2020, with additional interpretations in the process of being released.

This document can be found at:

www.cms.gov/manuals/Downloads/som107ap_g_rhc.pdf



§481.11 PROGRAM EVALUATION

J-0161 §491.11 (*Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20*)

- (a) The clinic . . . carries out, or arranges for, a *biennial* evaluation of its total program.
- (b) The evaluation includes review of:
 - (1) The utilization of clinic 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 health care policies.
- (c) The purpose of the review is to ensure:
 - (1) The utilization of services was appropriate;
 - (2) The established policies were followed; and
 - (3) Any changes are needed.



HOW OFTEN? BY WHOM?

How Often?

The clinic's program evaluation must be reviewed at least biennially.

By Whom?

This evaluation may be done by RHC staff or through arrangement *with other appropriate professionals*. The RHC must have documentation of who conducts the review or portions of the review, and what their qualifications are to do so.



ANNUAL EVALUATION - PARTICIPANTS

Make sure the Program Evaluation policy includes an Executive Committee, which includes:

- Medical Director
- NP/PA
- Administrator or Office Manager
- RHC Consultant or Other Professional
- Other personnel as deemed appropriate.



WHAT DO WE INCLUDE?

- ✓ “The evaluation must include, at a minimum, the number of patients served, and the volume of services provided.”
- ✓ “The evaluation should be able to determine whether the RHC provides appropriate types and volume of services based upon the needs of its patient population.
- ✓ It should also be able to evaluate whether RHC patient policies were followed and whether or not changes to the policies or to procedures are warranted.”



WERE PATIENT CARE POLICIES FOLLOWED?

The review also must evaluate whether all personnel providing direct patient care adhere to the RHC's patient care policies.

The evaluation of whether the RHC's patient care policies were followed may be conducted by an MD/DO, a non-physician practitioner, an RN, or other personnel who meet the RHC's qualifications criteria.



VOLUME AND SCOPE OF SERVICES

“The evaluation must include, at a minimum, the number of patients served and the volume of services provided.”

- ✓ Top 20 CPT Codes
- ✓ Top 20 Dx Codes
- ✓ Payer Mix



§491.11 Program Evaluation

“The evaluation includes review of –

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

SOM App G: The evaluation must also include a review of a representative sample of both active and closed clinical records of RHC patients. The sample must also include at least 5 percent of the RHC’s current patients or 50 records, whichever is less.

ACTIVE AND CLOSED MEDICAL RECORDS

“A representative sample of both *active and closed* clinical records;”

Closed = Patient Deceased or Not Seen in > 3 years.



ACTIVE AND CLOSED MEDICAL RECORDS

“A representative sample of both *active and closed* clinical records;”

Suggestion: Pull One Inactive Chart per Month or Quarter or review 5-10 inactive charts annually.



MEDICAL RECORD CONTENT

- ✓ Identification and Social Data
- ✓ Evidence of Consent Forms
- ✓ Pertinent Medical History
- ✓ Assessment of the Health Status and Health Care Needs
- ✓ Episodic Summary, Disposition, and Instructions to the Patient;
- ✓ Reports of Physical Examinations,
- ✓ Diagnostic and Laboratory Test Results,
- ✓ Consultative Findings



Medical Record Chart Audit

Audit Date:

Patient/ Med Record #	Completed Registration	Patient Information	Consent forms Signed/Dated	Problem List Current	Medication List Current	Assessments/ Findings	Progress Notes	Entries Signed/Dated	Reports Signed	HIPAA	Active/ Inactive
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MEDICAL RECORD REVIEW

- ✓ This is a quantitative review “for completeness”.
- ✓ This is not a qualitative review, or one that assesses medical decision making.

PRO TIP: Lack of Patient Consent forms account for 99% of Medical Record deficiencies.



DETERMINE WHAT CHANGES ARE NEEDED ACTION TAKEN.

- (c) The purpose of the review is to determine whether:**
- (3) Any changes are needed.**

PRO-TIP: The Biennial Evaluation is not complete without Plans of Correction for identified deficiencies.



A MEETING IS NOT REQUIRED; A DOCUMENT IS.

The RHC should be reviewed to determine that all RHC Compliance Standards are met.

A final document, signed by participants, must be available for surveyors.



QUALITY ASSURANCE (QAPI)

“If a RHC has developed a QAPI program and that program meets/exceeds the regulatory requirements for a Program Evaluation, the QAPI program would be acceptable.”



