RURAL HEALTH WORKSHOP

The Rural Health Clinic: What Has Changed?

WELL-AHEAD

LOUISIANA RURAL HEALTH ASSOCIATION

Speaker

- Kate Hill
  - VP Clinic Division
  - The Compliance Team, Inc.

The Rural Health Clinic: What Has Changed?

Kate Hill RN
VP Clinic Division

KORH WEEKLY UPDATE
Kentucky Office of Rural Health

The ComplianceTeam

Learning Objectives

- What has Changed?
- What hasn't Changed?
- Self Survey to Enhance Compliance

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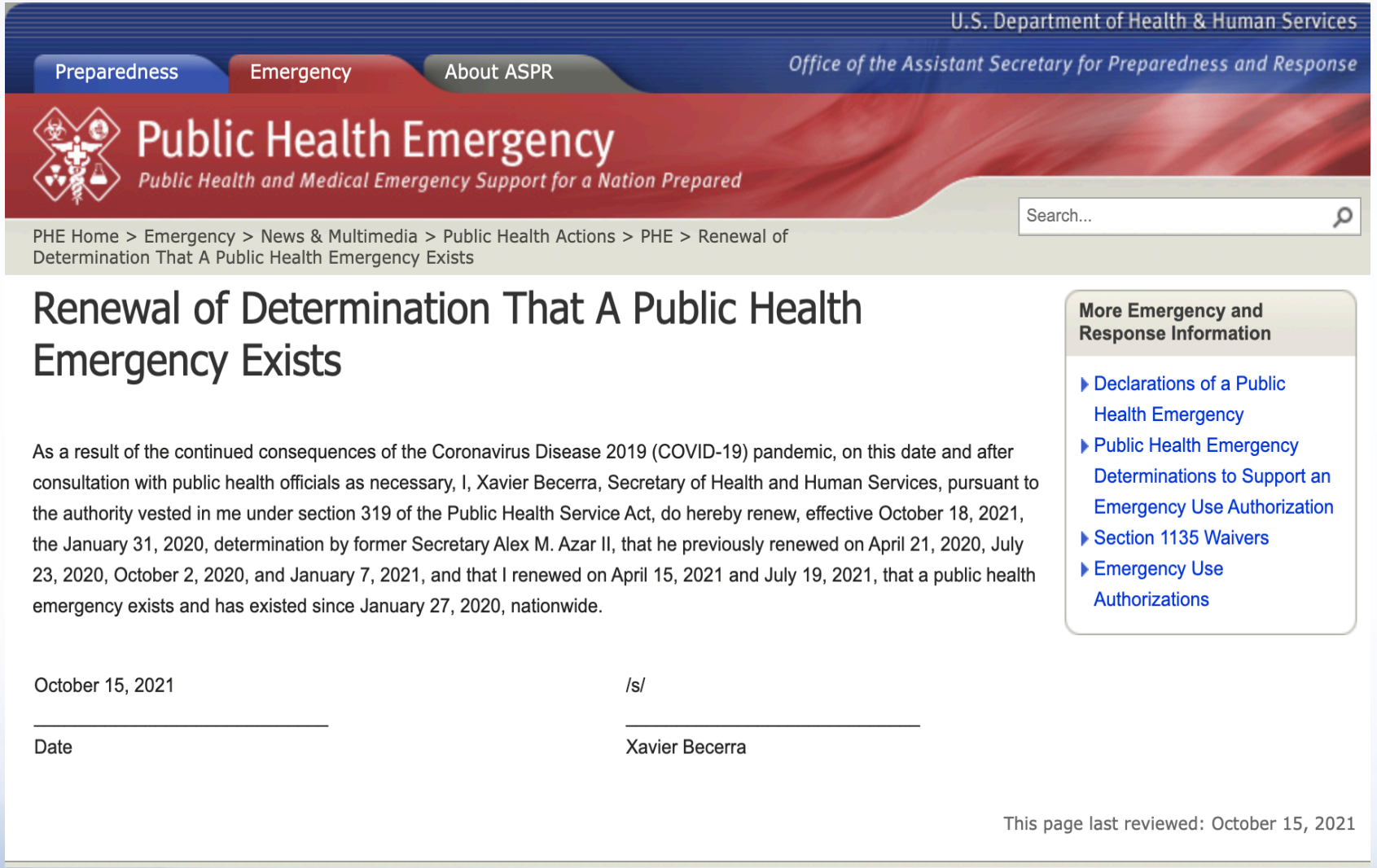
Secretary Becerra Extends PHE to January 2022



