



RHC Survey and Certification

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Today's Objectives

Participants will understand the basic RHC certification process required by Medicare.

Participants will become familiar with the recertification process for RHCs.



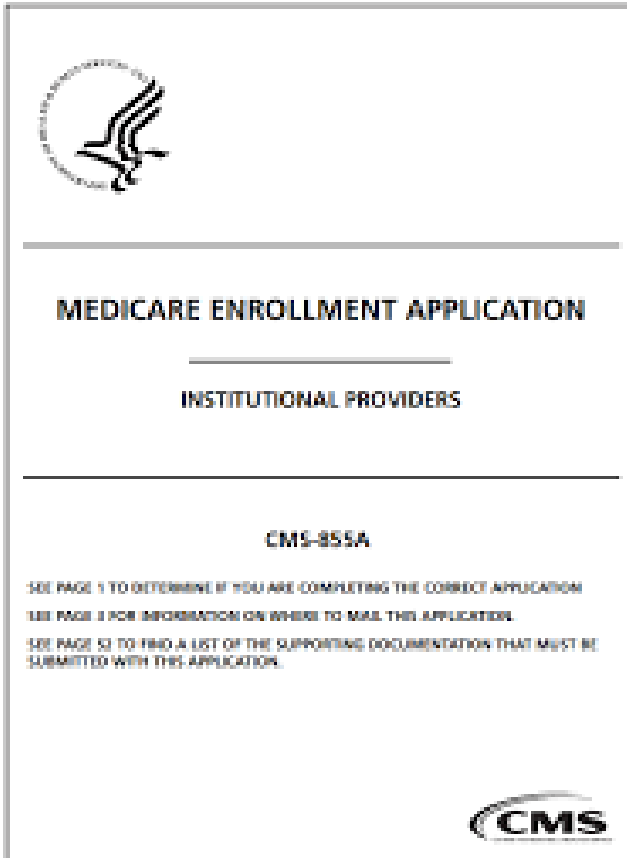
Overview


The RHC Certification Process

Preparing for the RHC Certification Survey

RHC Certification Process

- Applications are filed with Centers for Medicare and Medicaid (CMS) and the state. This includes:
 - an **855A** for Medicare,
 - **CMS-29** and other forms for rural health clinic certification, and
 - other state forms needed for Medicaid.
- CMS reviews the 855A form.
- The state reviews the application forms sent to it. When the full application is determined to be complete, a date is scheduled for a Rural Health Clinic survey. This schedule may or may not be shared with the clinic.






MEDICARE ENROLLMENT APPLICATION

INSTITUTIONAL PROVIDERS

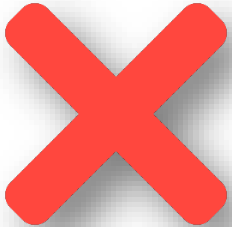
CMS-855A

SEE PAGE 1 TO DETERMINE IF YOU ARE COMPLETING THE CORRECT APPLICATION.
SEE PAGE 2 FOR INFORMATION ON WHERE TO MAIL THIS APPLICATION.
SEE PAGE 3 TO FIND A LIST OF THE SUPPORTING DOCUMENTATION THAT MUST BE SUBMITTED WITH THIS APPLICATION.



RHC Certification Process

- The surveyor uses the CMS-30 form to conduct the survey.
- If no deficiencies are found, the state forwards its approval to the CMS Regional Office (RO) for final review. When the certification is approved, a letter with the new provider number is sent to the clinic.
- If there are deficiencies, the state sends a letter of deficiencies to the clinic. The clinic responds with a plan of corrections (POC). Depending on the seriousness of the deficiencies, a second survey may be necessary. When the deficiencies are remedied, state approval is sent to the RO.



RHC Certification Process

The state Medicaid program is informed of the new rural health clinic.

Interim payment rates are established.

Effective date in the program is generally the date of survey (in the case of no deficiencies) or the date when the deficiencies are remedied and the POC is filed with the state.

