



# RHC Compliance 201

Oregon Office of Rural Health

Kate Hill, RN

# RHC Conditions of Certification

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- § 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>

# 491.6 Physical Plant

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## 491.6 Physical plant and environment.

**(a) Construction.** The clinic or center is constructed, arranged, and maintained to insure 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 or center 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.**

# Equipment

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- 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



## 6 Required tests in the Clinic:

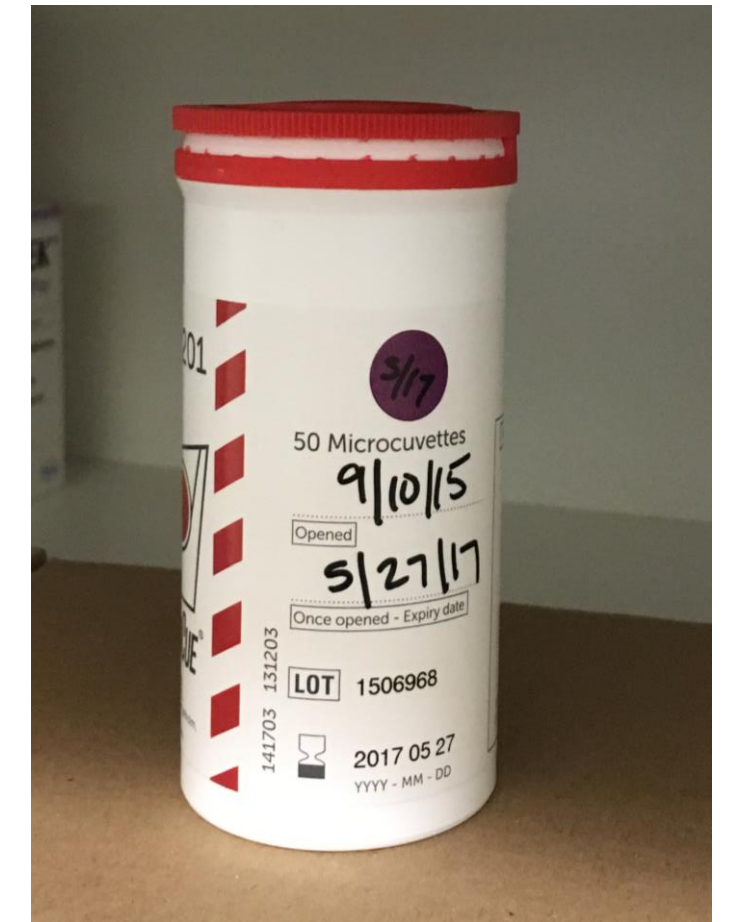
- Chemical examination of urine by stick or tablet method
- Hemoglobin or Hematocrit
- Blood Glucose
- Examination of stool specimens for occult blood
- Pregnancy Test
- Primary Culturing for transmittal to a certified lab

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

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(b) *Patient care policies.*

**(3)** The policies include:

**(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 under [paragraph \(b\)\(2\)](#) of this section and reviewed as necessary by the clinic or center.

Including the Medical Director, the NP or PA and one outside person, not employed by the clinic.



