Click here to view PRESENTATION RECORDING.

This project is supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award totaling $205,000 (25 percent) funded by HRSA/HHS and $615,000 (75 percentage) funded by nongovernment sources through an award with the Missouri Department of Health and Senior Services, Office of Rural Health and Primary Care (DHSS, ORHPC). The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by HRSA/HHS, or the U.S. Government.

March 2021

Session 2

Rural Health Clinics: Regulations to Rural Excellence

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The Compliance Team™

Session Two: Learning Objectives

- Operational Excellence leads to Clinical Excellence
- TCT RHC Standards, Most Common Deficiencies and Compliance
- Preparing your clinic and staff with Kim Tatum

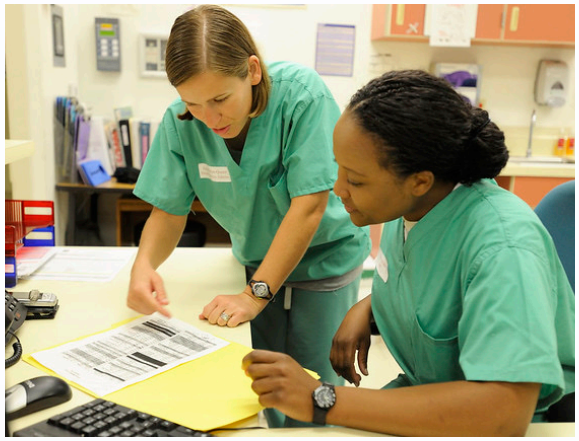
Reminder!

Register for Session 3 to complete the training series,

“Rural Health Clinics: Regulations to Rural Excellence”

The Compliance Team™

The Compliance Team Philosophy



Operational Excellence

Clinical excellence is interdependent on operational excellence.

Safety, Honesty, Caring

The Compliance team standards focus on safety, honesty and caring.

Exemplary Provider

Achieving “Exemplary Provider” status demonstrates your commitment to quality care.

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EPP Quality Standards & Evidence of Compliance (EOC)

Quality Standards are Operationally Based
EPP Quality Standards Meet or Exceed Conditions for Certification

Universal Quality Standards

- Corporate Compliance
- Administration
  - Shortage Area
  - Governing Body
  - Medical Records
  - Physical Plant
- Human Resources
- Quality Improvement Plan
- Risk Management

Specialty Quality Standards

- Equipment management
- Infection control
- Patient services & Instructions
- Pharmaceutical Services
- Diagnostic Services
- Regulatory
- Emergency Preparedness

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Universal Standards

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COM 1.0

COM 1.0 - The organization has a Corporate Compliance plan.

Evidence of Compliance:

1) The clinic has a written plan that identifies the elements required for an effective compliance program and clinic mission or vision. Plan includes the following core elements:
   a. Written policies and procedures.
   b. Standards of Conduct that includes a non-retaliation statement.
   c. A designated Compliance officer in a leadership role.
   d. Evidence of Internal communication system and methods for reporting non-compliance.
   e. Evidence of Quality improvement techniques: Monitoring and auditing, problem identification, investigation and corrective action.
   f. Evidence of Clinic Risk Assessment that must address areas in which the clinic is vulnerable.
   g. Disciplinary and corrective actions when non-compliance is suspected.

COM 2.0

COM 2.0 - The clinic is in good standing with the Medicare/Medicaid Programs

Evidence of Compliance:

1) The clinic that participates in the Medicare/Medicaid program has been free of sanctions for a period of at least 2 years.

2) The clinic prohibits employment/contracting with individuals or companies, which have been convicted of a criminal felony offense related to healthcare.
   a. There is evidence of verification required of individuals through the OIG exclusion database, www.oig.hhs.gov.
   b. There is evidence of the process & documentation upon hire and re-verification at a minimum annually.

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

COM 3.0

COM 3.0 - Staff of the clinic are licensed, certified, or registered in accordance with applicable State and local laws. (§491.4(b)).

Evidence of Compliance:

1) The clinic has a process to verify personnel are licensed, certified, or registered with applicable State laws.
2) This information is documented and tracked in an organized format.

ADM 1.0, 2.0 and 3.0

ADM 1.0 - The clinic meets the purpose and scope of 42 CFR 491.1 in order to meet reimbursement requirements for Medicare and Medicaid. (§491.1)

ADM 2.0 - The clinic is located in an area that meets the criteria for classification as a shortage area. (§491.5(a)(1))

ADM 3.0 - The clinic meets the Rural Health certification procedures.

1) The clinic's hours of operation are posted outside the clinic.

2) All clinic documents and signage (both internal and external) are consistent with the CMS-855A enrollment application. The name must match one of the names listed on the 855A.

ADM 4.0

ADM 4.0 - The clinic must have a governing body or individual who has legal responsibility for the conduct of the clinic.

Evidence of Compliance:

1) The clinic disclosure the names of the following:
   a. Name of the owner(s)
   b. Person responsible for medical direction
2) The clinic must report any change in the medical director to CMS and the Compliance Team.
3) The clinic has an organizational chart.
4) The clinic policies and its line of authorities and responsibilities are clearly set forth in writing.

ADM 5.0

ADM 5.0 - The clinic is under the medical direction of a physician and has a healthcare staff that meets the requirements at 42 CFR 491.8. (§491.7(a)(1)))

Evidence of Compliance:

1) The Medical Director, who must be a physician, is accountable for the clinic's medical direction and quality of care.

2) The clinic has written policies and procedures for identifying categories of practitioners that includes, at a minimum, the following:
   a. One or more physicians.
   b. One or more physician's assistants, nurse practitioners or nurse-midwife.
   c. Ancillary staff.

3) 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 patients beyond the front desk unless one of these providers is in the building.

4) A PA, NP or certified nurse mid-wife is available to furnish patient care services at least 50 percent of the clinic's operating hours.

ADM 5.0

ADM 5.0 - The clinic is under the medical direction of a physician and has a healthcare staff that meets the requirements at 42 CFR 491.8. (§491.7(a)(1)))

Evidence of Compliance:

5) The PA or NP performs the following functions, to the extent they are not being performed by a physician:
   a. Provides RHC services in accordance with the clinic's policies.
   b. Arranges for or refers patients to, needed services that cannot be provided at the clinic.
   c. Assures that adequate patient health records are maintained and transferred as required when patients are referred.

6) An RHC must have at least one NP or PA who is an employee and may contract with others.

7) 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.

8) If an established RHC does not have an NP or PA fulfilling the staffing requirements the clinic must submit a staffing waiver request to CMS and copy the Compliance Team.

ADM 6.0

ADM 6.0 - 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)

1. The clinic has written policies and a mechanism in place for review and approval of policies.
2. The physician, in conjunction with the PA and or NP participates in developing, executing and periodically reviewing the clinic's written policies and services provided.
3. The physician periodically reviews the clinic's patient health records, provides medical orders, and provides services to the patients.
4. The PA and/or NP participate with the physician in a periodic review of the patient health records.
5. The clinic is primarily engaged in providing outpatient health services.

   * That means 51% primary care.

ADM 7.0

ADM 7.0 - The clinic has written policies & procedures for maintaining patient health records. (§491.10(a)(1))

Evidence of Compliance:

1) 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.

2) There is a healthcare record for each person receiving services.

3) The clinic has a process in place that ensures patient health records are complete when patients are referred or transferred.

ADM 8.0

ADM 8.0 - The clinic has policies and procedures addressing the protection of record information. (§491.10(b))

Evidence of Compliance:

1) 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.
   a. The clinic ensures the Privacy Notice is posted and available to all patients at time of initial contact.
   b. The clinic ensures all Business Associate Agreements (BAA) are maintained according to applicable HIPAA regulations.
2) The clinic ensures confidentiality is maintained in all aspects of protected health information.
3) The clinic maintains the confidentiality of the patient health records and provides safeguards against loss and destruction and unauthorized use.
4) The patient's written consent is necessary before any information not authorized by law may be released.
5) 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.
6) There is evidence that the clinic staff is trained on patient confidentiality upon hire and annually.

ADM 9.0

ADM 9.0 - The clinic ensures patient health care records are complete. (§491.10(a)(3))

Evidence of Compliance:

1) Complete patient health records include:
   a. Identification and social data.
   b. Evidence of consent forms.
   c. Pertinent medical history.
   d. Assessment of the health care status and health care needs of the patient.
   e. Brief summary of the episode, disposition and instructions to the patient.
   f. Reports of physical examinations, diagnostic and laboratory test results and consultative findings.
   g. All physicians' orders, reports of treatment and medications (including allergies), and other pertinent information necessary to monitor the patient's progress.
   h. Signatures and dates of the physician or other healthcare professional.

2) 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.

Ensure Patient Healthcare Files are Complete and Accurate

Facility Name/Clinic:		
	Survey Date:	
Total Number of Exam Rooms:	Time In:	Time Out:

NOTE: DEFICIENCIES IDENTIFIED DURING THE PATIENT HEALTH CARE RECORD REVIEW ARE CITED UNDER ADM 9.0 (§491.10(a)(3)

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	Comments
1.									
2.									
3.									
4.									
5.									
6.									
7.									
8.									
9.									
10.									

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

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ADM 10.0

ADM 10.0 - Emergency Services are provided to the patient for life threatening injuries or acute illness. (§491.9(c)(3))

Evidence of Compliance:

1) The clinic provides medical emergency procedures as a first response to common life-threatening injuries and acute illness and has:

a. 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)).

b. 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.

c. The clinic's emergency equipment and drugs are organized in one place.

d. One oxygen tank with oxygen delivery device such as a nasal canula or simple oxygen mask.

ADM 11.0

ADM 11.0 - 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))

1) The clinic has a preventive maintenance program to ensure that:
    a. All essential mechanical, electrical and patient-care equipment is maintained in safe operating condition.
        i. 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.
        ii. The clinic maintains written documentation of all equipment maintenance/repairs and preventative maintenance.
        iii. The clinic has a process in place for handling equipment/product hazards defects or recalls.
    b. The premises of the clinic are clean and orderly.
    c. The clinic has written policies for a clean and orderly environment that address the following:
        i. Techniques for cleaning and disinfecting environment surfaces, carpeting, and furniture. Staff much know the wet time for disinfectants.
        ii. Disposal of regulated waste.
2) Evidence that the clinic monitors housekeeping and maintenance (including repair, renovation, and construction activities) to ensure a functional, safe, and orderly environment.

