Compliance in your RHC

Washington | **RURAL HEALTH ASSOCIATION**
strengthening rural health

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VP Clinical Services

September 2, 2020

RHC Conditions of Certification

- § 491.1 Purpose and scope.
- § 491.2 Definitions.
- § 491.3 Certification procedures.
- § 491.4 Compliance with Federal, State and local laws.
- § 491.5 Location of clinic.
- § 491.6 Physical plant and environment.
- § 491.7 Organizational structure.
- § 491.8 Staffing and staff responsibilities.
- § 491.9 Provision of services.
- § 491.10 Patient health records.
- § 491.11 Program evaluation.
- § 491.12 Emergency preparedness.

https://www.law.cornell.edu/cfr/text/42/491.4

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Safe accessible entrance

Posted Hours

Posted Hours of Operation

Signage

Name on the sign is consistent with CMS 855A application.

42 CFR 491.4 Licensing

Staff of the clinic or center are licensed, certified or registered in accordance with applicable State and local laws.

OIG Exclusion list: https://exclusions.oig.hhs.gov/

HR Files

- Application
- I-9
- W-4
- OIG Exclusion
- Signed Job Description
- Standards of Conduct
- Performance evaluations, according to your clinic schedule
- Annual Training
- Competency
- Background checks as appropriate

- TB screening on hire
- Hep B for those who work with patients

42 CFR 491.4 Licensing

Staff of the clinic or center are licensed, certified or registered in accordance with applicable State and local laws.

Staff Member	Personnel File Audit Tool Insert "Y" (YES) if evidence is found, "N" (NO) if evidence of is missing, or "NA" if not applicable.										
	Application Resume or CV	I-9 and W-4 For Employees	OIG Exclusion	Signed Job Description	Signed Standard of Conduct	Orientation/ Training & Competency	Current License or Certification	Performance Evaluation	Background Check	Hepatitis B	TB

42 CFR 491.5 location of the Clinic

- Report name changes to CMS.

- Report change in Medical Director to CMS.

- Update your 855a and CMS 29 as things change.

491.6 Physical Plant and Environment

491.6 Physical plant and environment.

(a) *Construction.* 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. (Direct services means services provided by the clinic's staff)
(b) *Maintenance.* 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;
(2) Drugs and biologicals are appropriately stored; and
(3) The premises are clean and orderly.

491.6 Physical Plant

Physical Plant

Physical Plant

- Sharps containers cannot be easily accessible.

- Several states require specific times on emptying of sharps containers.

- Must be marked with Bio-Hazard sticker

Physical Plant

- Safe storage of Oxygen: chained or in an approved cart.

- Keep full separated from empty.
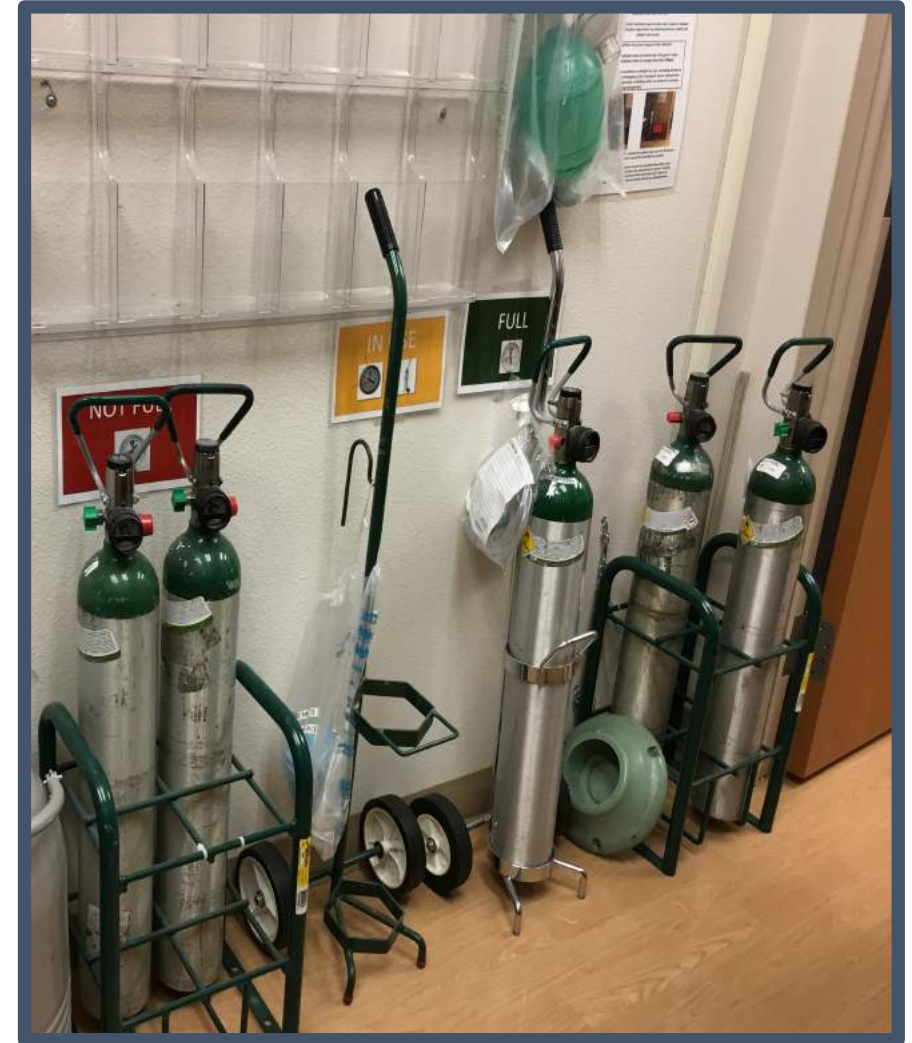
Physical Plant