# 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



**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



Beyond Use Date

28 days

## Single Dose Vials

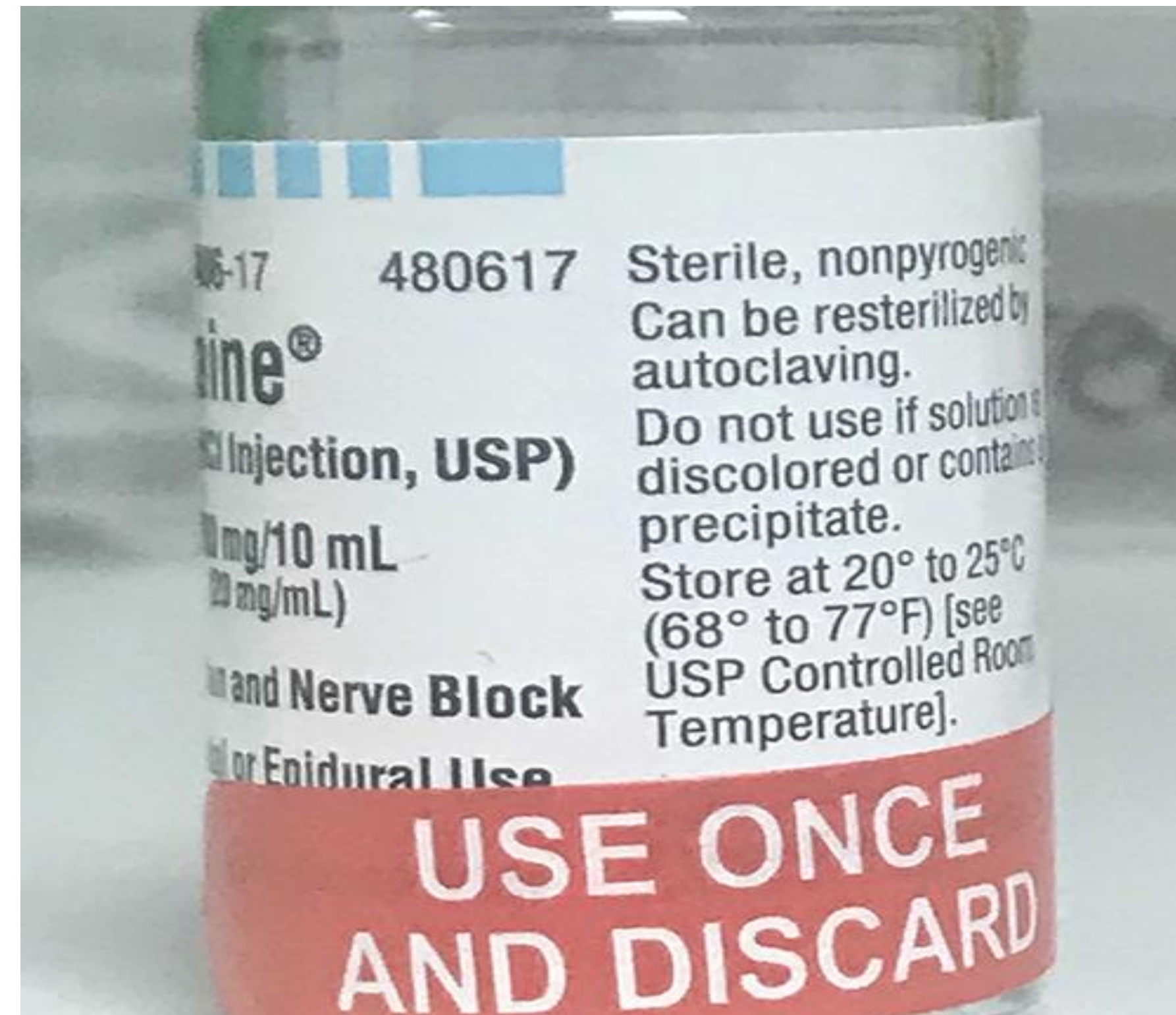


NEVER DATED

# Medications

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



# Controlled Substances

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- 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



Samples  
Secured/Organized In  
Original Containers



Use the sticker method!



# Sample Log

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Sample Medications Secured and  
Logged to Track in the Event of a Recall



# Medication Refrigerators

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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>



# Prefilled Syringes

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- Once vaccine is inside the syringe, it is difficult to tell which vaccine is which; this may lead to administration errors.
- Prefilling syringes leads to vaccine wastage and increases the risk of vaccine storage under inappropriate conditions. Most syringes are designed for immediate administration and not for vaccine storage.
- Bacterial contamination and growth can occur in syringes you prefill with vaccines that do not contain bacteriostatic agents, such as the vaccines supplied in single-dose vials.

# Prefilled Syringes

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- No stability data are available for vaccines stored in plastic syringes. Vaccine components may interact with the plastic syringe components with time and thereby reduce vaccine potency.
- Finally prefilling syringes is a violation of medication administration guidelines, which state that an individual should only administer medications he or she has prepared and drawn up.
- This is a quality control and patient safety problem because if you do not draw up the vaccine yourself, you cannot be sure of the composition and sterility of the dose you are administering.



# Emergency Medications

- 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.
- **CMS Memo September 3, 2019**
  - “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

- Remember the regulation says expired medications and SUPPLIES.
- Telfa, gloves, peroxide, electrodes, needles
- Iodoform gauze, etc.
- Check anything with a date!





# Safety

**NO** medications or hazardous material in this lower exam table drawer.

- ThinPrep: a preservative with the following warnings:
- Inhaled: May cause depression of the Central Nervous System resulting in weakness, nausea, drowsiness and possibly blindness.
- Skin Contact: May cause irritation and or dermatitis.
- Ingestion: May cause intoxication, CMS depression, nausea and dizziness. May damage liver, kidneys and nervous system.