HR 1.0

HR 1.0 - The clinic has policies and procedures in place for hiring, orienting and training of all employees.

Evidence of Compliance:

1) 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.

2) 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 is validated.

HR 2.0

HR 2.0 - The clinic documents the job responsibilities and accountabilities for all employees.

Evidence of Compliance:

1) 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 in employee file.

2) The job descriptions and employee job functions are in line with the CMS definitions of the practitioner. (see Standards)

3) Only MDs or DOs may fulfill the requirements for supervision, collaboration and oversight of non-physician practitioners in an RHC.

HR 3.0

HR 3.0 - The clinic maintain files on all employees and independent contractors.

Evidence of Compliance:

1) The clinic's confidential personnel files contain the following:
   a. W-4, I-9 for employees.
   b. Curriculum Vitae, Application or Resume with references.
   c. Signed job description or contractual agreement.
   d. Orientation/Training /Competency Assessment checklists.
   e. Signed Standards of Conduct.
   f. Verification & copies of professional license, registration and/or certification is maintained if applicable.
   g. OIG exclusion list verification.
   h. Annual performance evaluations.
   i. Background checks (when required by the State or organizational policy).
   j. Hepatitis B Vaccine Record or Declination/TB Evaluation Requirements (for staff members with patient contact, specific to the job description). These items are maintained in a separate and secure Employee Health file.
   k. Copies of current Basic Life Support (BLS) certification (at a minimum) is required for all licensed and certified patient care personnel.

HR Audit – Licensed Staff Members

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

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Ensure HR Files are Complete for Clinic Staff and Providers

Facility Name/Clinic:		
	Survey Date:	
Total Number of Exam Rooms:	Time In:	Time Out:

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

Personnel File Audit Tool
Insert "Y" (YES) if evidence is found, "N" (NO) if evidence of is missing, or "NA" if not applicable.

Staff Member	Application Resume or CV	I-9 and W-4 For Employees	OIG Exclusion	Signed Job Description	Signed Standard of Conduct	Orientation/ Training & Competency	Current License or Certification	Performance Evaluation	Background Check	Hepatitis B	TB	Comments

Medical Director
Physicians
Nurse Practitioners
Physician Assistants
Registered Nurses
Licensed Nurses
Medical Assistants
Radiology Technologists
Receptionist
Other Clinic Staff

Notes: Give extent of missing element. (Example 1 of 10)

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QI 1.0

QI 1.0 - The clinic maintains continuous quality improvement processes and carries out, or arranges for, a biennial evaluation of its total program. (§491.11(a))

Evidence of Compliance:

1) The clinic has a written biennial evaluation policy determining who is to do the evaluation, how it is to be done and what is to be reviewed. The plan is developed and implemented by key leaders representing management and clinic personnel.

2) The biennial program evaluation includes a review of the following:
   a. Utilization review of all services provided by clinic
   b. Number of patients served and volume of services.
   c. A representative sample of both active and closed patient health records.
   d. Review of all clinic health care policies.

At the end of year two you will need to complete 1st Biennial Program Evaluation

QI 1.0

QI 1.0 - The clinic maintains continuous quality improvement processes and carries out, or arranges for, a biennial evaluation of its total program. (§491.11(a))

Evidence of Compliance:

3) The program evaluation must be completed by the clinic professional personnel or through arrangement with other appropriate professionals.

4) The program evaluation can be broken into parts and completed 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 years between the evaluations of each section.

5) 5. The program evaluation results are reviewed to determine the following:
   a. The Utilization of services was appropriate.
   b. The established policies were followed.
   c. Identify changes needed.
   d. Staff reviews the findings of the evaluation and corrective actions are taken if necessary.

QI 2.0

QI 2.0 - The clinic collects data for patient/client satisfaction and dissatisfaction.

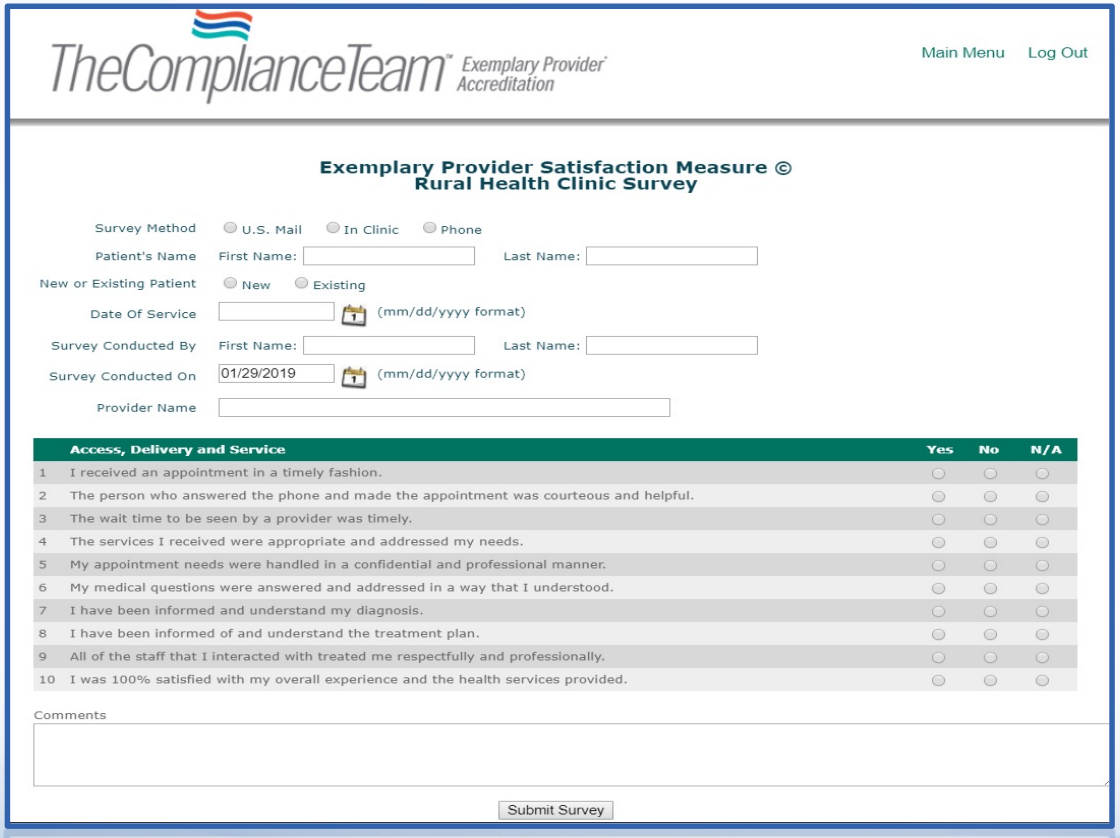
Patient Satisfaction Survey

1) The clinic ensures a sample of patients receive a patient satisfaction survey.
2) The results of the patient satisfaction surveys are collected, evaluated and presented at QI/staff meetings.
3) The clinic has a process to develop and implement corrective action if the result of the patient satisfaction evaluation reveals possible issues.

Complaints

4) The clinic has a written policy and procedure for defining, handling, reviewing and resolving complaints.
5) The following complaint statement is posted in the waiting room by day of survey:
6) " In the event your complaint remains unresolved 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."
7) When a complaint is received, the clinic provides its patients with written information on the complaint process, and then notifies the complainant that the issue is being investigated within the timeframe identified in the clinic policy.

TCT – Patient Satisfaction Survey



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RSK 1.0

RSK 1.0 - The clinic has a process for receiving, reviewing and preventing patient incidents.

1) The clinic has evidence that incidents are documented on a specific form.
2) 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 to QA@thecomplianceteam.org
3) There is evidence that employees are knowledgeable of the process.

RSK 2.0

RSK 2.0 - The clinic has a process in place for the handling of employee injuries and/or exposure.

1) 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, amputation, or loss of an eye.

2) 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 to QA@thecomplianceteam.org

3) There is evidence that employees are knowledgeable of the process.

RHC Specialty Standards

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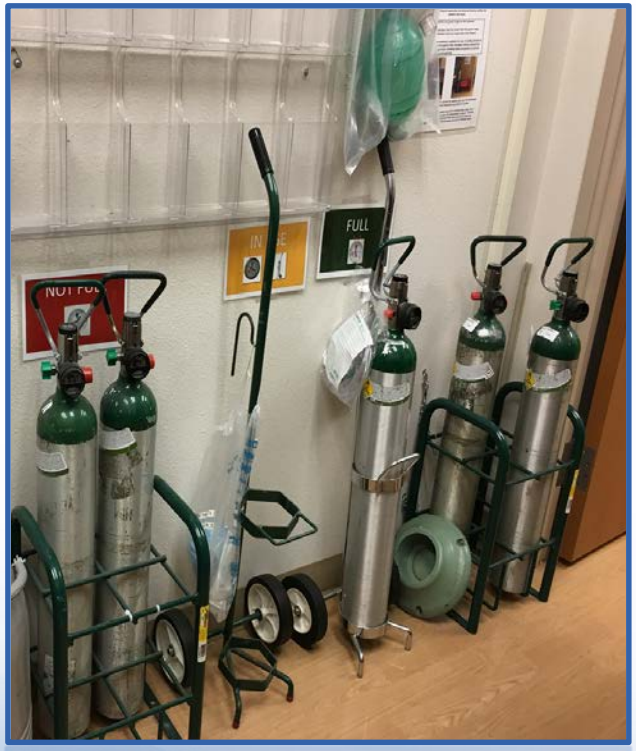
EQP 1.0

EQP 1.0 - The clinic has written policy and procedures for equipment management.

1) Equipment management policy and procedures clearly state the process for cleaning, maintaining and storing all equipment. Policies should include the following:
   a. All equipment is cleaned with a healthcare disinfectant according to manufacturer's directions and kept sanitary prior to each patient's use.
   b. 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.
   c. Equipment used in the clinic or loaned to patients (e.g., crutches, wheelchairs or walkers) must be cleaned between patients and appropriately stored.
   d. Clean equipment is segregated from dirty equipment.
   e. Equipment/supplies is stored on shelves, in cabinets and off the floor.
   f. Defective and obsolete equipment is appropriately labeled.