- State and Federal Posters are required to be in places visible to the staff.

- Make sure you have the current year.

- Provider based clinics must have these postings in the clinic even when the clinic in the hospital building.

Physical Plant: Equipment

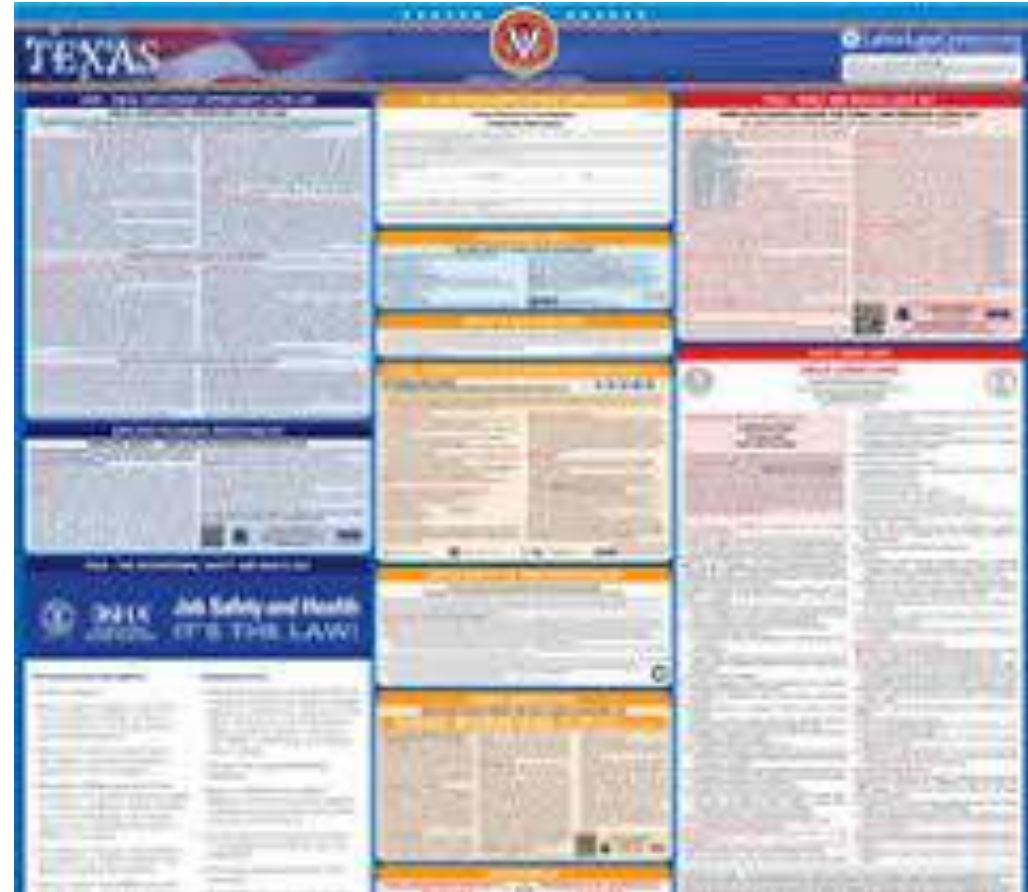- All equipment resides on an Inventory List

