

Rural Health Clinic Compliance



**Indiana Rural Health Association
RHC Workshop
Kate Hill, RN
August 23, 2018**

**Be Calm and Prepare,
It's an open book test!**



Who Is In The Room Today?

- Already a certified Rural Health Clinic?
- Preparing for Initial RHC Survey?
- Provider Based ?
- Independent ?



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RHC Survey Is An Open-Book Test...

There Should Be No Surprises

- Title 42 Code of Federal Regulations (CFR)
Part 491 Rural Health Clinics Conditions for Certification
- Any State Regulations Affecting the Provision of Healthcare Services
- Any Accreditation Organization Standards that Exceed the CFR

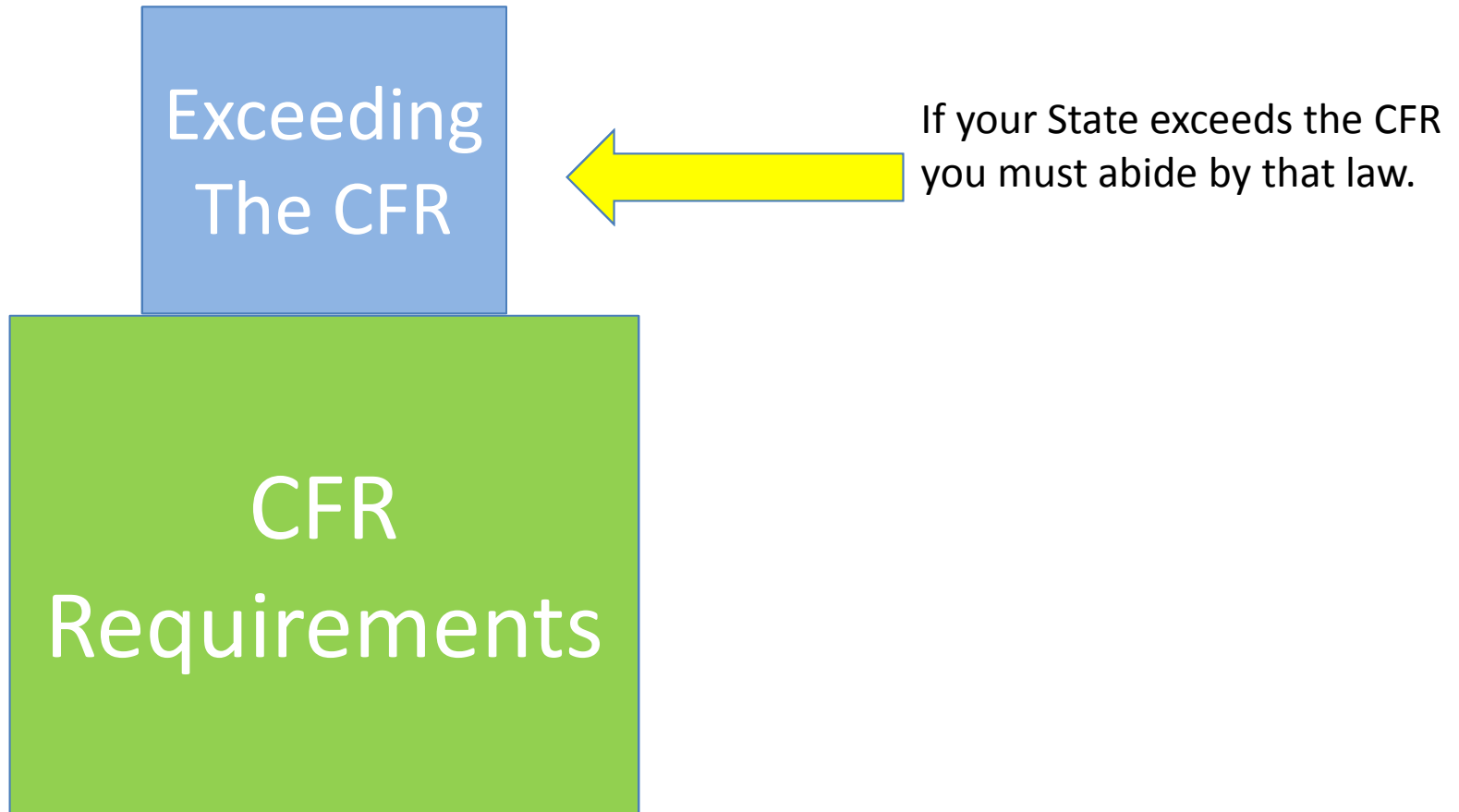
RHC Conditions of Certification

- § 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>

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Understanding RHC Standards



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RHC Interpretive Guidelines

State Operations Manual Appendix G
-Guidance

For Surveyors: Rural Health Clinics
(RHCs)

Table of Contents

(Rev. 177, 01-26-18)

Caution: From 24 pages to 91 pages!

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_g_rhc.pdf

Want a little
extra insight?



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Roadmap to Success

- Leadership submits application
- Tapping Resources
- RHC Training for Providers and Staff
- Making/Completing the “To Do” list
- Fine-tuning Provider and Staff education
- Adoption of RHC policies
- Ensuring processes are in place to keep the clinic ready for day of survey

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Survey Planning Tips

- Develop a Survey Readiness Binder
 - Policies
 - Reports
 - Other evidence of compliance
- Determine space for Surveyor to work
- Determine who will attend/how to inform
- Keep the Clinic “Company Ready”

Surveyor's Approach

- Expect Surveyor to...
 - Review Documents and Records
 - Observe Processes
 - Interview Staff w/ Open-ended Questions to Reveal Underlying Issues
 - Discuss/Teach Best Practices when Non-Compliance is Discovered

Surveyor/Staff Interaction Tips

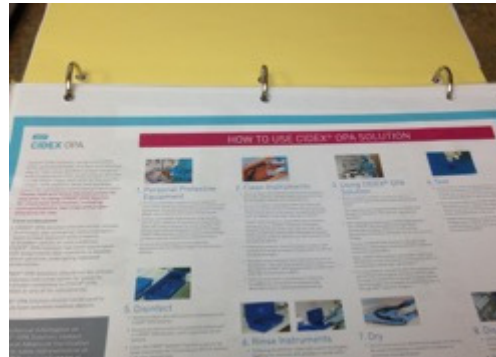
- Staff should be familiar with routine policies/procedures and be able to describe the “how” and “why” of a process
- If unable to answer completely, it is acceptable to say “I would consult policy”
