Click here to view PRESENTATION RECORDING.



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MARCH 2021

# *Session 3*

## Rural Health Clinics: Regulations to Rural Excellence

Kate Hill, VP Clinic Division

The Compliance Team™

# Session 3: Learning Objectives

- Conducting a Mock Survey
- Surveyor's Perspective
- Tour of TCT Resources and Application Process

**REMINDER!**

Register for the Patient Centered Medical Home training series, "PCMH – A Practice Model to Improve Quality"

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## Final Session in Series “Regulations to Rural Excellence”

**Session 1:** Learned the Federal Code of Regulations 491.1 to 491.12 for RHCs

**Session 2:** Learned TCT RHC Quality Standards – Universal and Specialty

**Session 3:** Completes the series with Preparing for accreditation: Mock Survey process, Discussion with a TCT surveyor, the application process, submission of documents and Onsite Ready Form.

# Overview of Mock Survey

Work the TCT checklist!  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 standards? Are there areas of concern that need more attention?
- Complete a policy review based on the policy section of the checklist with yellow headers.  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!

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# Conducting a Self Survey – Time to Shine!

Everyone has worked hard to prepare for accreditation 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 standard on the checklist, your clinic is ready for survey day.

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:<br>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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# Mock Survey – Signage


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

## 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 CMS.
- Update your 855a and CMS 29 as things change.

# The Entrance

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# The Entrance


## Posted Hours of Operation

# The Waiting Room

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# The Exam Rooms and Patient Bathroom

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# Biohazard 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

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# Mock Survey – Supply Storage and Oxygen


## Safe storage of Oxygen:

- Chained or in an approved cart.
- Keep full separated from empty.

# Mock Survey – Posters


- 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.

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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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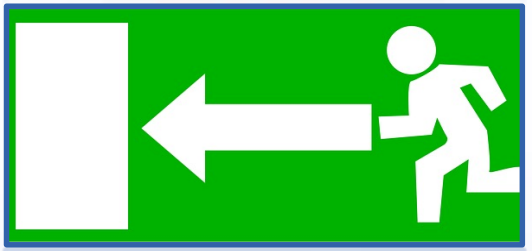
# Mock Survey – Fire Safety





## Fire Safety Process per State Regulations

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# Mock Survey – HR Files

| Personnel File Audit Tool<br>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 |
| | | | | | | | | | | | |
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| | | | | | | | | | | | |

**Are your HR Files complete and in order? Accessible for review?**

Staff of the clinic or center are licensed, certified or registered in accordance with applicable State and local laws.

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# HR File


**OIG** Exclusion list:

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

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# HR File Elements

- 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


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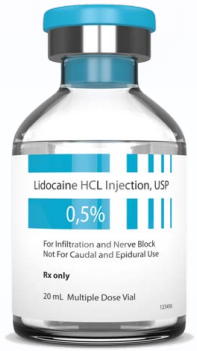
# Mock Survey – Vials and Outdated Supplies

- 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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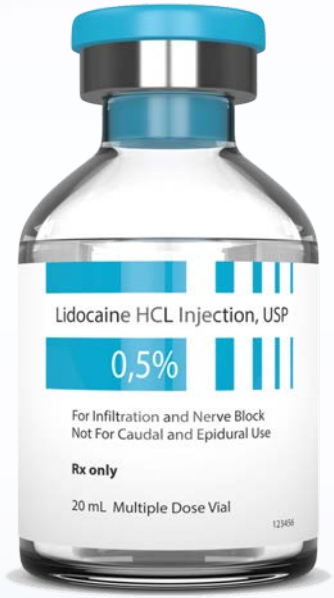
# Vials and Outdated Supplies




**Single Dose Vials**

Beyond-Use Date

28 Days

**Multi Dose Vials**

**NEVER DATED**

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# Vials and Outdated Supplies

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

Once and done, discard!


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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

# Controlled Substances

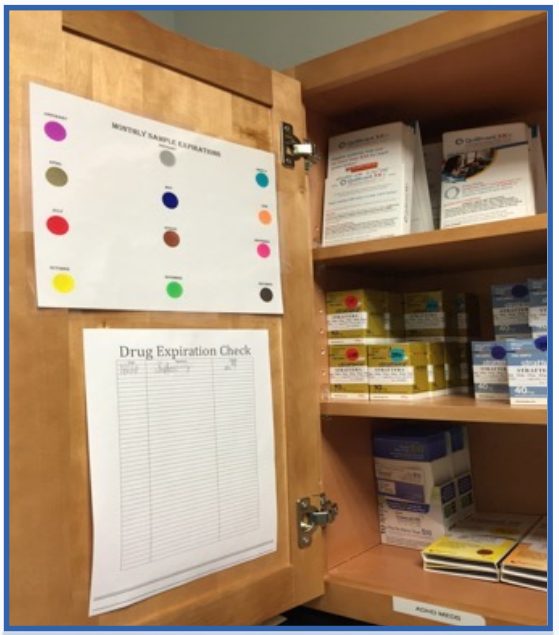

Controlled Substances (CS) locked in a Substantial Cabinet.

Recordkeeping Logs for Ordering/ Dispensing.

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

# Mock Survey – Samples

Use the sticker method




Secured/Organized
In Original Containers

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# Mock Survey – Sample Log


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

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# Mock Survey – Supplies

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

Check anything with a date!

The red sharp container is not acceptable.

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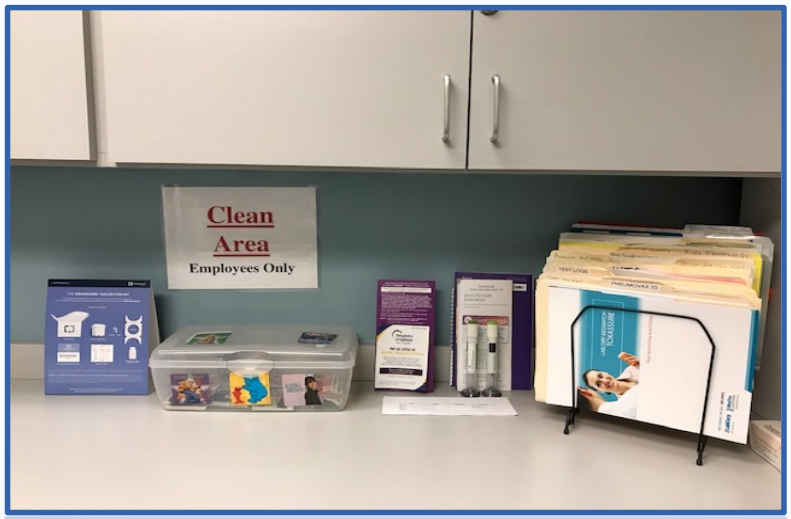
# Infection Prevention





**Clean to Dirty Process to Avoid Cross Contamination**

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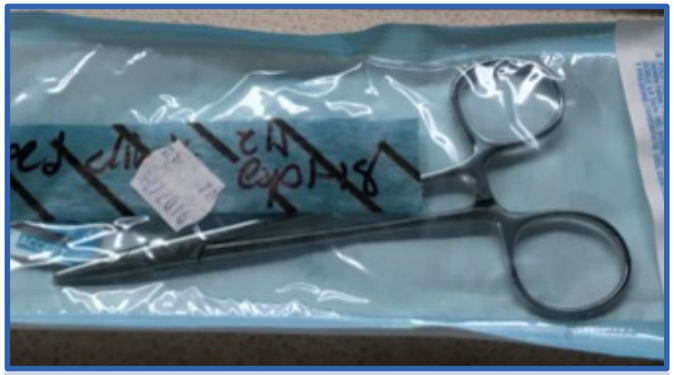
# Instruments

**Sterilizing instruments in the clinic.**

**- OR -**

**Accepting sterilized instruments from the hospital.**



# Table Top Sterilizers


## Tabletop Sterilizers

## OH My!

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# Mock Survey – Infection Prevention



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

Once and done!

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# HIPPA


- Visible PHI
- Computer Time Outs
- Cloud Storage
- Passwords
- Social Media

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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.

# Mock Survey – Staff Responsibilities

- 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.
- This means no patient gets out of the waiting room unless there is a provider in the building.
- 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.