- Manufacturer's IFUs determines need for Inspection vs Preventive Maintenance (PM)

- Process in place for tracking due dates for PM

- Evidence of initial inspection BEFORE use in patient care

- Annual Bio-Med inspection is evident with stickers or report

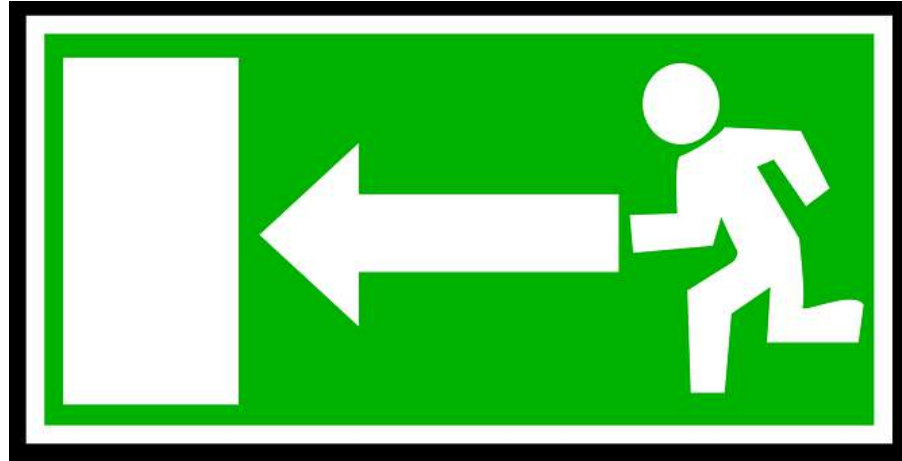- Equipment not in use is labeled as such and stored away

Physical Plant

Physical Plant

Physical Plant

Fire Safety Process per State Regulations

Why have vials become such a problem?

- Possibly a staff member does not know the difference between a single dose or multi-dose vial.
- Possibly a certain drug always comes to you as an MDV but your supplier sent a shipment where the drug was an SDV.
- Possibly we store MDVs and SDVs together making it easy to confuse.

What to do:
- Train all staff to always look at the vial to verify if it's an SDV or MDV and to check the date.
- Train staff that SDVs do not have a preservative in the vial and why that's important.
- In the drug closet, separate the MDVs from the SDVs
- Label all SDVs with a sticker

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Single Dose Vials

Ensure Single-Dose Vials (SDVs) Are Never Used for More Than One Patient

Multi Dose Vials

Do Not Assume All Staff Know the Difference Between SDVs and MDVs.

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Why have vials become such a problem?

Multi Dose Vials
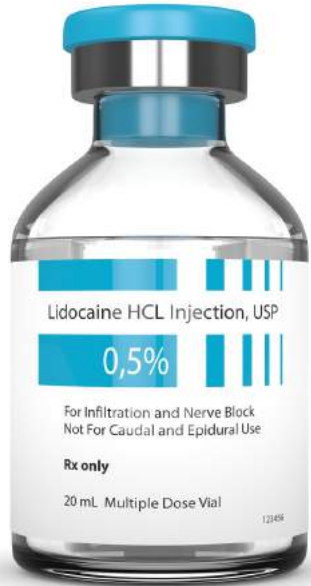
Beyond-Use Date

28 Days

Single Dose Vials

NEVER DATED

Medications

Ensure Single-Dose Vials (SDVs) Are **Never** Used for More Than One Patient.

Once and done, discard!

Medication Refrigerators

No medications in the door of the refrigerator
Use water bottles to take up dead space

https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf

Controlled Substances

- Controlled Substances (CS) locked in a Substantial Cabinet.

- Recordkeeping Logs for Ordering/ Dispensing.

- MDVs, Storage in Sample Closet, Med Fridge, or Emergency Boxes must be secured.

Medications: Samples

Use the sticker method!