- When a surveyor is observing, staff should just do what they normally do

Surveyor/Staff Interaction Tips

- Understanding the rationale for why they do what they do helps staff anchor information in their memory
- Placing written/visual reminders in the environment will help staff during day to day operations and when they interact with a surveyor

Place Hints Throughout The Clinic

****LIDOCAINE AND XYLOCAINE are single use vials and should be discarded after each use.****



STANDARD PRECAUTIONS

Assume that every patient is potentially infected or colonized with an organism that requires transmission in the healthcare setting and apply the following infection-control practices.

ATTENTION!

Hand Hygiene
Wash hands: routinely, after contact with a patient, after contact with a patient's environment, after procedures, before and after contact with blood, fluids, secretions, or excretions, after contact with a patient's wound or skin breaks, after contact with a patient's mucous membranes, after contact with a patient's body fluids, or after contact with a patient's skin or mucous membranes, after contact with a patient's clothing or linens, after contact with a patient's equipment, or after contact with a patient's environment.
If hands are not visibly soiled, an effective hand sanitizer with adequate alcohol concentration (hand and forearm sanitizer) may be used in lieu of hand washing.

Perform hand hygiene
- before every direct contact with a patient
- after contact with blood, fluids, secretions, or excretions, mucous membranes, non-intact skin, or wound dressings
- after contact with a patient's wound or skin breaks
- after contact with a patient's mucous membranes, non-intact skin, or wound dressings
- after contact with a patient's clothing or linens
- after contact with a patient's equipment, or after contact with a patient's environment
- after contact with a patient's skin or mucous membranes, after contact with a patient's body fluids, or after contact with a patient's skin or mucous membranes, after contact with a patient's clothing or linens, after contact with a patient's environment

Personal Protective Equipment (PPE)
Wear PPE when the nature of the anticipated patient interaction indicates the contact with blood or body fluids may occur.
Before leaving the patient's room or suite, remove and discard PPE.