U.S. Department of Health & Human Services

Preparedness | Emergency | About ASPR

Office of the Assistant Secretary for Preparedness and Response

Public Health Emergency

Public Health and Medical Emergency Support for a Nation Prepared

Search...

PHE Home > Emergency > News & Multimedia > Public Health Actions > PHE > Renewal of Determination That A Public Health Emergency Exists

Renewal of Determination That A Public Health Emergency Exists

As a result of the continued consequences of the Coronavirus Disease 2019 (COVID-19) pandemic, on this date and after consultation with public health officials as necessary, I, Xavier Becerra, Secretary of Health and Human Services, pursuant to the authority vested in me under section 319 of the Public Health Service Act, do hereby renew, effective October 18, 2021, the January 31, 2020, determination by former Secretary Alex M. Azar II, that he previously renewed on April 21, 2020, July 23, 2020, October 2, 2020, and January 7, 2021, and that I renewed on April 15, 2021 and July 19, 2021, that a public health emergency exists and has existed since January 27, 2020, nationwide.

More Emergency and Response Information

- Declarations of a Public Health Emergency
- Public Health Emergency Determinations to Support an Emergency Use Authorization
- Section 1135 Waivers
- Emergency Use Authorizations

October 15, 2021 — Date

/s/ — Xavier Becerra

This page last reviewed: October 15, 2021

The ComplianceTeam

Appendix Z update

New Guidance March 26, 2021. Effective 4.26.21

Your exercise must be one of your listed items on your HVA, unless it's an event.

HVA must include EID (Emerging infectious Disease)

> Since Emerging infectious disease outbreaks may affect any facility in any location across the country, a comprehensive EP program should include emerging infectious diseases.
>
> The plan should encompass how the facility will plan, coordinate and respond to a localized and widespread pandemic.

Facilities should ensure their EP programs are aligned with their State and local emergency plans/pandemic plans.

The plan must be in writing.

Appendix Z update

New Guidance March 26, 2021. Effective 4.26.21

Testing

Survey Procedures: Refer to the facility's risk assessment to determine if the training and testing program is reflecting risks and hazards identified within the facility's program.

- This means you can't use something as an exercise unless it's on your hazard list.

Testing should also not test the same thing year after year or the same response processes. The intent is to identify gaps in the facility's EP program as it relates to responding to various emergencies and ensure staff are knowledgeable on the facility's program.

Appendix Z update

New Guidance March 26, 2021. Effective 4.26.21

Volunteers:

While not required to use volunteers as part of their plans to supplement or increase staffing during an emergency, the facility must have policies and procedures to address plans or emergency staffing needs.

Survey Procedures:

Ask facility leadership to explain their staffing strategies. Do they use volunteers? If no volunteers are used, does the facility have other emergency staffing strategies?

Verity the facility has included policies and procedures for the use of volunteers another emergency staffing strategies in its emergency plan.

Verify that the facility's program includes a policy and procedures which address surge needs during an emergency.

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Appendix Z update

New Guidance March 26, 2021. Effective 4.26.21

Waivers during a PHE

- The facility's emergency preparedness program must include policies and procedures which outline the facilities role in the provision of care and treatment under 1135 waivers during a declared public health emergency in alternate care sites (ACS).
- Survey; Verify the facility has included policies and procedures in its emergency plan describing the facility's role in providing care and treatment at alternate care sites under an 1135 waiver.