EQP 1.0 Continued



Oxygen Tank(s):

a. All oxygen tanks must be properly secured (chained or in a cart) and maintained in a well-ventilated area.

b. If multiple oxygen tanks are maintained within the clinic, full tanks are stored separately from those that are empty or partially full.

Clean to Dirty

“Clean to Dirty” Process to Avoid Cross-Contamination

Clean Area (Meds)

Dirty Area (Labs)

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INF 1.0

INF 1.0 - The clinic follows infection prevention techniques that relate to the type of patient served, services provided and the staff's risk for exposure.

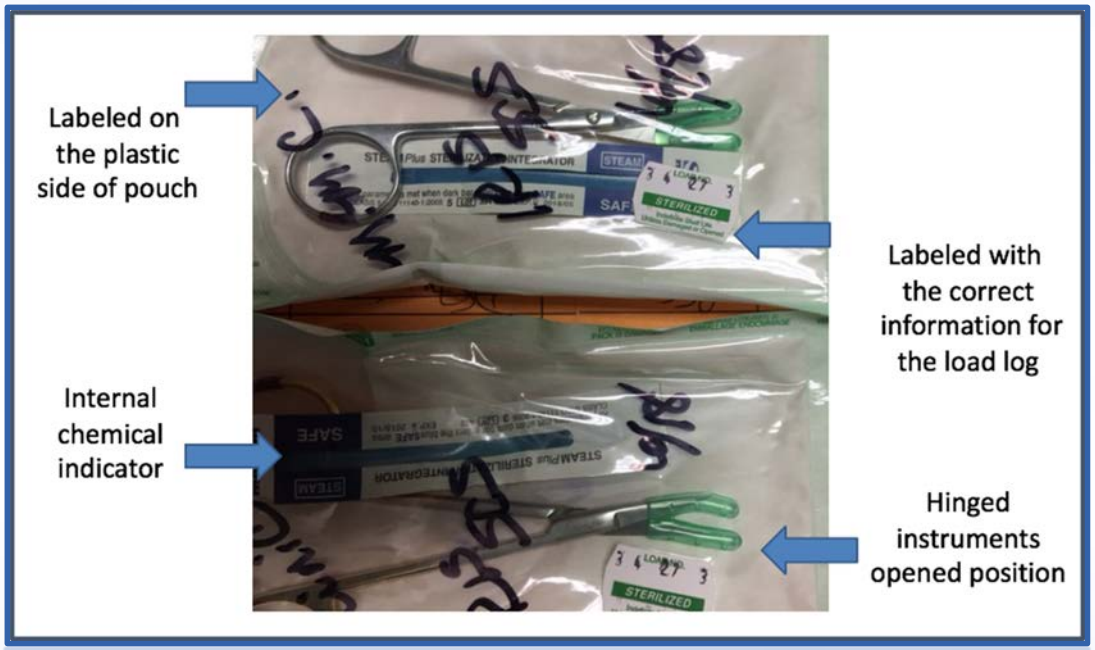
1. The clinic has a written infection control policy and procedure reviewed annually.
2. The clinic practices infection prevention techniques by utilizing the following:
    a. Hand washing or use of alcohol-based gel before and after each patient contact.
    b. Utilization of gloves while handling or cleaning dirty equipment.
    c. Proper disposal of gloves, sharps and other waste throughout the clinic including red bag use.
    d. Standard Precautions when at risk for exposure to blood-borne pathogens.
    e. Prevents cross-contamination by segregating clean from dirty in utility and or storage areas.

INF 1.0

INF 1.0 - The clinic follows infection prevention techniques that relate to the type of patient served, services provided and the staff's risk for exposure.

3. All sterilization equipment and procedures follow manufacturer guidelines for use.
    a. All instruments are cleaned according to the manufacturer's instructions for use.
    b. All sterile packaging has an identifiable expiration due date according to manufacturer guidelines.
    c. 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.
4. The clinic's personnel receive education and training on infection control annually.

Sterilization Procedures



Event Related Sterility

Talk with your Hospital about their process

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PTS 1.0

PTS 1.0 - The clinic has a process to protect patient rights and responsibilities.

1. The clinic has a written patient rights and responsibilities document that is posted and available to patients upon request.
2. There is evidence the staff is trained on the patient rights and responsibilities.

PTS 2.0

PTS 2.0 - All patient care services are provided in accordance with Federal, State and local laws. (§491.9(a)(1))

1. The clinic has an agreement or arrangement with one or more Medicare or Medicaid participating providers or suppliers to furnish the following services:
   a. Inpatient hospital care.
   b. Physician services.
   c. Additional and specialized diagnostic and laboratory services that are not available at the clinic.
2. If the agreements are not in writing, there must be evidence that the patients referred are being accepted and treated.

PTS 3.0

PTS 3.0 - Written healthcare policies are required for all patient care services. (§491.9(b))

1. Healthcare services are provided in accordance with written policies, which are consistent with applicable State law.
2. The patient care policies are developed and reviewed at least biennially by an advisory group that includes, at a minimum, a physician, and physician's assistant or nurse practitioner, and one person who is not a member of the clinic staff.
3. The clinic has a written referral policy for referring.

PTS 3.0

PTS 3.0 - Written healthcare policies are required for all patient care services. (§491.9(b))

4. The patient care policies include:
    a. A description of patient care services furnished directly and those furnished through agreement, arrangement or referral.
    b. 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.
    c. The clinic will specify in the policy, which reference sources the Medical Director and the non-physician provider have agreed on. The references may be textbooks, written polices or electronic software.
5. There is evidence that staff is trained on the policies.

PTS 4.0

PTS 4.0 - The clinic has a process for follow-up that is related to the type of service provided and the patient's condition.

1. The clinic has an organized process in place for the follow-up of their patients regarding the following:
    a. Missed appointments.
    b. New medication or treatment.
    c. Lab or diagnostic results.
    d. Referrals and consultations.
2. Documentation of follow-up is found in the patient record.
3. After a follow-up call is made, appropriate staff incorporate any necessary changes in the patient's health record.

PTS 5.0

PTS 5.0 - The clinic presents written information to all adult age patients upon admission to services.

1. The clinic has a process that information given to patients contains individual rights under State law to make decisions concerning medical care which includes:
    a. Attaining written consent to treat.
    b. The right to accept or refuse care concerning medical or surgical treatment.
    c. The relationship of an authorized representative must be clearly documented for all minors and adult patients not capable of giving their consent.
    d. Acknowledging advanced directive as required by the State.

DRG 1.0

DRG 1.0 - The clinic has written policies for the storage, handling and dispensing of drugs, biologicals, and supplies. (§491.9(b)(3)(iii))

1. The clinic's written policies must include:
    a. Requirements that drugs are stored in original manufacturer's containers to maintain proper labeling.
    b. Requirements that multiple dose vials and single dose vials are stored according to current CDC infection control guidelines.
    c. Requirements that drugs and biologicals dispensed to patients have complete and legible labeling of containers.
    d. 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

DRG 1.0 - The clinic has written policies for the storage, handling and dispensing of drugs, biologicals, and supplies. (§491.9(b)(3)(iii))

e. Requirements for a process to handle outdated, deteriorated, or adulterated drugs, biological, and supplies. These must be stored separately, and the disposal must be in compliance with applicable State laws.

f. Requirements for storage in a space that provides proper humidity temperature and light to maintain quality of drugs and biological that includes the following:

(i) Refrigerated or frozen medication or vaccines are monitored for storage temperature at least twice daily.

(ii) Temperatures are recorded in a log and staff reports variances in normal findings to clinic leadership.

(iii) No drugs or biological are stored in the door of the refrigerator or freezer.

(iv) Water bottles are placed in the door of the medication refrigerator to promote temperature stability.

g. Requirements that current drugs references, antidote information and manufacturer guidelines are available on the premises.

DRG 1.0

DRG 1.0 - The clinic has written policies for the storage, handling and dispensing of drugs, biologicals, and supplies. (§491.9(b)(3)(iii))

h. 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.

(i) Schedule II drugs are stored in a securely constructed locked compartment, separate from other drugs.

(ii) Schedule III, IV, and V drugs are secured in a substantially constructed cabinet.

(iii) 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 must be accounted for separately. Any thefts or significant losses must be reported to the DEA.

i. Requirements that containers used to dispense drugs and biologicals to patients conform to the Poison Prevention Packaging Act of 1970.

j. Requirements that all prescribing and dispensing of drugs shall be in compliance with applicable State laws.

DGS 1.0

DGS 1.0 –The clinic furnishes those diagnostic, therapeutic services and supplies commonly furnished in a physician's office or at the entry point into the health care delivery system. (§491.9(c)(1)).

Diagnostic and therapeutic services include:

a. Medical History
b. Physical examination
c. Assessment of health status
d. Treatment for a variety of medical conditions

DGS 2.0

DGS 2.0 - The clinic provides basic laboratory services essential to immediate diagnosis and treatment. (§491.9(c)(2))

1. The clinic delivers laboratory services in accordance with part 42 CFR 493, 2.
2. The clinic's laboratory services include:
   a. Chemical examination of urine by stick or tablet method (including urine ketones)
   b. Hemoglobin or hematocrit
   c. Blood Glucose
   d. Examination of stool specimens for occult blood
   e. Pregnancy tests
   f. Primary culturing for transmittal to a certified lab
3. The clinic has evidence of training and competency for all staff performing lab services.

REG 1

REG 1 - The Clinic and its staff are in compliance with applicable local, State and Federal laws and regulations (§491.4)

1. The clinic is licensed in accordance with applicable State and local law.
2. The clinic displays all licenses, certificates and permits to operate.

REG 2.A

REG 2.A - 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

1. 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 must have evidence of an environmental housekeeping schedule. The plan must be reviewed and/or updated at least annually.
2. All personnel protective equipment must be provided by the employer and readily accessible to staff.
3. If identified as being at risk for exposure to bloodborne pathogens, the clinic staff must be offered full Hepatitis B vaccination series at the employer's expense. If declined, a signed declination form must appear in personnel file.
4. Annual training on OSHA Bloodborne Pathogens Standard upon hire and annually

Thinking Beyond the Usual

PPE for Liquid Nitrogen Tank Refills

The Compliance Team™

REG 2.B

REG 2.B - The clinic is in compliance with current OSHA and CDC guidelines for preventing the transmission of Mycobacterium Tuberculosis in Health Care Settings.