Preparing for the RHC Certification Survey

- If you prepare thoroughly, the survey can be uneventful.
- There are four key elements to preparing for the RHC Certification Survey. They are:

Policy and
Procedure
Manual
Review

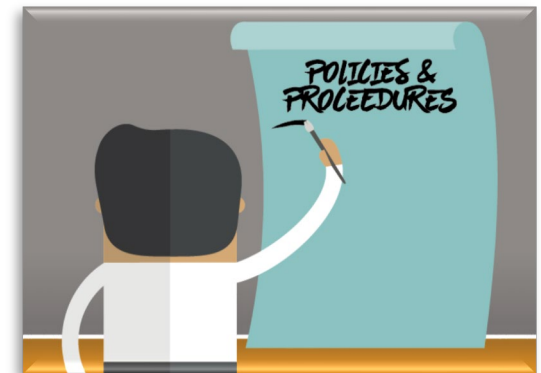
Medical
Records
Review

Facility
Inspection

Program
Evaluation

Preparing for the RHC Certification Survey

- RHC Policy and Procedure Manual
 - The policy and procedure manual should cover key human resource policies, administrative policies, clinical procedures and protocols, and medical guidelines per RHC Code of Federal Regulations (CFR) §491.7(a)(2).
 - Each clinic's policy and procedures manual should be drafted with that clinic in mind. This document should be an accurate reflection of how the clinic truly intends to operate.



Preparing for the RHC Certification Survey

- RHC Policy and Procedure Manual (continued)
- The Policy and Procedures Manual section of the RHC Interpretive Guidelines states:

“Written policies should consist of both administrative and patient care policies. Patient care policies are discussed under 42 CFR 491.9(b). 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. Topics covered by written policies may have been influenced by requirements of the founders of the clinic, as well as agencies that have participated in supporting the clinic’s operation.”

Preparing for the RHC Certification Survey

- RHC Policy and Procedure Manual (continued)
 - Human resources:
 - When looking at developing human resource policies, there are a variety of laws, administrative rules, acts, and regulations that must be considered including RHC Code of Federal Regulations, RHC Interpretative Guidelines, State and Federal Laws, State Public Health Code, and Professional Practice Standards.
 - The human resource policies should include:
 - job descriptions
 - benefits, compensation and pay practice
 - employment criteria and conditions of employment
 - smoking, drug use/possession and distribution
 - appointment of providers/credentialing
 - confidentiality
 - personnel files (organization, management, and access)
 - harassment, and employee privacy

Preparing for the RHC Certification Survey

- RHC Policy and Procedure Manual (continued)
 - Human resources: (continued)
 - **CFR Section 491.8** (Staffing and staff responsibilities) outlines some of the program requirements for physician assistants, nurse practitioners and certified nurse midwives. The regulations state that, “A nurse practitioner or a physician assistant is available to furnish patient care services at least 50 percent of the time the clinic operates.” When developing the job description of the PA/NP/CNM, part of their responsibilities should include the following: “The PA/NP/CNM will be scheduled in the clinic and available to provide patient care services for at least 50 percent of the time the clinic operates.”



Preparing for the RHC Certification Survey

- RHC Policy and Procedure Manual (continued)
 - Administrative:
 - As you develop your Administrative section, you will want to consider the following resources:
 - RHC Code of Federal Regulations and Interpretative Guidelines,
 - State and Federal laws,
 - State court rules,
 - Federal and State OSHA Standards,
 - Medicare and Medicaid reimbursement policy,
 - State Public Health Code,
 - Administrative rules, and
 - the Freedom of Information Act

Preparing for the RHC Certification Survey

- RHC Policy and Procedure Manual (continued)
 - Administrative: (continued)
 - Start with the Code of Federal Regulations (CFR). An example of an administrative policy would be Preventive Maintenance. **CFR Section 491.6(b)** states, “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.”
 - The RHC Interpretive Guideline for this regulation defines the requirement further, “A program of preventive maintenance should be followed by the clinic. This includes inspection of all clinic equipment at least yearly, or as the type, use, and condition of equipment dictates.”

Preparing for the RHC Certification Survey

- RHC Policy and Procedure Manual (continued)
 - Administrative: (continued)
 - By using these two resources, the preventive maintenance policy could contain the statements like:
 - All clinic equipment will be inspected at least yearly, or as the type, use, and condition of equipment dictates. Each time an inspection or repair occurs, an entry will be made in the Inspection and Maintenance Log and signed by the service person to verify the event.
 - The medical/clinical assistant prior to each use must inspect all equipment.
 - An electrician or bio-medical engineer will inspect each piece of bio-medical equipment. The inspection will ensure that the equipment is in proper operating condition, is safe to use, and is calibrated properly.