42. CFR 491.1 to 491.12

- § 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.

Location

An RHC must:

- Be in an area defined by the U. S. Census Bureau as non-urbanized
- Be in an area currently designated by the Health Resources and Services Administration (HRSA) within the last 4 years as 1 of the following:

  Primary Care Geographic Health Professional Shortage Area
  Primary Care Population-Group Health Professional Shortage Area
  Medically Underserved Area
  Governor-designated and Secretary-certified Shortage area

Staffing

An RHC must:

- Employee an NP or PA
  (may contract with NPs, CNMS and CSWs but must employ one)
- Have an NP, PA or CNM working at least 50% of the operating hours
- 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 patient gets out of the waiting room unless there is a provider in the building.

Service Requirements

An RHC must:

- Directly provide routine diagnostic and laboratory services
- Have arrangements with 1 or more hospitals to provide medically necessary services unavailable at the RHC.
- Have drugs and biologicals available to treat emergencies
- Provide the following laboratory tests on site:
  - Stick or tablet chemical urine exam or both
  - Hemoglobin or hematocrit
  - Blood sugar
  - Occult blood stool specimen exam
  - Pregnancy Test
  - Primary culturing to send to a certified lab

An RHC may not be primarily a mental disease treatment facility or a rehabilitation agency.
An RHC must be at least 50% Rural Health Clinic services commonly called primary care.

Your Internal Compliance

Conduct your own mock survey with clinic staff based off the agenda that we provided as a handout.

- Hold a kickoff conference with staff and discuss how the mock survey will prepare them for the onsite visit.
- Complete a walk through of the clinic with checklist in hand. Can you answer yes to all the regulations? Are there areas of concern that need more attention?
- Complete a policy review based on the policy section of the checklist. Do you have all the policies? Are they complete? If you are provider-based, are the policies specific to your clinic? (or have you clearly identified that you follow hospital policy?)
- Interview staff to ensure they are knowledgeable about clinic policy, procedures and their individual job responsibilities. They should be comfortable answering any questions that the surveyor may ask.
- Finish with a wrap up conference to discuss any areas of concern that need to be addressed prior to survey. Once you are confident you are ready for survey day, take time to celebrate your accomplishments!

Conducting a Self Survey – Time to Shine!

- Everyone has worked hard to stay compliant and now is their time to shine!
- Set the tone for the mock survey with a discussion to remind staff this is an “open book test” and there should be no surprises.
- If you can answer yes to each item on the checklist, your clinic is in compliance.
- Enthusiasm not apprehension! Your surveyor will conduct a fair and unbiased survey. Staff should not be nervous but ready to show the surveyor what they do best.

The RHC Checklist

Facility Name/Clinic:	Surveyor Number(s):	
	Survey Start Date:	Survey End Date:
Total Number of Exam Rooms:	Time In: Time Out:	Hours Onsite:

CORPORATE COMPLIANCE	STANDARD	YES	NO
The Clinic has a written Corporate Compliance Plan.	COM 1.0		
The Clinic is in good standing with the Medicare/Medicaid Programs.	COM 2.0		
The clinic that participates in Medicare/Medicaid programs has been free of sanctions for a period of at least 2 years.	COM 2.0.1		
The clinic prohibits employment/contracting with individuals or companies, which have been convicted of a criminal felony offense related to healthcare.	COM 2.0.2		
Clinic can provide evidence of verification of individuals through OIG exclusion database.	COM 2.0.2(a)		
Evidence of the process and documentation upon hire and re-verification at a minimum annually.	COM 2.0.2(b)		
Staff of the clinic are licensed, certified, or registered in accordance with applicable State and local laws. (§491.4(b))	COM 3.0		
The clinic has a process to verify personnel are licensed, certified, or registered with applicable State laws.	COM 3.0.1		
This information is documented and tracked in an organized format.	COM 3.0.2		
ADMINISTRATION	**STANDARD**	**YES**	**NO**
The clinics hours of operation are posted outside the clinic.	ADM 3.0.4		
All clinic documents and signage (both internal and external) are consistent with the CMS-855A enrollment application.	ADM 3.0.5		
The Clinic has a governing body or individual who has legal responsibility for the conduct of the clinic.	ADM 4.0		
The clinic discloses the names and addresses of the following: (§491.7(b))	ADM 4.0.1		
• Names of the owner(s). (§491.7(b)(1))	ADM 4.0.1(a)		
• Person principally responsible for directing the clinic's operation. (§491.7(b)(2))	ADM 4.0.1(b)		
• Person responsible for medical direction. (§491.7(b)(3))	ADM 4.0.1(c)		

