Assuring RHC Compliance

2020 NRHA Rural Health Clinic & Critical Access Hospital Conference

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TheComplianceTeam™
Exemplary Provider® Accreditation

First a Huge Thank You!

Code of Federal Regulations

- § 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/42/491.1

Safe Accessible Entrance

Posted Hours

Posted Hours of Operation

Signage

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

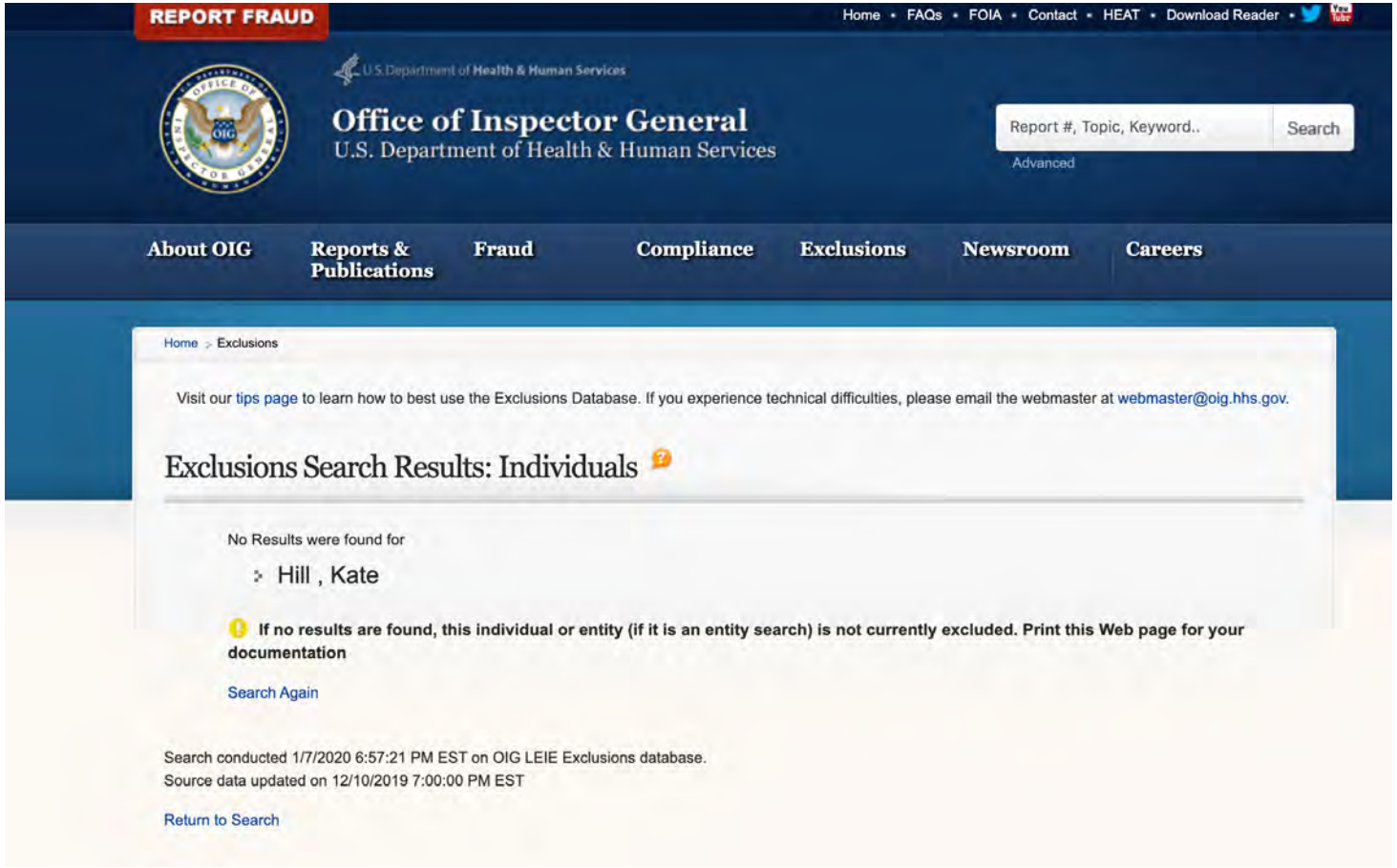
Notifications

- Report name changes to CMS.
- Report change in Medical Director to CMS.
- Update your 855a and CMS 29 as things change
- Never move without checking with your Office of Rural Health, Run that HPSA!

