

RHC COMPLIANCE AND REGULATIONS

ROBIN VELTKAMP

HEALTH SERVICES ASSOCIATES



OBJECTIVES

- Participants will gain an understanding of the basic Federal RHC Regulations.
- Participants will gain an understanding of the importance of teaching these regulations to support staff within the RHC.
- Participants will gain an understanding in effective monitoring of the regulations within the RHC.



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 ***Electronic version is current
 - CMS Form 30 (J Tags)
 - State Operating Manual
 - Federal & State OSHA Guidelines
 - Deeming entity Guidelines



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 Meds, etc.
- Conditions are severe deficiencies. You may receive deficiencies in Conditions if you don't have key elements.



CERTIFICATION VS. 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 types of visits are unannounced.



SURVEY ENTITIES

- The RHC survey for new certifications are not being conducted by the State of Michigan.
- All NEW certifications must choose one of two (2) deeming entities.
 - The Compliance Team
 - AAAASF
- If the clinic was initially surveyed by the State of Michigan, then the State will continue to conduct recertification.



CFR 491.4 (J3-J4)

- Make sure that the identification of the clinic/ownership is evident.
- Hours of operation are to be posted where they can be viewed from the parking lot.
- Post the patient care hours vs. business/clinic hours.
- What if the clinic is within a building?



CFR 491.4 (J5)

- PERSONNEL FILES:
 - Applications, Resume or CV
 - Signed Job Descriptions for EACH Employee (also providers)
 - Signed Confidentiality Statement
 - Signed Standard of Conduct
 - Signed W-4
 - Signed I-9
 - Annual OIG Sanction Search
 - BLS Certification for clinical personnel
 - License/Certifications and Training



CFR 491.4 (J5)

- PERSONNEL FILES:
 - TB Testing upon hire and annual questionnaire or retest.
 - Hep B Vaccination or declination.
 - Evidence of annual training for:
 - Fire
 - Tornado
 - Inclement Weather
 - Bloodborne Pathogen
 - Fraud/Waste/Abuse
 - HIPAA
 - Compliance



CFR 491.5 LOCATION OF CLINIC

- Be located in a HPSA approved area.



CFR 491.6 PHYSICAL PLANT & ENVIRONMENT

- Exit doors are appropriately identified
- Clinic does not have exposed building materials
- Fire extinguishers are checked on a monthly basis
- Emergency exit routes are free of barriers
- Exit doors prevent any unauthorized access from the outside but does allow for emergency exit from within.
- Secondary doors are lock at all times.



CFR 491.6 PHYSICAL PLANT & ENVIRONMENT

- Overhead ceilings are free of bugs and debris
- List of hazardous chemical are available (MSDS – Paper or electronic)
- Child safety plug protectors are present in ALL outlets
- Sharps containers are secured throughout the clinic
 - Michigan OSHA states 90 days then remove
- The clinic has an OSHA approved eye wash station.
- Floor plans are posted throughout the clinic.



CFR 491.6 PHYSICAL PLANT & ENVIRONMENT

- Treatment trays are free of dust and debris
- There is nothing under the exam room sinks
- Closed trash containers are utilized in the patient care areas
- Clean and dirty work surfaces in the lab are clearly defined.
- Patient bathrooms have an emergency notification system



CFR 491.6 PHYSICAL PLANT & ENVIRONMENT

- ALL equipment has to have current (annual) inspection.
 - This must be itemized or sticker system utilized
 - All adult and pediatric scales are balanced
 - Patient care equipment is appropriately calibrated
 - AED (not required) is maintained and is tested in accordance to manufacture recommendations
 - Manual BP cuffs
 - Digital Thermometers



CFR 491.6 PHYSICAL PLANT & ENVIRONMENT

- Clinic Housekeeping
 - Patient Restrooms
 - Clinic is free from clutter
 - Who is doing the cleaning?
- Emergency Training
 - ALL staff (including providers)
 - Documented
 - Know their roles
 - Fire, Tornado, Inclement weather, etc.



CFR 491.7 ORGANIZATIONAL STRUCTURE

- Organizational Chart
 - List positions and names
 - Medical Director
 - Practice or Office Manager
- Job Descriptions
- OIG Sanctions
 - Exclusions.oig.hhs.gov
 - Annual requirement



CFR 491.8 STAFFING AND STAFF RESPONSIBILITIES

- Collaboration Agreements, Scope of Practice, Licensure
- Clinic Schedule reflects appropriate staffing levels
- Medical Director/Supervising Physician chart review of non-physician providers. Education and communication.
- Participation in the ANNUAL review, development and execution of policies.
- On site supervision vs. availability



CFR 491.9 PROVISION OF SERVICES

- Policies reflect current services offered in the clinic.
- Annual Advisory Committee Meeting
- LABORATORY SERVICES REQUIRED
 - Urinalysis
 - Blood Glucose
 - Hemoglobin or Hematocrit
 - Occult Stool
 - Pregnancy
 - Primary Culture



