



Survey Readiness during the Public Health Emergency (PHE)



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VP Clinic Division
Feb 23, 2021

First a Huge Thank You



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>

Update your 855a and CMS 29 as things change
Never move without checking the HPSA & with State office



Hours posted

Name matches 855a

Safe, accessible
entrance

42 CFR 491.4 Licensing

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

Personnel File Audit Tool											
Insert "Y" (YES) if evidence is found, "N" (NO) if evidence of is missing, or "NA" if not applicable.											
Staff Member	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

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

491.6 Physical Plant and Environment

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.

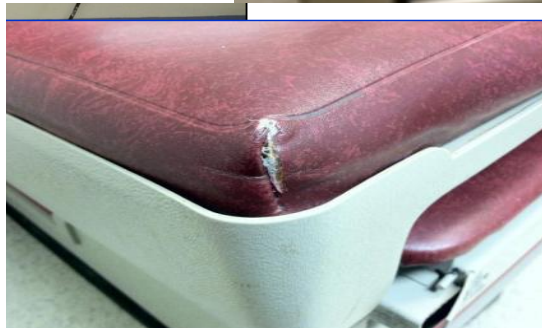
Maintenance. The clinic has a preventive maintenance program to ensure that:

- (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

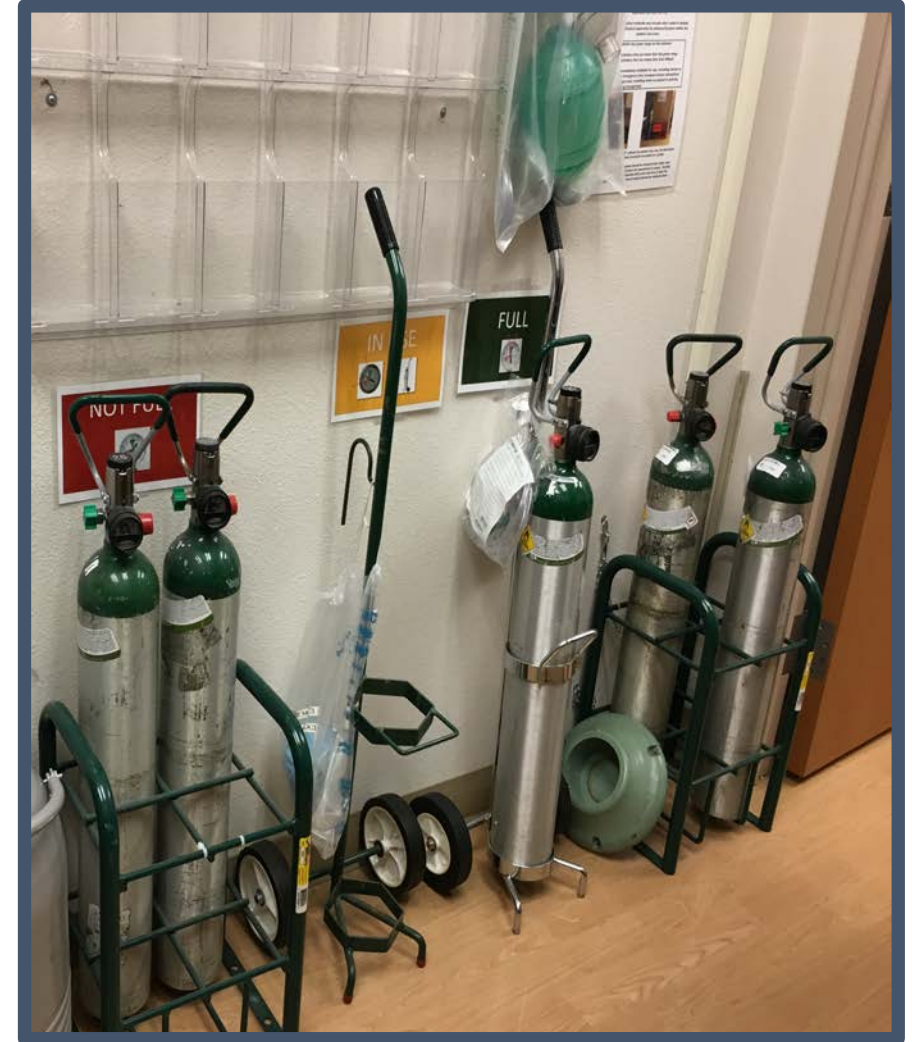
- Sharp containers cannot be easily accessible.
- Several states require specific times on emptying of sharps containers.
- Must be marked with Bio-Hazard sticker



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.