# Staff Responsibilities

**Physician responsibilities.**

The physician performs the following:

- 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.
- 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?**

# Staff Responsibilities

**Physician assistant and nurse practitioner responsibilities.**

- Practices in accord with clinic policies
- Participate with a physician in a periodic review of the patients' records.
- Sign the policy binder review page

# 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

# Mock Survey – 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.

Check for outdated 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

# 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.

# *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<br>Insert "Y" (YES) if evidence is found, "N" (NO) if evidence of is missing, or "NA" if not applicable.<br>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. | | | | | | | | |

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# Biennial Evaluation

A review of your program every two years:
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.

# Biennial Evaluation

## 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


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# Mock Survey


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# Lessons Learned

- 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

**A lesson learned from Hurricane Katrina:**

In 2005, only 25% of office-based providers were using electronic medical records. Entire lifetimes of healthcare documentation were lost forever for many critically and chronically ill patients.  EMR is now the standard

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# Lessons Learned

## What did we learn from Harvey?

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

## COMMUNICATION ISSUES?

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# Mock Survey – Risk Assessment

## All Hazards Risk Assessment

**Community-Based**
**Clinic-Based**

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# 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.

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# Emergency Preparedness CMS AAR

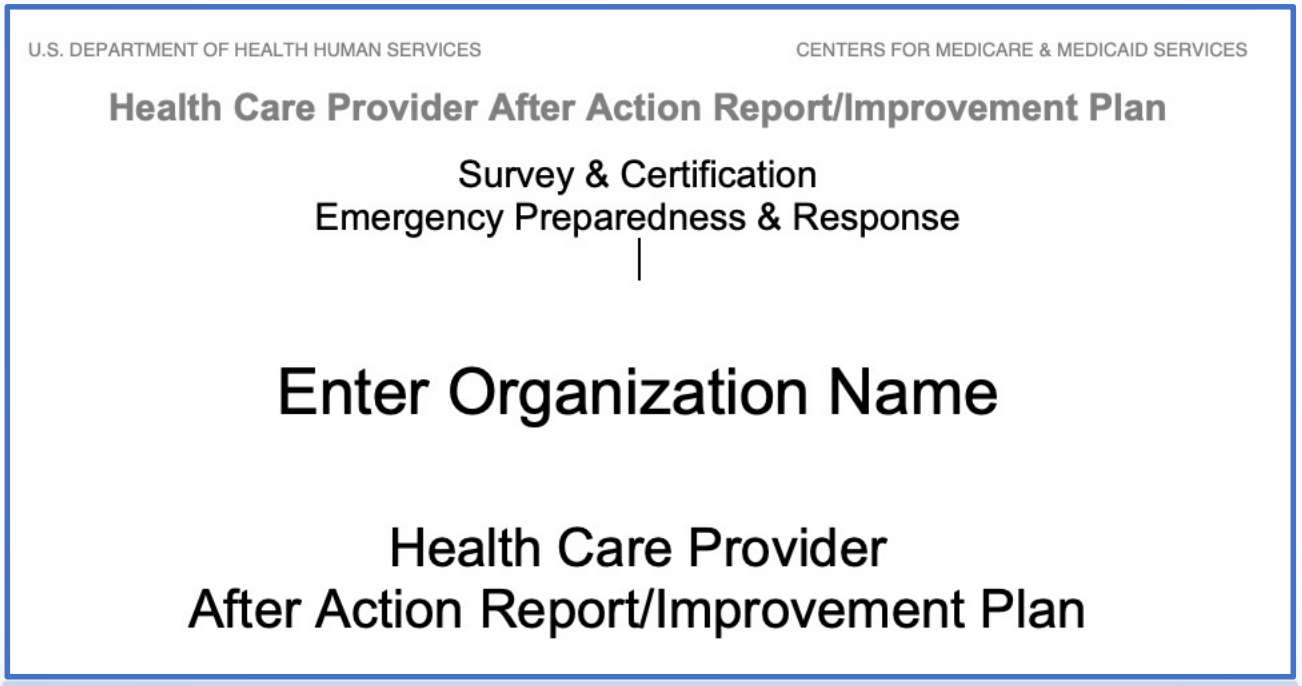
CMS After Action Report (AAR) or similar document

- 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.

# 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.

# Emergency Preparedness Resources


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

# CERT: Community Emergency Response Team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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://www.ready.gov/cert

# MO Community Emergency Response Team

CERT

BOONE COUNTY, MO

Contact: Doug Westhoff
Phone: 573-447-5000
Email: dwesthoff@bcfdmo.com

CERT

MAPLEWOOD, MO (ST. LOUIS COUNTY)

Contact: Matt Wilcox
Phone: 314-646-3666
Email: mw3114@hotmail.com

CERT

BRANSON, MO (TANEY COUNTY)

Contact: Paul Harkins
Phone: 417-243-2760
Email: pharkins@bransonmo.gov

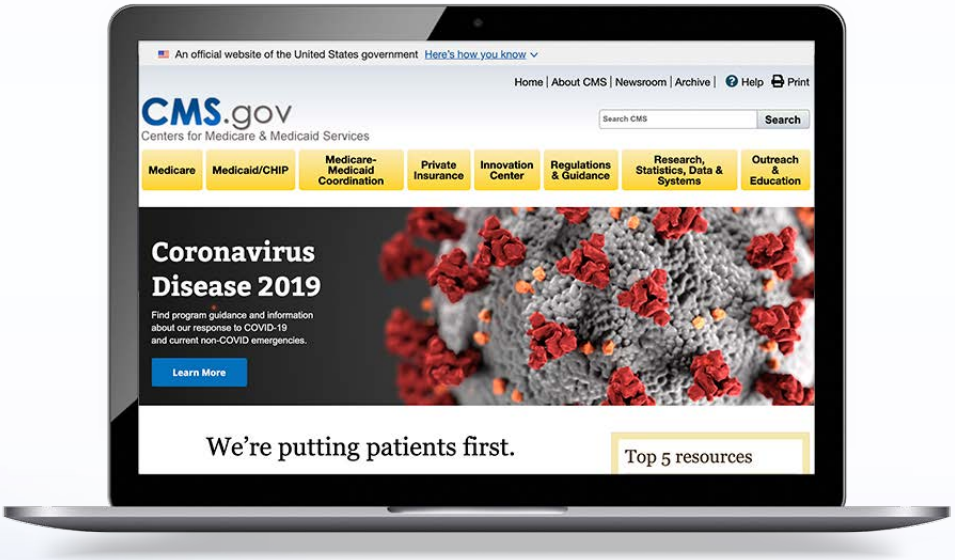
CERT

MARION COUNTY, MO

Contact: John Hark
Phone: 573-221-5346
Email: hark203@mywdo.com

https://www.cert-la.com/cert-missouri/

# Emergency Preparedness




Website:

https://www.cms.gov/

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# Mock Survey – Policy Review

- Yellow header on the checklist
- Do you have all policies?
- All elements in the policy to meet the standard requirements?
- Easily accessible in either electronic file or hard copy binder?

# 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.

Session 1, Part 2

# *Surveyor Perspective: A Discussion*

## Regulations to Rural Excellence

What to Expect on Survey Day

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# TCT Application Process and Resources

Should you decide to choose The Compliance Team as your accreditation provider, we have a simplified application process and outstanding resources that will be provided to you at the time of application including:

One on one calls with an Accreditation Advisor to assist you throughout the process.

A library of webinars and other resources to assist in developing RHC protocols. You will receive a username and password for easy access to all resources.

Patient Satisfaction Survey Portal

A fair and unbiased survey that is transparent. You are provided with the same checklist used by our surveyors. No surprises.