Gloves
Wear gloves when contact with blood or other potentially infectious material, mucous membranes, non-intact skin, or wound dressings, or when contact with a patient's wound or skin breaks, or when contact with a patient's mucous membranes, non-intact skin, or wound dressings, or when contact with a patient's clothing or linens, or when contact with a patient's equipment, or when contact with a patient's environment, or when contact with a patient's skin or mucous membranes, after contact with a patient's body fluids, or after contact with a patient's skin or mucous membranes, after contact with a patient's clothing or linens, after contact with a patient's environment

Change gloves during patient care
When the task requires for a contaminated task, use a pair of gloves and a clean pair, use a pair of gloves.

Gown
Wear a gown to protect skin and prevent soiling or contamination of clothing during procedures and patient care activities when contact with blood, body fluids, secretions, or excretions is anticipated.

Mask and eye protection
Wear a mask to avoid patient contact with patient's respiratory secretions or excretions.
Wear eye protection when performing hand hygiene, when wearing patient equipment.

Mouth-to-mouth Resuscitation
Use PPE to protect the mucous membranes of the eyes, nose and mouth during procedures and patient care activities that are likely to generate splashes or sprays of blood, body fluids, secretions, or excretions.
During aerosol-generating procedures, wear one of the following: a face shield that fully covers the front and sides of the face, a mask with adequate seal, or a mask and goggles.

*****REMEMBER*****
Multidose Vials
MUST BE LABELED WITH A 28 DAY EXPIRATION DATE ONCE PUNCTURED.
NOT the initial date vial is punctured.
Vials should be discarded after the beyond use date of **28 days.**
Thank you!
-JCMH Pharmacy

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Day of Survey Agenda

- On-site Meeting with Key Leadership
- Review of RHC policies
- Tour the entire Facility
- Observe Medication Storage
- Observe Infection Prevention Practices
- Interview Staff and Providers
- Patient Health Record review
- Personnel Files
- Exit interview

What The Surveyor Will Request

- P&P and Other Manuals
- Evidence of Annual Program Evaluation/Template
- Copy of RHC Organization Chart
- Equipment List and Maintenance Report
- HR Files
- Staffing Schedule (to calculate provider hours)
- Evidence of PA/NP Records reviewed by Physician
- Patient Records to Review (10 random files)

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Review of Policies and Documents

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Clinic Policies & Procedures

- P&P personalized, not generic templates
- Staff should be familiar with policies
- Must follow the state's physician on-site and chart review regulations
- Should have evidence of adoption and annual review by an advisory group that includes, at a minimum, a physician, NP or PA, and one person not on staff

Required Policies & Procedures

- Lines of Authority
- Categories of Practitioners
- Annual Review of Policies by MD and NP/PA
- Maintenance of Medical Records
- Protection and Release of PHI
- Annual Program Evaluation
- Scope of Patient Care Services

Required Policies & Procedures

- Healthcare (HC) Policies for Services Provided
 - Provided Directly vs. Referred
 - Guidelines for Medical Management
- HC Services are provided per State law
- Pt Care Policies developed by Advisory Group
- Policies for Storage of Drugs & Biologicals
- Emergency Preparedness

Required Policies & Procedures

Common Deficiency:

Policies are not signed by Nurse Practitioner or Physician's Assistant.
This is an annual requirement.



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Touring the Facility

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Facility Tour



Signage Consistent with CMS 855A Application

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Facility Tour

NOTE: DO NOT MOVE WITHOUT CHECKING WITH STATE OFFICE OF RURAL HEALTH AND YOUR MAC.