1. TB testing on hire and on-going risk assessment for TB transmission by occupational exposure.
2. 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.
3. There is evidence clinic conducts TB screening upon hire.
4. There is evidence that the clinic staff has received TB Transmission Prevention training upon hire and annually.

REG 2.C

REG 2.C - The clinic is in compliance with OSHA's Right to Know standard.

1. Safety Data Sheets (SDS) are current and available for all hazardous material in the clinic's workplace and employees are knowledgeable of the location.
2. The clinic posts all mandatory OSHA posters for all employees to view.
3. There is evidence that the clinic provides training upon hire to all employees on OSHA's Right to Know.

Emergency Preparedness

EP 1.0

EP 1.0 - The clinic has an emergency preparedness program that addresses an emergency on-site, off-site (natural disaster) and disruption of service. (§491.12)

The plan contains the following elements:

a. A documented, clinic-based and community-based risk assessment that utilizes an all-hazards approach.

b. Strategies for addressing emergency events identified by the risk assessment.

c. Addresses patient population, including the type of services the clinic has the ability to provide in an emergency and continuity of operations, including delegation of authority and succession plans.

d. 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.

EP 2.0

EP 2.0 - The clinic has developed and implemented emergency preparedness policies and procedures that are based on its emergency preparedness plan. (42 CFR 491.12(b))

The policies and procedures are based on the emergency preparedness plan, risk assessment, and the communication plan.

The policies and procedures include the following elements:

a) Safe evacuation from the clinic, inc. exit signs, staff responsibilities.

b) A means to shelter in place for patients, staff, and volunteers who remain in the clinic.

c) A system of medical documentation that preserves patient information, protects confidentiality of patient information, and secures and maintains the availability of patient health records.

d) The use of volunteers in an emergency.

e) How refrigerated/frozen medications such as vaccines, etc. are handled in a power outage.

EP 3.0

EP 3.0 - The clinic develops and maintains an emergency communication plan that complies with Federal, State, and local laws. (42 CFR 491.12(c))

Names and contact information for the following:

- Staff
- Entities providing services under arrangement
- Patient's physicians
- Other RHCs
- Volunteers
- Federal, State, tribal, regional, and local EP staff
- Other sources of assistance

Alternate means for communicating with the following:

- RHC staff, Federal, State, tribal, regional, and local EP agencies.
- A means of providing information about the general condition and location of patients under the facility's care.
- 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.

EP 3.0

EP 3.0 - The clinic develops and maintains an emergency communication plan that complies with Federal, State, and local laws. (42 CFR 491.12(c))

Process for handling an on-site emergency which addresses the following:

a. How employees will be notified of emergency.
b. Staff responsible for calling the Fire Department.
c. Location of where employees should meet outside the building.
d. Staff person responsible to do head count upon evacuation of the building.

Process for handling an off-site emergency (e.g., snowstorm, flood, hurricane, etc.)

a. How employees will be notified of emergency.
b. Staff responsible for notification and triaging of patient services.
c. Contingency plan that includes alternative provider in the event the clinic cannot service its own customers.

EP 4.0

EP 4.0 - 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))

1. The training and testing program is reviewed and updated at least every two years.
2. The training program includes all the following:
    a. 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.
    b. Provide emergency preparedness training, at a minimum, at least every 2 years.
    c. Training is documented. This documentation demonstrates knowledge of emergency procedures.
    d. If the emergency preparedness policies and procedures are significantly updated, the RHC must conduct training on the updated policies and procedures.

EP 5.0

EP 5.0 - Testing Program: The clinic conducts exercises to test the emergency plan, at least annually. (42 CFR 491.12(d)(2))

Testing:

a. Every other year a full-scale exercise or event

b. Every other year a tabletop exercise or full scale or event

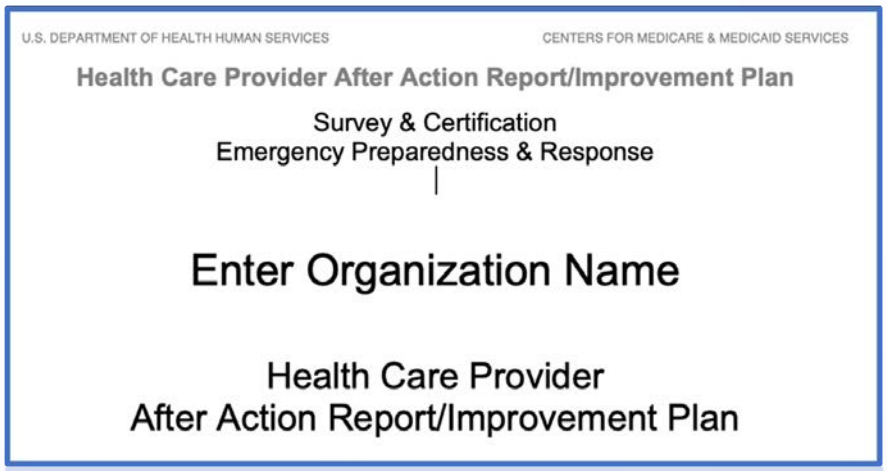
EP 6.0

EP 6.0 - 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. (42 CFR 491.12(e))

1. 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:
    a. Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program.
    b. b. Be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered.
    c. c. 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.
    d. d. The unified and integrated emergency plan must also include the all the following elements: (§491.12(e)(4))
        i. A documented community-based risk assessment, utilizing an all-hazards approach.
        ii. A documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach.
    e. e. 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)

CMS After-Action Report

- 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.


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

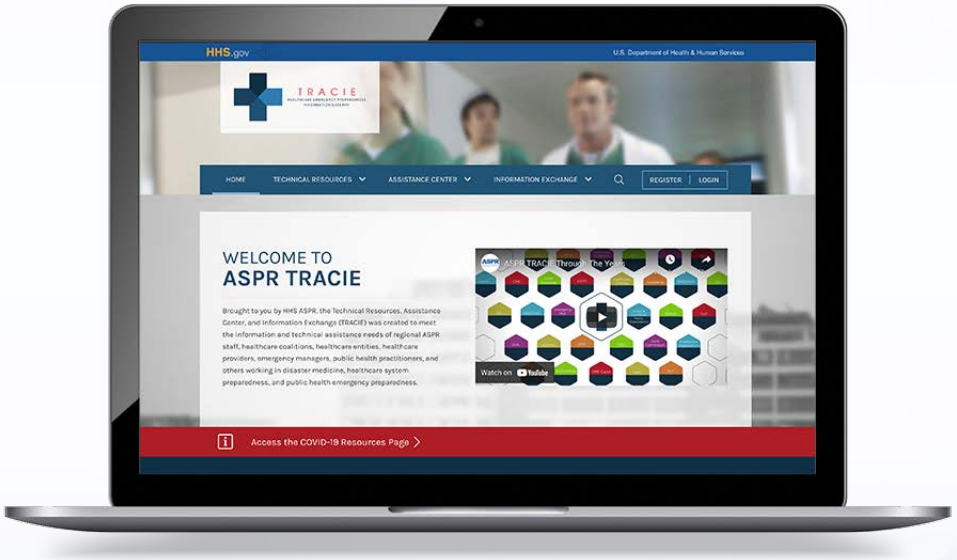
Enter Organization Name

Health Care Provider
After Action Report/Improvement Plan

Online Resource for Emergency Preparedness

Welcome to ASPR TRACIE

https://asprtracie.hhs.gov/



The Compliance Team™

Important Reminder!

Your organization must be functioning as a RHC on the date of survey.

TCT RHC Quality Standards

Session 2, Handout 2

The Compliance Team™

Session 2, Part 2

Clinic Perspective: Preparing your Clinic and Staff With Kim Tatum

Regulations to Rural Excellence

Kate Hill, VP Clinic Division

The Compliance Team™

Most Common Deficiencies

Top 5 Deficiencies cited by TCT Surveyors in 2020

The Compliance Team™

#1 MCD-Single Dose and Multi-Dose Vials

1. Single Dose and Multi-dose Vials Common Deficiencies

- Not properly dating multiple dose vials (MDV)-Multi-dose vials must be labeled and dated properly per organization's policy and manufacturer's instructions.
- Not disposing of expired vials- Expired vials must be disposed of properly per organization's policy
- Not following storage instructions (refrigeration etc.)- All drugs and biologicals must be stored according to manufacturer's instructions and the organization's policy.

Why are vials problematic?

- 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

#2 MCD – Patient Care Policies

2. Patient Care Policies Common Deficiencies

- Not reviewing the patient care policies every 2 years
- Not having the required 3 reviewer signatures on the patient care policies
- Not including a 3rd reviewer from outside the clinic

Why are Patient Care Policies problematic?

- Possibly the clinic doesn't know the review must be conducted every 2 years.
- Possibly the review team doesn't know that their signature is required.
- Possibly the Provider and NP or PA doesn't realize they must include a third reviewer from outside the clinic.

What to do:

- Set up a schedule to review the clinic's Patient Care Policies every 2 years.
- Have a designated review team which includes a provider, an NP or PA and a person from outside the clinic.
- Verify that the patient care policies have 3 signatures.

#3 MCD-Chart Reviews

3. Chart Reviews-2 Types Common Deficiencies:

- Not following clinic policy and State requirements (if applicable)
- Clinic policy doesn't specify the number of charts to be reviewed or time period.
- Not conducting 2 types of chart review

Why is chart review problematic?

- Possibly the clinic policy doesn't identify the number of chart reviews required to be performed in a specified time period or if there is a State requirement.
- Possibly the policy doesn't define the two types of chart review to be performed.

What to do:

- Ensure your policy defines the 2 types of chart review.

Physician Oversight:

- Identify the number of chart reviews per NP or PA in your policy.
- If the State is silent, you must decide and put it in your policy.

Quality Improvement:

- Identify the number of patient charts you are reviewing for completeness.
- Save them in a file for your Biennial Evaluation.

