

Rural Health Clinic Compliance



Survey



Review new rules.

Review common deficiencies.

Learn how to avoid deficiencies.

What's New?

- Mental health providers can see patients in the clinic alone.
 - Can they handle a medical emergency.
 - What does your Emergency Services policy say?
- You must have some primary care.
 - This allows for specialists.
 - 49% Mental Health remains.
- Only 4 required labs.
 - Hematocrit or Hemoglobin removed.
 - Fecal occult blood removed.

HPSA Review

The Health Resources and Services Administration (HRSA) has requested that all state Departments of Health (DOH) update the Full-Time Equivalent (FTE) data for existing primary care, mental health, and dental Health Professional Shortage Areas (HPSAs) across the United States.

These HPSA designations are currently under federal review through **August 2025**, with the results being published now through **September 2025**.

If a designation does not meet criteria for a continue HPSA based on the updated state data, it will be placed in a “**Proposed for Withdrawal**” status. We anticipate that these proposed withdrawals will become final (Withdrawn) in **December 2025** or **July 2026**, unless updated clinician data is submitted demonstrating a continued provider shortage.

Action Recommended:

We encourage all providers to monitor the status and ‘update date’ of their HPSA designations—especially those in primary care—by visiting the HPSA Find tool:

 <https://data.hrsa.gov/tools/shortage-area/hpsa-find>

Issues on Survey!

- When the manager is out staff should know where everything is stored.
- Things go sideways very quickly when the staff can't find them.

Your Name

**Does your name match
what's on your 855a?**

Established clinics check it on
QCOR.

QCOR CMS Data Base

<https://qcor.cms.gov/main.jsp>

**Are your clinic hours
posted near or on the door?**



Medication Management

- Is there a robust medication policy?
- Are all drugs secured in the clinic?
- Are drugs stored according to manufacturer's instructions?
- Are all medications delivered in the clinic properly documented in the EMR?
- Are we noting the 5 rights?
 - Right patient, Right medication, Right dose, Right route and Right time.
- Is every person dealing with drugs trained on vials?
- Is everyone trained on safe injection practices?
- Is there proper recording for receipt and disposition of scheduled drugs?

Pre-Filled Syringes: Quality control and patient safety problem



- Once vaccine is inside the syringe, it is impossible to tell which vaccine is which; this may lead to administration errors.
- Prefilling syringes leads to vaccine waste 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 don't contain bacteriostatic agents, such as the vaccines supplied in single-dose vials.
- No stability data is 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 because if you do not draw up the vaccine yourself you should not administer it.

Manufacturers Instruction for Use (MFU)

Equipment.

Is there documentation that mechanical and electrical equipment is regularly inspected, tested and ...

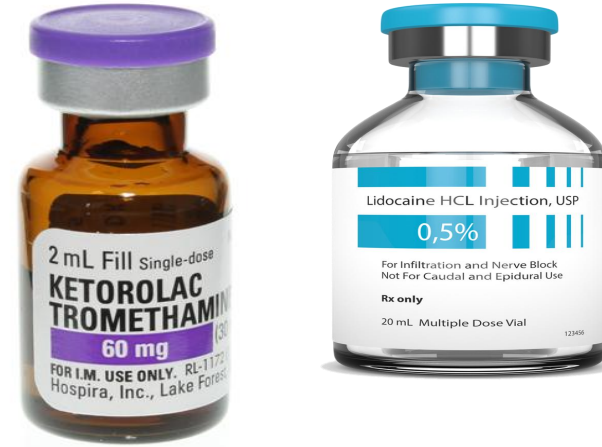
- Maintained in accordance with manufacturer's recommendations?
- If documentation is missing, review the policy to determine if the policy was not followed or is incomplete.
- Review the manufacturer's instructions for a piece of equipment.