ALSO: NAME CHANGES AND CHANGE OF MEDICAL DIRECTOR MUST BE SUBMITTED ON AN 855A

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Facility Tour



Hours of Operation Outside of the Clinic

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ADA Accessible and Free from Obstacles

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Clean and Maintained

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Facility Tour



Local Licenses or Certificates

State Postings

Federal Postings

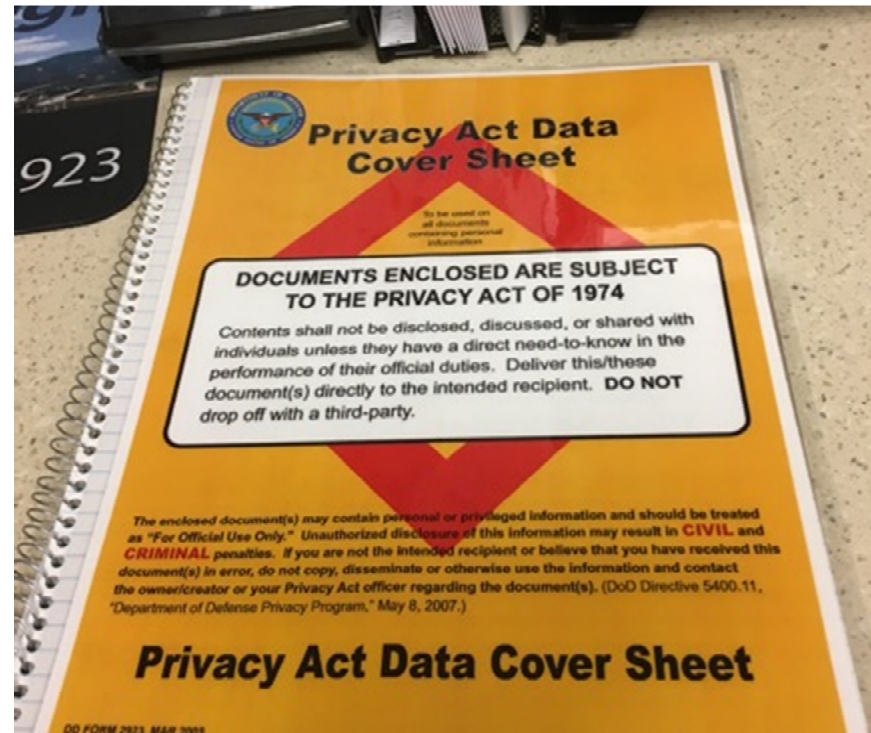
Dangerous Drug Certificates

Provider Licenses

State and Federal Posters are required to be in Visible Places

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The Clinic Secures Protected Health Information

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Fire Safety Process per State Regulations

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Securing Hazards

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**Preventing
Access to Hazards**



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Facility Tour



Equipment Maintenance Best Practices

- All equipment resides on an Inventory List
- Policy determines need for Inspection vs Preventive Maintenance
- PM based on Manufacturer's IFUs
- 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

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Facility Tour

Equipment Management Best Practices

- Manufacturer's IFUs determine cleaning process
- Healthcare Disinfectant is used
- Staff follows directions on the Disinfectant
- Dirty equipment is stored away from Clean
- Equipment stored off of the floor

Review of Laboratory Area

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Review of Laboratory Services

Laboratory Compliance

- 6 Required tests must be able to be performed in the Clinic
 - Urine Analysis
 - Hemoglobin/Hematocrit
 - Blood Glucose Testing
 - Urine Pregnancy Test
 - Occult Fecal Blood Test
 - Primary Culturing
- Clinic follows all Manufacturer's IFU for equipment and supplies
- Staff should have training/verification of competency (BEST PRACTICE)

TEST	LOT #	EXP DATE	OPEN DATE	TEST RESULT	TEST RESULT	TEST RESULT	TEST RESULT	TEST RESULT
GLU	079922	5/1/17	5/28/16	Clear	0.2	0.2	0.2	0.2
STRIP	STA 5000027	5/1/17	5/28/16	Clear	0.2	0.2	0.2	0.2
STRIP	STA 5000027	5/1/17	5/28/16	Clear	0.2	0.2	0.2	0.2
HCO								
HPYOD								
Hemoglobin	15D1922	04/2016	8/24/15	15.1	15.1	15.1	15.1	15.1
Hemoglobin	15D1922	04/2016	8/24/15	15.1	15.1	15.1	15.1	15.1
Hemoglobin	15D1922	04/2016	8/24/15	15.1	15.1	15.1	15.1	15.1

8/28/16 Hemocrit out of range - on medication that affects hemoglobin



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Review of Laboratory Services

Common Deficiency:

Clinic does not have the ability to do all 6 required tests.
Most common one missing is Hemoglobin or Hematocrit.