#4 MCD-Laboratory Tests and Valid CLIA

4. Laboratory-6 Required Tests Common Deficiencies:

- Not having the ability to perform all 6 required tests in the clinic.
- Not having the necessary supplies in the clinic to perform the tests.
- Not checking expiration dates of laboratory supplies.
- Not having a valid CLIA certificate posted with the correct name and address of the clinic.

Why are lab tests problematic?

- Possibly the clinic prefers to outsource lab testing.
- Possibly clinic staff hasn't been properly trained to perform the required tests.
- Possibly the lab supplies are not inventoried on a regular basis.

What to do:

- Ensure that your clinic has the ability and supplies necessary to perform all 6 required lab tests.
- Have a process in place to monitor inventory and expiration dates of laboratory supplies.

#5 MCD-Emergency Preparedness

5. Emergency Preparedness Common Deficiencies:

- Not having an All-Hazards Assessment documented and a plan for each hazard.
- Not including an adequate communication plan that includes all required agencies.
- Not addressing volunteer status.
- Not addressing how refrigerated medications are handled in a power outage.
- Not documenting participation in a full-scale community-based exercise or if community based is not available, that an individual clinic-based exercise was conducted.
- Not completing one full scale exercise and one tabletop exercise or actual event biennially.
- Not documenting the analysis of the clinic's response or activation plan.

Why Emergency Preparedness problematic?

- Possibly the clinic depends on a hospital-based emergency preparedness plan.
- Possibly staff training hasn't been adequately documented or staff training is incomplete.
- Possibly the clinic's policies for Emergency Preparedness doesn't include all the necessary documentation to meet the requirements.
- Possibly the hazard training has been conducted but the analysis of the clinic's response has not been documented.

What to do:

- Complete an All Hazards Assessment and develop a plan for each hazard (i.e. active shooter, hurricane, tornado or other natural disasters, power outage, etc.)
- Ensure your Communication Plan is complete and includes contact information for staff, local, state and federal agencies, tribal (if within 50 miles) volunteers (if applicable) and another RHC closest in proximity to you.
- If you do not use volunteers, include a statement in your emergency preparedness policies that volunteers are not utilized.
- Document in the EP policies how refrigerated medications will be handled in a power outage.
- Document participation in a full -scale exercise and tabletop exercise including participant signature sheet.
- Complete an After Action Report (AAR) for each exercise to analyze the clinic's response and/or activation plan for an actual event. (i.e. Covid 19 pandemic)

Thank You For All You Do!

The Compliance Team™

Join us on

Wednesday March 24, 2021 for Session 3!

Thank you!

QUESTIONS?

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The Compliance Team

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Accreditation Program

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www.thecomplianceteam.org or call 1 215 654 9110 USA

Revised Standards – 01/2021

CORPORATE COMPLIANCE

ADMINISTRATION

HUMAN RESOURCES

QUALITY IMPROVEMENT PLAN

RISK MANAGEMENT

UNIVERSAL STANDARDS

CORPORATE COMPLIANCE

COM 1.0 The clinic has a Corporate Compliance plan.

EVIDENCE OF COMPLIANCE:

1. The clinic has a written plan that identifies the elements required for an effective compliance program and clinic mission or vision. Plan includes the following core elements:
   a. Written policies and procedures.
   b. Standards of Conduct that includes a non-retaliation statement.
   c. A designated Compliance officer in a leadership role.
   d. Evidence of Internal communication system and methods for reporting non-compliance.
   e. Evidence of Quality improvement techniques: Monitoring and auditing, problem identification, investigation and corrective action.
   f. Evidence of Clinic Risk Assessment that must address areas in which the clinic is vulnerable.
   g. Disciplinary and corrective actions when non-compliance is suspected.

UNIVERSAL STANDARDS

CORPORATE COMPLIANCE

COM 2.0 The clinic is in good standing with the Medicare/Medicaid Programs.

EVIDENCE OF COMPLIANCE:

1. The clinic that participates in the Medicare/Medicaid program has been free of sanctions for a period of at least 2 years.
2. The clinic prohibits employment/contracting with individuals or companies, which have been convicted of a criminal felony offense related to healthcare.
    a. There is evidence of verification required of individuals through the OIG exclusion database, www.oig.hhs.gov.
    b. There is evidence of the process & documentation upon hire and re-verification at a minimum annually.

COM 3.0 Staff of the clinic are licensed, certified, or registered in accordance with applicable State and local laws. (§491.4(b)).

EVIDENCE OF COMPLIANCE:

1. The clinic has a process to verify personnel are licensed, certified, or registered with applicable State laws.
2. This information is documented and tracked in an organized format.

UNIVERSAL STANDARDS

ADMINISTRATION

ADM 1.0 The clinic meets the purpose and scope of 42 CFR 491.1 in order to meet reimbursement requirements for Medicare and Medicaid. (§491.1)

EVIDENCE OF COMPLIANCE:

1. This subpart sets forth the conditions that rural health clinics must meet in order to qualify for reimbursement under Medicare (title XVIII of the Social Security Act) and that rural health clinics must meet in order to qualify for reimbursement under Medicaid (title XIX of the Act). (§491.1)

ADM 2.0 The clinic is located in a rural area that is designated as a shortage area. (§491.5(a)(1))

EVIDENCE OF COMPLIANCE:

1. Rural area means an area that is not delineated as an urbanized area by the Bureau of the Census. (§491.2)
2. Rural health clinic or clinic means a clinic that is located in a rural area designated as a shortage area, is not a rehabilitation agency or a facility primarily for the care and treatment of mental diseases, and meets all other requirements of this subpart. (§491.2)
3. Shortage area means a defined geographic area designated by the Department of Health and Human Services as having either a shortage of personal health services (under section 1302(7) of the Public Health Service Act) or a shortage of primary medical care manpower (under section 332 of that Act.) (§491.2)
4. Secretary means the Secretary of Health and Human Services, or any official to whom he has delegated the pertinent authority. (§491.2)
5. The RHC may be permanent or mobile unit. (§491.4(5)(a)(3))

UNIVERSAL STANDARDS

ADMINISTRATION

a. Permanent unit. The objects, equipment, and supplies necessary for the provision of the services furnished directly by the clinic are housed in a permanent structure. (§491.5(a)(3)(i))

b. Mobile unit. The objects, equipment and supplies necessary for the provision of the services furnished directly by the clinic are housed in a mobile structure, which was fixed, scheduled location(s). (§491.5(a)(3)(ii))

c. Permanent unit in more than one location. If clinic services are furnished at permanent units in more than one location, each unit is independently considered for approval as a rural health clinic. (§491.5(a)(3)(iii))

6. Location of Clinic Exceptions. (§491.5(b))

a. CMS does not disqualify an RHC approved under this subpart if the area in which it is located subsequently fails to meet the definition of a rural, shortage area. (§491.5(b)(1))

b. A private, nonprofit facility that meets all other conditions of this subpart except for location in a shortage area will be certified if, on July1, 1977, it was operating in a rural area that is determined by the Secretary (on the basis of the ratio of primary care physicians to the general population) to have an insufficient supply of physicians to meet the needs of the area served. (§491.5(b)(2))

c. Determinations on these exceptions will be made by the Secretary of Health and Human Services upon application by the facility. (§491.5(b)(3))

7. Criteria for designation of rural areas. (§491.5(c))

PLEASE NOTE FOR TCT STANDARDS ADM 2.0.7 through ADM 2.0.8(b)(iii): The Centers for Medicare & Medicaid Services (CMS) Regional Office (RO) Survey and Certification staff are responsible for making RHC applicant eligibility determinations related to the RHC rural location and shortage area criteria. Although CMS approved accreditation organizations (AO) like TCT make preliminary assessments of eligibility when planning their survey schedule, the authority to make a determination may not be delegated to the SA or other an AO. In making a determination, ROs rely upon publicly available information from the U.S. Census Bureau and the U.S. Department of Health and Human Services Health Resources and Services Administration (HRSA). S&C 15-09, issued on November 14, 2014 provides RHCs the most current location determination guidance. To access a complete copy of S&C 15-09, please click on the following link https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-15-09.pdf

a. Rural areas are areas not delineated as urbanized areas in the last census conducted by the Census Bureau. (§491.5(c)(1))

UNIVERSAL STANDARDS

ADMINISTRATION

b. Excluded from the rural area classification are: (§491.5(c)(2))

i. Central cities of 50,000 inhabitants or more; (§491.5(c)(2)(i))

ii. Cities with at least 25,000 inhabitants which, together with contiguous areas having stipulated population density, have combined populations of 50,000 and constitute, for general economic and social purposes, single communities; (§491.5(c)(2)(ii))

iii. Closely settled territories surrounding cities and specifically designated by the Census Bureau as urban. (§491.5(c)(2)(iii))

c. Included in the rural area classification are those portions of extended cities that the Census Bureau has determined to be rural. (§491.5(c)(3))

8. Criteria for designation of shortage area. (§491.5(d))

a. The criteria for determination of shortage of personal health services (under section 1302 (7) of the Public Health Services Act), are: (§491.5(d)(1))

i. The ratio of primary care physicians practicing within the area to the resident population; (§491.5(d)(1)(i))

ii. The infant mortality rate; (§491.5(d)(1)(ii))

iii. The percent of the population 65 years of age or older; and (§491.5(d)(1)(iii))

iv. The percent of the population with a family income below the poverty level. (§491.5(d)(1)(iv))

b. The criteria for determination of shortage of primary medical care manpower (under section 332(a)(1)(A) of the Public Health Services Act) are: (§491.5(d)(2))

UNIVERSAL STANDARDS

ADMINISTRATION

(i) The area served is rational area for the delivery of primary medical care services; (§491.5(d)(2)(i))

(ii) The ratio of primary care physicians practicing within the area to the resident population; and (§491.5(d)(2)(ii))

(iii) The primary medical care manpower in contagious areas is over utilized, excessively distant, or inaccessible to the population in this area. (§491.5(d)(2)(iii))

9. Medically underserved population. A medically underserved population includes the following: (§491.5(e))

    a. A population of an urban or rural area that is designated by PHS as having a shortage of personal health services. (§491.5(e)(i))

    b. A population group that is designated by PHS as having a shortage of personal health services. (§491.5(e)(ii))

ADM 3.0 The clinic meets the Rural Health certification procedures.