The Compliance Team Quality Standards and Checklist incorporate the federal regulatory requirements with universal and specialty standards to demonstrate rural excellence through Exemplary Provider Accreditation

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Common Deficiencies

Name on the sign is consistent with CMS 855A application

Posted hours of operation

Changes to Clinic Name, location and Medical Director

- **Before moving:** Check with State office of Rural Health and your MAC to be certain your new address is still in a HPSA, even if it's next door.
  - Your location is grandfathered in at your present location.
- Report name changes to CMS.
- Report change in Medical Director to the State on a CMS29

Biohazard Containers

- Sharps containers cannot be easily accessible.
- Must be marked with a Bio-Hazard sticker

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Mock Survey – 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

Mock Survey – What to Lock

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OIG Exclusion Data Base

OIG Exclusion list:

https://exclusions.oig.hhs.gov/

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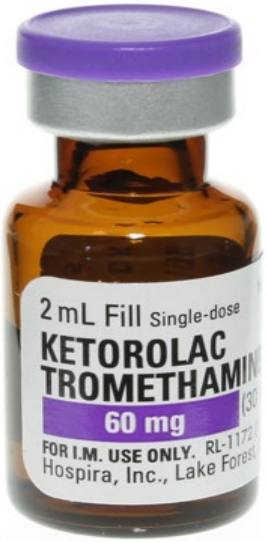
Vials and Outdated Supplies

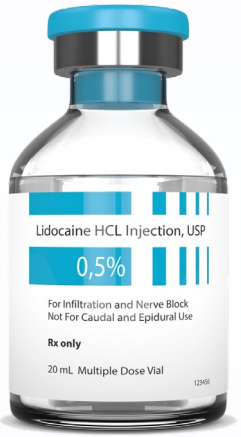
- Possibly a staff member does not know the difference between a single dose or multi-dose vial.
- Possibly a certain drug always comes to you as an MDV but your supplier sent a shipment where the drug was an SDV.
- Possibly we store MDVs and SDVs together making it easy to confuse.

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



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

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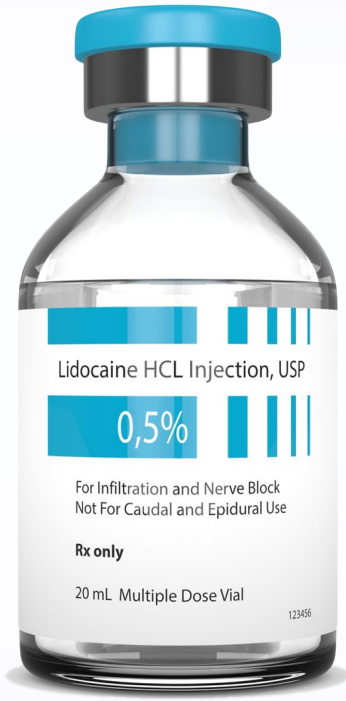
Vials and Outdated Supplies