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# Preparation Timeline

**Initial Steps**

- Complete TCT Application Process
- Open Email Welcome Letter to Access TCT Website Login and Password for Resources
- Review TCT RHC Quality Standards, Survey Checklist, and Guidance Documents
- RHC Accreditation Advisor Will Make Initial Contact Via Email

**RHC Orientation**

- Live Orientation Call with Accreditation Advisor
- Watch TCT Universal Quality Standards Webinar
- Watch TCT Specialty Quality Standards Webinar
- Watch TCT Clinical Concerns Webinar
- Communicate RHC Requirements to all Staff Members
- Contact Accreditation Advisor with Questions or Concerns

**Preparation**

- Access TCT Website for RHC Resources to Aid in the Development of RHC Protocols
- Create RHC Policies and Organization Chart
- Utilize the RHC Checklist to Track Progress
- Build an RHC Evidence Binder
- Make Rounds to Assess Compliance in the Clinic

**Pre-Survey**

- Ensure Required Documents Have Been Sent to TCT
  - 855A Approval Letter
  - Business Associates Agreement with The Compliance Team
  - State License (if applicable)
  - Floor Plan
  - Current CLIA
  - Completed HR Audit Information (Submit in a Word File, not a PDF)
- Complete TCT Onsite Survey Ready Form (OSSR) Signaling Readiness for Survey Scheduling and Declaring Blackout Dates
- Once OSSR is Submitted, the Clinic Will Be Placed in the Cue for an Unannounced Onsite Accreditation Survey

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# Onsite Survey Readiness

Once you have completed all the requirements in the preparation timeline, your clinic is considered as OSSR – Onsite Survey Ready

REMEMBER – CMS requires that the RHC surveys be unannounced! Normally, the survey is scheduled within 30 days of submission of the OSSR form.

One last item to keep in mind – Due to the Public Health Emergency, counties that are not in green may have a virtual survey with TCT. This is a fluid situation that could change at any time so prepare for your onsite visit but be aware that the process may be modified depending on travel restrictions.

# What to Expect on Survey Day

- RHC surveys are unannounced so be prepared!
- Session 3, Handout 2 is the Survey Agenda.  It describes what to expect during the day of survey.
- Most surveys take between 6 to 9 hours per clinic depending on the size and number of providers/staff.  If multiple clinics are being surveyed at the same time, the surveyor or survey team will inform you upon arrival of the number of days they expect to be onsite.
- Remember that having easy access to policies, personnel records and medical records as they are requested will allow the surveyor to proceed without delay. The agenda in Handout 2 includes a list of items the surveyor will request.
- Once complete, the surveyor will conduct an exit interview to discuss the survey findings.

# Survey Findings

- 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 loose billing number).

# Thank You for Attending the Training!


**Thank you for all you do.**
**We wish you great success!**
**Stay safe and healthy.**

The Compliance Team™

Join us on

# Tuesday April 6, 2021

## PCMH “A Practice Model for Quality Improvement!”

Thank you!

# QUESTIONS?

**Kate Hill**, RN, VP Clinic Division

**215-654-9110**

khill@thecomplianceteam.org

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

| CORPORATE COMPLIANCE | STANDARD | YES | NO | COMMENTS |
|---|---|---|---|---|
| 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** | **COMMENTS** |
| 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) | | | |

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| • 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 clinic must report any change in the medical director to CMS and the Compliance Team. | ADM 4.0.2 | | | |
| The clinic has an organizational chart. | ADM 4.0.3 | | | |
| The clinic has a protocol for identifying who is in charge of day to day operations in the absence of key leadership. | ADM 4.0.5 | | | |
| The Clinic is under the medical direction of a physician, and has a healthcare staff that meets the staff and staffing requirements at §491.8. (§491.7(a)(1)) | ADM 5.0 | | | |
| The Medical Director, who must be a physician, is accountable for the clinic's medical direction and quality of care. (§491.8(b)) | ADM 5.0.1 | | | |
| The clinic staff may also include ancillary personnel who are supervised by the professional staff. (§491.8(a)(4)) | ADM 5.0.3 | | | |
| The healthcare staff is sufficient to provide the services essential for the operation of the clinic. (§491.8(a)(5)) | ADM 5.0.4 | | | |
| A physician, nurse practitioner, physician assistant, certified nurse-midwife, clinical social worker, or clinical psychologist is available to furnish patient care services at all times the clinic operates. (§491.8(a)(6)) | ADM 5.0.5(a) | | | |
| A physician assistant, nurse practitioner or certified nurse mid-wife is available to furnish patient care services at least 50 percent of the clinic's operating hours. (§491.8(a)(6)). | ADM 5.0.6 | | | |
| The physician assistant or nurse practitioner performs the following functions, to the extent they are not being performed by a physician: (§491.8(c)(2)) | ADM 5.0.7 | | | |
| • Provides RHC services in accordance with the clinic's policies. (§491.8(c)(i)) | ADM 5.0.7(a) | | | |

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| • Arranges for or refers patients to, needed services that cannot be provided at the clinic. (§491.8(c)(2)(ii) | ADM 5.0.7(b) | | | |
| • Assures that adequate patient health records are maintained and transferred as required when patients are referred. (§491.8(c)(2)(iii)) | ADM 5.0.7(c) | | | |
| The RHC has at least one nurse practitioner (NP) or physician assistant (PA) who is an employee and may contract with others. (§491.8(a)(3)) | ADM 5.0.8 | | | |
| The physician provides medical orders, medical direction; medical care services, consultation, and supervision of the healthcare staff and chart review. He or she is also available through direct telecommunication for consultation, assistance with medical emergencies, or patient referral. (§491.8(b)(1)) | ADM 5.0.9 | | | |
| If an established RHC does not have an NP or PA fulfilling the staffing requirements at §491.8(a)(1) and §491.8(a)(6), the clinic has submitted a staffing waiver request to CMS and copy the Compliance Team. | ADM 5.0.10 | | | |
| The clinic's professional staff, that includes the physician, physician assistant and/or nurse practitioner develops, executes and reviews the clinic's policies and services provided. (§491.8(b)(2)-physicians, §491.8(c)-Physician Assistant and/or Nurse Practitioner) | ADM 6.0 | | | |
| The physician periodically reviews the clinic's patient health records, provides medical orders, and provides services to the patients. (§491.8(b)(3)) | ADM 6.0.3 | | | |
| The physician assistant and/or nurse practitioner participate with the physician in a periodic review of the patient health records. ((§491.8(c)(1)(ii)) | ADM 6.0.4 | | | |
| The clinic is primarily engaged in providing outpatient health services and meets all other conditions of 42 CFR 491, subpart A. (§491.9(a)(2)) | ADM 6.0.5 | | | |

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| A designated member of the clinic's professional staff is responsible for maintaining the patient health records and for ensuring that they are completely and accurately documented, readily accessible, and systematically organized. (§491.10(a)(2) | ADM 7.0.1 | | | |
| There is a healthcare record for each person receiving services. (§491.10(a)(3)) | ADM 7.0.2 | | | |
| The clinic has a process in place that ensures patient health records are complete when patients are referred or transferred. | ADM 7.0.3 | | | |
| The clinic ensures the Privacy Notice is posted and available to all patients. | ADM 8.0.1(a) | | | |
| The clinic ensures all Business Associate Agreements (BAA) are maintained according to applicable HIPAA regulations. | ADM 8.0.1(b) | | | |
| The clinic maintains the confidentiality of the patient health records and provides safeguards against loss and destruction and unauthorized use. (§491.10(b)(1)) | ADM 8.0.2 | | | |
| The patient's written consent is necessary before any information not authorized by law may be released. (§491.10(b)(3)) | ADM 8.0.3 | | | |
| The clinic, at a minimum, retains patient health records a period of 6 years from the last entry date or longer if required by State statue. (§491.10(c)) | ADM 8.0.4 | | | |
| There is evidence that the clinic staff is trained on patient confidentiality upon hire and annually. | ADM 8.0.5 | | | |
| The clinic ensures patient health care records are complete. (§491.10(a)(3)) | ADM 9.0 | | | |
| There is evidence the clinic periodically audits its Patient Health Records for completeness and the results are documented at QI meetings. The number of records is identified in clinic policy. The leadership reviews and documents the chart review findings and takes corrective actions. | ADM 9.0.2 | | | |
| Emergency Services are provided to the patient for life threatening injuries or acute | ADM 10.0 | | | |