Preparing for the RHC Certification Survey

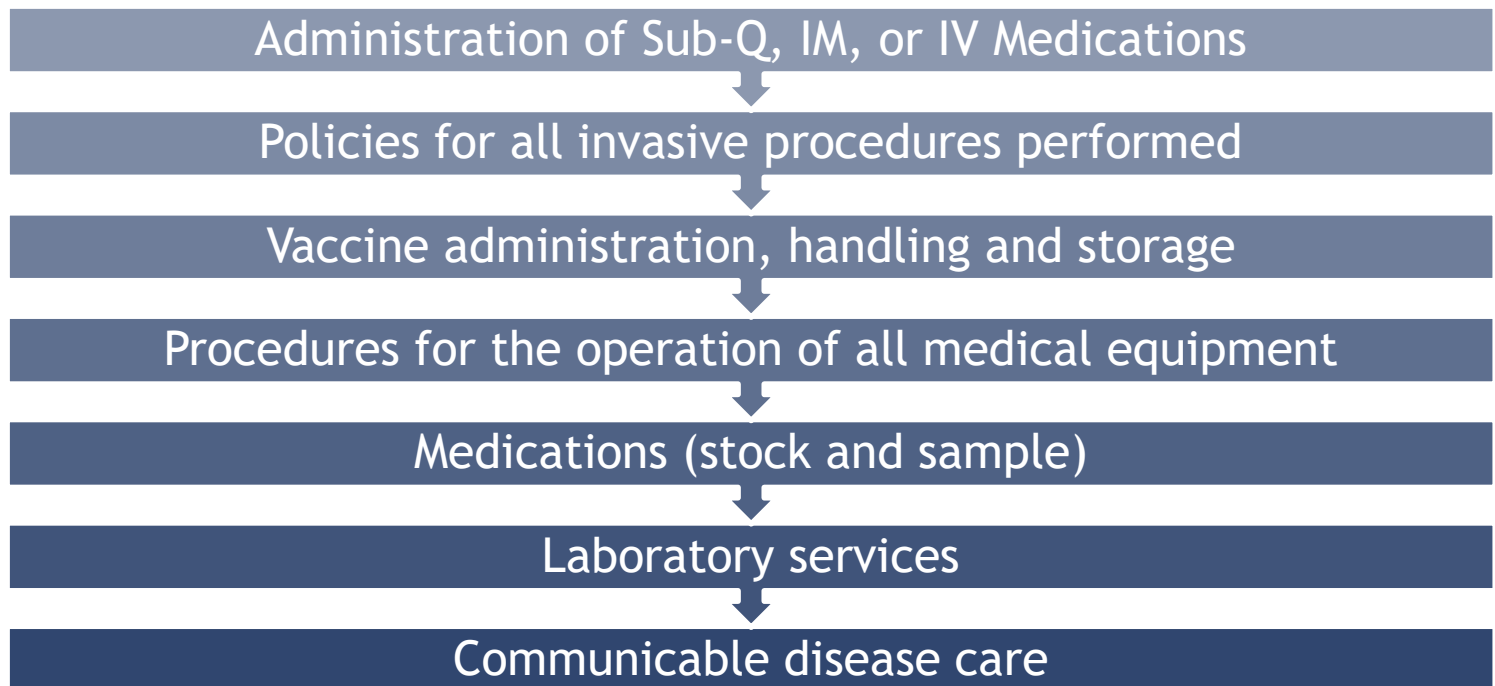
- RHC Policy and Procedure Manual (continued)
 - Administrative: (continued)
 - Besides the RHC Regulations and Interpretive Guidelines, some resources that you might want to consider as you developed the administrative section include:
 - manufacturer recommendations
 - professional practice standards
 - pharmacy regulations and administrative rules
 - American Heart Association
 - Federal and State OSHA standards
 - CLIA regulations
 - CDC
 - State Public Health Code
 - American Academy of Pediatrics and PHS Standards for Pediatric Immunization Practices.