Waiting Room Posting:

Privacy Notice

Patient Rights and responsibilities



Physical Plant: Equipment

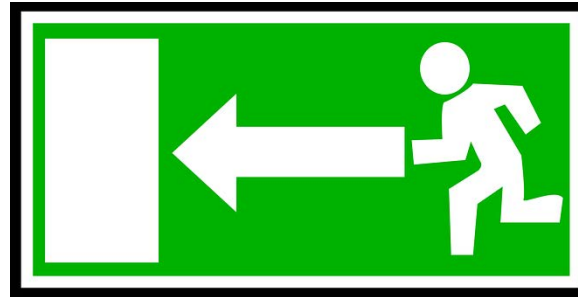
- All equipment resides on an Inventory List
- Manufacturer's IFUs determines need for Inspection vs Preventive Maintenance (PM)
- Process in place for tracking due dates for PM
- Evidence of initial inspection BEFORE use in patient care
- Annual Bio-Med inspection is evident with stickers or report
- Equipment not in use is labeled as such and stored away



Physical Plant



Physical Plant



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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Multi Dose Vials

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

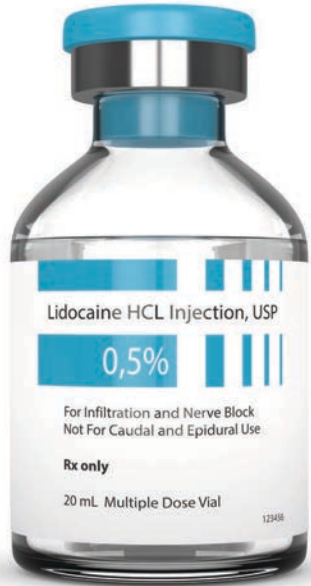


Single Dose Vials

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

Why have vials become such a problem?