EVIDENCE OF COMPLIANCE:

1. A rural health clinic will be certified for participation in Medicare in accordance with subpart S of 42 CFR part 405. (§491.3)
2. The Secretary will notify the State Medicaid agency whenever he has certified or denied certification under Medicare for a prospective rural health clinic in that State. (§491.3)
3. A clinic certified under Medicare will be deemed to meet the standards for certification under Medicaid. (§491.3)
4. The clinic's hours of operation are posted outside the clinic.
5. All clinic documents and signage (both internal and external) are consistent with the CMS-855A enrollment application. The name must match one of the names listed on the 855A.

UNIVERSAL STANDARDS

ADMINISTRATION

ADM 4.0 The clinic must have a governing body or individual who has legal responsibility for the conduct of the clinic.

EVIDENCE OF COMPLIANCE:

1. The clinic disclosures the names and addresses of the following: (§491.7(b))
    a. Name of the owner(s), in accordance with section 1124 of the Social Security Act (42 U.S.C 132A-3). (§491.7(b)(1))
    b. Person principally responsible for directing the clinic's operation (§491.7(b)(2))
    c. Person responsible for medical direction (§491.7(b)(3))
2. The clinic must report any change in the medical director to CMS and the Compliance Team.
3. The clinic has an organizational chart.
4. The clinic policies and its line of authorities and responsibilities are clearly set forth in writing. (§491.7(a)(2))
5. The clinic has a protocol for identifying who is in charge of day-to-day operations in the absence of key leadership.

UNIVERSAL STANDARDS

ADMINISTRATION

ADM 5.0 The clinic is under the medical direction of a physician, and has a healthcare staff that meets the requirements at 42 CFR 491.8. (§491.7(a)(1))

EVIDENCE OF COMPLIANCE:

1. The Medical Director, who must be a physician, is accountable for the clinic's medical direction and quality of care. (§491.8(b))
2. The clinic has written policies and procedures for identifying categories of practitioners that includes, at a minimum, the following: (§491.8(a))
    a. One or more physicians. (§491.8(a)(1)),
    b. One or more physician's assistants, nurse practitioners or nurse-midwife. (§491.8(a)(1))
    c. The physician member of the staff may be the owner of the clinic, a clinic employee, or under agreement to carry out the responsibilities required. (§491.8(a)(2))
    d. 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))
3. The clinic staff may also include ancillary personnel who are supervised by the professional staff. (§491.8(a)(4))
4. The healthcare staff is sufficient to provide the services essential for the operation of the clinic. (§491.8(a)(5))
5. Direct services mean services provided by the clinic's staff. (§491.2)
    a. 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))

UNIVERSAL STANDARDS

ADMINISTRATION

6. 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)).

7. 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))

    a. Provides RHC services in accordance with the clinic's policies. (§491.8(c)(2)(i)).

    b. Arranges for or refers patients to, needed services that cannot be provided at the clinic. (§491.8(c)(2)(ii))

    c. Assures that adequate patient health records are maintained and transferred as required when patients are referred. (§491.8(c)(2)(iii))

8. An RHC must have at least one nurse practitioner (NP) or physician assistant (PA) who is an employee and may contract with others. (§491.8(a)(3))

9. 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)); (§491.8(b)(3))

    *Some state regulations may supersede the Federal regulations regarding an every two-week on-site visit.

10. 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 must submit a staffing waiver request to CMS and copy the Compliance Team.

UNIVERSAL STANDARDS

ADMINISTRATION

ADM 6.0	**The clinic's professional staff, that includes the physician, and 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)**

EVIDENCE OF COMPLIANCE:

1. The clinic has written policies and a mechanism in place for review and approval of policies.
2. 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)).
3. The physician periodically reviews the clinic's patient health records, provides medical orders, and provides services to the patients. (§491.8(b)(3))
4. 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))
5. 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))

UNIVERSAL STANDARDS

ADMINISTRATION

ADM 7.0 The clinic maintains a clinical record system in accordance with written policies & procedures. (§491.10(a)(1))

EVIDENCE OF COMPLIANCE:

1. 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))
2. There is a healthcare record for each person receiving services. (§491.10(a)(3))
3. The clinic has a process in place that ensures patient health records are complete when patients are referred or transferred.

UNIVERSAL STANDARDS

ADMINISTRATION

ADM 8.0 The clinic has policies and procedures addressing the protection of record information. (§491.10(b))

EVIDENCE OF COMPLIANCE:

1. 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))
    a. The clinic ensures the Privacy Notice is posted and available to all patients.
    b. The clinic ensures all Business Associate Agreements (BAA) are maintained according to applicable HIPAA regulations.
2. The clinic maintains the confidentiality of the patient health records and provides safeguards against loss and destruction and unauthorized use. (§491.10(b)(1))
3. The patient's written consent is necessary before any information not authorized by law may be released. (§491.10(b)(3))
4. 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))
5. There is evidence that the clinic staff is trained on patient confidentiality upon hire and annually.

UNIVERSAL STANDARDS

ADMINISTRATION

ADM 9.0 The clinic ensures patient health care records are complete. (§491.10(a)(3))

EVIDENCE OF COMPLIANCE:

1. Complete patient health records include:
   a. Identification and social data. (§491.10(a)(3)(i))
   b. Evidence of consent forms. (§491.10(a)(3)(i))
   c. Pertinent medical history. (§491.10(a)(3)(i))
   d. Assessment of the health care status and health care needs of the patient. (§491.10(a)(3)(i))
   e. Brief summary of the episode, disposition and instructions to the patient. (§491.10(a)(3)(i))
   f. Reports of physical examinations, diagnostic and laboratory test results and consultative findings. (§491.10(a)(3)(ii))
   g. All physicians' orders, reports of treatment and medications (including allergies), and other pertinent information necessary to monitor the patients progress. (§491.10(a)(3)(iii))
   h. Signatures and dates of the physician or other healthcare professional. (§491.10(a)(3)(iv))
2. 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.

UNIVERSAL STANDARDS

ADMINISTRATION

ADM 10.0 Emergency Services are provided to the patient for life threatening injuries or acute illness. (§491.9(c)(3))

EVIDENCE OF COMPLIANCE:

1. The clinic provides medical emergency procedures as a first response to common life-threatening injuries and acute illness and has: (§491.9(c)(3))
    a. 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)).
    b. 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.
    c. The clinic's emergency equipment and drugs are organized in one place.
    d. One oxygen tank with oxygen delivery device such as a nasal canula or simple oxygen mask.

UNIVERSAL STANDARDS

ADMINISTRATION

ADM 11.0 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))

EVIDENCE OF COMPLIANCE:

1. The clinic has a preventive maintenance program to ensure that: (§491.6(b))

    a. All essential mechanical, electrical and patient-care equipment is maintained in safe operating condition. (§491.6(b)(1))

        i. 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.
        ii. The clinic maintains written documentation of all equipment maintenance/repairs and preventative maintenance.
        iii. The clinic has a process in place for handling equipment/product hazards defects or recalls.

    b. The premises of the clinic are clean and orderly. (§491.6(b)(3)).

    c. The clinic has written policies for a clean and orderly environment that address the following:

        i. Techniques for cleaning and disinfecting environment surfaces, carpeting, and furniture.
        ii. Disposal of regulated and waste.

2. Evidence that the clinic monitors housekeeping and maintenance (including repair, renovation, and construction activities) to ensure a functional, safe, and orderly environment.

3. 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.)

4. The clinic meets the following Fire Safety Requirements:

    a. Fire and sanitation inspections are current as required by the State.
    b. Exit doors are clearly marked with illuminated or reflective signs.

UNIVERSAL STANDARDS

ADMINISTRATION

c. Exit doors must unlock from the inside without a key.
d. Exits from the building are unobstructed and accessible for occupants having limited mobility.
e. Fire extinguishers are mounted and have been inspected annually.
f. Floor plans, as appropriate, identifying the nearest emergency exit route are posted throughout the clinic.

UNIVERSAL STANDARDS

HUMAN RESOURCES

HR 1.0 The clinic has policies and procedures in place for hiring, orienting and training of all employees.

EVIDENCE OF COMPLIANCE:

1. 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.
2. 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 is validated.

UNIVERSAL STANDARDS

HUMAN RESOURCES

HR 2.0 The clinic documents the job responsibilities and accountabilities for all employees.

EVIDENCE OF COMPLIANCE:

1. 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.
2. The job descriptions and employee job functions are in line with the CMS definitions of the practitioner:

   A. **Nurse practitioner** means a registered professional nurse who is currently licensed to practice in the State, who meets the State's requirements governing the qualifications of nurse practitioners, and who meets one of the following conditions: (§491.2))

   a. Currently certified by the American Nurses' Association or by the National Board of Pediatric Nurse Practitioners and Associates or The American Academy of Nurse Practitioners or the American Nurses Credentialing Center; or (§491.2(1))

   b. Has satisfactorily completed a formal 1 academic year educational program that: (§491.2(2))

      i. Prepares registered nurses to perform an expanded role in the delivery of primary care; (§491.2(2)(i))

      ii. Includes at least 4 months (in the aggregate) of classroom instruction and a component of supervised clinical practice; and (§491.2(2)(ii)

      iii. Awards a degree, diploma, or certificate to persons who successfully complete the program; or (§491.2(2)(iii))

   c. Has successfully completed a formal educational program (for preparing registered nurses to perform an expanded role in the delivery of primary care) that does not meet the requirements of paragraph (2) this definition, and has been performing an expanded role in the delivery of primary care for a total of 12 months during the 18-month period immediately preceding the effective date of this subpart. (§491.2(3))

UNIVERSAL STANDARDS

HUMAN RESOURCES

B. **Physician** means, as it pertains to the supervision, collaboration, and oversight requirements in section 1861(aa)(2)(B) and (aa)(3) of the Social Security Act, a doctor of medicine or osteopathy, legally authorized to practice medicine or surgery in the State in the function is performed; and within limitations as to the specific services furnished, a doctor of dental surgery or of dental medicine, a doctor of optometry, a doctor of podiatry or surgical chiropody or a chiropractor (see section 1861(r) of the Social Security Act for specific limitations). (§492.2(1) and (§492.2(2))

Only MDs or DOs may fulfill the requirements for supervision, collaboration and oversight of non-physicians practitioners in an RHC.