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| illness. (§491.9(c)(3)) | | | | |
| The clinic provides medical emergency procedures as a first response to common life-threatening injuries and acute illness and has: (§491.9(c)(3)) | ADM 10.0.1 | | | |
| • Available treatment includes the use of drugs & biologicals commonly used in life saving procedures such as analgesics, anesthetics (local), antibiotics, anticonvulsants, antidotes, emetics, serums and toxoids. (§491.9(c)(3)) | ADM 10.01(a) | | | |
| • The clinic's emergency equipment and drugs are organized in one place. | ADM 10.01(c) | | | |
| • One oxygen tank with oxygen delivery device such as a nasal cannula or simple oxygen mask. | ADM 10.0.1(d) | | | |
| The clinic is constructed, arranged, and maintained to ensure access to and safety of patients, and provides adequate space for the provision of direct services. (§491.6(a)) | ADM 11.0 | | | |
| The clinic has a preventive maintenance program to ensure that: (§491.6(b)) | ADM 11.0.1 | | | |
| • All essential mechanical, electrical and patient-care equipment is maintained in safe operating condition. (§491.6(b)(1)) | ADM 11.0.1(a) | | | |
| ○ All equipment is tested, inspected in accordance with manufacturer's guidelines, and a maintenance schedule is retained that ensures clinic equipment is in working order and assessed prior to patient use. | ADM 11.0.1(a)(i) | | | |
| ○ The clinic maintains written documentation of all equipment maintenance/repairs and preventative maintenance. | ADM 11.0.1(a)(ii) | | | |
| ○ The clinic has a process in place for handling equipment/product hazards defects or recalls. | ADM 11.0.01(a)(iii) | | | |
| • The premises of the clinic are clean and orderly. (§491.6(b)(3)). | ADM 11.0.01(b) | | | |
| Evidence that the clinic monitors housekeeping and maintenance (including repair, renovation, and construction activities) to ensure a functional, safe, and orderly environment. | ADM 11.0.2 | | | |

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| Drugs, Biological, and Supplies are appropriately stored (§491.6(b)(2)). *(This includes ensuring all sharp containers, sharps, chemicals and electrical hazards in patient care areas are secured.) | ADM 11.0.3 | | | |
| The clinic meets the following Fire Safety Requirements: | ADM 11.0.4 | | | |
| • Fire and sanitation inspections are current as required by the State. | ADM 11.0.4(a) | | | |
| • Exit doors are clearly marked with illuminated or reflective signs | ADM 11.0.4(b) | | | |
| • Exit doors unlock from the inside without a key. | ADM 11.0.4(c) | | | |
| • Exits from the building are unobstructed and accessible for occupants having limited mobility. | ADM 11.0.4(d) | | | |
| • Fire extinguishers are mounted and have been inspected annually. | ADM 11.0.4(e) | | | |
| • Floor plans, as appropriate, identifying the nearest emergency exit route are posted throughout the clinic. | ADM 11.0.4(f)) | | | |
| **HUMAN RESOURCES** | **STANDARD** | **YES** | **NO** | **COMMENTS** |
| The clinic has evidence of appropriate training and validation of competency upon hire and annually. When new services are added or when a staff member's performance warrants, additional training is given or competency validation is validated. | HR 1.0.2 | | | |
| The clinic documents the job responsibilities and accountabilities for all employees. | HR 2.0 | | | |
| The clinic has written job descriptions (or checklists) outlining the employee's responsibilities and accountabilities. Job descriptions are signed and dated by the employee and a copy is placed in the employee's personnel file. | HR 2.0.1 | | | |
| The clinic maintains personnel files on all employees and Independent Contractors. | HR 3.0 | | | |
| **QUALITY IMPROVEMENT** | **STANDARD** | **YES** | **NO** | **COMMENTS** |
| The clinic maintains continuous quality improvement processes and carries out, or | QI 1.0 | | | |

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| arranges for, a biennial evaluation of its overall program. (§491.11(a)) | | | | |
| The biennial program evaluation includes a review of the following: (§491.11(b)) | QI 1.0.2 | | | |
| • Utilization review of all services provided by clinic. (§491.11(b)(1)) | QI 1.0.2(a) | | | |
| • Number of patients served and volume of services. (§491.11(b)(1)) | QI 1.0.2(b) | | | |
| • A representative sample of both active and closed patient health. (§491.11(b)(2)) | QI 1.0.2(c) | | | |
| • Review of all clinic health care policies. (§491.11(b)(3)) | QI 1.0.2(d) | | | |
| The program evaluation is completed by clinic professional personnel or through arrangement with other appropriate professionals | QI 1.0.3 | | | |
| The program evaluation can be broken into parts and competed separately. When performed separately, sections of the biennial program evaluation (QI Plan) should directly relate to how the clinic completes the biennial evaluation of its total program and describe its continuous quality improvement for clinic services. There may not be more than 2 calendar year difference between the evaluations of each section. | QI 1.0.4 | | | |
| The program evaluation results are reviewed to determine the following: (§491.11(c)) | QI.1.0.5 | | | |
| • The Utilization of services was appropriate. (§491.11(c)(1)) | QI.1.0.5(a) | | | |
| • The established policies were followed. (§491.11(c)(2)) | QI.1.0.5(b) | | | |
| • Identify changes needed (§491.11(c)(3)) | QI.1.0.5(c) | | | |
| • Staff reviews the findings of the evaluation and corrective actions are taken if necessary. (§491.11(d)) | QI.1.0.5(d) | | | |
| The clinic collects data for patient/client satisfaction and dissatisfaction. | QI 2.0 | | | |

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| The clinic ensures a sample of patients receive a patient satisfaction survey. | QI 2.0.1 | | | |
| The results of the patient satisfaction surveys are collected, evaluated and presented at QI/staff meetings. | QI 2.0.2 | | | |
| The clinic has a process to develop and implement corrective action if the result of the patient satisfaction evaluation reveals possible issues. | QI 2.0.3 | | | |
| The complaint process is defined in a written document (or waiting room display) that includes the statement "In the event your complaint remains unsolved with <clinic name>, you may file a complaint with our Accreditor, The Compliance Team, Inc. via their website (www.thecomplianceteam.org) or via phone 1-888-291-5353." | QI 2.0.5 | | | |
| The clinic provides its patients with written information on the complaint process, and then notifies the complainant that the issue is being investigated with the timeframe identified in the clinic policy. | QI 2.0.6 | | | |
| **RISK** | **STANDARD** | **YES** | **NO** | **COMMENTS** |
| The clinic has a process for receiving, reviewing and preventing patient incidents. | RSK 1.0 | | | |
| The clinic has evidence that incidents are documented on a specific form. | RSK 1.0.1 | | | |
| There is a designated staff member responsible for reviewing all incidents and a process in place for taking corrective action and following-up. If the incident results in hospitalization or death, it is be reported to TCT within 48 hours. | RSK 1.0.2 | | | |
| There is evidence that employees are knowledgeable of the process. | RSK 1.0.3 | | | |
| The clinic has a process in place for the handling of employee injuries and/or exposure. | RSK 2.0 | | | |
| The clinic has evidence that employee incidents, injuries or exposures are documented on a specific form. RHCs are exempt from OSHA 300 recordkeeping but must report any workplace incident that results in an employee's fatality, inpatient hospitalization, | RSK 2.0.1 | | | |

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| amputation, or loss of an eye. | | | | |
| There is a designated staff member responsible for reviewing all incidents and a process in place for taking corrective action and following-up. If the incident results in hospitalization or death, it must be reported to TCT within 48 hours at QA@thecomplianceteam.org . | RSK 2.0.2 | | | |
| There is evidence that employees are knowledgeable of the process. | RSK 2.0.3 | | | |
| **EQUIPMENT MANAGEMENT** | **STANDARD** | **YES** | **NO** | **COMMENTS** |
| All oxygen tanks are properly secured (chained or in a cart) and maintained in a well-ventilated area. | EQP 1.0.2(a) | | | |
| If multiple oxygen tanks are maintained within the clinic, full tanks are stored separately from those that are empty or partially full | EQP 1.0.2(b) | | | |
| **INFECTION CONTROL** | **STANDARD** | **YES** | **NO** | **COMMENTS** |
| The clinic follows infection prevention techniques that relate to the type of patient served, services provided and the staff's risk for exposure. | INF 1.0 | | | |
| The clinic practices infection prevention techniques by utilizing the following: | INF 1.0.2 | | | |
| • Hand washing or use of alcohol based gel before and after each patient contact. | INF 1.0.2(a) | | | |
| • Utilization of gloves while handling or cleaning dirty equipment. | INF 1.0.2(b) | | | |
| • Proper disposal of gloves, sharps and other waste throughout the clinic including red bag use. | INF 1.0.2(c) | | | |
| • Standard Precautions when at risk for exposure to blood-borne pathogens. | INF 1.0.2(d) | | | |
| • Prevents cross-contamination by segregating clean from dirty in utility and or storage areas. | INF 1.0.2(e) | | | |