Survey – Vials

- Possibly a staff member does not know the difference between a single-dose or multi-dose vial. Do Not Assume all staff know the difference between SDVs and MDVs.
- 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:

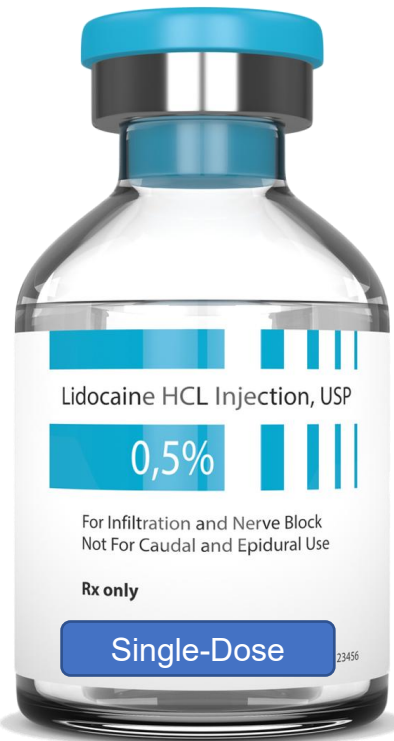
- Train all staff to always look at the vial to verify if it's an SDV or MDV and to check the date.
- Train staff that SDVs don't have a preservative in the vial and why that's important.
- In the drug closet, separate the MDVs from the SDVs.
- Label all SDVs with a sticker.



Single-Dose Vials

Ensure single-dose vials (SDVs) are never used for more than one patient.

Survey – Vials



Single-Dose Vials

Multi-Dose Vials



28 Days

Survey – Vials



Ensure Single-Dose Vials (SDVs) are never used for more than one patient.

- Once and done, discard!
- Do Medical Assistants know the difference between single-dose and multi-dose vials?

Hot Topic!

Staff Education:

- Find out what they know.
- Train them and document that training.

28-Day Calendar

April 25 _____	May 23 _____
April 26 _____	May 24 _____
April 27 _____	May 25 _____
April 28 _____	May 26 _____
April 29 _____	May 27 _____
April 30 _____	May 28 _____

May 25 _____	June 22 _____
May 26 _____	June 23 _____
May 27 _____	June 24 _____
May 28 _____	June 25 _____
May 29 _____	June 26 _____
May 30 _____	June 27 _____
May 31 _____	June 28 _____

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Medical Direction

The Medical Director must be an MD or DO/

- He must be licensed in the state where the clinic resides.
- The Medical Director is a reportable event.
 - Reported on a CMS 29 to the state or to your accreditor.
- There is no waiver for Medical Director.
 - CMS provides a reasonable time to come back into compliance.
 - Can you show your efforts to find a new Medical Director?
 - Can you show what efforts you have made for a temporary Medical Director?

Staffing

NP/ PA Waivers.

- An existing RHC may request a waiver from the state after 90 days for one year on the loss of an NP or PA.
- During that 90 days, the RHC must demonstrate it has been unable, despite reasonable efforts, to hire an NP or PA in the 90-day period.

Staffing

- An NP, PA or Certified nurse midwife is available to furnish patient care at least 50% of the operating hours.
- All time spent in the clinic counts toward the 50%
- Also, time spent in a patient's home or a SNF counts toward the 50%.

How do you document that time?

Infection Prevention

Is the clinic appropriately monitoring house keeping?

How does the clinic prevent the spread of infection:

- Hand hygiene for staff?
- Are single-use devices only used once?
- How are the clinic surfaces cleaned?
- Does the person know the wet/kill time?
- How is medical waste disposed of?
- Are we certain that instruments are sterile?
- Is the staff trained on point of care devices?

**PREVENTION
WORKS!**

Sterilizing Instruments: MFU



What is your process?

Record Review

Medical Record Review:

- If your State is silent, then you must determine how many and how often this occurs.
- What is your policy on record review by a physician?
- What is your documentation to show the record review has been done?

Policies Matching to Process



Clinics can be cited if a policy does not match their process.

Example #1:

- Some clinics call for an annual consent even though it's not a requirement.
- So, if the surveyor reviews files and there is no new consent, but the policy says annual, you will receive a deficiency.

Example #2:

- Several policies recently still say Annual Evaluation, while the reg says Biennial.