Samples

Secured/Organized In Original Containers

Sample Log

Sample Medications secured and

Logged to track in the event of a recall

Infection Prevention
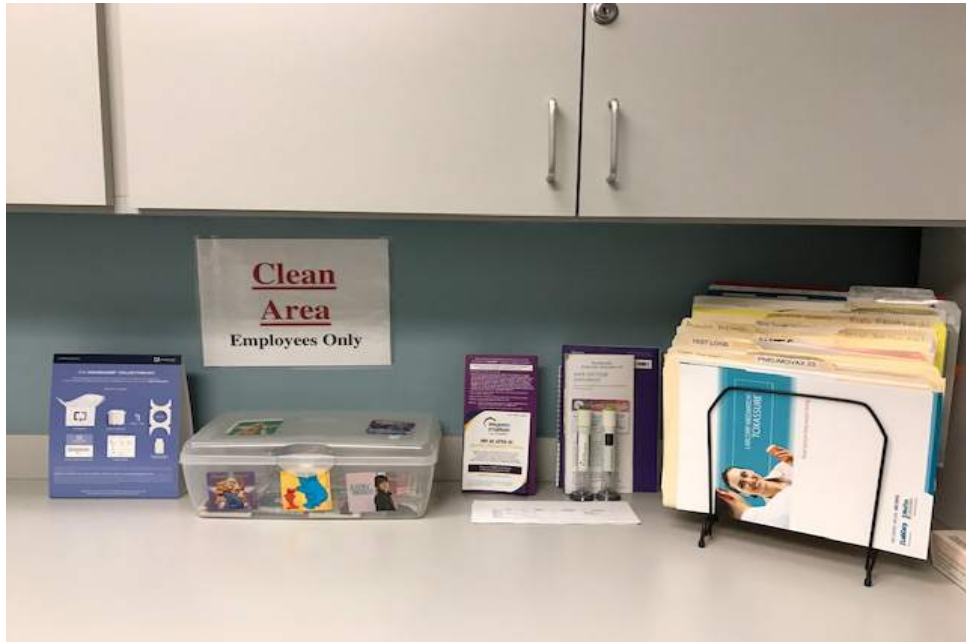
Clean to Dirty Process to Avoid Cross Contamination

Infection Prevention Best Practices

- OSHA training upon hire and annually

- PPEs are available and accessible

- Hand Hygiene when appropriate (2020 CMS Focus) ABHR as a priority

- Clean/Dirty Segregation in work and storage areas

- Avoid Cross-Contamination (disinfecting environment, cleaning patient equipment, sterile processing

- No Reuse of Meds/Supplies Designated for Single Use

Infection Prevention

If you are sterilizing instruments be certain you are doing it correctly.

If you are accepting sterilized instruments from the hospital, be certain your staff knows what to accept or reject.

Infection Prevention

Disposable Instrumentation is the easiest way to be compliant with recommended practices from nationally recognized organizations.

HIPAA

Visible PHI

Computer Time Outs

Cloud Storage

Passwords

Social Media

491.7 Organizational structure

§ 491.7 Organizational structure.

    (a) *Basic requirements.*
        (1) The clinic is under the medical direction of a physician
        (2) The organization's policies and its lines of authority and responsibilities are clearly set forth in writing.

    (b) *Disclosure.*
        The clinic discloses the names and addresses of:
        (1) Its owners
        (2) The person principally responsible for directing the operation of the clinic
        (3) The person responsible for medical direction.

491.8 Staffing and Staff Responsibilities

Staffing.

- At least **one PA or NP** must be an **employee** of the clinic.
  .
- A Physician, NP, PA, certified nurse-midwife, clinical social worker, or clinical psychologist is
  available to furnish patient care services at all times the clinic operates.
  In addition, for RHCs, an NP, PA, or certified nurse-midwife Is available to
  furnish patient care services at least **50 percent** of the time the RHC operates.

491.8 Staffing and Staff Responsibilities

Physician responsibilities. The physician performs the following:

(1) Provides medical direction for the clinic's health care activities and consultation for, and medical supervision of the health care staff.

(2) In conjunction with the PA or NP participates in developing, executing, and periodically reviewing the clinic's written policies and the services provided to Federal program patients.

(3) Periodically reviews the clinic's patient records, provides medical orders, and provides medical care services to the patients of the clinic

What does your review policy say? How many charts per month or quarter per NP or PA?

491.8 Staffing and Staff Responsibilities

Physician assistant and nurse practitioner responsibilities.

(1) The PA or NP members of the clinic'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' records.

(2) The PA or NP performs the following functions, to the extent
        they are not being performed by a physician:
    (i) Provides services in accordance with the clinic's policies;
    (ii) Arranges for or refers patients to needed services that cannot be
        provided at the clinic; and
    (iii) Assures that adequate patient health records are maintained
        and transferred as required when patients are referred.