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| All sterilization equipment and procedures follow manufacturer guidelines for use. | INF 1.0.3 | | | |
| • All instruments are cleaned according to the manufacturer's instructions for use. | INF 1.0.3(a) | | | |
| • All sterile packaging has an identifiable expiration due date according to manufacturer guidelines. | INF 1.0.3(b) | | | |
| • For those clinics that receive sterilized instruments from the hospital, the clinic must have a process for sterilizing, transporting and receiving instruments from the hospital. | INF 1.0.3(c) | | | |
| The clinics' personnel receive education and training on infection control annually. | INF 1.0.4 | | | |
| **PATIENT SERVICES AND INSTRUCTION** | **STANDARD** | **YES** | **NO** | **COMMENTS** |
| The clinic has a process to protect patient rights and responsibilities. | PTS 1.0 | | | |
| The clinic has a written patient rights and responsibilities document is posted and available to patients upon request. | PTS 1.0.1 | | | |
| There is evidence the staff is trained on the patient rights and responsibilities. | PTS 1.0.2 | | | |
| All patient care services are provided in accordance with Federal, State and local laws. (§491.9(a)(1)) | PTS 2.0 | | | |
| The clinic has an agreement or arrangement with one or more Medicare or Medicaid participating providers or suppliers to furnish the following services: (§491.9(d)(1)) | PTS 2.0.2 | | | |
| • Inpatient hospital care. (§491.9(d)(1)(i)) | PTS 2.0.2(a) | | | |
| • Physician services. (§491.9(d)(1)(ii)) | PTS 2.0.2(b) | | | |
| • Additional and specialized diagnostic and laboratory services that are not available at the clinic. (§491.9(d)(1) (iii)) | PTS 2.0.2(c) | | | |

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| If the agreements with other providers or suppliers are not in writing, there is evidence that the patients referred are being accepted and treated. (491.9(d)(2)) | PTS 2.0.3 | | | |
| The clinic has a process for follow-up that is related to the type of service provided and the patient's condition. | PTS 4.0 | | | |
| The clinic has an organized process in place for the follow-up of their patients regarding the following:<br>a. Missed appointments.<br>b. New medication or treatment.<br>c. Lab or diagnostic results.<br>d. Referral and consultations. | PTS 4.0.1 | | | |
| Documentation of follow-up is found in the patient record. | PTS 4.0.2 | | | |
| After a follow-up call is made, appropriate staff incorporate any necessary changes in the patients' health record. | PTS 4.0.3 | | | |
| The clinic presents written information to all adult age patients upon admission to services. | PTS 5.0 | | | |
| The clinic has a process that information given to patients contains individual rights under State law to make decisions concerning medical care which includes:<br>a. Attaining written consent to treat.<br>b. The right to accept or refuse care concerning medical or surgical treatment.<br>c. The relationship of an authorized representative is clearly documented for all minors and adult patients not capable of giving their consent.<br>d. Acknowledging advanced directive as required by the State. | PTS 5.0.1 | | | |
| **DIAGNOSTIC SERVICES** | **STANDARD** | **YES** | **NO** | **COMMENTS** |
| The clinic furnishes those diagnostic, therapeutic services and supplies commonly furnished in a physician's office or at the entry point into the healthcare delivery | DGS 1.0 | | | |

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| system. (§491.9(c)(1)). | | | | |
| Diagnostic and therapeutic services include: | DGS 1.0.1 | | | |
| • Medical History. (§491.9(c)(1)) | DGS 1.0.1(a) | | | |
| • Physical examination. (§491.9(c)(1)) | DGS 1.0.1(b) | | | |
| • Assessment of health status. (§491.9(c)(1)) | DGS 1.0.1(c) | | | |
| • Treatment for a variety of medical conditions. (§491.9(c)(1)) | DGS 1.0.1(d) | | | |
| The clinic provides basic laboratory services essential to immediate diagnosis and treatment. (§491.9(c)(2)) | DGS 2.0 | | | |
| The clinic delivers laboratory services in accordance with part 42 CFR 493, which implements the provisions of section 353 of the Public Health Service Act. [CLIA Certificate of Waiver] (§491.9(a)(3), (§491.9(c)(2)) | DGS 2.0.1 | | | |
| The clinic's laboratory services include: | DGS 2.0.2 | | | |
| • Chemical examination of urine by stick or tablet method (including urine ketones). (§491.9(c)(2)(i) | DGS 2.0.2(a) | | | |
| • Hemoglobin or hematocrit. (§491.9(c)(2)(ii) | DGS 2.0.2(b) | | | |
| • Blood Glucose. (§491.9(c)(2)(iii) | DGS 2.0.2(c) | | | |
| • Examination of stool specimens for occult blood. (§491.9(c)(2)(iv) | DGS 2.0.2(d) | | | |
| • Pregnancy tests. (§491.9(c)(2)(v) | DGS 2.0.2(e) | | | |
| • Primary culturing for transmittal to a certified lab. (§491.9(c)(2)(vi) | DGS 2.0.2(f) | | | |
| The clinic has evidence of training and competency for all staff performing lab services. | DGS 2.0.3 | | | |
| **REGULATORY** | **STANDARD** | **YES** | **NO** | **COMMENTS** |

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| The clinic and its staff are in compliance with applicable local, State and Federal laws and regulations. (§491.4) | REG 1.0 | | | |
| The clinic is licensed in accordance with applicable State and local law. (§491.4(a)) | REG 1.0.1 | | | |
| The clinic displays all licenses, certificates and permits to operate. | REG 1.0.2 | | | |
| The clinic is in compliance with the OSHA Blood-borne Pathogen Standard as it relates to the type of patient served, services provided and staff's risk for exposure. (29 CFR 1910.1030) | REG 2.A | | | |
| The clinic has a written work-exposure plan that determines the job classifications of staff at risk of blood-borne pathogen exposure and the work-practice controls and personnel protective equipment that are made available to protect them. The clinic has evidence of an environmental housekeeping schedule. The plan has been reviewed and/or updated at least annually. | REG 2.A.1 | | | |
| All personnel protective equipment is provided by the employer and readily accessible to staff. | REG 2.A.2 | | | |
| If identified as being at risk for exposure to bloodborne pathogens, the clinic staff is offered full Hepatitis B vaccination series at the employer's expense. If declined, a signed declination form appears in personnel file. | REG 2.A.3 | | | |
| There is evidence that the clinic staff has received training on OSHA Bloodborne Pathogens Standard upon hire and annually. | REG 2.A.4 | | | |
| The clinic is in compliance with current OSHA and CDC guidelines for preventing the transmission of Mycobacterium Tuberculosis in Health Care Settings. | REG 2.B | | | |
| The clinic conducts an initial and on-going risk assessment for TB transmission by occupational exposure. Factors to be considered should include: risk by geographical location as determined by the State Department of Health, the type of patient | REG 2.B.1 | | | |

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| population served including fluctuations of population caused by temporary workers or tourism, and the reported cases of TB in the clinic in the past year. | | | | |
| Based upon assessment of risk, the clinic follows current OSHA and CDC Guidelines to determine the types of administrative, environmental, respiratory protection controls, and medical surveillance needed. | REG 2.B.2 | | | |
| There is evidence clinic conducts TB screening upon hire. | REG 2.B.3 | | | |
| There is evidence that the clinic staff has received TB Transmission Prevention training upon hire and annually. | REG 2.B.4 | | | |
| The clinic is in compliance with OSHA's Right to Know standard. | REG 2.C | | | |
| Safety Data Sheets (SDS) are current and available for all hazardous material in the clinic's workplace and employees are knowledgeable of the location. | REG 2.C.1 | | | |
| The clinic posts all mandatory OSHA posters for all employees to view. | REG 2.C.2 | | | |
| There is evidence that the clinic provides training upon hire to all employees on OSHA's Right to Know. | REG 2.C.3 | | | |
| **EMERGENCY PREPAREDNESS** | **STANDARD** | **YES** | **NO** | **COMMENTS** |
| The clinic has an emergency preparedness program that addresses an emergency on-site, off-site (natural disaster) and disruption of service. (§491.12) | EP 1.0 | | | |
| The clinic complies with all applicable Federal, State and local emergency preparedness requirements. (§491.12) | EP 1.0.1 | | | |
| The clinic has an emergency preparedness plan that is reviewed and updated at least every two years. This plan must contain the following elements: (§491.12(a) | EP 1.0.2 | | | |
| • A documented, clinic-based and community-based risk assessment that | EP 1.0.2(a) | | | |