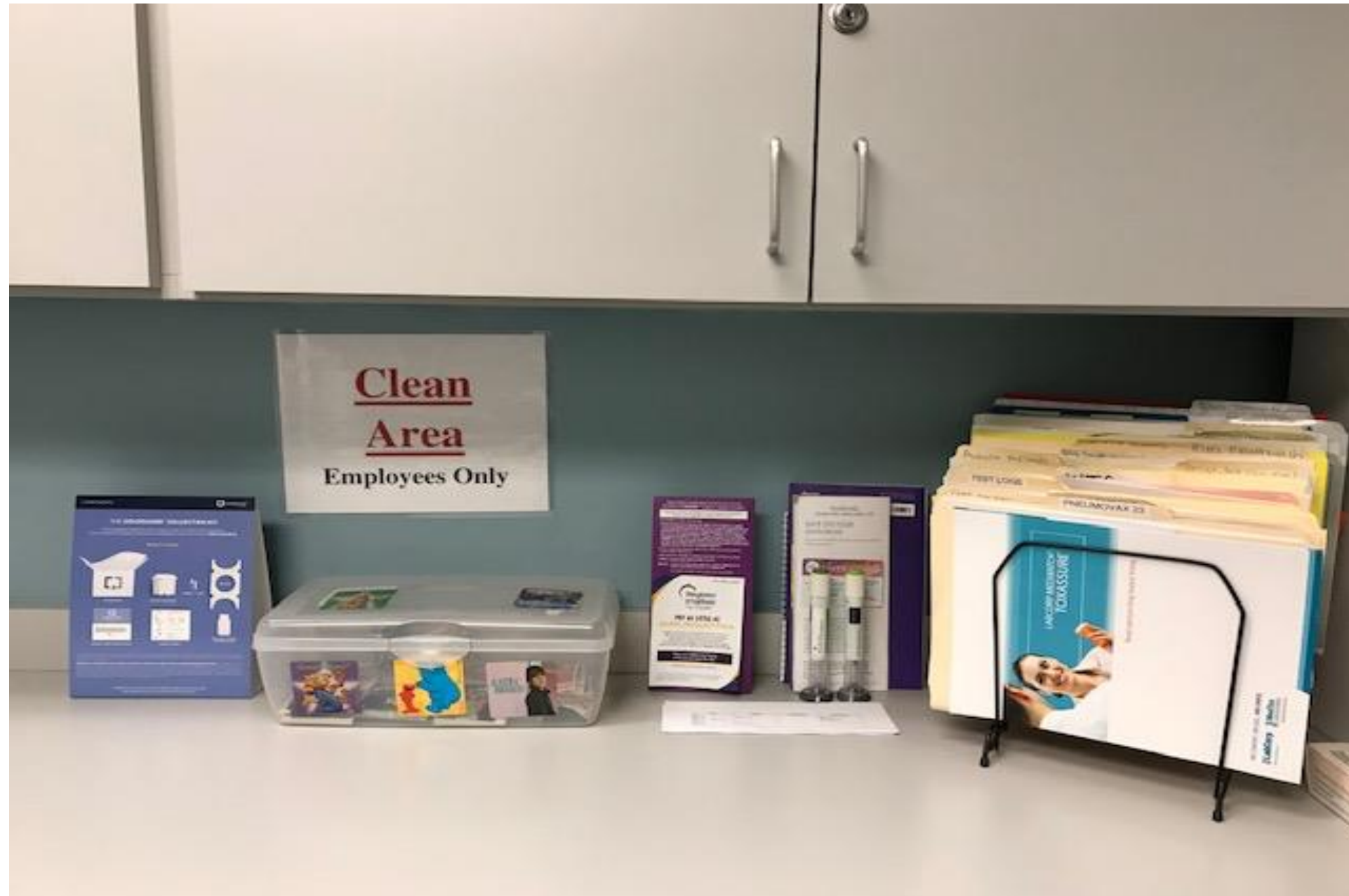


# Medical Records 491.10

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.								



# Infection Prevention



Infection Prevention

Clean to Dirty Process to Avoid Cross Contamination

# Infection Prevention Best Practices

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- 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

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Hinged instruments should be sterilized in an unlocked position.



# Infection Prevention



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



# Personal Protective Equipment (PPE)



Personal Protective Equipment for Staff who handle liquid nitrogen:  
Heavy duty gloves and goggles for safety.