Preparing for the RHC Certification Survey

- RHC Policy and Procedure Manual (continued)
 - Clinical:
 - When developing clinical procedures/protocols, it is helpful to keep in mind that this section refers to those procedures that are performed by support personnel, e.g., nurse, certified medical assistant, registered radiologic technologist, clinical assistant, etc.

Preparing for the RHC Certification Survey

- RHC Policy and Procedure Manual (continued)
 - Clinical:
 - Clinical policies should include:



Preparing for the RHC Certification Survey

- RHC Policy and Procedure Manual (continued)
 - Clinical: (continued)
 - As with the Human Resources and Administrative sections, the first resources to consider are the Code of Federal Regulations and the Interpretive Guidelines. Using the Code you can easily start to put together your clinical procedures/protocol section. For example, **CFR Section 491.6(b)(2)** states, “The clinic has a preventive maintenance program to ensure that drugs and biologicals are appropriately stored.” Based on this regulation, the medication policy could contain the following statements (among others):

Medications will be refrigerated as necessary and will be kept separate from any food substances. Refrigerator and freezer temperatures will be obtained and recorded on a daily basis.

On a monthly basis, medications will be checked for expiration dates and those which are outdated will be discarded in the following manner: Given back to drug representative or discarded via the biohazard container. A log will be maintained to indicate when monthly checks are done and by whom.

All medications stored on the clinic premises will be kept in cabinets, shelves, drawers, and/or refrigerators and locked during non-patient care hours.

Preparing for the RHC Certification Survey

- RHC Policy and Procedure Manual (continued)
 - Clinical: (continued)
 - Finally, the RHC program requires that the clinic have 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. Acceptable guidelines may follow various formats.
 - Some guidelines are collections of general protocols, arranged by presenting symptoms; some are statements of medical directives arranged by the various systems of the body (such as disorders of the gastrointestinal system); some are standing orders covering major categories such as health maintenance, chronic health problems, common acute self limiting health problems, and medical emergencies.

Preparing for the RHC Certification Survey

- RHC Policy and Procedure Manual (continued)
 - Clinical: (continued)
 - Even though approaches to describing guidelines may vary, acceptable guidelines for the medical management of health problems must include the following essential elements:

They are comprehensive enough to cover most health problems that patients usually see a physician about;

They describe the medical procedures available to the nurse practitioner, certified nurse-midwife, and/or physician assistant; and

They are compatible with applicable State laws.

The professional organizations of the health professionals typically found in an RHC (physician, PA, NP and CNM) have published a number of patient care guidelines. Should a clinic choose to adopt such guidelines (or adopt them essentially with noted modifications), this would be acceptable if the guidelines include the aforementioned essential elements.

Preparing for the RHC Certification Survey

- RHC Policy and Procedure Manual (continued)
 - Clinical: (continued)

Often the regulations will overlap and you need to be aware of the areas where this occurs. Policy and procedure development is one area. The physician and PA, NP or CNM responsibilities include participation in developing, executing, and periodic reviewing of the clinic's written policies. Additionally, 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 of the advisory group must not be a member of the clinic staff.

Preparing for the RHC Certification Survey

► Medical Records

- The clinic has written policies and procedures of how it will maintain confidentiality of patient health records and provide a safeguard against: loss, destruction, or unauthorized use of patients' health record. CFR Section 491.10 (Patient Health Records) of the Code outlines expectations for medical record confidentiality, maintenance, organization, content, protection, release and retention.
- As part of the Certification Survey process, a representative sample of the clinic's medical records will be reviewed. The focus should be on Medicare and Medicaid records only. The clinic may have the opportunity to select the records for review. If not, it will be the surveyor who determines the records to be reviewed.



Preparing for the RHC Certification Survey

- Medical Records (continued)
 - Documentation must include but is not limited to:

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 provider orders, reports of treatments and medications and other pertinent information necessary to monitor the patient's progress; and

Signatures of the provider and other health care professionals.

In addition to these program expectations, the clinic must also comply with reimbursement policy, legal expectations, and standard of practice guidelines. Remember, if it wasn't documented, it wasn't done.