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| utilizes an all hazards approach. (§491.12(a)(1)) | | | | |
| • Strategies for addressing emergency events identified by the risk assessment. (§491.12(a)(2) | EP 1.0.2(b) | | | |
| • 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. (§491.12(a)(3)) | EP 1.0.2(c) | | | |
| • 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. (§491.12(a)(4)) | EP 1.0.2(d) | | | |
| The clinic develops and maintains an emergency communication plan that complies with Federal, State, and local laws. (42 CFR 491.12(c)) | EP 3.0 | | | |
| The clinic's emergency preparedness communication plan is reviewed and updated at least every 2 years. (§491.12(c)) | EP 3.0.1 | | | |
| . The clinic's communication plan must include the following elements: (§491.12(c)) | EP 3.0.2 | | | |
| Names and contact information for the following: (§491.12(c)(1) | EP 3.0.2(a) | | | |
| • Staff (§491.12(c)(1)(i) | EP 3.0.2(a)(i) | | | |
| • Entities providing services under arrangement. (§491.12(c)(1)(ii) | EP 3.0.1(a)(ii) | | | |
| • Patient's physicians. (§491.12(c)(1)(iii) | EP 3.0.2(a)(iii) | | | |
| • Other RHCs. (§491.12(c)(1)(iv) | EP 3.0.2(a)(iv) | | | |
| • Volunteers. (§491.12(c)(1)(v) | EP 3.0.2(a)(v) | | | |
| . Contact information for the following: (§491.12(c)(2) | EP 3.0.2(b) | | | |
| • Federal, State, tribal, regional, and local emergency preparedness staff. (§491.12(c)(2)(i) | EP 3.0.2(b)(i) | | | |
| • Other sources of assistance. (§491.12(c)(2)(ii) | EP 3.0.2(b)(ii) | | | |

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

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| . **Primary and alternate means for communicating with the following: (§491.12(c)(3)** | **EP 3.0.2(c)** | | | |
| • **RHC (§491.12(c)(3)(i)** | **EP 3.0.2(c)(i)** | | | |
| • **Federal, State, tribal, regional, and local emergency management agencies. (§491.12(c)(3)(ii)** | **EP 3.0.2(c)(ii)** | | | |
| . **A means of providing information about the general condition and location of patients under the facility's care as permitted under 45 CFR 164.510(b)(4). (§491.12(c)(4))** | **EP 3.0.2(d)** | | | |
| **A means of providing information about the clinic's needs, and its ability to provide assistance, to the authority having jurisdiction or the Incident Command Center, or designee. (§491.12(c)(5)** | **EP 3.0.2(e)** | | | |
| **The clinic's communication plan contains an organized process for handling an on-site emergency which addresses the following:**<br>a. **How employees will be notified of emergency.**<br>b. **Staff responsible for calling the Fire Department.**<br>c. **Location of where employees should meet outside the building.**<br>d. **Staff person responsible to do head count upon evacuation of the building.** | **EP 3.0.3** | | | |
| **The clinic' communication plan has an organized process for handling an off-site emergency (e.g. Snowstorm, flood, hurricane, etc.)**<br>a. **How employees will be notified of emergency.**<br>b. **Staff responsible for notification and triaging of patient services.**<br>c. **Contingency plan that includes alternative provider in the event the clinic cannot service its own customers.** | **EP 3.0.4** | | | |
| **Training Program: The clinic develops and maintains an emergency preparedness training and testing program that is based on the emergency preparedness plan, risk assessment, policies and procedures, and the communication plan. (42 CFR 491.12(d)(1))** | **EP 4.0** | | | |

| Facility Name/Clinic: | Surveyor Number(s): | |
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| . The training and testing program is reviewed and updated, at a minimum at least every 2 years. (§491.12(d)) | EP 4.0.1 | | | |
| . The training program must include all of the following: (§491.12(d)(1)) | EP 4.0.2 | | | |
| • Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles. (§491.12(d)(1)(i)) | EP 4.0.2(a) | | | |
| • Provide emergency preparedness training, at a minimum at least every 2 years. (§491.12(d)(1)(ii) | EP 4.0.2(b) | | | |
| • Emergency preparedness training of staff, individual providing services under arrangement, and volunteers is documented. This documentation demonstrates knowledge of emergency procedures. (§491.12(d)(1)(iii), (§491.12(d)(1)(iv)) | EP 4.0.2(c) | | | |
| • If the emergency preparedness policies and procedures are significantly updated, the RHC must conduct training on the updated policies and procedures. (§491.12(d)(1)(v)) | EP 4.0.2(d) | | | |
| Testing Program: The clinic conducts exercises to test the emergency plan, at a minimum, at least annually. (42 CFR 491.12(d)(2)) | EP 5.0 | | | |
| The clinic must do the following: (§491.12(d)(2)) | EP 5.0.1 | | | |
| • Participate in a full-scale exercise that is community-based or when a community-based exercise is not assessable, an individual, facility based functional exercise every 2 years. (§491.12(d)(2)(i)) | EP 5.0.1(a) | | | |
| ○ When a community-based exercise is not accessible, an individual, facility-based functional exercise every 2 years; or. (§491.12(d)(2)(i)(A)) | EP 5.0.1(a)(i) | | | |
| ○ If the RHC experiences an actual natural or man-made emergency that requires activation of the emergency plan, the RHC is exempt from engaging in its next required full-scale community- | EP 5.0.1(a)(ii) | | | |

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| based or individual, facility-based functional exercise following the onset of the emergency event. (§491.12(d)(2)(i)(B)) | | | | |
| • Conduct an additional exercise every 2 years, opposite the year the full-scale or functional exercise in paragraph EP 5.0.2(a) of this section is conducted, that may include, but is not limited to the following: (§491.12(d)(2)(ii)) | EP 5.0.1(b) | | | |
| ○ A second full-scale exercise that is community-based or individual, facility-based functional exercise; or. (§491.12(d)(2)(ii)(A)) | EP 5.0.1(b)(i) | | | |
| ○ A mock disaster drill; or. (§491.12(d)(2)(ii)(B)) | EP 5.0.1(b)(ii) | | | |
| ○ A tabletop exercise or workshop that is led by a facilitator and includes a group discussion, using a narrated, clinically relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan. (§491.12(d)(2)(ii)(C)) | EP 5.0.1(b)(iii) | | | |
| • Analyze the clinic's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the clinic's emergency plan, as needed. (§491.12(d)(2)(iii)) | EP 5.0.1(c) | | | |
| If a clinic that is part of a healthcare system consisting of multiple separately certified healthcare facilities elects to have a unified and integrated emergency preparedness program, the clinic may choose to participate in the healthcare system's coordinated emergency preparedness program. (§ 491.12(e)) | EP 6.0 | | | |
| If the clinic elects to participate in the healthcare system's emergency preparedness plan, the unified and integrated emergency preparedness program must do all of the following: (§491.12(e)) | EP 6.0.1 | | | |
| • Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program. (§491.12(e)(1)) | EP 6.0.1(a) | | | |
| • Be developed and maintained in a manner that takes into account each | EP 6.0.1(b) | | | |

| Facility Name/Clinic: | Surveyor Number(s): | |
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| separately certified facility's unique circumstances, patient populations, and services offered. (§491.12(e)(2)) | | | | |
| • Demonstrate that each separately certified facility is capable of actively using the unified and integrated emergency preparedness program and is in compliance with the program. (§491.12(e)(3)) | EP 6.0.1(c) | | | |
| • Include a unified and integrated emergency plan that meets the requirements of 42 CFR 491.12(a)(2), (3), and (4). The unified and integrated emergency plan must also include the all of the following elements: (§491.12(e)(4) ) | EP 6.0.1(d) | | | |
| • A documented community-based risk assessment, utilizing an all hazards approach. (§491.12(e)(4)(i)) | EP 6.0.1(d)(i) | | | |
| • A documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach. (§491.12(e)(4)(ii)) | EP 6.0.1(d)(ii) | | | |
| • Include integrated policies and procedures that meet the requirements at 42 CFR 491.12(b), a coordinated communication plan, and training and testing programs that meet the requirements of 42 CFR 491.12(c) and 491.12(d) | EP 6.0.1(e) | | | |