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/



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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
- BLS if applicable

491.6 Physical Plant

Physical Plant

Physical Plant

- Safe storage of Oxygen: chained or in an approved cart.
- Keep full separated from empty.
- Ambu bag for population served near the oxygen

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

Best Practice: An Equipment List

Item	Manufacturer	Serial #	Location	Initial Inspection	Preventive Maintenance	Frequency
M11 Steam Sterilizer	Ritter	00012345	E102	11/01/2016	Bio-Med	Annually
Mac 1200 12-Lead ECG	GE Healthcare	00067891	E102	11/01/2016	Bio-Med	Annually
5300 VS Monitor	Welch Allyn	34500123	E102	11/01/2016	Bio-Med	Annually
Lena 354 Baby Scale	SECA	89445092	Triage Area	11/01/2016	Calibration	Annually
777 Integrated Wall System	Welch Allyn	09876511	E106	11/01/2016	NO PM	NO PM
777 Integrated Wall System	Welch Allyn	09876512	E107	11/01/2016	NO PM	NO PM
Sure Temp Plus 690	Welch Allyn	44453808	Triage Area	11/01/2016	NO PM	NO PM

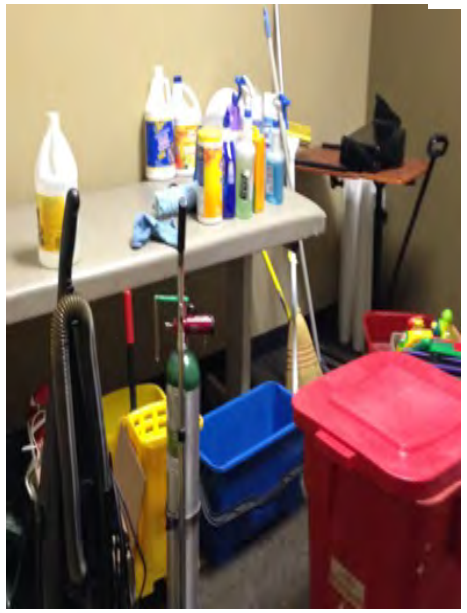
Equipment

Is there a Preventive Maintenance policy describing the plan?
What equipment requires bio-med inspection?
Is the evidence of bio-medical inspection on a sticker or in a report?

Storage: Medications, Sharps, Hazardous Supplies

Medications, sharps, and hazardous supplies should be secured in areas where there is a reasonable expectation that any unauthorized person may gain access.
Sharps containers cannot be easily accessible.
Red bag containers if you have them, must be marked with a Bio-Hazard sticker.

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.

Multi Dose Vials

Single Dose Vials

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

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

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

Why have vials become such a problem?

Multi Dose Vials

28 Days

Single Dose Vials

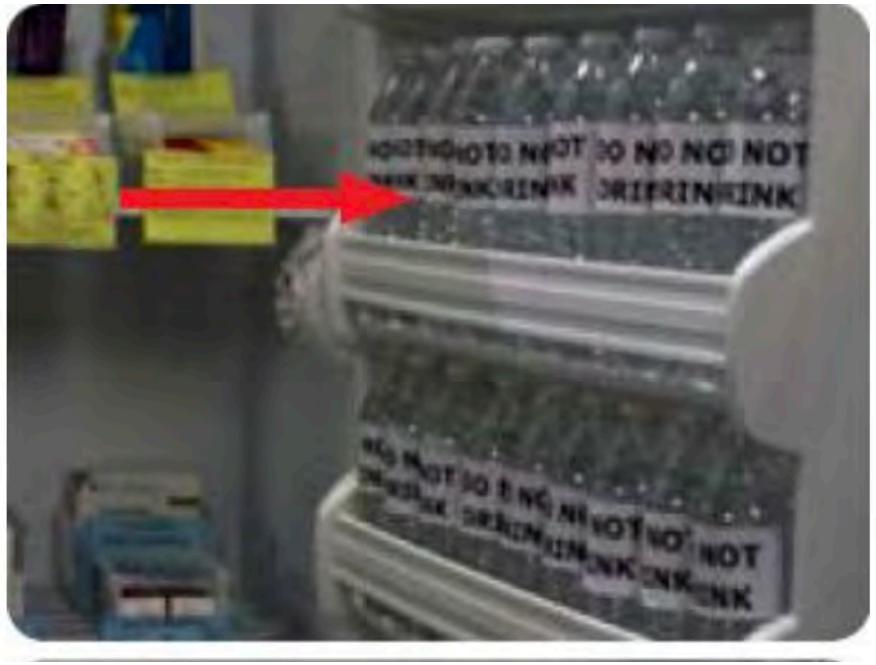
NEVER DATED

Medications

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

Once and done, discard!