Multi Dose Vials

28 Days



Single Dose Vials

** There should never be an opened SDV in the drug closet.

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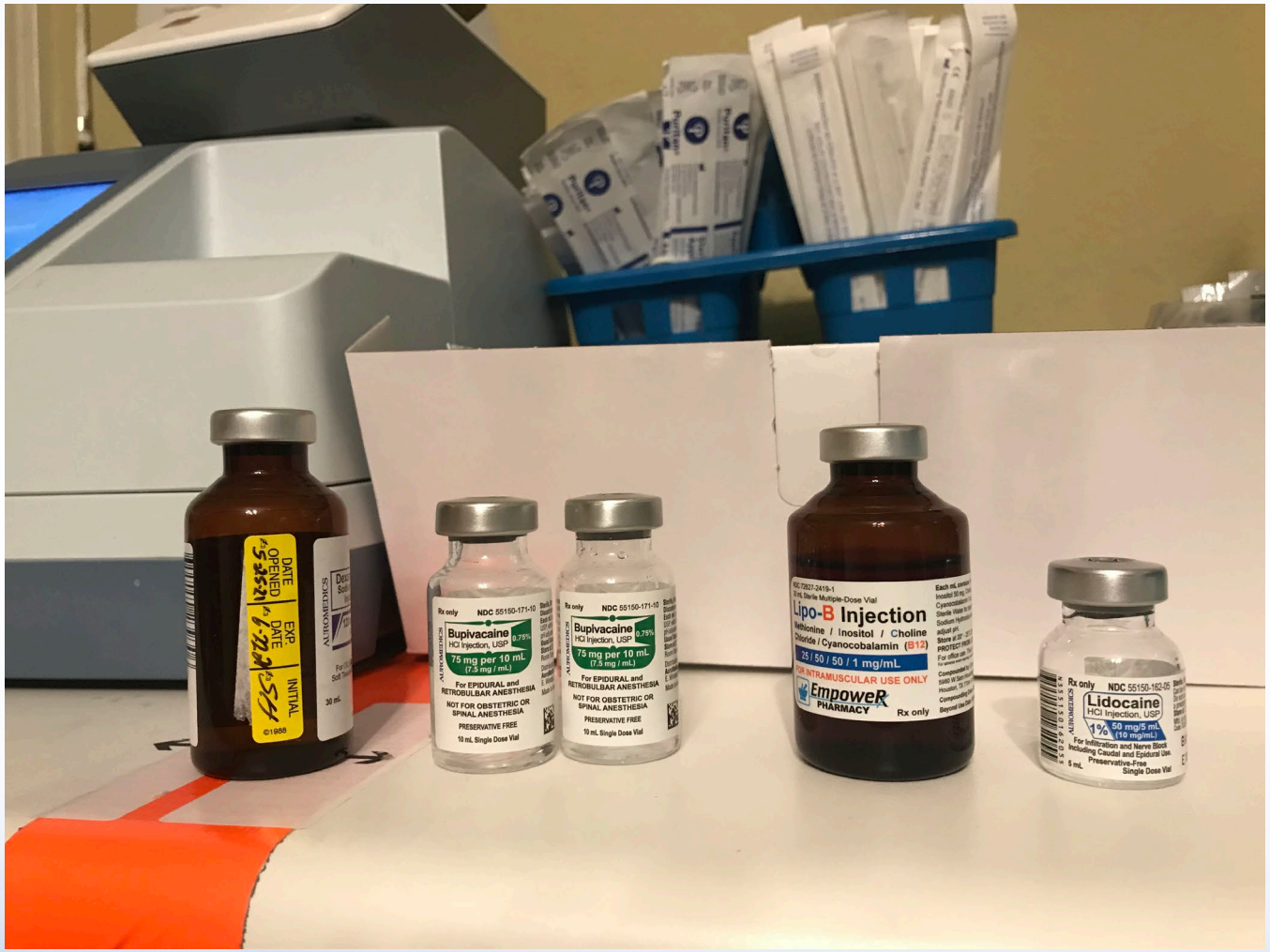
Vials and Outdated Supplies