**RHC POLICY REVIEW**

| CORPORATE COMPLIANCE | STANDARD | YES | NO | COMMENTS |
|---|---|---|---|---|
| The Clinic has a written Corporate Compliance Plan. | COM 1.0 | | | |
| The Corporate Compliance Plan contains the following required elements: | COM 1.0.1 | | | |
| • Written policies and procedures. | COM 1.0.1(a) | | | |
| • Standards of Conduct. | COM 1.0.1(b) | | | |

| Facility Name/Clinic: | Surveyor Number(s): | |
|---|---|---|
| | Survey Start Date: | Survey End Date: |
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| • A designated compliance officer. | COM 1.0.1(c) | | | |
| • Evidence of Internal communication system and methods for reporting non-compliance. | COM 1.0.1(d) | | | |
| • Evidence of Quality Improvement techniques: Monitoring and auditing, problem identification, investigation and corrective action. | COM 1.0.1(e) | | | |
| • Evidence of Clinic Risk Assessment addresses areas in which the clinic is vulnerable. | COM 1.0.1(f) | | | |
| • Disciplinary and Corrective actions when non-compliance is identified. | COM 1.0.1(g) | | | |
| **ADMNISTRATION** | **STANDARD** | **YES** | **NO** | **COMMENTS** |
| The clinic policies and its line of authorities and responsibilities are clearly set forth in writing. (§491.7(a)(2)) | ADM 4.0.4 | | | |
| The clinic has written policies and procedures for identifying categories of practitioners that includes, at a minimum, the following: (§491.8(a)) | ADM 5.0.2 | | | |
| • One or more physicians. (§491.8(a)(1)) | ADM 5.0.2(a) | | | |
| • One or more physician assistants, nurse practitioners, or nurse mid-wife. (§491.8(a)(2). | ADM 5.0.2(b) | | | |
| • The physician member of the staff may be the owner of the clinic. (§491.8(a)(3)) | ADM 5.0.2(c) | | | |
| • The physician assistant, nurse practitioner, nurse mid-wife, clinical social worker or clinical psychologist member of the staff may be the owner or an employee of the clinic, or may furnish services under contract to the clinic. (§491.8(a)(3)) | ADM 5.02(d) | | | |
| The clinic has written policies and a mechanism in place for review and approval of policies. | ADM 6.0.1 | | | |
| The physician, in conjunction with the physician assistant and or nurse practitioner participates in developing, executing and periodically reviewing the clinic's written policies and services provided. (§491.8(b)(2)) | ADM 6.0.2 | | | |

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| The clinic has written policies & procedures for maintaining patient health records. (§491.10(a)(1)) | ADM 7.0 | | | |
| The clinic has policies and procedures addressing the protection of record information. (§491.10(b)) | ADM 8.0 | | | |
| The clinic has written policies and procedures that govern the use and removal of patient health records from the clinic and the conditions for the release of information. (§491.10(b)(2)) | ADM 8.0.1 | | | |
| The Medical Director and other providers will determine the contents of the emergency box. The contents are listed on the exterior of the emergency box and in a written policy. | ADM 10.01(b) | | | |
| The clinic has written policies for a clean and orderly environment that address the following: | ADM 11.0.1(c) | | | |
| • Techniques for cleaning and disinfecting environment surfaces, carpeting, and furniture. | ADM 11.0.1(c)(i) | | | |
| • Disposal of regulated waste. | ADM 11.0.1(c)(ii) | | | |
| **HUMAN RESOURCES** | **STANDARD** | **YES** | **NO** | **COMMENTS** |
| The clinic has policies and procedures in place for hiring, orienting and training of all employees. | HR 1.0 | | | |
| The clinic has written human resources policies and procedures specifying personnel qualifications, training, experience, and continuing education requirements consistent with the services it provides to beneficiaries. | HR 1.0.1 | | | |
| **QUALITY IMPROVEMENT** | **STANDARD** | **YES** | **NO** | **COMMENTS** |
| The clinic has a written annual evaluation policy determining who is to do the evaluation, how it is to be done and what is reviewed. The plan is developed and implemented by key leaders representing management and clinic personnel. (This requirement is for initial surveys only) | QI 1.0.1 | | | |

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| The clinic has a written policy and procedure for defining, handling, reviewing and resolving complaints. | QI 2.0.4 | | | |
| When a complaint is received, the clinic provides notice to the complainant that the issue is being investigated within the timeframe identified in the clinic policy. | QI 2.0.6 | | | |
| **EQUIPMENT MANAGEMENT** | **STANDARD** | **YES** | **NO** | **COMMENTS** |
| The clinic has written policy and procedures for equipment management. | EQP 1.0 | | | |
| The clinic's equipment management policy and procedures clearly state the process for cleaning, maintaining and storing all equipment. Policies should include the following: | EQP 1.0.1 | | | |
| • All equipment is cleaned with a healthcare disinfectant according to manufacturer's directions and kept sanitary prior to each patient's use. | EQP 1.0.1(a) | | | |
| • Environmental surfaces are cleaned with a healthcare disinfectant according to the manufacturer's directions, using products, which will at a minimum kill Hepatitis B and HIV and are registered with the U.S Environmental Protection Agency (EPA) and/or OSHA. | EQP 1.0.1(b) | | | |
| • Equipment used in the clinic or loaned to patients (e.g. crutches, wheelchairs or walkers) is be cleaned between patients and appropriately stored. | EQP 1.0.1(c) | | | |
| • Clean equipment is segregated from dirty equipment. | EQP 1.0.1(d) | | | |
| • Equipment/supplies stored on shelves, in cabinets and off the floor. | EQP 1.0.1(e) | | | |
| • Defective and obsolete equipment is appropriately labeled. | EQP 1.0.1(f) | | | |
| **INFECTION CONTROL** | **STANDARD** | **YES** | **NO** | **COMMENTS** |
| The clinic has a written infection control policy and procedure reviewed annually. | INF 1.0.1 | | | |
| **PATIENT SERVICES AND INSTRUCTION** | **STANDARD** | **YES** | **NO** | **COMMENTS** |
| The clinic has list of patient care services provided directly to patients and a list of patient care services provided through agreement, arrangement or through referral. (§491.9(d)) (e.g. Scope of service policy) | PTS 2.0.1 | | | |
| Written healthcare policies for all patient care services. (§491.9(b)) | PTS 3.0 | | | |

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| Healthcare services are provided in accordance with written policies, which are consistent with applicable State law. (§491.9(b)(1)) | PTS 3.0.1 | | | |
| The patient care policies are initially developed and reviewed biennially by an advisory group that includes, at a minimum, a physician, physician's assistant or nurse practitioner and one person who is not a member of the clinic staff. (Please cite §491.9(b)(2) if the patient care policies are not developed and cite §491.9(b)(4) if the patient care policies are not reviewed at least biennially). | PTS 3.0.2 | | | |
| The clinic has a written policy for referring patients to needed services that cannot be provided at the clinic. | PTS 3.0.3 | | | |
| The patient care policies include: (§491.9(b)(3)) | PTS 3.0.4 | | | |
| • A description of patient care services furnished directly and those furnished through agreement, arrangement or referral. (§491.9(b)(3)(i)) | PTS 3.0.4(a) | | | |
| • Guidelines for the medical management of health problems which includes the conditions requiring medical consultation and/or patient referral, maintenance of patient health records, and procedures for the periodic review and evaluation of the services provided by the clinic. (§491.9(b)(3)(ii)) | PTS 3.0.4(b) | | | |
| • The clinic will specify in the policy, which reference sources the Medical Director and the non- physician provider have agreed on. The reference may be textbooks, written polices or electronic software. | PTS 3.0.4(c) | | | |
| There is evidence that staff is trained on the policies. | PTS 3.0.5 | | | |
| **PHARMACEUTICAL SERVICES** | **STANDARD** | **YES** | **NO** | **COMMENTS** |
| The clinic has written policies for the storage, handling and dispensing of drugs, biologicals, and supplies. (§491.9(b)(3)(iii)) | DRG 1.0 | | | |
| The clinic's written policies include: | DRG 1.0.1 | | | |
| • Requirements that drugs are stored in original manufacturer's containers to maintain proper labeling. | DRG 1.0.1(a) | | | |