Preparing for the RHC Certification Survey

- Facility
 - Preparing the facility is not only a requirement of the RHC program but may also be a requirement for compliance with local, State and Federal laws.
 - An inspection of the physical plant is one of the key elements of the survey process.
 - Some of the regulations, laws, rules, and standards that impact the facility include RHC Code of Federal Regulations, Clean Indoor Air Act, OSHA Hazardous Communication Standard, local building, zoning and fire ordinances, and State laws for storage and disposal of medical waste.

Preparing for the RHC Certification Survey

- Facility (continued)
 - To insure the safety of patients, personnel, and the public, the physical plant should be maintained consistent with appropriate State and local building, fire, and safety codes.



Reports prepared by State and local personnel responsible for insuring that the appropriate codes are met should be available for review.

The facility must have safe access and be free from hazards that may affect the safety of patients, personnel, and the public.

The clinic must also be constructed, arranged, and maintained to insure access to and safety of patients, and provide adequate space for the provision of direct services.

The clinic must provide laboratory services directly to its patients. Each clinic must have, at a minimum, its own CLIA certificate of waiver. Provider-based RHCs may not use the CLIA certificate of the parent hospital.

Preparing for the RHC Certification Survey

- Facility (continued)
 - To insure the safety of patients, personnel, and the public, the physical plant should be maintained consistent with appropriate State and local building, fire, and safety codes. (continued)
 - The clinic must have a preventive maintenance program to ensure that all essential mechanical, electrical, and patient-care equipment is maintained in safe operating condition.
 - The clinic must make provisions for the appropriate storage of drugs and biologicals and the premises must be clean and orderly.
 - The clinic is responsible for assuring the safety of patients in case of non-medical emergencies that include, placing exit signs in appropriate locations and taking other appropriate measures that are consistent with the particular conditions of the area in which the clinic is located.

Preparing for the RHC Certification Survey

- Program Evaluation
 - An evaluation of the clinic's total operation including the overall organization, administration, policies and procedures covering personnel, fiscal and patient care areas must be done at least annually.
 - This evaluation may be done by:

the clinic;

an outside group of professional personnel that includes one or more physicians and one or more physician assistants or nurse practitioners and at least one individual who is not part of the clinic staff; or

through arrangement with other appropriate professionals.

Preparing for the RHC Certification Survey

- Program Evaluation (continued)
 - The State survey does not constitute any part of this program evaluation.
 - The total evaluation does not have to be done all at once or by the same individuals. It is acceptable to do parts of it throughout the year, and it is not necessary to have all parts of the evaluation done by the same staff person.
 - However, if the evaluation is not done all at once, no more than one year should elapse between evaluating the same parts.
 - For example, a clinic may have its organization, administration, and personnel and fiscal policies evaluated by a health care administrator(s) at the end of the fiscal year; and its utilization of clinic services, clinic records, and health care policies evaluated six months later by a group of health care professionals.

Preparing for the RHC Certification Survey

- Program Evaluation (continued)
 - If the facility has been operational for at least a year at the time of the survey and has not completed an evaluation of its total program, the surveyor must report this as a deficiency. If the facility has been operational for less than one year or is in the start-up phase, it is not required to complete a program evaluation. However, the clinic should have a written plan that specifies who is to do the evaluation, when it is to be done, how it is to be done, and what will be covered in the evaluation.
 - The evaluation must include a review of the following:



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

Preparing for the RHC Certification Survey

- Program Evaluation (continued)
 - The purpose of the evaluation is to determine whether: the utilization of services was appropriate; the established policies were followed; and whether any changes are needed.
 - The clinic staff or a group of professional personnel must consider the findings of the evaluation and take corrective action if necessary.
 - The Balanced Budget Act of 1997 required RHCs to have a clinical quality assessment and performance improvement plan (QAPI). CMS issued a memo allowing RHCs to use this as an alternate evaluation method until the new regulations are put in place.



Preparing for the RHC Certification Survey

- Once the clinic submits its Letter of Readiness to the State agency, the State agency has 90 days in which to schedule the RHC Certification Survey. Some clinics may experience a delay in the process depending on national initiatives and budget constraints.
- The State agency does have the option, under certain conditions, of giving clinics a 48-hour notice of the scheduled survey. Some States, however, will not exercise this option and the survey will be unannounced.