# 491.11 Biennial Evaluation

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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

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Why do this ?

- To determine whether:
  - 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

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# Lessons learned in 2005



- 2005, only 25% of office-based providers were using electronic medical records.
- The IT supervisor at Medical Center of Louisiana in New Orleans, thought removing the bottom rows of records in her hospital's basement storage facility would be enough to guard against Hurricane Katrina's punch
- In a matter of hours, 400,000 medical records were reduced to pulp.
- Entire lifetimes of healthcare documentation were lost forever for many critically and chronically ill patients. EMR is now the standard.



# Lessons Learned 2017



What did we learn from Harvey?

Nursing home with 15 patients stranded in waist high water because of a lack of ability to communicate.



# Lessons Learned 2017





# All Hazards Risk Assessment



Community-Based  
Clinic-Based



# Emergency Preparedness: Risk Assessment

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Example: What are the 5 most likely things that could happen in your clinic that would impact your ability to care for your patients:

- Short-term Inclement Weather Events
- Power or Water Interruptions
- Provider/Staff Illness
- Technological/Communication Failures
- On-site Events Requiring Evacuation (Fire, Active shooter threat)

# Emergency Preparedness

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- 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 participate in a full-scale exercise that is community-based or when not accessible, an individual, facility-based exercise.
- If one year is full-scale exercise, then the other can be tabletop. Every other year for full-scale or at least a clinic-based exercise.
- Documentation of the clinic's efforts to contact EP officials.
- Analyze the clinic's response to exercise or activation of plan.



# Emergency Preparedness

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- If the clinic experiences an actual natural (or man-made emergency) that requires activation of the emergency plan, the clinic is exempt from engaging in a community-based or individual, facility-based full-scale exercise for 1 year following the onset of the actual event.

# Emergency Preparedness CMS AAR

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CMS After Action Report (AAR) or similar document

- Brief overview of the exercise.
- Enter the capabilities tested by the exercise.
- Enter the major strengths identified during the exercise.
- Enter areas for improvement identified during the exercise, including recommendations.
- Describe the overall exercise as successful or unsuccessful, and briefly state the areas in which subsequent exercises should focus.
- Can be used after an exercise or an event.



# Emergency Preparedness After Action Report (AAR)

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U.S. DEPARTMENT OF HEALTH HUMAN SERVICES

CENTERS FOR MEDICARE & MEDICAID SERVICES

## Health Care Provider After Action Report/Improvement Plan

Survey & Certification  
Emergency Preparedness & Response

Enter Organization Name

Health Care Provider  
After Action Report/Improvement Plan

# Emergency Preparedness Resources

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## RHC Emergency Preparedness (EP) Checklist

The clinic must have an emergency preparedness program that addresses an emergency on-site, off-site (natural disaster) and disruption of service. This program must comply with all applicable Federal, State and local emergency preparedness requirements.

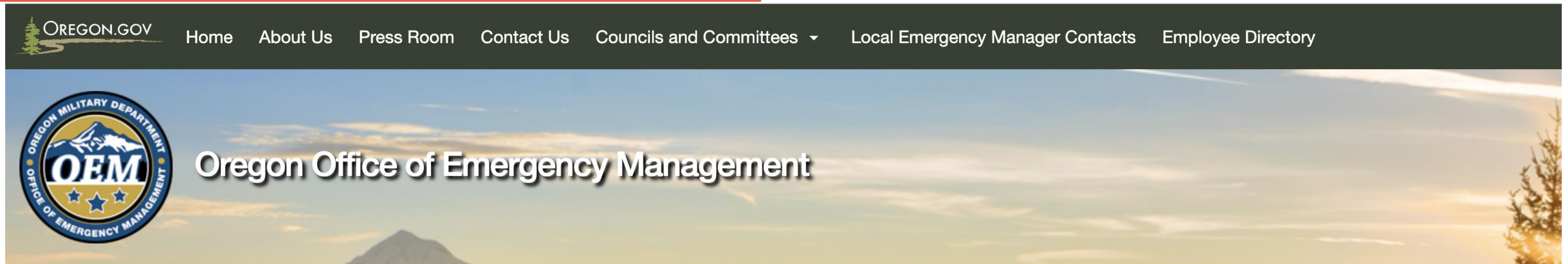
### Developing the RHC EP Plan

The clinic must develop and maintain an emergency preparedness plan that is reviewed and updated biennially.