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Review of Medication Storage

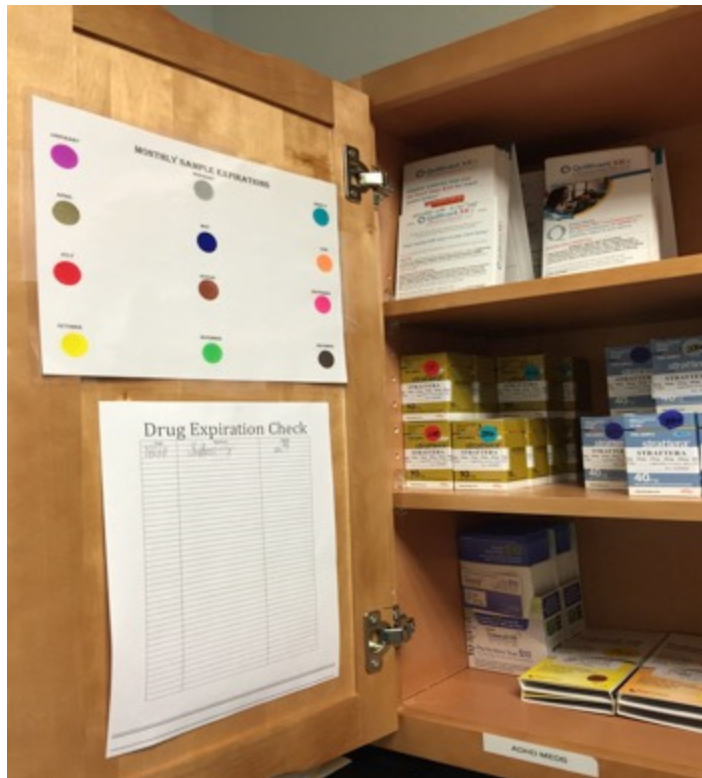
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The Sticker Method

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Medication Storage



**Sample Medications
Secured
Logged to Track In the Event
of a Recall**

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Medication Storage

MDVs dated for
28 or 30 days



**Secured/Organized In Original Containers, Not Expired/Past BUD,
No MDV in Immediate Treatment Areas, SDV contents Not Saved**

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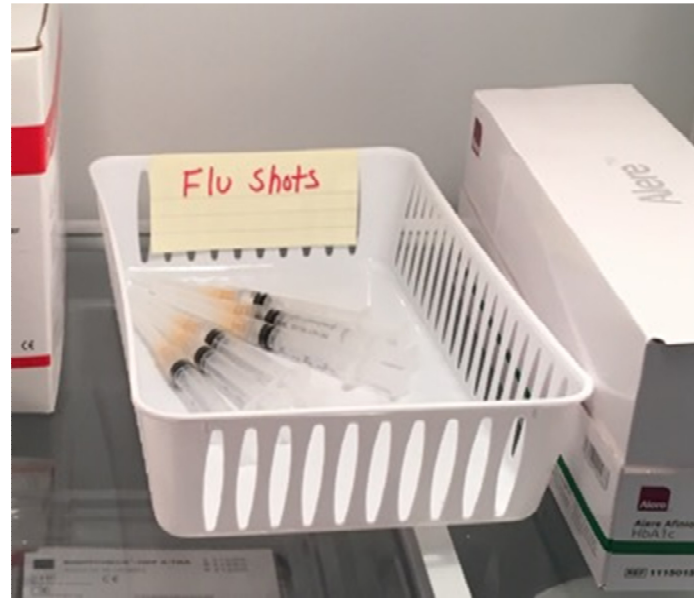
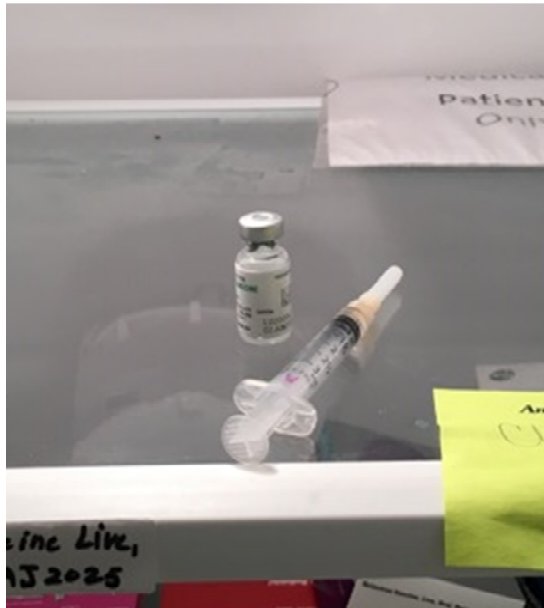
Medication Storage