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491.9 Provision of Services

491.9 Provision of services.

    (a) *Basic requirements.*

        (1) All services offered by the clinic are furnished in accordance with applicable Federal, State, and local laws; and

        (2) The clinic is primarily engaged in providing outpatient health services and meets all other conditions of this subpart.

        (3) The laboratory requirements in <u>paragraph (c)(2)</u> of this section apply to RHCs.

Lab

6 Required tests in the Clinic:

- Chemical examination of urine by stick or tablet method
- Hemoglobin or Hematocrit
- Blood Glucose
- Examination of stool specimens for occult blood
- Pregnancy Test
- Primary Culturing for transmittal to a certified lab

Clinic follows all Manufacturer's IFU for equipment and supplies.

.

Lab

- Clinic must have the ability to do all 6 required tests.

- Most common one missing is Hemoglobin or Hematocrit for Provider Based clinics.

- All reagents, strips, controls, etc., must be in date.

- CLIA Certificate is current and posted.

- CLIA has correct clinic name, address and lab director

491.9 Provision of Services

(b) *Patient care policies.*

(1) The clinic'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 PAs or NPs. ******At least one member is not a member of the clinic or center staff.**

491.9 Provision of Services

(b) *Patient care policies.*

    (3) The policies include:
        (i) A description of the services the clinic furnishes directly and those furnished through agreement or arrangement.
        (ii) 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.
        (iii) Rules for the storage, handling, and administration of drugs and biologicals.
    (4) These policies are reviewed at least **biennially** by the group of professional personnel required. (Physician, NP/PA and outside person)

491.9 Provision of Services

(C) Direct Services

          (3) *Emergency.* 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.

- While each category of drugs and biologicals must be considered, all are not required to be stored. An RHC must have those drugs and biologicals that are necessary to provide its medical emergency procedures to common life-threatening injuries and acute illnesses.
- The RHC should have written policies and procedures for determining what drugs/biologicals are stored to provide emergency services.
- Policies and procedures should also reflect the process for determining which drugs/biologicals to store, including who is responsible for making the determination.
- They should also be able to provide a complete list of which drugs/biologicals are stored and in what quantities.

Supplies

- Telfa, gloves, peroxide, electrodes, needles

- Iodoform gauze, etc.

- Check anything with a date!

Medical Records 491.10

	Medical Record Audit Tool Insert "Y" (YES) if evidence is found, "N" (NO) if evidence of is missing, or "NA" if not applicable. Insert an "M" next the patient number if the patient is a minor child.							
Patient	**Patient ID & Social Data**	**Written Consent to Treat**	**Medical History**	**Health Status & Patient Health Needs**	**Summary & Patient Instructions**	**Labs Diagnostics & Consult Info**	**Physicians' Orders & Treatments & Medications (includes allergies)**	**Signature of Provider & Date**
1.								
2.								
3.								
4								

491.11 Biennial Evaluation

A review of your program every two years:

Must include review of:

- 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; and
- The clinic's health care policies.

491.11 Biennial Evaluation

Why do this ?

- To determine whether:

    - Utilization of services was appropriate;
    - The established policies were followed; and
    - Any changes are needed.

The clinic considers the findings of the evaluation and takes corrective action if necessary.

RHC Emergency Preparedness (EP)

Lessons Learned 2005

A lesson learned from Hurricane Katrina: In 2005, only 25% of office-based providers were using electronic medical records.

Entire lifetimes of healthcare documentation were lost forever for many critically and chronically ill patients. EMR is now the standard.

Lessons Learn 2017

Camp Fire

Paradise, CA

- Getting ambulances is a big problem
- When to evacuate

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Risk Assessment and Planning

All Hazards Risk Assessment

Community-Based
Clinic-Based

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Risk Assessment and Planning

_What events are most likely to impact
the services your organization delivers to patients?_

- Short-term Inclement Weather Events

- Power or Water Interruptions

- Provider/Staff Illness

- Technological/Communication Failures

- Fire

- Wildfires

- Floods

Policies and Procedures

- Reviewed and updated biennially.

Including:

(1) Safe evacuation from the RHC, which includes appropriate placement of exit signs; staff responsibilities and needs of the patients.

(2) A means to shelter in place for patients, staff, and volunteers who remain in the facility.