Preparing for the RHC Certification Survey

- To ensure a successful survey, have a plan and prepare ahead.
- The following documents should be prepared and available to the surveyor.
 - Policy and Procedure Manual
 - MSDS Manual
 - All Professional Group, Staff, and Provider meeting minutes
 - Minimum of 10 medical records
 - (Medicare/Medicaid only) - mix of all life cycles and providers
 - Fire and Evacuation
 - Training logs
 - CLIA Certificate
 - Exposure Control and Blood borne Pathogen Training
 - Quality Assessment and Performance Improvement Activity
 - Personnel Files
 - Preventative Maintenance Reports
 - X-ray Certificate (if applicable)
 - Laboratory Control Logs
 - Sample Drug Log
 - Diagnostic Results Tracking System

CMS-30 Survey Form

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

Form Approved
OMB No. 0938-0074

RURAL HEALTH CLINIC SURVEY REPORT

PROVIDER NUMBER

(J1)

NAME OF CLINIC STREET NUMBER CITY COUNTY STATE ZIP CODE

SURVEYED BY SURVEYOR'S PROFESSIONAL TITLE DATE SURVEYED

INITIAL SURVEY RESURVEY

(J2)

LIST ADDITIONAL SURVEYOR'S NAMES

TITLE

PARTICIPATION UNDER TITLES 18 AND 19

A clinic certified under Medicare will be deemed to meet the standards for certification under Medicaid.

CODE	YES	NO	N/A		EXPLANATORY STATEMENTS
J3				<input type="checkbox"/> MET <input type="checkbox"/> NOT MET II. §481.4 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.	CLINIC LICENSE NUMBER (IF APPLICABLE) PHYSICIAN(S) NAME LIC. NO. CERT. NO. REG. NO.
J4				<input type="checkbox"/> MET <input type="checkbox"/> NOT MET <input type="checkbox"/> N/A (a) Licensure of clinic. The clinic is licensed pursuant to applicable State and local law.	NURSE PRACTITIONER(S) NAME LIC. NO. CERT. NO. REG. NO.
J5				<input type="checkbox"/> MET <input type="checkbox"/> NOT MET (b) Licensure, certification or registration of personnel. Staff of the clinic are licensed, certified or registered in accordance with applicable State and local laws.	PHYSICIAN ASSISTANT(S) NAME LIC. NO. CERT. NO. REG. NO. OTHER LICENSED PERSONNEL - IDENTIFY

30 Most Common Deficiencies

- Common deficiencies include:
 - Lack of preventive maintenance program
 - Inadequate staff emergency training
 - Inadequate policies and procedures or policies and procedures not developed according to regulations
 - Providers not taking on required responsibilities
 - Lack of appropriate medical records
 - Evaluation not performed according to regulations
- The complete list is provided as a hand-out.

What Happens After the Survey?

When the Certification Survey results in no deficiencies, the State agency has ten (10) calendar days to prepare the Survey Packet for the CMS Regional Office (RO) with a recommendation of approval.

The RO has 60 days to review and approve the survey packet and issue the Medicare Provider Letter to the clinic. For those clinics that file their application as a Provider-based entity, the provider-based request must be submitted to the RO with the survey packet. The RO will make the Provider-based determination and will notify the appropriate Fiscal Intermediary via the Medicare Tie-In Notice.

What Happens After the Survey?

- Should the survey result in deficiencies or citations, a Statement of Deficiencies will be sent to the clinic by the State agency within ten (10) days of the survey.
- The clinic will have 10 days to develop a Plan of Correction (POC) and submit the POC back to the State agency. An initial applicant to the Medicare program cannot be certified or approved unless they are in compliance with the Conditions for Coverage. If in the judgment of the surveyor, the deficiencies evince non-compliance at the Condition level, then the applicant cannot be approved until those deficiencies have been corrected and the corrections have been verified through a follow-up survey. If there are deficiencies but they do not constitute non-compliance at the condition level, then the facility can be approved for participation with an approved plan of correction in place. The State agency will then review the POC for completeness.



What Happens After the Survey?