C. **Physician assistant** means a person who meets the applicable State requirements governing the qualifications for assistants to primary care physicians, and who meets at least one of the following conditions: (§491.2)

a) Is currently certified by the National Commission on Certification of Physician Assistants to assist primary care physicians; or (§491.2(1))

b) Has satisfactorily completed a program for preparing physician's assistants that: (§491.2(2)

(i) Was at least 1 academic year in length; (§491.2(2)(i))

(ii) Consisted of supervised clinical practice and at least 4 months (in the aggregate) of classroom instruction directed toward preparing students to deliver health care; and (§491.2(2)(ii)

(iii) Was accredited by the American Medical Association's Committee on Allied Health Education and Accreditation; or (§491.2(2)(iii)

(iv) Has satisfactorily completed a formal educational program (for preparing physician assistants) that does not meet the requirements of paragraph (2) of this definition and assisted primary care physicians for a total of 12 months during the 18-month period that ended on December 31, 1986. (§491.2(3))

UNIVERSAL STANDARDS

HUMAN RESOURCES

HR 3.0 The clinic maintains personnel files on all employees and Independent Contractors.

EVIDENCE OF COMPLIANCE:

1. The clinic's confidential personnel files contain the following:
    a. W-4, I-9 for employees
    b. Curriculum Vitae, Application or Resume with references.
    c. Signed job description or contractual agreement.
    d. Orientation/Training /Competency Assessment checklists.
    e. Signed Standards of Conduct.
    f. Verification & copies of professional license, registration and/or certification is maintained if applicable.
    g. OIG exclusion list verification.
    h. Annual performance evaluations.
    i. Background checks (when required by the State or organizational policy).
    j. Hepatitis B Vaccine Record or Declination and TB Evaluation Requirements (for staff members with patient contact, specific to the job description). These items are maintained in a separate and secure Employee Health file.
    k. Copies of current Basic Life Support (BLS) certification (at a minimum) is required for all licensed and certified patient care personnel.

UNIVERSAL STANDARDS

QUALITY IMPROVEMENT

QI 1.0 The clinic maintains continuous quality improvement processes and carries out, or arranges for, a biennial evaluation of its total program. (§491.11(a))

EVIDENCE OF COMPLIANCE:

1. The clinic has a written evaluation policy determining who is to do the evaluation, how it is to be done and what is to be reviewed. The plan is developed and implemented by key leaders representing management and clinic personnel (This requirement is for initial surveys only).
2. The biennial program evaluation includes a review of the following: (§491.11(b))
    a. Utilization review of all services provided by clinic (§491.11(b)(1))
    b. Number of patients served and volume of services. (§491.11(b)(1))
    c. A representative sample of both active and closed patient health. (§491.11(b)(2))
    d. Review of all clinic health care policies. (§491.11(b)(3))
3. The program evaluation must be completed by the clinic professional or through arrangement with other appropriate professionals.
4. The program evaluation can be broken into parts and completed 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.
5. The program evaluation results are reviewed to determine the following: (§491.11(c))
    a. The Utilization of services was appropriate. (§491.11(c)(1))
    b. The established policies were followed. (§491.11(c)(2))
    c. Identify changes needed (§491.11(c)(3))
    d. Staff reviews the findings of the evaluation and corrective actions are taken if necessary. (§491.11(d))

UNIVERSAL STANDARDS

QUALITY IMPROVEMENT

QI 2.0 The clinic collects data for patient/client satisfaction and dissatisfaction.

EVIDENCE OF COMPLIANCE:

PATIENT SATISFACTION SURVEY

1. The clinic ensures a sample of patients receive a patient satisfaction survey.
2. The results of the patient satisfaction surveys are collected, evaluated and presented at QI/staff meetings.
3. The clinic has a process to develop and implement corrective action if the result of the patient satisfaction evaluation reveals possible issues.

COMPLAINTS

4. The clinic has a written policy and procedure for defining, handling, reviewing and resolving complaints.
5. The complaint process is defined in a written document or waiting room display that includes the statement " In the event your complaint remains unresolved 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."
6. When a complaint is received, the clinic provides its patients with written information on the complaint process, and then notifies the complainant that the issue is being investigated within the timeframe identified in the clinic policy.

SPECIALTY STANDARDS

RISK MANAGEMENT

RSK 1.0 The clinic has a process for receiving, reviewing and preventing patient incidents.

EVIDENCE OF COMPLIANCE:

1. The clinic has evidence that incidents are documented on a specific form.
2. 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.
3. There is evidence that employees are knowledgeable of the process.

RSK 2.0 The clinic has a process in place for the handling of employee injuries and/or exposure.

EVIDENCE OF COMPLIANCE:

1. 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, amputation, or loss of an eye.
2. 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 .
3. There is evidence that employees are knowledgeable of the process.

EQUIPMENT MANAGEMENT

INFECTION CONTROL

PATIENT SERVICES AND INSTRUCTION

PHARMACEUTICAL SERVICES

DIAGNOSTIC SERVICES

REGULATORY

EMERGENCY PREPAREDNESS

SPECIALTY STANDARDS

EQUIPMENT MANAGEMENT

EQP 1.0 The clinic has written policy and procedures for equipment management.

EVIDENCE OF COMPLIANCE:

1. The clinic's equipment management policy and procedures clearly state the process for cleaning, maintaining and storing all equipment. Policies should include the following:
    a. All equipment is cleaned with a healthcare disinfectant according to manufacturer's directions and kept sanitary prior to each patient's use.
    b. 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.
    c. Equipment used in the clinic or loaned to patients (e.g. crutches, wheelchairs or walkers) must be cleaned between patients and appropriately stored.
    d. Clean equipment is segregated from dirty equipment.
    e. Equipment/supplies is stored on shelves, in cabinets and off the floor.
    f. Defective and obsolete equipment is appropriately labeled.

Specialty Evidence of Compliance: Respiratory

2. Oxygen tank(s):
    a. All oxygen tanks must be properly secured (chained or in a cart) and maintained in a well-ventilated area.
    b. If multiple oxygen tanks are maintained within the clinic, full tanks are stored separately from those that are empty or partially full.

SPECIALTY STANDARDS

INFECTION CONTROL

INF 1.0 The clinic follows infection prevention techniques that relate to the type of patient served, services provided and the staff's risk for exposure.

EVIDENCE OF COMPLIANCE .

1. The clinic has a written infection control policy and procedure reviewed annually.
2. The clinic practices infection prevention techniques by utilizing the following:
    a. Hand washing or use of alcohol-based gel before and after each patient contact.
    b. Utilization of gloves while handling or cleaning dirty equipment.
    c. Proper disposal of gloves, sharps and other waste throughout the clinic including red bag use.
    d. Standard Precautions when at risk for exposure to blood-borne pathogens.
    e. Prevents cross-contamination by segregating clean from dirty in utility and or storage areas.
3. All sterilization equipment and procedures follow manufacturer guidelines for use.
    a. All instruments are cleaned according to the manufacturer's instructions for use.
    b. All sterile packaging has an identifiable expiration due date according to manufacturer guidelines.
    c. 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.
4. The clinics' personnel receives education and training on infection control annually.

SPECIALTY STANDARDS

PATIENT SERVICES AND INSTRUCTION

PTS 1.0 The clinic has a process to protect patient rights and responsibilities.

EVIDENCE OF COMPLIANCE

1. The clinic has a written patient rights and responsibilities document that is posted and available to patients upon request.
2. There is evidence the staff is trained on the patient rights and responsibilities.

PTS 2.0 All patient care services are provided in accordance with Federal, State and local laws. (§491.9(a)(1)).

EVIDENCE OF COMPLIANCE

1. 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))
2. 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))
    a. Inpatient hospital care (§491.9(d)(1)(i))
    b. Physician services (§491.9(d)(1)(ii))
    c. Additional and specialized diagnostic and laboratory services that are not available at the clinic. (§491.9(d)(1) (iii))
3. If the agreements are not in writing, there must be evidence that the patients referred are being accepted and treated. (491.9(d)(2))

SPECIALTY STANDARDS

PATIENT SERVICES AND INSTRUCTION

PTS 3.0 Written healthcare policies are required for all patient care services. (§491.9(b))

EVIDENCE OF COMPLIANCE

1. Healthcare services are provided in accordance with written policies, which are consistent with applicable State law. (§491.9(b)(1))
2. The patient care policies are initially developed and reviewed at least biennially by an advisory group that includes, at a minimum, a physician, and 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)
3. The clinic has a written policy for referring patients to needed services that cannot be provided at the clinic.
4. The patient care policies include: (§491.9(b)(3))
    a. A description of patient care services furnished directly and those furnished through agreement, arrangement or referral. (§491.9(b)(3)(i))
    b. 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))
    c. The clinic will specify in the policy, which reference sources the Medical Director and the non-physician provider have agreed on. The references may be textbooks, written polices or electronic software.
5. There is evidence that staff is trained on the policies.

SPECIALTY STANDARDS

PATIENT SERVICES AND INSTRUCTION

PTS 4.0 The clinic has a process for follow-up that is related to the type of service provided and the patient's condition.

EVIDENCE OF COMPLIANCE:

1. The clinic has an organized process in place for the follow-up of their patients regarding the following:
    a. Missed appointments.
    b. New medication or treatment.
    c. Lab or diagnostic results.
    d. Referrals and consultations.
2. Documentation of follow-up is found in the patient record.
3. After a follow-up call is made, appropriate staff incorporate any necessary changes in the patients' health record.

PTS 5.0 The clinic presents written information to all adult age patients upon admission to services.

EVIDENCE OF COMPLIANCE:

1. The clinic has a process that information given to patients contains individual rights under State law to make decisions concerning medical care which includes:
    a. Attaining written consent to treat.
    b. The right to accept or refuse care concerning medical or surgical treatment.
    c. The relationship of an authorized representative must be clearly documented for all minors and adult patients not capable of giving their consent.
    d. Acknowledging advanced directive as required by the State.