COMPLIANCE WITH FEDERAL, STATE, LOCAL LAWS

- ✓ The clinic must be in compliance with federal RHC regulations and Medicare law. (J3)
- ✓ The clinic and staff are licensed pursuant to applicable State and local law. (J3 and J4)
- ✓ The clinic building meets applicable building and fire codes. (J5)



CORPORATE COMPLIANCE PRACTICES - AO

Corporate Compliance Practices - AO	
Copy of Corporate Compliance Program	Evidence of Quality improvement techniques: Monitoring and auditing, problem identification, investigation and corrective action.
Written Policies and Procedures	Evidence of Clinic Risk Assessment that must address areas in which the clinic is vulnerable.
Designated Corporate Compliance Officer	Annual Fraud, Waste, Abuse training
Evidence of Internal communication system and methods for reporting non-compliance.	Employee Background Checks (if required by State or Corporate Policy)
OIG Exclusion List	Disciplinary and corrective actions when non-compliance is suspected



EVIDENCE OF CORPORATE COMPLIANCE

- ✓ The clinic/organization has been free of sanctions for a period of at least 2 years.
- ✓ The clinic prohibits employment/contracting with individuals or companies, which have been convicted of a criminal felony offense related to healthcare.
- ✓ Verification required of individuals through the OIG exclusion database, www.oig.hhs.gov.
- ✓ Evidence of the process & documentation upon hire and re-verification at a minimum annually.



CLINIC SIGNAGE – OFFICE HOURS

- ✓ Exterior clinic signage and the clinic name should match what has been reported on the CMS-855A.
- ✓ Clinic office hours should be posted on the outside of the clinic.



WAITING ROOM CONSIDERATIONS

- ✓ Patient Rights & Responsibilities & HIPAA
- ✓ If provider-based, are patients aware of the parent entity. If so, how?
- ✓ Are patient communications in the waiting/reception area HIPAA compliant?
- ✓ Are clinic hours posted, visible from outside?



LOCATION OF CLINIC (J6 THRU J18)

Must be in HPSA or MUA - updated within the last four years

<https://datawarehouse.hrsa.gov/tools/analyzers/hpsafind.aspx>

Must be rural – Use this search tool <https://www.ruralhealthinfo.org/am-i-rural>

The location may be permanent or mobile



AM I RURAL?

Am I Rural? – Report

Report produced by the Rural Health Information Hub on 10/12/21.


Location

Report Address:
Comanche, OK *

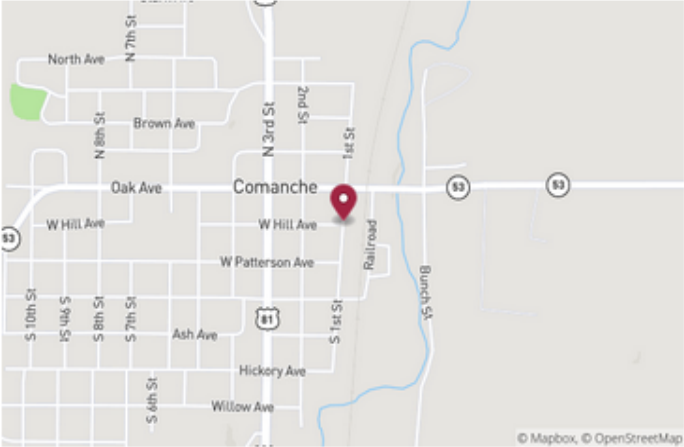
Latitude: 34.3679
Longitude: -97.96145

Census Tract: 40137001100
(Based on 2019 boundaries)

County:
Stephens County, OK



* Report is for a specific point in Comanche, OK. Results may not be the same for all points in Comanche, OK.



© Mapbox, © OpenStreetMap

Shortage Designations		
Health Professional Shortage Areas		
Primary Care	YES	<ul style="list-style-type: none">• Name: LI - Stephens County• Date of Designation: April 7, 2016• Last Update: August 6, 2021
Dental Care	YES	<ul style="list-style-type: none">• Name: LI - Stephens County• Date of Designation: December 28, 2015• Last Update: September 8, 2021
Mental Health	YES	<ul style="list-style-type: none">• Name: LI - MHCA 8/Jim Taliaferro• Date of Designation: June 24, 2013• Last Update: August 18, 2021



ORGANIZATIONAL STRUCTURE

Define the organizational structure of the clinic.