ER Med Box/Cart is stocked according to a list and ready to meet the needs of the population.

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Medication Storage



DANGER: Unlabeled Vaccines in Pre-Drawn Syringes

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Medication Storage

Vaccination Storage Best Practices

- Temperature monitoring should alert staff to a temperature variance in the past 48 hours
- Clinic should have a process to be notified when the power goes off at the clinic (power grid call list, alarm with alerts, etc.)
- Bottled water stored in the doors, labeled not food
- No medications stored in the doors
- Expired medications **MUST** be identified
- No food or lab supplies stored in the med fridge or freezer

Medication Storage



**Controlled Substances (CS) locked in a Substantial Cabinet
Recordkeeping Logs for Ordering / Dispensing**

***Dilemmas:* MDVs, Storage in Sample Closet, Med Fridge, or ER Boxes**

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Free Medication Storage Training

THE PROVIDER
DO YOU MULTI-DOSE?

A SINGLE-DOSE VIAL (SDV) is approved for use on a **SINGLE** patient for a **SINGLE** procedure or injection.

SDVs typically lack an antimicrobial preservative. Do not save left over medication from these vials. Harmful bacteria can grow and infect a patient.

DISCARD after every use!

SIZE DOES NOT MATTER!

SDVs and MDVs can come in any shape and size. **Do not assume** that a vial is an SDV or MDV based on size or volume of medication.

ALWAYS check the label!

A MULTIPLE-DOSE VIAL (MDV) is recognized by its FDA-approved label.

Although MDV's can be used for more than one patient when aseptic technique is followed, **ideally even MDVs are used for only one patient.**

MDVs typically contain an antimicrobial preservative to help limit the growth of bacteria. Preservatives have no effect on bloodborne viruses (i.e. hepatitis B, hepatitis C, HIV).

Discard MDVs when the beyond-use date has been reached, when doses are drawn in a patient treatment area, or any time the sterility of the vial is in question!

Click for more information:
[FAQs Regarding Safe Practices for Medical Injections](#)

**CDC Safe Injection Practices
Training Videos on You Tube**

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Medication Storage

Common Deficiency:

MDVS found in procedure room

MDVS opened and undated

Sharps unsecured



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Review of Infection Prevention Practices

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Infection Prevention Best Practices

- OSHA training upon hire and annually
- PPEs are available and accessible
- Hand Hygiene when appropriate
- 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
- Safe Injection Practices

Infection Prevention Best Practices

“Clean to Dirty” Process to Avoid Cross-Contamination



Clean Area (Meds)

Dirty Area (Labs)

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Infection Prevention Best Practices



Disposable Instrumentation Is The Easiest Way To Meet Compliance with Recommended Practices from Nationally Recognized Organizations

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Infection Prevention Best Practices

Common Deficiency:

PPE (Personal Protection Equipment) for using with Liquid Nitrogen

Open Sterile water not discarded



Review of Medical Records

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Patient Health Records

§ 491.10 Patient Health Records

(3) For each patient receiving health care services, the clinic or center maintains a record that includes, as applicable:

- (i)** Identification and social data, evidence of consent forms, pertinent medical history, assessment of the health status and health care needs of the patient, and a brief summary of the episode, disposition, and instructions to the patient;
- (ii)** Reports of physical examinations, diagnostic and laboratory test results, and consultative findings;
- (iii)** All physician's orders, reports of treatments and medications, and other pertinent information necessary to monitor the patient's progress;
- (iv)** Signatures of the physician or other health care professional.

Surveyor will not record identifying information.

A clinic representative should identify any chart of concern.

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Patient Health Records

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								

Surveyor will not record identifying information.
 A clinic representative should identify any chart of concern.

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Patient Health Records

Common Deficiency:

Person signing the consent for minors is not identified by relationship



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Review of Personnel Records

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Licensed Providers and Staff

Licensed Staff Member	State of Origin License # (or Certificate #)	Expiration Date	DEA Certificate # (as applicable)	Expiration Date	BLS Exp For Licensed and Certified Patient Care Personnel	Verification & copies of professional license, registration and/or certification is maintained if applicable.

Human Resources Best Practices

Common Deficiency:

Staff who work with patients do not have current BLS



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Emergency Preparedness



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Emergency Preparedness...

Lessons From Hurricane Harvey

- Immediate Threat to Life and Safety
- Communication System Interruption
- Impact on Utilities (water, electricity)
- Impact to Provision of Services in Community
- Supply Chain Delays (Rx, med supplies)
- Financial Impact to Clinic Closure
- Staffing Interruptions

Emergency Preparedness...

Lessons From Hurricane Harvey



RHC Provider going to work in 2016

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TCT Handout

§491.12 Emergency Preparedness



Use this tool to see what will be assessed on day of survey.



The Compliance Team's Review of Appendix Z
Emergency Preparedness for Rural Health Clinics

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§491.12 Emergency Preparedness

Common Deficiencies:

- Conduct an additional exercise; must do two!
One can be a full scale community drill and one a table top.
- Provider based clinics only presenting the hospital's plan.
Although there are areas that are integrated, the EP plan should be RHC specific.
- Having an EP plan but no staff training
- Omitting the name and contact numbers of other RHCs.
- Having evidence that a community exercise is not accessible
- Analyze the clinics response to an actual event or an exercise.



Survey Findings

- 100% compliance is necessary for RHC Certification
- Statement of Deficiency will be received with in 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 (if the clinic already has a billing number)

It Seems Overwhelming...

But if you put processes in place it's very doable!

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Online Tools Available

§ 491.8(b) Physician responsibilities	
<p>§ 491.8(b)(1) The physician provides medical direction for the clinic's health care activities and consultation for, and medical supervision of the health care staff.</p>	<p><input type="checkbox"/> Evidence of supervision and consultation should be found in chart notes. Supervision should also be defined in clinic policy.</p>
<p>§ 491.8(b)(2) In conjunction with the physician's assistant and/or nurse practitioner member(s), the physician participates in developing, executing and periodically reviewing the clinic's written policies and the services provided to</p>	<p><input type="checkbox"/> A physician participated in the development and review of the clinic's policies <input type="checkbox"/> The physician's participation is documented <input type="checkbox"/> Make sure the time period for "periodically" is specified and signatures indicating review are documented at this specified interval.</p>
<p>§ 491.8(b)(3) The physician periodically reviews the clinic's patient records, provides medical orders and provides medical care services to the patients of the clinic.</p>	<p><input type="checkbox"/> The physician has reviewed 10 Dates of Service (only recommendation) of each Mid-level practitioner at least quarterly <input type="checkbox"/> The review is documented and shared with the Mid-level practitioner. Maintain documentation that this is completed.</p>

There are many mock-survey tools online. Some have “aggressive compliance” notes, but are great tools.

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Trusted Resources



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Thank you.

Questions ???



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