Multi Dose Vials



Beyond-Use Date

28 Days

Single Dose Vials

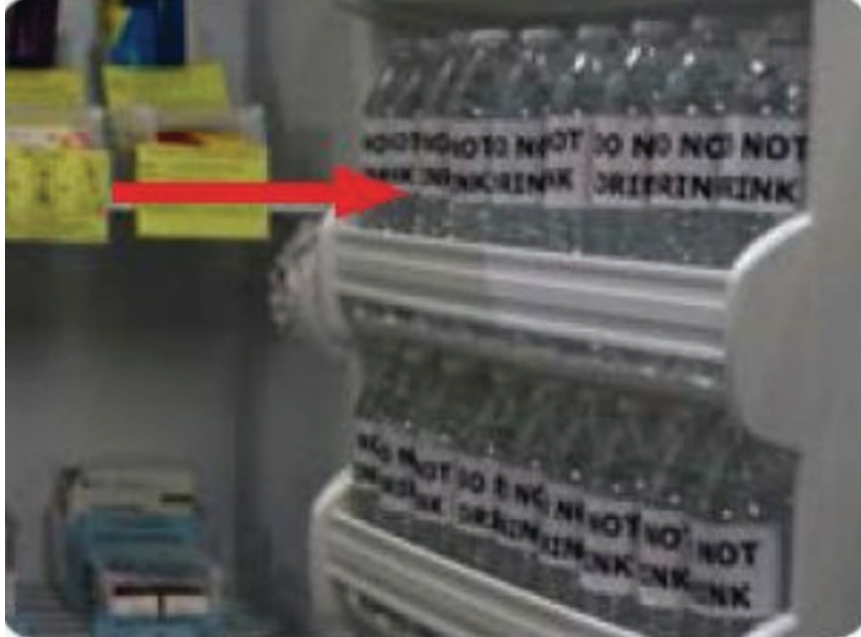


NEVER DATED



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



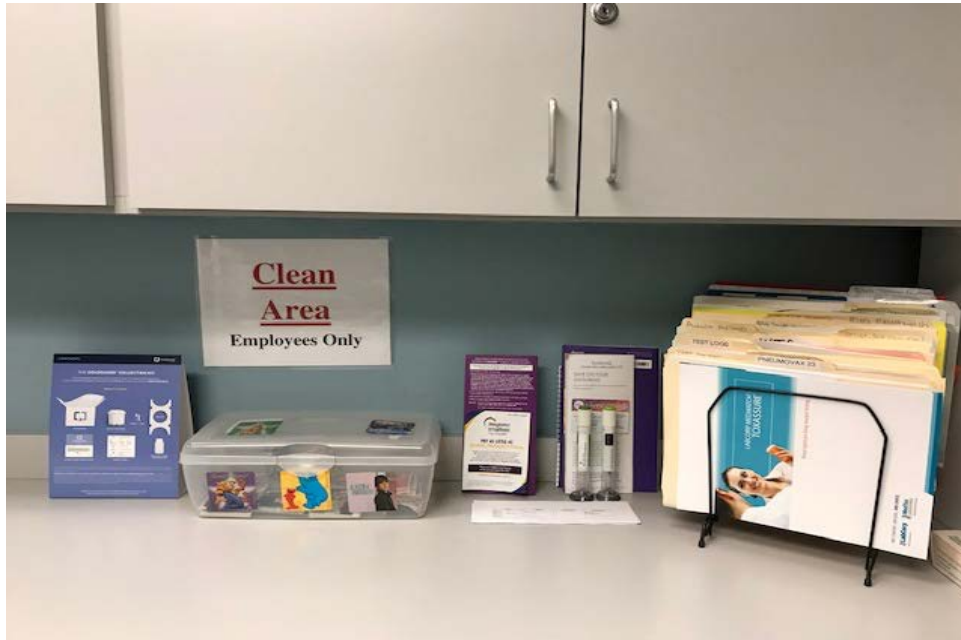
Logged to track in the event of a recall



Use the sticker method

Samples
are secured
and
organized
in original
containers

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



491.7 Organizational structure

Basic requirements.

The clinic is under the medical direction of a physician

The organization's policies and its lines of authority and responsibilities are clearly set forth in writing.

Disclosure.

The clinic discloses:

Its owners

The person responsible for medical direction

491.8 Staffing and Staff Responsibilities

- The clinic staff includes one or more physicians and one or more NPs or PAs.
- The physician member of the staff may be the owner of the rural health clinic, an employee of the clinic or center, or under agreement with the clinic to carry out the responsibilities.
- The PA or NP, nurse-midwife, clinical social worker or clinical psychologist member of the staff may be the owner or an employee of the clinic or may furnish services under contract.
- In the case of a clinic, 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.
This means no patients getting blood draws, weight or BP checks without a provider in the clinic.
- 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

(b) *Physician responsibilities.* The physician performs the following:

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

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.

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

(c) *Physician assistant and nurse practitioner responsibilities.*

(1) The PA or NP members of the clinic's staff:

Participate in the development, execution and periodic review of the written policies.

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:

Provides services in accordance with the clinic's policies

Arranges for or refers patients to needed services not at the clinic

Assures that adequate patient health records are maintained and transferred as required when patients are referred.

491.9 Provision of Services

Basic requirements.

All services offered by the clinic are furnished in accordance with applicable Federal, State, and local laws.

The clinic is primarily engaged in providing outpatient health services, means 51% Primary Care.

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

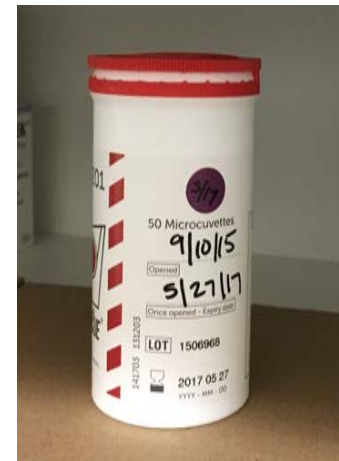
Must have the ability to do all 6 required tests

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 and address



Expired

491.9 Provision of Services

Patient care policies.

The clinic's health care services are furnished in accordance with appropriate written policies which are consistent with applicable State law.

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

Patient care policies.

The policies include:

- A description of the services the clinic furnishes directly and those furnished through agreement or arrangement.

- 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.

- Rules for the storage, handling, and administration of drugs and biologicals.

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

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.

The purpose of the evaluation is to determine whether:

- The utilization of services was appropriate;

- The established policies were followed; and

- Any changes are needed.

*** The clinic or center staff considers the findings of the evaluation and takes corrective action if necessary.

491.12 Emergency Preparedness

- 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 What is Different? Almost Everything



The Clinic Door

If you are experiencing any of these symptoms:

Cough

Fever

Shortness of breath

Please go back to your car and call us.

Enter Phone Number

We will come OUTSIDE to you.