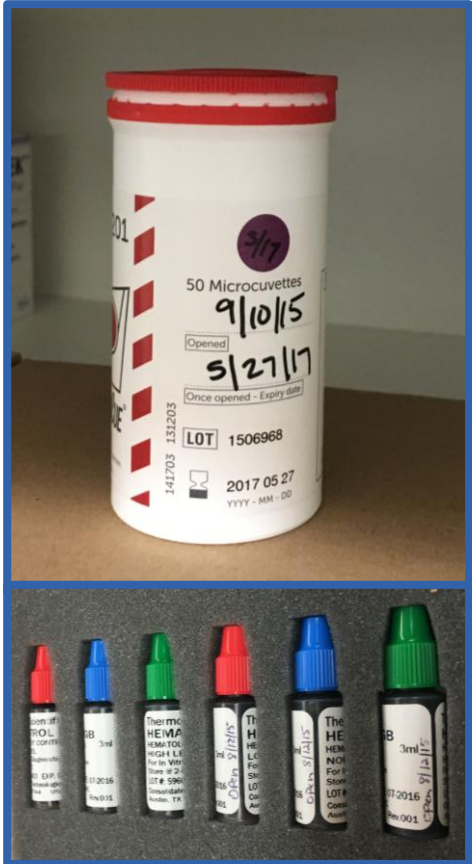
Policies

- 1) Keep policies organized.
- 2) Review a few policies each staff meeting.
- 3) Keep your policies simple, don't lock yourself into a tight corner.

Know what requires a policy.

- Patientcare Policies
- Biennial Review of Policies by Advisory Group
- Storage, Handling, & Dispensing of Drugs & Biologicals
- Emergency Preparedness
- Health Records
- HIPAA
- Scope of Services Provided and Referred
- Lines of Authority
- Equipment Management
- Infection Prevention
- Hiring, Training and Orienting
- Quality Improvement

The Lab: Point of Care Tests



- Labs are for immediate diagnosis!
- Clinic must have the ability to do all four required tests.
- All reagents, strips, controls, etc., must be in date.
- CLIA Certificate is current and posted.

Emergency Services

- The RHC ensures staff is available to appropriately handle medical emergencies, as a first response to common life-threatening injuries and acute illnesses, at all times the clinic operates.
- Must supply a complete list of drugs and biologicals it stocks.
- What does your emergency service policy say?
- Does it match your process?
- How did the RHC come to decide what is in that box?
- Is the box checked regularly for outdates?



Patient Records

Consents: For a minor patient, is there a relationship to patient on the consent?

Medications: Is the EMR capturing the medication, lot number, route of administration, dose, and date?

Abnormal Labs: Have abnormal labs been reported to patients

- The notes should reflect the patient has been notified of the lab results and the plan moving forward.
- What instructions are given to the patient?

Summary: Is there a documented summary of the visit with instructions for the patient?

Personnel File Record Review

- a. W-4 for at least one employed NP or PA, I-9 for employees
- b. Curriculum Vitae, Application or Resume with references.
- c. Signed job description or contractual agreement.
- d. Orientation and Training on hire and annually /Competency Assessment checklists.
- e. Signed Standards of Conduct.
- f. Verification of professional license and certification registration and/or certification is maintained if applicable.
- g. OIG exclusion list verification (www.oig.hhs.gov), documented upon hire and re-verified annually.
- h. Annual performance evaluations.
- i. Background checks (when required by the State or organizational policy).
- j. Hepatitis B Vaccine Record or Declination
- k. TB Evaluation Requirements (for staff members with patient contact.
- l. Basic Life Support (BLS) certification (at a minimum) is required for all licensed and certified patient care personnel.

RISK

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.



Protective Equipment

Personal Protective Equipment for staff who handle liquid nitrogen:

Heavy duty gloves and goggles for safety.



Work Safety

**OSHA Poster: right
year, right state**

Proper PPE

SDS Sheets



Exam Tables



How do you clean this table?

Wet time.

Health-grade disinfectant.



Can a torn table be disinfected?

Secured!



Biohazard/Sharps Containers

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



Biennial Evaluation

18-month reminder on several calendars so it's not missed.



Biennial Evaluation

- a. The clinic carries out, or arranges for, a biennial evaluation of its total program.**
- b. The evaluation includes review of:**
 - 1. The utilization of clinic or center services, including at least the number of patients served and the volume of services;
 - 2. A representative sample of both active and closed clinical records; and
 - 3. The clinic's health care policies.
- c. The purpose of the evaluation is to determine whether:**
 - 1. The utilization of services was appropriate;
 - 2. The established policies were followed; and
 - 3. Any changes are needed.
- d. The clinic or center staff considers the findings of the evaluation and takes corrective action if necessary.**