SPECIALTY STANDARDS

PHARMACEUTICAL SERVICES

DRG 1.0 The clinic has written policies for the storage, handling and dispensing of drugs, biologicals, and supplies. (§491.9(b)(3)(iii))

EVIDENCE OF COMPLIANCE

1. The clinic's written policies must include:

    a. Requirements that drugs are stored in original manufacturer's containers to maintain proper labeling.

    b. Requirements that multiple dose vials and single dose vials are stored according to current manufacturer guidelines.

    c. Requirements that drugs and biologicals dispensed to patients have complete and legible labeling of containers;

    d. 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.

    e. Requirements for a process to handle outdated, deteriorated, or adulterated drugs, biological, and supplies. These must be stored separately and the disposal must be in compliance with applicable State laws.

    f. Requirements for storage in a space that provides proper humidity, temperature and light to maintain quality of drugs and biological that includes the following:

        (i) Refrigerated or frozen medication or vaccines are monitored for storage temperature at least twice daily.

        (ii) Temperatures are recorded in a log and staff reports variances in normal findings to clinic leadership.

        (iii) No drugs or biological are stored in the door of the refrigerator or freezer.

SPECIALTY STANDARDS

PHARMACEUTICAL SERVICES

(iv) Water bottles are placed in the door of the medication refrigerator to promote temperature stability.

g. Requirements that current drugs references, antidote information and manufacturer guidelines are available on the premises.

h. 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.

(i) Schedule II drugs are stored in a securely constructed locked compartment, separate from other drugs.

(ii) Schedule III, IV, and V drugs are secured in a substantially constructed cabinet.

(iii)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 must be accounted for separately. Any thefts or significant losses must be reported to the DEA.

i. Requirements that containers used to dispense drugs and biologicals to patients conform to the Poison Prevention Packaging Act of 1970;

j. Requirements that all prescribing and dispensing of drugs shall be in compliance with applicable State laws.

SPECIALTY STANDARDS

DIAGNOSTIC SERVICES

DGS 1.0 The clinic furnishes those diagnostic, therapeutic services and supplies commonly furnished in a physician's office or at the entry point into the health care delivery system. (§491.9(c)(1)).

EVIDENCE OF COMPLIANCE

1. Diagnostic and therapeutic services include:

    a. Medical History. (§491.9(c)(1))

    b. Physical examination. (§491.9(c)(1))

    c. Assessment of health status. (§491.9(c)(1))

    d. Treatment for a variety of medical conditions. (§491.9(c)(1))

SPECIALTY STANDARDS

DIAGNOSTIC SERVICES

DGS 2.0 The clinic provides basic laboratory services essential to immediate diagnosis and treatment. (§491.9(c)(2))

EVIDENCE OF COMPLIANCE

1. 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. [Current CLIA certificate of waiver] (§491.9(c)(2)) **Note:** §491.9(a)(3) is crosswalked here but used in a deficiency statement.
2. The clinic's laboratory services include:
    a. Chemical examination of urine by stick or tablet method (including urine ketones); (§491(c)(2)(i)
    b. Hemoglobin or hematocrit; (§491(c)(2)(ii)
    c. Blood Glucose; (§491(c)(2)(iii)
    d. Examination of stool specimens for occult blood; (§491(c)(2)(iv)
    e. Pregnancy tests; and (§491(c)(2)(v)
    f. Primary culturing for transmittal to a certified lab. (§491(c)(2)(vi)
3. The clinic has evidence of training and competency for all staff performing lab services.

SPECIALTY STANDARDS

REGULATORY

REG 1.0 The clinic and its staff are in compliance with applicable local, State and Federal laws and regulations. (§491.4)

EVIDENCE OF COMPLIANCE:

1. The clinic is licensed in accordance with applicable State and local law. (§491.4(a)).
2. The clinic displays all licenses, certificates and permits to operate.

SPECIALTY STANDARDS

REGULATORY

REG 2.A 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)

EVIDENCE OF COMPLIANCE:

1. 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 must have evidence of an environmental housekeeping schedule. The plan must be reviewed and/or updated at least annually.
2. All personnel protective equipment must be provided by the employer and readily accessible to staff.
3. If identified as being at risk for exposure to bloodborne pathogens, the clinic staff must be offered full Hepatitis B vaccination series at the employer's expense. If declined, a signed declination form must appear in personnel file
4. There is evidence that the clinic staff has received training on OSHA Bloodborne Pathogens Standard upon hire and annually.

SPECIALTY STANDARDS

REGULATORY

REG 2.B The clinic is in compliance with current OSHA and CDC guidelines for preventing the transmission of Mycobacterium Tuberculosis in Health Care Settings.

EVIDENCE OF COMPLIANCE:

1. 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 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.
2. 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.
3. There is evidence clinic conducts TB screening upon hire.
4. There is evidence that the clinic staff has received TB Transmission Prevention training upon hire and annually.

SPECIALTY STANDARDS

REGULATORY

REG 2.C The clinic is in compliance with OSHA's Right to Know standard.

EVIDENCE OF COMPLIANCE:

1. Safety Data Sheets (SDS) are current and available for all hazardous material in the clinic's workplace and employees are knowledgeable of the location.
2. The clinic posts all mandatory OSHA posters for all employees to view.
3. There is evidence that the clinic provides training upon hire to all employees on OSHA's Right to Know.

SPECIALTY STANDARDS

EMERGENCY PREPAREDNESS

EP	**1.0**	**The clinic has an emergency preparedness program that addresses an emergency on-site, off-site (natural disaster) and disruption of service. (§491.12)**

EVIDENCE OF COMPLIANCE:

1. The clinic complies with all applicable Federal, State and local emergency preparedness requirements. (§491.12)
2. 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)
    a) A documented, clinic-based and community-based risk assessment that utilizes an all hazards approach. (§491.12(a)(1))
    b) Strategies for addressing emergency events identified by the risk assessment. (§491.12(a)(2)
    c) 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))
    d) 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))

SPECIALTY STANDARDS

REGULATORY

EP 2.0 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))

Evidence of Compliance

1. The policies and procedures are reviewed and updated, at a minimum, at least every 2 years. (§491.12(b))

2. The policies and procedures must include the following elements: (§491.12(b))

    a) Safe evacuation from the clinic, which includes appropriate placement of exit signs, staff responsibilities and needs of patients. (§491.12(b)(1))

    b) A means to shelter in place for patients, staff, and volunteers who remain in the clinic. (§491.12(b)(2))

    c) 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))

    d) 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)).

    e) How refrigerated/frozen medications such as vaccines, etc. are handled in a power outage.

SPECIALTY STANDARDS

EMERGENCY PREPAREDNESS

EP 3.0 The clinic develops and maintains an emergency communication plan that complies with Federal, State, and local laws. (42 CFR 491.12(c))

Evidence of Compliance

1. The clinic's emergency preparedness communication plan is reviewed and updated, at a minimum, at least every 2 years. (§491.12(c))

2. The clinic's communication plan must include the following elements: (§491.12(c))

    a. Names and contact information for the following: (§491.12(c)(1)
        i. Staff. (§491.12(c)(1)(i)
        ii. Entities providing services under arrangement. (§491.12(c)(1)(ii)
        iii. Patient's physicians. (§491.12(c)(1)(iii)
        iv. Other RHCs. (§491.12(c)(1)(iv)
        v. Volunteers. (§491.12(c)(1)(v)
    b. Contact information for the following: (§491.12(c)(2)
        i. Federal, State, tribal, regional, and local emergency preparedness staff. (§491.12(c)(2)(i)
        ii. Other sources of assistance. (§491.12(c)(2)(ii)
    c. Primary and alternate means for communicating with the following: (§491.12(c)(3)
        i. RHC staff (§491.12(c)(3)(i)
        ii. Federal, State, tribal, regional, and local emergency management agencies. (§491.12(c)(3)(ii)
    d. 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))
    e. 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)

3. The clinic's communication plan contains an organized process for handling an on-site emergency which addresses the following:
    a. How employees will be notified of emergency.

SPECIALTY STANDARDS

REGULATORY

b. Staff responsible for calling the Fire Department.
c. Location of where employees should meet outside the building.
d. Staff person responsible to do head count upon evacuation of the building.

4. The clinic' communication plan has an organized process for handling an off-site emergency (e.g. Snowstorm, flood, hurricane, etc.)
    a. How employees will be notified of emergency.
    b. Staff responsible for notification and triaging of patient services.
    c. Contingency plan that includes alternative provider in the event the clinic cannot service its own customers.

SPECIALTY STANDARDS

EMERGENCY PREPAREDNESS

EP 4.0 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))

Evidence of Compliance

1. The training and testing program is reviewed and updated, at a minimum, at least every 2 years. (§491.12(d))
2. The training program must include all of the following: (§491.12(d)(1))
    a. 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))
    b. Provide emergency preparedness training, at a minimum, at least every 2 years. (§491.12(d)(1)(ii)
    c. 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))
    d. 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))

SPECIALTY STANDARDS

REGULATORY

EP 5.0 Testing Program: The clinic conducts exercises to test the emergency plan at least annually. (42 CFR 491.12(d)(2))

Evidence of Compliance

1. The clinic must do the following: (§491.12(d)(2))

    a. Participate in a full-scale exercise that is community-based or when a community-based exercise is not assessible, an individual, facility based functional exercise every 2 years. (§491.12(d)(2)(i))

        (i). When a community-based exercise is not accessible, an individual, facility-based functional exercise every 2 years; or (§491.12(d)(2)(i)(A))

        (ii). 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-based or individual, facility-based functional exercise following the onset of the emergency event. (§491.12(d)(2)(i)(B))

    b. Conduct an additional exercise every 2 years, opposite the year full-scale or functional exercise 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)

        (i) A second full-scale exercise that is community-based or individual, facility based funcitional exercise; or (§491.12(d)(2)(ii)(A))

        (ii) A mock disaster drill; or (§491.12(d)(2)(ii)(B))

        (iii) 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))

    c. 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))

SPECIALTY STANDARDS

EMERGENCY PREPAREDNESS

EP 6.0 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. (42 CFR 491.12(e))

Evidence of Compliance

1. 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))

    a. 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))

    b. Be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered. (§491.12(e)(2))

    c. 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))

    d. 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)

        i. A documented community-based risk assessment, utilizing an all hazards approach. (§491.12(e)(4)(i))

        ii. 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)

    e. 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). (491.12(e)(5))