- ☐ The emergency preparedness plan must contain the following elements:
  - ☐ A documented, clinic-based and community-based risk assessment that utilizes an all hazards approach.
  - ☐ Strategies for addressing emergency events identified by the risk assessment.
  - ☐ Addresses patient population, including, but not limited to, the type of services the clinic has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.
  - ☐ A process for cooperation and collaboration with local, tribal, regional, State and Federal emergency preparedness official's efforts to maintain an integrated response during a disaster or emergency situation.
  - ☐ Is initially formally adopted by key leadership and then updated, at a minimum, biennially



# Emergency Preparedness



## Hazards and Preparedness

- [Cascadia Subduction Zone](#)
- [Hazards in Oregon](#)
- [Individual Preparedness](#)
- [Business Preparedness](#)
- [Community Preparedness](#)
- [Hazard Mitigation](#)



## Emergency Management Resources

- [Disaster Assistance](#)
- [Grants](#)
- [Plans and Assessments](#)
- [State Exercise Program](#)
- [State Training Program](#)
- [Toolkits for Emergency Managers](#)



## Emergency Operations

- [Current Operations](#)
- [Oregon Emergency Response System \(OERS\)](#)
- [Past Disasters](#)
- [Real-time Assessment and Planning Tool for Oregon \(RAPTOR\) and GIS](#)
- [Search and Rescue](#)



## State 9-1-1 Program

- [About 9-1-1 in Oregon](#)
- [9-1-1 Legislative Information](#)
- [Program Areas and Presentations](#)
- [Program Policies and Forms](#)
- [Emergency Communications Tax](#)
- [Committees and Working Groups](#)



# Emergency Preparedness Oregon

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## **Oregon Office of Homeland Security**

P.O. Box 14370  
3225 State Street  
Salem, Oregon 97309  
(503) 378-3056  
[www.oregon.gov](http://www.oregon.gov)

## **Local Information**

### **Clackamas County Emergency Management**

2200 Kaen Road  
Oregon City, OR 97045  
Phone: (503) 655-8378  
Fax: (503) 655-8531  
[www.clackamas.us/emergency/](http://www.clackamas.us/emergency/)

### **Douglas County Sheriff's Office**

Emergency Management  
1036 SE Douglas Avenue  
Roseburg, Oregon 97470  
Phone: (541) 440-4448  
Fax: (541) 440-4470  
[www.dcsso.com](http://www.dcsso.com)



## CERT: Community Emergency Response Team





# Emergency Preparedness

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## 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://<https://www.ready.gov/cert>](https://www.ready.gov/cert)



# Emergency Preparedness

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(503) 823-4375

Oregon State Citizen Corps


PO Box 14370

Salem, OR 97309

(503) 378-2911

[www.oregon.gov/OMD/OEM/](http://www.oregon.gov/OMD/OEM/)

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**Survey & Certification - Emergency Preparedness**

- [State Survey Agency Guidance](#)
- [Health Care Provider Guidance](#)
- [Lessons Learned/Archives](#)
- [Emergency Preparedness Rule](#)
- [Core EP Rule Elements](#)
- [Earthquakes](#)
- [Hurricanes](#)
- [Severe Weather](#)
- [Flooding](#)
- [Wild Fires and Fires General](#)
- [Influenza and Viruses](#)
- [Homeland Security Threats](#)
- [Templates & Checklists](#)

## Survey & Certification - Emergency Preparedness

### *Emergency Preparedness for Every Emergency*

#### Mission

Enable Federal, State, Tribal, Regional, and local governmental agencies, and health care providers to respond to every emergency in a timely, collaborative, organized, and effective manner.

The Centers for Medicare & Medicaid Services (CMS) Survey and Certification Group (SCG) has developed this site to provide useful information to CMS Central and Regional Offices, State Survey Agencies (SAs), their State, Tribal, Regional, and local emergency management partners, and health care providers, for developing effective and robust emergency plans and responses. This Web site provides information and tools, utilizing an “all hazards” approach for disruptive events such as:

- Pandemic flu (e.g., H1N1 influenza virus)
- Hurricanes
- Tornadoes
- Fires
- Earthquakes
- Power outages
- Chemical spills
- Nuclear or biological terrorist attack
- Etc.



# Appendix G since 2018

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Now permitted:

Mobile Clinics as a add on to your present clinic.

Suites at the same physical address (USPS)



# Survey Findings

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- 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).



# Trusted Resources

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# Thank You

Questions

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