



Rural Health Clinic Compliance

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Presentation Topics

- Components of RHC Regulations and Inspections
- Annual Requirements
- RHC regulatory resources



Presentation Objective #1

Help navigate the mysterious world of why we have to do what we do as a Rural Health Clinic, who says, and where it's written!



Presentation Objective #2

Show how to translate those darn RHC regulations into something meaningful to us humans.



Presentation Objective #3

Learn what inspectors are looking for and what documents inform the survey.



So first – Who's in charge?

Short Answer – CMS

The State Office of Rural Health functions as an agent of CMS for the purpose of an RHC survey. CMS interprets the federal RHC regulations

CMS makes the rules – The state office interprets them. CMS signs off on the interpretation.



The Rules - 42 CFR 491.1

This is the Code of Federal Regulations (CFR) which stipulates rural health clinics' conditions for certification.

Cut and Paste this into your browser:

http://www.access.gpo.gov/nara/cfr/waisidx_04/42cfr491_04.html



Rural Health Clinic Requirements

- Compliance with Federal, State, and Local laws
- Physical Plant and Environment
- Staffing (organization)
- Provision of Services
- Defined Organizational Structure
- Policy and Procedure Manual
- Medical Records
- Annual Evaluation (vs. Quality Assurance)



State Operations Manual

- The SOM is the surveyor's guide to an RHC inspection.
- It contains detailed explanation of requirements for each compliance component.
- This document can be found at:

http://cms.hhs.gov/manuals/Downloads/som107ap_g_rhc.pdf



HRSA Sample Policy Manual

- Part of HRSA – Starting an RHC/ A how-to manual
- Excellent resource for sample language
- Contains samples of each section of policy manual
- Health Resource and Services Administration
- A link to the manual:

<ftp://ftp.hrsa.gov/ruralhealth/RHCmanual1.pdf>



RHC Inspections

- State Operations Manual
- Rural Health Clinic Regulations and Survey Report
- Annual Requirements for RHCs
- How to avoid deficiencies



Compliance with Federal, State, Local Laws

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



Physical Plant and Environment

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.



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.



Physical Plant: Emergency Preparedness

Emergency procedures. The clinic assures the safety of patients in case of nonmedical emergencies by:

- Training staff in handling emergencies;
- Placing exit signs in appropriate locations;
- Taking other appropriate measures that are consistent with the particular conditions of the area in which the clinic is located.



Bio-medical Equipment Inspection

Ensure that the clinic has policies and documentation for equipment maintenance and inspection. An annual bio-medical equipment inspection is the gold standard.



Drug and Biological Storage

- LOCK all drug storage locations!
- Make sure all expired drugs are removed.
- Document/schedule this activity monthly.
- Documentation of review/removal activity should be available for review.
- Multi-use vials marked w/ date of opening and disposed 30 days after opening.



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.



Emergency Preparedness

- Arrange an Annual Fire Inspection.
- Document Fire/Natural Disaster In-services.
- Post facility layout diagrams and exit routes.
- Assess emergencies other than just fire (earthquake, tornado, etc.)
- CPR certification for clinical (and administrative?) should be completed.



RHC Staffing Requirements

- The clinic must have one or more physicians on staff.
- The clinic must employ one or more nurse practitioners, physician assistants, or nurse-midwife.
- The NP/PA must be available 50% of the time the clinic is open.



RHC Staffing Requirements (Cont'd)

- A provider must be available to furnish services at all times during clinic hours.
- One clinic physician must function as the Medical Director.



Medical Director Responsibilities

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.



RHC Staffing Recommendations

- Do not open the clinic if no provider is ***present***.
- Post Clinic hours.
- Make sure a provider (Doctor/APN/PA) is present during those hours.
- Make sure the NP/PA staffing is 50% of posted clinic hours.
- If NP/PA clinic, make sure the Medical Director is on-site every two weeks, provides *some* patient care, and signs charts.



Collaborative Physician Requirements

- The responsibilities of the clinic Medical Director are different than the requirements for collaboration with Nurse Practitioners and Physician Assistants.
- Reviewing and counter-signing charts for the NP/PA is a requirement collaborative agreement.