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Controlled Substances

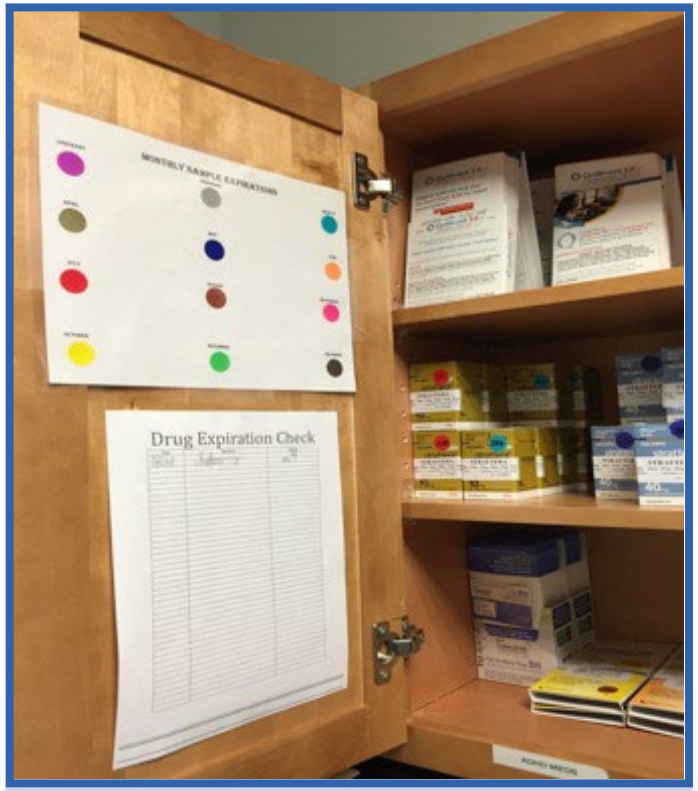
Controlled Substances (CS) locked in a Substantial Cabinet.

Recordkeeping Logs for Ordering/ Dispensing.

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

Mock Survey – Samples

Sample Medications secured and logged to track in the event of a recall



Secured/Organized In Original Containers

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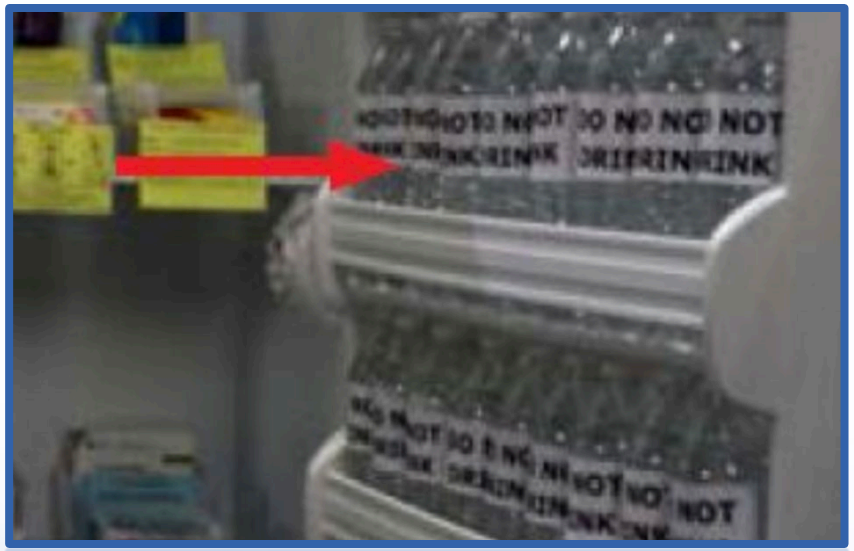
Mock Survey – Refrigerated Medications

- 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

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Mock Survey – Supplies

Telfa, gloves, peroxide, electrodes, needles
Iodoform gauze, etc.

Check anything with a date!

The red sharp container is not acceptable.

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Instruments

Sterilizing instruments in the clinic.