- Key elements to a POC include: it must be doable or realistic, it must have completion dates, it must specifically address the citation, and if appropriate, the clinic must be able to document proof of compliance.
 - There are no time constraints placed on the State agency when reviewing a POC.
 - Once the State agency has found the POC to be acceptable, they will submit the survey packet with recommendations to the RO.
- The RO has 60 days to review and approve the survey packet and issue the Medicare Provider Letter to the clinic.
 - For those clinics that file their application as a provider-based entity, the provider-based request must be submitted to the RO with the survey packet. The RO will make the provider-based determination and will notify the Fiscal Intermediary via the Medicare Tie-In Notice. Once the Medicare Provider Letter has been received by the clinic, the clinic is eligible to file a projected cost report and have their Medicare interim rate determined.





EMERGENCY PREPAREDNESS

42 CFR 491.12



42 CFR 491.12

491.12 (a) Emergency Plan

491.12 (b) Policies and Procedures

491.12 (c) Communication Plan

491.12 (d) Training and Testing

491.12 (e) Integrated Healthcare Systems

491.12 (a) Emergency Plan

“The RHC must develop and maintain an emergency preparedness plan that must be reviewed and updated at least annually.”

What does that actually look like?

491.12 (a) Emergency Plan

Table of Contents

Policy – Program Description

Document Cover Page

Document Table of Contents

Emergency Operation Plan

Attachment A: Facility Map

Attachment B: Facility Floor Plan

Attachment C: Risk Assessment

Attachment D: Organizational Chart

Attachment E: External Contact List

Attachment F: Notification Call Tree

Attachment G: Vendor Contact List

Attachment H: Facility Profile

Attachment I: Exercise Documentation

Policy for

Hazard 1

Policy for Hazard 2

Policy for Hazard 3

Policy for Hazard 4

Policy for Hazard 5

491.12 (b) Policies and Procedures

“The RHC must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually.”

491.12 (b) Policies and Procedures

- Policies to include:
 - Safe evacuation from the RHC
 - Shelter in place
 - Maintaining patient records
 - Documentation during an emergency
 - Volunteers
 - Medications
- Policies to consider:
 - Facility lock down
 - Suspension of services

491.12 (c) Communication Plan

“The RHC must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least annually.”

This is both internal and external. Don't forget to address BOTH.

491.12 (c) Communication Plan

- Internal Communication:
 - Name and contact info for the following:
 - Staff members (including providers)
 - Vendors
 - Other RHCs/Clinics
 - Entities providing services under agreement
 - Volunteers
 - External Communication:
 - Name and contact info for the following:
 - Federal, state, tribal, regional, and local emergency preparedness officials
 - Other assistance
- Paper AND electronic copies of both

491.12 (c) Communication Plan

- Other things to consider:
 - Alternate forms of communication (i.e. cell phones, walkie-talkies, pagers)
 - Patient information
 - Surge capacity and additional resources

491.12 (d) Training and Testing

“The RHC must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing must be reviewed and updated at least annually.”

491.12 (d) Training and Testing

- Initial Training
- Annual Training
 - Only providing training during the onboarding process is NOT enough
- Demonstrated knowledge of the EOP
 - Where is the EOP located?
 - Where is your meeting point?
 - Who is in charge during an emergency?
 - What is your role during an emergency?

491.12 (d) Training and Testing

- There are TWO (2) requirements annually:
 - Community-Based Event
 - Or Full-Scale Drill if community-based event is not available
 - Second Full-Scale Drill or Table-Top Exercise
- Full-Scale Drills and Table-Top Exercises should be based on one of your top 5 hazards
- Actual Emergency Events can also satisfy one of the two above requirements
 - After Action Report

491.12 (d) Training and Testing

- Examples of Full-Scale Drills:
 - Contact your local fire department to participate in a fire drill
 - Write “FIRE” on a piece of paper and drop it somewhere in the clinic
 - Use NERF guns and have a significant other simulate an Active Shooter
- Resource for drills: FEMA website

491.12 (e) Integrated Healthcare System

“If an RHC 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.”

491.12 (d) Integrated Healthcare System

- Even if you use the Hospital's policies, they must be **CLINIC SPECIFIC**
 - Would your clinic, that is 20 miles away from the Hospital, respond the same way to an emergency that a clinic within the Hospital walls would respond? **NO!**
 - Does your RHC have all of the same departments, job positions, and equipment available that the Hospital does? **NO!**
 - **If your RHC is not the same as your Hospital, your EOP should not be the same either.**



QUESTIONS ?





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