Develop an organizational chart that reflects the clinic.

If the clinic is owned/managed by a hospital – that should be part of the chart.



RHC STAFFING REQUIREMENTS (J29)

The clinic is under the direction of a physician. (J31)

The clinic must employ one or more nurse practitioners, physician assistants, or nurse- midwife. (J31)

The NP/PA must be available 50% of the time the clinic is open. (J41)



MEDICAL EMERGENCIES

The clinic provides medical emergency procedures as a first response to common life-threatening injuries and acute illness and has:
(§491.9(c)(3)).

Available treatment includes the use of drugs & biologicals commonly used in life saving procedures *such as analgesics, anesthetics (local), antibiotics, anticonvulsants, antidotes, emetics, serums and toxoids.*
(§491.9(c)(3)).



EMERGENCY MEDICATION REQUIREMENTS

It is the Medical Director and/or providers responsibility to determine the appropriate contents of the emergency box.

The contents of the emergency box should be listed on the exterior and in a written policy.

The clinic's emergency equipment and drugs are organized in one place.

One oxygen tank with Ambu bag-valve-mask ventilation supplies attached and appropriate to the type of patient population served.

All licensed and certified patient care personnel must have at a minimum, Basic Life Support Certification.



MEDICAL EMERGENCY PROVISIONS

Medication - Example	
Analgesics - ASA, Tylenol, Aleve	Antidotes - EpiPenR and EpiPenR
Anesthetics - Xylocaine, Lidocaine	Emetics - Activated Charcoal/911
Antibiotics - Rocephin	Serums/toxoids - Vaccines, Tetanus
Anticonvulsants - Valium, Cerebyx	

The Current Requirement is the Medical Director has reviewed each of the categories and determined which drugs are appropriate to store in the RHC. The determination must be made based on RHC patient population, clinic history, and proximity of Emergency Services.



PHYSICAL PLANT: PATIENT CARE EQUIPMENT AND DRUGS

The clinic has a preventive maintenance program to ensure that:

- ✓ All essential mechanical, electrical and patient care equipment is maintained in safe operating condition;
- ✓ Drugs and biologicals are appropriately stored;
- ✓ The premises are clean and orderly.



BIO-MEDICAL EQUIPMENT INSPECTION (PICTURE DATE: 3.8.2017)

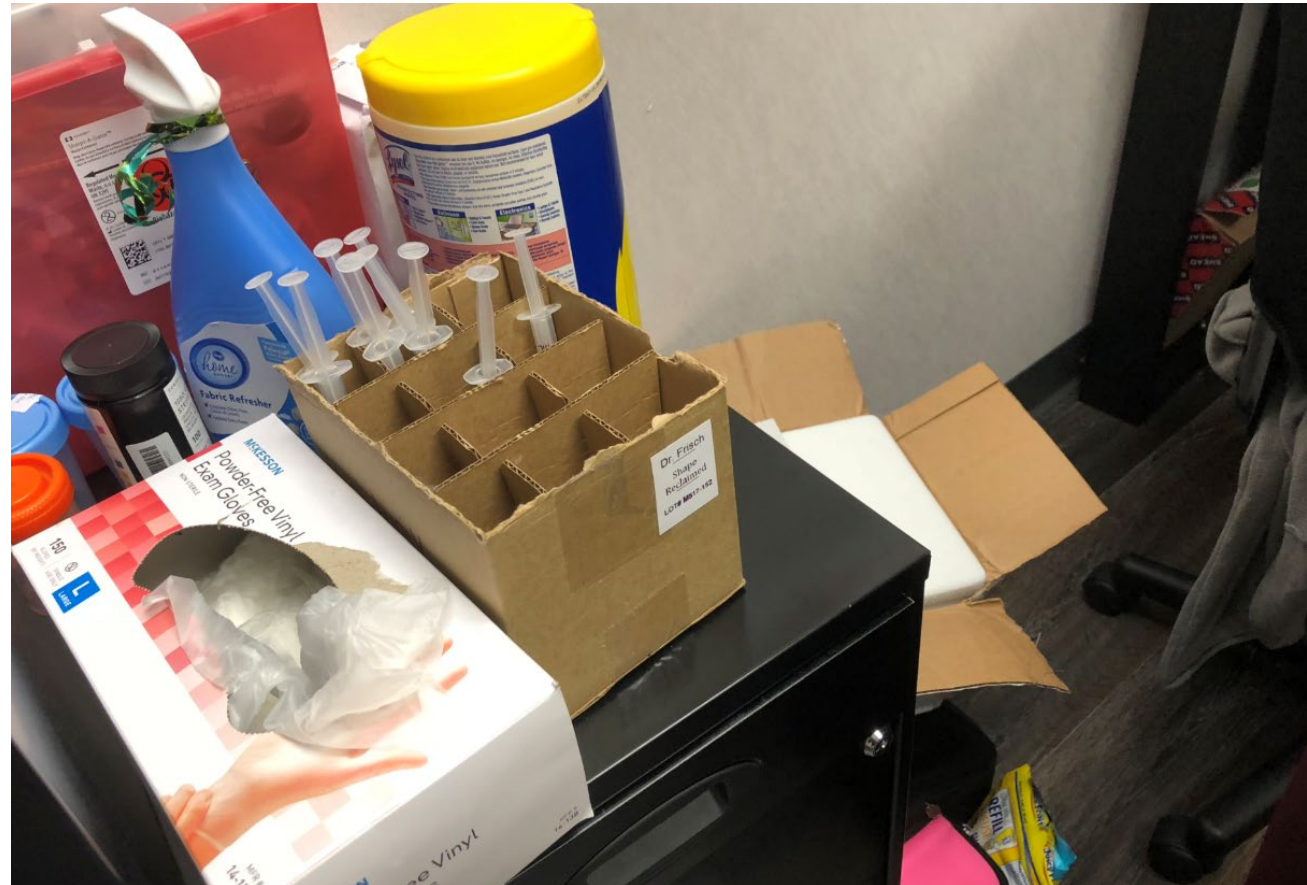
Ensure that the clinic has policies and documentation for equipment maintenance and inspection. (J22)