- OR -

Accepting sterilized instruments from the hospital.

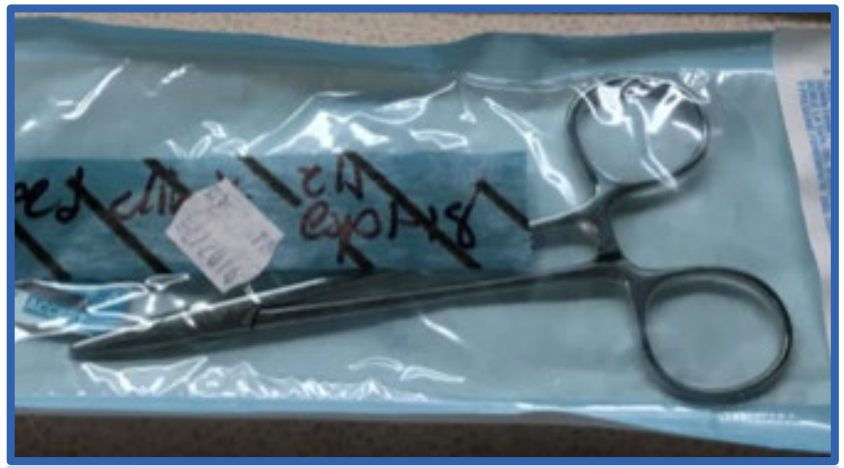

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Chart Review – 2 Types

1. Physician oversight If the State silent, you choose a number and put it in your policy
    - Even when the NP has autonomy
    - Have a review log to prove the number of reviews matches your policy.

2. Quality Improvement to feed into your Biennial Evaluation.
    - Maintain log and keep those charts for inclusion in your evaluation
    - Remember to add a closed record on occasion.

Patient Care Policies

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.

Provision of Services

The clinic is primarily engaged in providing outpatient health services…

Means 51% RHC services

"The services of these practitioners are those commonly furnished in a physician's office or at the entry point into the health care delivery system. These services include taking complete medical histories, performing complete physical examinations, assessments of health status, routine lab tests, diagnosis and treatment for common acute and chronic health problems and medical conditions, immunization programs and family planning."

Appendix G

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. (Medical Director, NP/PA and outside person)

Mock Survey – Emergency Services

- 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.

Mock Survey – Medical Record Review

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.								

Annual Program Evaluation

A review of your program every year:

- 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.

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.

Emergency Preparedness

Mock Survey – EP

Hazards assessment must be documented and a plan for each hazard identified.

Communication plan is complete including name and contact information for all staff and local, regional, state and federal emergency staff.

Must address volunteers

Address how refrigerated medications are handled in a power outage.

Training: Have a log to document the staff trained, signed and dated. (every year)

Testing

- Must participate in a full-scale exercise that is community-based or when not accessible, an individual, facility-based exercise.
- **2 Exercises, event or table top a year**
- Analyze the clinic's response to exercise or activation of plan.
- Your exercise or tabletop must be one of your hazard assessments

Mock Survey – Staff Interviews

- Can staff articulate procedures they are responsible for?
- If asked, “What do you have to do to get fired here?” Do they know the answer?
- If asked, “What do you do if you have to evacuate the clinic?” Do they know the protocol or have easy access to the emergency preparedness information for evacuation procedures?
- Staff should be prepared to answer questions related to their job responsibilities, clinic policies and emergency protocols.

NEW December 6th,2021 491.8 (d)

COVID-19 vaccination of staff.

The RHC/FQHC must develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID-19. For purposes of this section, staff are considered fully vaccinated if it has been 2 weeks or more since they completed a primary vaccination series for COVID-19. The completion of a primary vaccination series for COVID-19 is defined here as the administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine.