(3) A system of medical documentation that preserves patient information, protects confidentiality of patient information, and secures and maintains the availability of records.

(4) The use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of State and Federally designated health care professionals to address surge needs during an emergency.

Communication Plan

- Staff

- Providers

- Entities Providing Services Under Arrangement

- Other RHCs/FQHCs

- Volunteers

- Federal/State/Tribal/Regional/Local EP Staff

DON'T FORGET TO INCLUDE THE OTHER RHCs IN YOUR AREA – YOU MUST INCLUDE CONTACT INFORMATION EVEN IF THEY ARE NOT IN YOUR HEALTHCARE SYSTEM.

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Communication Plan

Are clinics required to have volunteers as part of their Emergency Preparedness Plan?

RHCs have the flexibility to include volunteers in the emergency plan as indicated by the individual risk assessment. _HOWEVER_, if volunteers are included, the policies should address their use and they must be trained on the EP Plan.

Communication Plan

Rethink the Phone Tree

Compile "advanced emergency phone trees" which not only requests staff member home phone numbers, but also:

- Mobile numbers for text messaging

- Email addresses for mass communication

- Emergency family contact information

- Alternate addresses in case of temporary relocation

Communication Plan

- 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.

Training

- Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles,

- Provide emergency preparedness training at least every 2 years.

- Maintain documentation of the training, i.e. training log

- Demonstrate staff knowledge of emergency procedures.

- If the emergency preparedness policies and procedures are significantly updated, the RHC/FQHC must conduct training on the updated

Testing

- One exercise or event a year.

- Alternate Active exercise/event with Table Top

- Analyze the <u>RHC</u>s response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the <u>RHC</u>'s emergency plan, as needed.

What we See

- Having the EP Plan, but not training the staff

- Omitting required contact information

- Lacking an all Hazards Vulnerability Assessment especially Provider based clinics

- Provider-Based Clinics stating they are part of an integrated healthcare system, but not meeting higher level of documentation

- No policy on volunteers

- No power outage policy for refrigerated medications

COVID-19
After Action Report

Pandemic 2020

- **Clinic Name: xxxxxx Clinic**

- **Event Name:** COVID 19 Outbreak 2020

- **Event Begin Date:** March 9, 2020

- **Event End Date: , 2020**

- **Duration:** 22 weeks

The purpose of this report is to analyze event results, identify strengths to be maintained and built upon, identify potential areas for further improvement, and support the development of corrective actions that will guide future emergency preparedness initiatives to advance overall emergency preparedness within our clinic.

Pandemic 2020

- This event in the 8 months of 2020 occurred as a result of a Corona Virus from Wuhan, China which resulted in a worldwide Pandemic.

- January 22, 2020 CDC confirmed the first case of COVID-19 in the U.S.

- January 30, 2020 The WHO declared the outbreak a Public Health Emergency (PHE)

- January 31, 2020 Secretary Azar declared a PHE in the U.S.

- March 11, 2020 The WHO declared COVID-19 a Pandemic

- March 13, 2020 President Trump declared a National Emergency in the U.S.

- March 5, 2020 Governor Inslee declares a state of emergency in Washington.

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Your COVID-19 After Action Report (AAR)

Executive Summary

- This event in the first half of 2020 occurred as a result of a Corona Virus from Wuhan, China which resulted in a worldwide Pandemic.

- The event began for ABC clinic on March __, 2020.

- The emergency team was composed of _____ (names of staff in leadership)

Major Strengths

- Enter the top three strengths of your Emergency Plan

  Such as: Staff training conducted on infection prevention

  Plan to triage patients who come to the clinic

  Plan to put sign on door to call from the car if symptomatic

AAR

Areas of Improvement

Need to order extra supplies such as masks and hand sanitizer earlier

Need to minimize things in the waiting room to decrease things needing disinfecting.

Need for more screening of clinic staff, temps in the morning

Need more separation of patients

AAR

Event Successes

Staff immediately began calling patients instead of visit to decrease exposure for patients

Some staff sent to hospital to assist with surg

Improvement Plan

Observations	Recommendations	Corrective Action	POC	Start Date	Completion Date
Lack of supplies	Keep more on hand	Ordered	X	6.1.20	7.15.20
Patients not coming to office	Increase in Telehealth				
More staff training	Monthly training				

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Staff

- Report reviewed with staff

- Assignments given

- Attendance log at AAR meeting

COVID-19

Removing PPE*

- Doffing (taking off the gear): More than one doffing method may be acceptable. Training and practice using your healthcare facility's procedure is critical.