An annual bio-medical equipment inspection by is the gold standard.



DRUGS AND BIOLOGICALS

Drugs and biologicals are appropriately stored (J23)



DRUG AND BIOLOGICAL STORAGE TO DO

- ✓ Drugs should be stored in the original manufacturers packaging.
- ✓ Schedules for ensuring that all expired drugs are monitored and removed must be maintained.
- ✓ Drug labeling should be legible and clear.
- ✓ Multi-use vials marked w/ date of opening and disposed 28 days after opening (CDC).
- ✓ Lot numbers should be recorded with receipt *and* distribution of samples.



FACILITY APPEARANCE

The term “a clean and orderly environment” is explicit in the regulation.

A neat, well-kept appearance makes a *dramatic* difference in the success of any type of inspection.



THE PREMISES ARE CLEAN AND TIDY. (J24)



THE PREMISES ARE CLEAN AND TIDY. (J24)



CLEAN AND TIDY – THAT’S A WINNER!



PROVISION OF SERVICES – LAB (J61)

An RHC must have the *ability to perform the following lab tests:*

- Blood Sugar
- Hemoglobin or Hematocrit
- Pregnancy
- Urinalysis – Dipstick
- Occult Blood



EMERGENCY PLAN

- ✓ The clinic's Emergency Preparedness (EP) plan needs to be reviewed and updated at least every 2 years as opposed to annually.
- ✓ The clinic's EP policies and procedures are reviewed and updated at a minimum at least every 2 years as opposed to annually.
- ✓ The clinic's EP communication plan is reviewed and updated, at a minimum at least every 2 year as opposed to annually.
- ✓ The clinic's EP training and testing program is reviewed and updated, at a minimum at least every 2 years as opposed to annually.



EMERGENCY PLAN

- ✓ Clinics should ensure their EP programs are aligned with their State and local emergency plans/pandemic plans.
- ✓ The EP plan must be in writing.
- ✓ Clinics are encouraged to have policies that address their ability to respond to a surge in patients. As required, these policies and procedures must be aligned with a facility's risk assessment and should include planning for EIDs. For example, clinics are encouraged to consider development of policies and procedures that could be implemented during an emergency to reduce non-essential healthcare visits and slow surge within the facility,



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PRESENTATION RESOURCES

Medicare Benefit Policy Manual – Chapter 13 Rural Health Clinics

“The Compliance Team: Appendix Z Update Simplified.”

thecomplianceteam.org/appendix-z-update-simplified/. June 1, 2021.

Accessed 10.12.2021.

“State Operations Manual Appendix G.” www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_g_rhc.pdf. (Rev.

200, 02-21-20). Accessed 10.12.2021



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