Biennial Evaluation

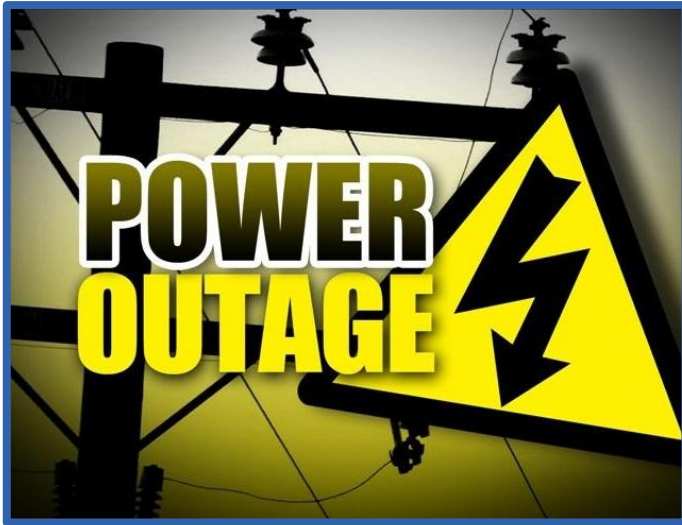
Lack of a Biennial review of the clinic.

- This must be done every two years.
- There was no waivers for this.
- Look at the date of the last one and make sure it's not more than two years old.
- This is a failed survey if not completed.

Policy review sheet: Who signed?

- Must be an MD, NP/PA, and an outside person.
- Is the date within two years?

Emergency Preparedness



Power Grid Failure
Refrigerated Medications
PHI/EMR



Natural Disasters
Clinic Closure
Disruption of Services



Emerging Infectious Disease
Protocols
Risks

Emergency Preparedness

Elements:

Risk Assessment and a plan for each

Communication Plan

Training

Testing

Survey Emergency Preparedness

- Your exercise must be one of your listed items on your HVA, unless it's an event.
- 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.
- Communication plan is complete, including name and contact information for all staff and local, regional, state, tribal, and federal emergency staff.
- Volunteers must be addressed in the EP Policy.
- Address how refrigerated medications are handled in a power outage.

Training: Have a log to document the staff trained, with signatures and dated. (every 2 years)

Survey Emergency Preparedness Testing

- 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.
- Analyze the clinic's response to exercise or activation of plan.
- The exercise or tabletop must be one of your hazard assessments.
- Testing should not test the same thing year after year. 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.

Analysis for Event, Tabletop or Exercise

- The purpose of this report is to analyze event results.
- Identify strengths to be maintained and built upon.
- Identify potential areas for further improvement.
- Support the development of corrective actions that will guide future emergency preparedness initiatives to advance overall emergency preparedness within your clinic.
 - Report reviewed with staff
 - Assignments given
 - Attendance log at AAR meeting

Summary of Common Deficiencies

1. Single-dose vials dated.
2. Drugs not secured.
3. NP/PA not signing off on policies.
4. No analysis of an emergency event or exercise.
5. Not having all contact information in your EP binder.
6. No documentation of chart review.
7. No outside person signing off on policies.
8. Not abiding by the wet time of your disinfectant.
9. Signage not matching the name you told CMS you were called.
10. Expired supplies in the clinic, i.e. iodoform, gloves, Blood glucose supplies, etc.

Staff Interviews

- Can staff articulate procedures they are responsible for?
- 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.

Deficiencies

The regulation at 42 CFR 488.26(b) says:

- The decision as to whether there is compliance depends on manner and degree.

Standard or Condition level:

- How serious is the deficiency in terms of its potential or actual harm to patients and
- The extent of noncompliance e.g. how many or how widespread?
- One incidence of noncompliance that poses a serious threat to patient health and safety is CONDITION.
- Or many instances of a standard level deficiency could lead to a CONDITION level citation e.g., 15 of 20 charts have no consent.

Plan of Correction (PoC)

Must contain the following:

- The process or lack of process that led to the deficiency.
- Action that will be taken to correct each deficiency.
- Description of how the actions will correct and or improve the issue.
- Monitoring procedures to ensure the plan is effective to keep the RHC in compliance.
- The title of the person responsible (no names) for implementing the PoC.
- Signature of an administrator.

What to Expect on Survey Day

- RHC surveys are unannounced, so be prepared!
- Managers share your knowledge with staff.
- Most surveys take between 6 to 8 hours per clinic depending on the size and number of providers/staff.
- Remember that having easy access to policies, personnel records and medical records as they are requested, will allow the survey to proceed without delay.
- Once complete, the surveyor will conduct an exit interview to discuss the findings.

QUESTIONS?

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