Below is one example of doffing.

1. Remove gloves. Ensure glove removal does not cause additional contamination of hands. Gloves can be removed using more than one technique (e.g., glove-in-glove or bird beak).

2. Remove gown. Untie all ties (or unsnap all buttons). Some gown ties can be broken rather than untied. Do so in gentle manner, avoiding a forceful movement. Reach up to the shoulders and carefully pull gown down and away from the body. Rolling the gown down is an acceptable approach. Dispose in trash receptacle.*

3. HCP may now exit patient room.

4. Perform hand hygiene.

*cdc.gov/COVID-19

AT THE CLINIC

- Go to the car, give them a mask and triage the patient in the car.

    Ask screening questions:
        Have you been in contact with someone who has the virus

- Check for fever, sore throat, and shortness of breath.

- Decide: If suspicious for COVID-19, three choices
    Send them home if minimal symptoms to self quarantine
    Send them for testing
    Send them to a hospital if acute symptoms needing further care.

- Inform infection prevention and control services, local and state public health authorities, and other healthcare facility staff as appropriate about the presence of a person under investigation for COVID-19.

- Limit the number of patients in the waiting room.

YOUR FACE

- Try not to touch your face.

- The mucus membranes on your face are easy entry-ways for the coronavirus.

- Sounds simple but most people touch their face 92 times a day and we touch it more when we are stressed.

- Yes someone did a study on that.

- Maybe that will help you remember!

Suspected Positive Patients

- Use one room only and have a sign on that door.

- If patient is able, they should come in alone.

- Alert Public health authorities.

- Keep a log on everyone who enters that room, staff included.

- Keep the number of people in that room to a minimum, only essential staff PPE for Staff.

If you use non-disposable linen, how are you handling it? Try not to use it at this time.

Get Your Clinic Ready

- Train your Staff, take daily staff temperatures since so many are asymptomatic.

- Ensure that clinical staff know the right ways to put on, use, and take off PPE safely
-
- Recognize the symptoms of COVID-19— fever, cough, shortness of breath

- Implement procedures to quickly triage and separate

- Emphasize hand hygiene and cough etiquette for everyone.

- Ask staff to stay home if they are sick.

- Send staff home if they develop symptoms while at work.

Risk Assessment and Planning

EP PLAN Must:

- 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.

- Address patient population, including 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.

Risk Assessment and Planning

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

New as of 11.29.19

Documentation of efforts to contact these officials is no longer required but you must have a process.

ASPRTRACIE.HHS.GOV

CMS.GOV and CDC.GOV

- Providers and Suppliers should refer to the resources on the CMS website for assistance in developing emergency preparedness plans.

CMS Website Link:

https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/index.html

CMS.GOV

CMS.GOV

CMS.GOV

Frequently Asked Questions (FAQs) have been developed and are posted on the CMS Emergency Preparedness Website https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/Emergency-Prep-Rule.html

SCGEmergencyPrep@cms.hhs.gov

FEMA.GOV

CERT DRILLS AND EXERCISES: TABLETOP EXERCISE #1

Table of Contents

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CERT: Community Emergency Response Team

https://www.citizencorps.fema.gov/cc/listCert.do

CERT: Community Emergency Response Team

The Community Emergency Response Team (CERT) program educates volunteers about disaster preparedness for the hazards that may impact their area and trains them in basic disaster response skills, such as fire safety, light search and rescue, team organization, and disaster medical operations.

CERT offers a consistent, nationwide approach to volunteer training and organization that professional responders can rely on during disaster situations, which allows them to focus on more complex tasks.

Through CERT, the capabilities to prepare for, respond to and recover from disasters is built and enhanced.

https://www.citizencorps.fema.gov/cc/listCert.do

CALHOSPITALPREPARE.ORG

Survey Findings

- 100% compliance is necessary for RHC Certification
- Statement of Deficiency will be received within 10 _business_ days
- Clinic has 10 _calendar_ days to submit an acceptable Plan of Correction.
- Standard level deficiencies must be corrected within 60 calendar days.
- Condition level deficiencies require re-survey within 45 calendar days from the original survey date (can loose billing number).

We Do Accreditation, Call us!

Kate Hill, RN

VP Clinic Division

215-654-9110

khill@thecomplianceteam.org

Thank You.

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