COVID-19 Best Practices

- Process for screening patients and staff
- Stop sign on clinic door
- Hand sanitizers at entrance, mask sign
- Use of PPE and ABHR
- Social distancing as much as possible especially in the waiting room, visitor restrictions
- Separate well from symptomatic patients in the clinic
- Quarantine policy for sick employees
- Use of Telehealth
- Limiting patients in the waiting room
- Limiting any unnecessary items in the waiting room
- Disable water fountain
- Robust cleaning, what surfaces?, how often?

CMS 1135 Waivers

There are 32 Waiver which apply to RHCs.

CMS regularly updates a webpage that includes Interim Final Rules, waivers, and provider-specific fact sheets related to COVID-19, which can be found here:

<https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf>

CMS 1135 Waivers

6. Practitioner Locations

CMS is waiving the Medicare requirement that a physician or non-physician practitioner must be licensed in the State in which s/he is practicing for individuals for whom the following four conditions are met:

- 1) must be enrolled as such in the Medicare program,
- 2) must possess a valid license to practice in the State which relates to his or her Medicare enrollment,
- 3) is furnishing services – whether in person or via telehealth – in a State in which the emergency is occurring in order to contribute to relief efforts in his or her professional capacity, and
- 4) is not affirmatively excluded from practice in the State or any other State that is part of the 1135 emergency area.

CMS 1135 Waivers

3. Virtual Check-Ins, Remote Evaluations, & E-Visits

Clinicians can provide virtual check-in, remote evaluation of patient-submitted video/images, and e-visit services to both new and established patients.

4. Remote Patient Monitoring

Clinicians can provide remote patient monitoring services to both new and established patients. These services can be provided for both acute and chronic conditions and can now be provided for patients with only one disease.

CMS 1135 Waivers

9. Temporary Expansion Locations for RHCs and FQHCs

CMS is waiving the requirements at 42 CFR §491.5(a)(3)(iii) which require RHCs and FQHCs be independently considered for Medicare approval if services are furnished in more than one permanent location.

Due to the current PHE, CMS is temporarily waiving this requirement removing the location restrictions to allow flexibility for existing RHCs/FQHCs to expand services locations to meet the needs of Medicare beneficiaries. This flexibility includes areas which may be outside of the location requirements 42 CFR §491.5(a)(1) and (2) for the duration of the PHE.

CMS 1135 Waivers

18. Certain Staffing Requirements for RHCs and FQHCs

42 CFR 491.8(a)(6). CMS is waiving the requirement in the second sentence of § 491.8(a)(6) that a nurse practitioner, physician assistant, or certified nurse-midwife be available to furnish patient care services at least 50 percent of the time the RHC operates. CMS is not waiving the first sentence of § 491.8(a)(6) that requires a physician, nurse practitioner, physician assistant, certified nurse midwife, clinical social worker, or clinical psychologist to be available to furnish patient care services at all times the clinic or center operates.

Your After-Action Report: Pandemic Event

Clinic Name:

- Event Begin Date: March 9, 2020
- Event End Date: Feb 2021
- Duration: 11 + months

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.

- Jan 22, 2020 The Center for Disease Control (CDC) confirmed first COVID-19 case in the U.S.
- Jan 30, 2020 The World Health Organization (WHO) declared the outbreak a public health emergency (PHE) of international concern.
- Jan 31, 2020 HHS Secretary Azar declares a PHE in the U.S.
- March 23, 2020 Governor Brown declared a State of Emergency and activated the Emergency Operations Center.
- March 11, 2020 The COVID-19 outbreak characterized as a pandemic by the WHO.
- March 13, 2020 President Trump declares a National Emergency concerning the COVID-19 outbreak.
- Jan 2021, the Acting HHS Secretary extended the PHE to April 20, 2021.

Your After-Action Report: Pandemic Event

Executive Summary

- This event in 2020 occurred as a result of a Corona Virus from Wuhan, China which resulted in a worldwide Pandemic. The emergency team was composed of _____ (names of staff in leadership)

Major Strengths

Staff training conducted on infection prevention

Plan to triage patients who come to the clinic

Plan to put a sign on the door to go back to car and call.

Areas of Improvement

Need to order extra PPE 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 to set up refill process during Pandemic or epidemic

Need for more telehealth

Public service announcements to tell community we are seeing patients

Need to change message on answering machine

More local testing

Your After-Action Report: Pandemic Event

Event Successes

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

Some staff sent to hospital to assist with surge

Recruited some experienced staff from hospital to help with triage

Sign on door sending patients to the car to call

Limited seating in the waiting room

Extra hand sanitizer and tissues in the waiting room

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 lose billing number).

Thank You and Be Safe out There



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We accredit RHCs, Call us.