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.



Provision of Services

- Basic requirements: The clinic is primarily engaged in providing outpatient health services as described in §481.9 (c).
- §481.9 (c): 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.



Provision of Services - Lab

- An RHC must have the ***ability to perform the following lab tests:***
 - Blood Sugar
 - Hemoglobin or Hematocrit
 - Pregnancy
 - Urinalysis – Dipstick
 - Occult Blood



Lab - PPM

- Provider-Performed Microscopy
- This means being licensed by CLIA to use a microscope in the office.
- Short answer – if you are using a microscope, be sure your CLIA license says this.



Emergency Kit

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.



In-Patient Services and Specialists

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:

- (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.



Provision of Service Recommendations

- An emergency kit is required – a defibrillator is not (yet).
- Make sure the clinic can perform a Hemoglobin or Hematocrit and that your supplies are current.
- The RHC must be able to admit to a hospital - or have a written agreement with someone who can.



Policy and Procedure Manual

- The clinic must have written policies and procedures – administrative and patient care.
- The policies are developed by professional personnel that include at least one physician and one NP or PA. [481.9 b(2)]



RHC Policy Manual Requirement

- Written policies should consist of both administrative and patient care policies.
- 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.



Written Policies and Procedures

- The clinic must be able to provide written documentation of clinic policies.
- It 'must be possible to ascertain who developed them'.
- If the personnel have changed since originally developed, then the doctor, APN, and/or PA must have in-depth knowledge of the policies...



Patient Care Policies

The RHC Policy Manual must include:

- a description of services furnished directly and those furnished by arrangement;
- guidelines for the medical management of health problems, including conditions for referral and consultation;
- guidelines for storage of drugs and biologicals,
- procedures for the periodic review and evaluation of the services furnished by the clinic;



Description of Services

- ▶ “Such statements as the following sufficiently describe services: Taking complete medical histories, performing complete physical examinations, assessments of health status, routine lab tests...”
- ▶ “Statements such as ‘complete management of common acute and chronic health problems’ standing alone, do not sufficiently describe services.” (CMS State Operations Manual)



Services by Arrangement (SOM)

- ▶ Additional services, furnished through referral, are sufficiently described in such statements as:
 - Arrangements have been made with 'X' hospital,
 - 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.



Guidelines for Medical Mgmt

- Scope of Services for APN/PA are critical.
- These represent an agreement between the APN/PA which stipulate medical direction, and designate their privileges and limits of medical diagnosis and treatment.
- Track APN/PA collaboration/supervision!
- Confirm/assess state collaborative



Drugs and Biological Policies

Policies must stipulate requirements for dealing with:

- Storage of drug samples,
- dealing with outdated medications,
- Securing and accounting for Schedule II drugs.
- Others...(See SOM)



Policy Review

It MUST be documented that the Medical Director and APN/PA review all policies annually. This is absolutely mission critical.

This can be achieved by signing and dating the manual annually!!



RHC Manual Recommendations

- Organize Manual according to RHC regulations.
- Keep business, personnel, and medical licenses current!!
- Make certain the Medical Director and NP/PA review polices and sign the manual – Annually!!!
- Make sure that patient care and administrative polices are included and current!
- Maintain the organizational chart.
- Assign one person and an alternate responsibility for the manual in case of inspection.



RHC Manual Format

- Compliance with Federal, State, and Local laws
- Physical Facility
- Staffing
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Other Documentation Components

- Documentation of Compliance with clinic and personnel licensure requirements
- Document all nursing licenses/ CPR certifications.
- Patient Referral Policies
- After-Hours Coverage Policies
- Hospital Privileges
- Fiscal/Purchasing Policies
- Medical Record Policies (Confidentiality, Safeguards from Loss, Retention)
- Annual Evaluations/Executive Committee



Medical Records I

- The clinic 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.



Medical Records II

For each patient receiving health care services, the clinic 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;



Medical Records III

(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.