CFR 491.9 PROVISION OF SERVICES

- CLIA Certificate
- Waste Manage evidence
- Lab Supplies/Reagents are inventoried monthly
- Lab tracking
- Clean and Dirty Work surfaces
- Control logs



CFR 491.9 PROVISION OF SERVICES

- Emergency First Aid Response Kit
- AED (Not required)
- CPR Certifications
- Spill Kit



CFR 491.10 PATIENT HEALTH RECORDS

- Evidence of Documentation:
 - Chief Complaint
 - Social Data
 - H & P
 - Provider Signature
 - Labs signed where applicable
 - Medication list noted
 - Allergies notes and reaction
 - Treatment reports where applicable



CFR 491.10 PATIENT HEALTH RECORDS

- Evidence of Documentation:
 - Consent to Treat
 - Informed Consent for procedures
 - Instructions to Patient/Education
 - Treatment Plan



CFR 491.11 PROGRAM EVALUATION

- Annual meeting
- Key attendees:
 - Medical Director
 - Non physician provider
 - Community Member



CFR 491.12 EMERGENCY PREPAREDNESS

- Emergency Plan
- The RHC must develop and maintain an emergency preparedness plan that must be reviewed and updated at least annually. The plan **MUST** do all of the following:
 - Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.
 - Include strategies for addressing emergency events identified by the risk assessment.



CFR 491.12 EMERGENCY PREPAREDNESS

- 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.
- 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 emergency situation, including documentation of the RHC's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts.



CFR 491.12 EMERGENCY PREPAREDNESS

- Policies and Procedures:
 - Base them on the emergency plan
 - Risk Assessment
 - Communication Plan
 - Review annually and update



CFR 491.12 EMERGENCY PREPAREDNESS

- At a MINIMUM Policies:
 - Safe evacuation from the RHC
 - A means to shelter those who remain in the facility
 - System of medical documentation that preserves:
 - Patient information
 - Protects confidentiality of patient information
 - Secures and maintains the availability of records



CFR 491.12 EMERGENCY PREPAREDNESS

- Use of volunteers in an emergency or other emergency staffing strategies, including:
 - Process and role for integration of State and Federally designated health care professionals to address surge needs during an emergency
- Communication Plan
 - Develop and Maintain and Emergency preparedness communication plan and must be updated annually.



CFR 491.12 EMERGENCY PREPAREDNESS

- Communication Plan MUST Include:
 - Names and contact information for the following:
 - Staff
 - Entities providing services under arrangement
 - Patient's Physicians
 - Other RHCs
 - Volunteers



CFR 491.12 EMERGENCY PREPAREDNESS

- Communication Plan MUST Include:
 - Contact information for:
 - Federal, State, tribal, regional, and local emergency preparedness staff.
 - Other sources of assistance
 - Primary and alternate means for communicating with the following:
 - RHC Staff
 - Federal, State, tribal, regional, and local emergency management agencies.



CFR 491.12 EMERGENCY PREPAREDNESS

- Communication Plan MUST Include:
 - 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's needs, and its ability to provide assistance, to the authority having jurisdiction or the incident Command Center, or designee.



CFR 491.12 EMERGENCY PREPAREDNESS

- Training and Testing.
 - The RHC must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan:
 - Risk Assessment
 - Policies and Procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles
 - Provide training at least annually
 - Maintain documentation of evidence of trainings
 - Demonstrate staff knowledge of emergency preparedness

CFR 491.12 EMERGENCY PREPAREDNESS

- Training and Testing.
 - The RHC MUST conduct exercises to test the emergency plan at least annually.
 - The RHC MUST DO THE FOLLOWING:
 - Participate in a full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, facility-based.
 - Exempt if the RHC participated in an actual natural or man-made emergency that required activation of the plan for 1 year following the onset of the actual event.



CFR 491.12 EMERGENCY PREPAREDNESS

- Integrated Health Care Systems. If an RHC is part of a healthcare system consisting of multiple certified facilities that elects to have a unified and integrated emergency preparedness program, the RHC may choose to participate in the healthcare system's coordinated program. If this option is chosen, the RHC MUST do the following:
 - Demonstrate that EACH facility within the system actively participated.
 - Take into consideration EACH unique circumstances, patient populations and services offered.
 - Demonstrate that EACH facility is capable of being integrated into the compliance of the program.



CFR 491.12 EMERGENCY PREPAREDNESS

- Training and Testing.
 - Include a unified and integrated emergency plan that includes
 - Documented community-based risk assessment utilizing an all-hazards approach
 - Document individual facility-based risk assessment for each facility within the system.
 - Include integrated policies and procedures that show:
 - Coordinated communication plan
 - Training and testing programs





- Robin VeltKamp, RHC Quality Assurance and Education Email: rveltkamp@hsagroup.net
- Health Services Associates, Inc. 2 East Main Street Fremont, MI 49412
- PH: 231.924.0244 FX: 231.924.4882
- www.hsagroup.net