Medication Refrigerators



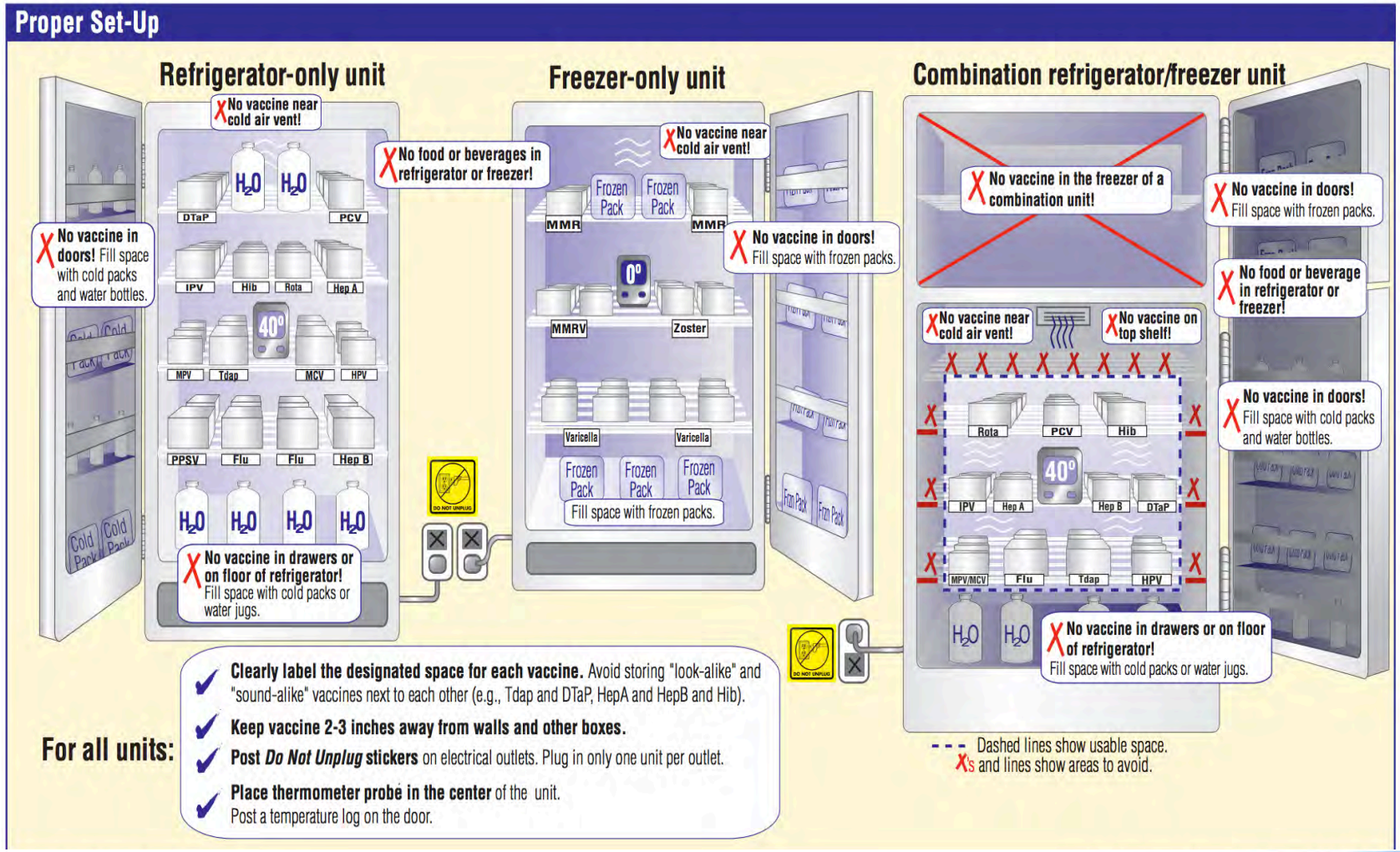
No medications in the door of the refrigerator
Use water bottles to take up dead space

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

Medication Refrigerators

Do not store any vaccine in a dorm style
Refrigerator combined refrigerator/freezer unit under any circumstances.