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| • Requirements that multiple dose vials and single dose vials are stored according to manufacturer guidelines. | DRG 1.0.1(b) | | | |
| • Requirements that drugs and biologicals dispensed to patients have complete and legible labeling of containers; | DRG 1.0.1(c) | | | |
| • Requirements for a process to regularly monitor the inventory of clinic drugs, biologicals, and supplies for expiration by the manufacturer's date, beyond-use-dating, or evidence of recall, to prevent harmful or ineffective treatment to patients. | DRG 1.0.1(d) | | | |
| • Requirements for a process to handle outdated, deteriorated, or adulterated drugs, biological, and supplies. Outdated, deteriorated or adulterated drugs, biologicals and supplies are stored separately and the disposal is in compliance with applicable State laws. | DRG 1.0.1(e) | | | |
| • Requirements for storage in a space that provides proper humidity, temperature and light to maintain quality of drugs and biological that includes the following:<br>○ Refrigerated or frozen medication or vaccines are monitored for storage temperature at least twice daily.<br>○ Temperatures are recorded in a log and staff reports variances in normal findings to clinic leadership.<br>○ No drugs or biological are stored in the door of the refrigerator or freezer.<br>○ Water bottles are placed in the door of the medication refrigerator to promote temperature stability. | DRG 1.0.1(f) | | | |
| ▪ Requirements that current drugs references, antidote information and manufacturer guidelines are available on the premises. | DRG 1.0.1(g) | | | |

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| | Survey Start Date: | Survey End Date: |
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| ▪ All Controlled Substances are handled, as directed by the Drug Enforcement Agency (DEA) Practitioner's Manual, in a manner that guards against theft and diversion.<br>○ Schedule II drugs are stored in a securely constructed locked compartment, separate from other drugs.<br>○ Schedule III, IV, and V drugs are secured in a substantially constructed cabinet.<br>○ The clinic maintains adequate record keeping of the receipt of controlled drugs and a reconcilable log of the distribution. Should Schedule II drugs be administered in the clinic, these drugs are accounted for separately. Any thefts or significant losses have been reported to the DEA. | DRG 1.0.1(h) | | | |
| • Requirements that containers used to dispense drugs and biologicals to patients conform to the Poison Prevention Packaging Act of 1970. | DRG 1.0.1(i) | | | |
| • Requirements that all prescribing and dispensing of drugs shall be in compliance with applicable State laws. | DRG 1.0.1(j) | | | |
| **EMERGENCY PREPAREDNESS** | **STANDARD** | **YES** | **NO** | **COMMENTS** |
| The clinic has developed and implemented emergency preparedness policies and procedures that are based on its emergency preparedness plan, risk assessment and communication plan. (42 CFR 491.12(b)) | EP 2.0 | | | |
| . The policies and procedures are reviewed and updated, at a minimum, at least every 2 years. (§491.12(b)) | EP 2.0.1 | | | |
| . The policies and procedures must include the following elements: (§491.12(b)) | EP 2.0.2 | | | |
| • Safe evacuation from the clinic, which includes appropriate placement of exit signs, staff responsibilities and needs of patients. (§491.12(b)(1)) | EP 2.0.2(a) | | | |
| • A means to shelter in place for patients, staff, and volunteers who remain in the clinic. (§491.12(b)(2)) | EP 2.0.2(b) | | | |

| Facility Name/Clinic: | Surveyor Number(s): | |
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| • A system of medical documentation that preserves patient information, protects confidentiality of patient information, and secures and maintains the availability of patient health records. (§491.12(b)(3)) | EP 2.0.2(c) | | | |
| • The use of volunteers in an emergency or other staffing strategies, including the process and role for integration of State and Federally designated health care professionals to address surge needs during an emergency. (§491.12(b)(4)) | EP 2.0.2(d) | | | |
| • How refrigerated/frozen medications such as vaccines, etc. are handled in a power outage | EP 2.0.2(e) | | | |

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

| Licensed Staff Member | State of Origin License # (or Certificate #) | License Expiration Date | DEA Certificate # (as applicable) | DEA Expiration Date | BLS Expiration Date For Licensed and Certified Patient Care Personnel (HR 3.0.1(k)) | Verification & copies of professional license, registration and/or certification is maintained if applicable. |
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**Comments:**

| Facility Name/Clinic: | Surveyor Number(s): | |
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| Total Number of Exam Rooms: | Time In:<br>Time Out: | Hours Onsite: |

**NOTE: DEFICIENCIES IDENTIFIED DURING THE HUMAN RESOURCES FILE REVIEW ARE CITED UNDER HR 3.0**

| Personnel File Audit Tool<br>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 (HR 3.0.1(a)) | Signed Job Description ( HR 3.0.1(c)) | Orientation/Training/Competency Assessment checklists (HR 3.0.1(d)) | Signed Standard of Conduct (HR 3.0.1(e)) | Current License or Certification (HR 3.0.1(f)) | OIG Exclusion (HR 3.0.1(g) | Performance Evaluation (HR 3.0.1(h)) | Background Check (HR 3.0.1) | Verification of Hepatitis B or signed declination (HR 3.0.1(j)) | Verification of TB or signed declination (HR 3.0.1(j)) | Comments |
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**Notes: Give extent of missing element. (Example 1 of 10)**

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

**NOTE: DEFICIENCIES IDENTIFIED DURING THE PATIENT HEALTH CARE RECORD REVIEW ARE CITED UNDER ADM 9.0 (§491.10(a)(3)**
***Review of Patient Health Records of Minor Patient- Please include (M) after the patient identifier.**

| Medical Record Audit Tool<br>Insert "Y" (YES) if evidence is found, "N" (NO) if evidence of is missing, or "NA" if not applicable.<br>Insert an "M" next the patient number if the patient is a minor child. | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Patient<br><br>Ex: 1BR060418S | 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 | Comments |
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| **Facility Name/Clinic:** | **Surveyor Number(s):** | |
| | **Survey Start Date:** | **Survey End Date:** |
| **Total Number of Exam Rooms:** | **Time In:**<br>**Time Out:** | **Hours Onsite:** |

**Notes: (Give extent of missing element(s) For example 1 of 10 files missing…..)**

**PATIENT INTERVIEWS**

| RHC Patient Questions | Patient Interview (1) | Patient Interview (2) |
|---|---|---|
| **Able to get an appointment?** | | |
| **Wait time?** | | |
| **Understand Diagnosis?** | | |
| **Understand Treatment?** | | |
| **Follow-up Instructions?** | | |
| **Enough time spent to answer all?** | | |
| **Any problems or adverse reaction to treatment?** | | |
| **Grade for the Clinic?** | | |
| **Comments** | | |

TheComplianceTeam
An accreditation organization.
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# RHC ON-SITE CLINIC EVALUATION AGENDA

Following is an overview of the day our surveyors will spend in your clinic during your evaluation. This is intended to provide you with a general idea of the day. Additional areas may be reviewed based on the advisor's observations. The order of day is subject to change based on activities in the clinic.

- Meeting with the management staff and providers, as many as are available. We will need a small conference room.
- Tour of the facility.
- Observation of infection control practices.
- Inspection of medicine/supplies storage area.
- Interview of staff members conducted throughout the day.
- Patient interactions: one or two patients will be interviewed throughout the day.
- Wrap up meeting and exit conference.

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Please provide the following:

- ☐ Policy and procedure manuals and forms.
- ☐ Patient medical record review - 10 random files.
- ☐ Copy of an up-to-date RHC organization chart.
- ☐ HR files of all personnel.
- ☐ List and verification of licensed and certified personnel.
- ☐ Copy of RHC floor plan or emergency exit posting.
- ☐ Copy of the most recent annual RHC program evaluation (*if applicable*).
- ☐ Evidence of annual review of policies and procedures.
- ☐ Quality improvement meeting minutes (*if applicable*).
- ☐ List of equipment in the clinic.
- ☐ Maintenance records for equipment.
- ☐ Copy of most recent RHC survey report and plan of correction if not previously sent (*if applicable*).
- ☐ Copy of PA/NP staffing schedule.
- ☐ Appointment schedule for the day (1-3 patient interviews).
- ☐ List of patient files which have been reviewed for quality improvement.
- ☐ List of PA/NP files, which have been reviewed by the Medical Director.
- ☐ Evidence of employee training and competency testing.