Medical Records IV

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 or records from the clinic and the conditions for release of information.
- the patient's written consent is required for release of information not authorized by law.



Medical Record Recommendations

- Maintain individual patient charts.
- Use problem and medication lists.
- Sheets must be attached.
- Physician writing must be legible.
- No financial data in charts. (Insurance info is OK)
- Must have written policies regarding retention, confidentiality, and release of information.
- A designated staff member should be assigned responsibility for overseeing medical records.



Annual 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. (CMS State Operations Manual)



Annual Evaluation – Current Rules

- MMA calls for the Annual Evaluation to be replaced by a Quality Assurance and Performance Improvement program (QAPI).
- Technically, the Annual Evaluation is still the operative rule.
- Some states allow QAPI to replace the Annual Evaluation.
- Do not leave out the remaining Annual components.



Annual Evaluation - Current

VIII. §481.11 Program evaluation -

(a) The clinic carries out, or arranges for, an annual 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.



Annual Evaluation – Current II

- (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 staff considers the findings of the evaluation and takes corrective action if necessary.



Annual Evaluation - Format

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Annual Evaluation - Content

- Use patient count from the cost report.
- Review each component of the RHC regulation.
- Make sure active and closed records are reviewed.
- Document and follow up on corrective action for deficient areas!
- Make sure it's signed.
- Do the annual evaluation annually!



Quality Assurance/ Employee Education

- Does your clinic have any type of quality assurance/employee education.
- What is your mechanism for documenting employee education?
- Document Monthly or Quarterly In-services for fire/natural disaster in-services, etc.



Annual Evaluation - Participants

- Can be performed in parts throughout the year.
- Make sure the Annual Evaluation policy includes an Executive Committee, which includes the
 - Medical Director
 - NP/PA
 - Administrator or Office Manager
 - Outside Community Member



Annual To-Do List

- Make ***SURE*** the medical director and NP/PA have signed the manual **ANNUALLY!!**
- Insert all ***CURRENT*** medical personnel licenses in manual.
- Insert all current medical malpractice, building, and liability insurance certificates.
- Make sure that NP/PA hours equal at least 50% of posted clinic hours.
- Post NP/PA hours to make it official.



To Do List II

- Make sure personnel on organizational chart are current.
- Have an Annual Fire Inspection (if you can).
- Make sure all staff is CPR certified.
- Document annual fire/natural disaster in-services.
- Bio-medical equipment inspection - the 110% solution.
- Make sure 'crash cart' drugs are not expired.



Annual To-Do List III

- Drug sample storage and expirations have been reviewed and activity logged.
- Multi-use vials – mark date of opening and dispose of 30 days after opening.
- Make sure that all lab supplies are current that that all tests can be performed.
- Make sure you have Annual Evaluations/ Medical Record reviews documented.



What to do when the inspector shows up...

Hint: This is not the time to update your Policy and Procedure manual.



Inspections

- Take a second – catch your breath – police the clinic. Panic is not an option.
- Be nice, not argumentative.
- If you don't know, say that you'll confirm and come right back.
- Know where your manual is!
- Assign an alternate in your absence.
- Be transparent – but let the inspector ask the questions.



CMS Resources

Main Site – www.cms.gov

State Operations Manual –

http://cms.gov/manuals/Downloads/som107ap_g_rhc.pdf

Sample RHC Manual:

<ftp://ftp.hrsa.gov/ruralhealth/RHCmanual1.pdf>

CMS Rural Health Center – www.cms.gov/center/rural.asp



More CMS Resources

Medicare Claims Processing Manual – UB04 Completion

www.cms.gov/manuals/downloads/clm104c25.pdf

Medicare Claims Processing Manual – Chapter 9 RHC/FQHC
Coverage Issues

www.cms.gov/manuals/downloads/clm104c09.pdf

MedLearn Catalog

www.cms.gov/MLNProducts/downloads/MLNCatalog.pdf



Where to find the rules...

This presentation, the State Operations Manual, and the RHC Survey report will be posted at:

www.northamericanhms.com



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