Medication Refrigerators



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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.

Medications

Requirements that multiple dose vials and single dose vials are stored according to current CDC infection control guidelines.

https://www.youtube.com/user/OneandOnlyCampaign

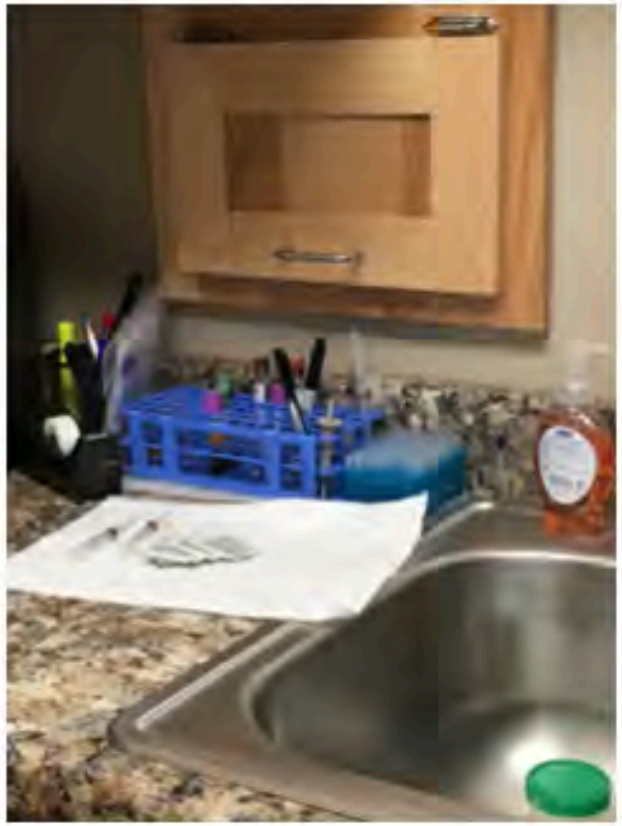
Medications: Samples

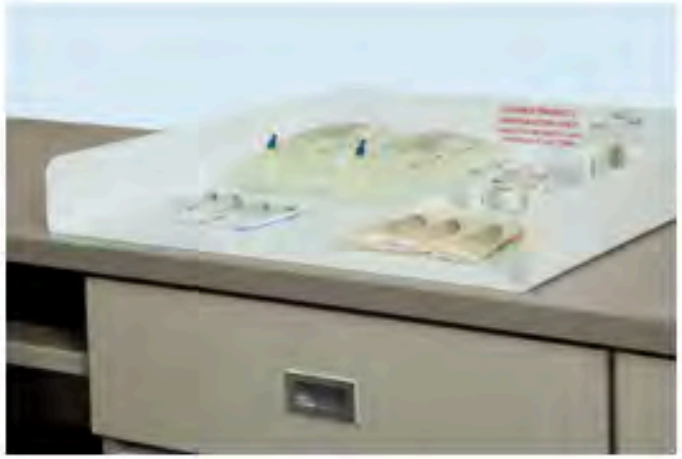
Must have a sample log in case of recall

Samples

Secured/Organized In Original Containers

Infection Prevention: Clean to dirty workflow





Segregating Clean and Dirty Workspaces

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
- Avoid Cross-Contamination with clean dirty segregation (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 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

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Basic requirements.

The clinic is primarily engaged in providing outpatient health services and meets all other conditions of this subpart.
This means 51% RHC services
The laboratory requirements

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.

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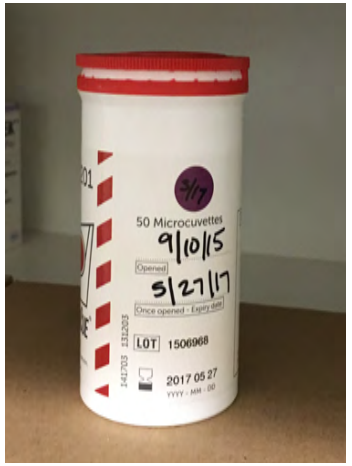
Lab

- 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

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

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.