(1) Regardless of clinical responsibility or patient contact, the policies and procedures must apply to the following clinic or center staff, who provide any care, treatment, or other services for the clinic or center and/or its patients:

(i) RHC/FQHC employees;

(ii) Licensed practitioners;

(iii) Students, trainees, and volunteers; and

(iv) Individuals who provide care, treatment, or other services for the clinic or center and/or its patients, under contract or by other arrangement

NEW December 6th,2021 491.8 (d)

(2) The policies and procedures of this section do not apply to the following clinic or center staff:

(i) Staff who exclusively provide telehealth or telemedicine services outside of the clinic or center setting and who do not have any direct contact with patients and other staff specified in paragraph (d)(1) of this section; and

(ii) Staff who provide support services for the clinic or center that are performed exclusively outside of the clinic or center setting and who do not have any direct contact with patients and other staff specified in paragraph (d)(1) of this section.

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NEW December 6th,2021 491.8 (d)

(3) The policies and procedures must include, at a minimum, the following components:

have
section, or
CDC, due to
or the
any

(i) A process for ensuring all staff specified in paragraph (d)(1) of this section (except for those staff who pending requests for, or who have been granted, exemptions to the vaccination requirements of this those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the clinical precautions and considerations) have received, at a minimum, a single-dose COVID-19 vaccine, first dose of the primary vaccination series for a multi-dose COVID-19 vaccine prior to staff providing care, treatment, or other services for the clinic or center and/or its patients;

(ii) A process for ensuring that all staff specified in paragraph (d)(1) of this section are fully vaccinated for COVID-19, except for those staff who have been granted exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations;

NEW December 6th,2021 491.8 (d)

(iii) A process for ensuring that the clinic or center follows nationally recognized infection prevention and control guidelines intended to mitigate the transmission and spread of COVID-19, and which must include the implementation of additional precautions for all staff who are not fully vaccinated for COVID-19;

(iv) A process for tracking and securely documenting the COVID-19 vaccination status for all staff specified in paragraph (d)(1) of this section;

(v) A process for tracking and securely documenting the COVID-19 vaccination status of any staff who have obtained any booster doses as recommended by the CDC;

(vi) A process by which staff may request an exemption from the staff COVID-19 vaccination requirements based on an applicable Federal law;

(vii) A process for tracking and securely documenting information provided by those staff who have requested, and for whom the facility has granted, an exemption from the staff COVID-19 vaccination requirements;

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NEW December 6th,2021 491.8 (d)

(viii) A process for ensuring that all documentation, which confirms recognized clinical contraindications to COVID-19 vaccines and which supports staff requests for medical exemptions from vaccination, has been signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable State and local laws, and for further ensuring that such documentation contains

(A) All information specifying which of the authorized COVID-19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications; and

(B) A statement by the authenticating practitioner recommending that the staff member be exempted from the clinic or center's COVID-19 vaccination requirements for staff based on the recognized clinical contraindications;

(ix) A process for ensuring the tracking and secure documentation of the vaccination status of staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations, including, but not limited to, individuals with acute illness secondary to COVID-19, and individuals who received monoclonal antibodies or convalescent plasma for COVID-19 treatment; and

(x) Contingency plans for staff who are not fully vaccinated for COVID-19.

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Summary

- Vaccination is the only option. Unlike the OSHA regulation, CMS is not allowing for testing of unvaccinated individuals as an alternative to vaccination.
- Have a plan or process for providing exemptions and accommodations for those who are exempt.
- Have a plan or process for tracking and documenting staff vaccinations.
- Vaccination requirements apply to all eligible staff, both current and new, working at a facility regardless of clinical responsibility or patient contact, including those listed below.
- Have a process for preventing the spread of COVID in your clinic.

QUESTIONS?

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The ComplianceTeam

Don’t Forget to Join!

- Building a Better Board: Experience in Education
  - December 8
  - 9-10 a.m.

RURAL **HEALTH** WORKSHOP

Thank you for joining us!

WELL-AHEAD

LOUISIANA RURAL HEALTH ASSOCIATION