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QUALITY STANDARDS AND EVIDENCE OF COMPLIANCE

Rural Health Clinics

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UNIVERSAL STANDARDS

CORPORATE COMPLIANCE

ADMINISTRATION

- **SHORTAGE AREA**
- **GOVERNING BODY**
- **MEDICAL RECORDS**
- **PHYSICAL PLANT**

HUMAN RESOURCES

QUALITY IMPROVEMENT PLAN

RISK MANAGEMENT

UNIVERSAL STANDARDS

CORPORATE COMPLIANCE

COM 1.0 The clinic has a Corporate Compliance plan.

**42 CFR 491.7, PCACA, 2010,
(SECTION 6102 & SECTION 6401 OF THE HEALTHCARE REFORM LAW)
EVIDENCE OF COMPLIANCE:**

1. The clinic has a written plan that addresses the following:
 - Clinic Philosophy
 - Designated Compliance Officer in a leadership role in the clinic
 - Objectives
 - Training of employees on Fraud Waste Abuse, Corporate Compliance, and Standards of Conduct annually.
 - Internal communication system identified
 - Corporate policies & procedures on: Standards of conduct; Billing practices; Marketing; Disciplinary and corrective action
 - Quality Improvement techniques utilized for: Problem identification, Investigation of problems; Monitoring and audits
 - Clinic Risk Assessment. Must address areas in which the industry is vulnerable (i.e. The OIG work Plan) or areas where the clinic has vulnerability.
2. All employees must agree to abide by the elements of the Compliance Plan and the Standards of Conduct.

UNIVERSAL STANDARDS

CORPORATE COMPLIANCE

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

42 CFR 491.4, 491.7

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 shall comply with Medicare coverage, claim processing and payment policies.
3. The clinic shall comply with Medicare disclosure of ownership and control information.
4. The clinic prohibits employment/contracting with individuals or companies which have been convicted of a criminal felony offense related to healthcare. (Verification required through the OIG exclusion database, www.oig.hhs.gov and System for Award)
5. Management, www.sam.gov/portal/public/SAM/ and documentation must be maintained in the HR file.

UNIVERSAL STANDARDS

CORPORATE COMPLIANCE

COM 3.0 The clinic has written standards of conduct.

42 CFR 491.7

EVIDENCE OF COMPLIANCE:

1. The clinic has standards of conduct in writing.
2. There is written documentation of training on above in personnel or training files.
3. Employees agree to abide by the Standards of Conduct and documentation is found in their personnel file.
4. Employees are knowledgeable of the standards when interviewed.
5. Standards of Conduct should include a non-retaliation statement.

COM 4.0 The clinic has policies and procedures regarding disciplinary and corrective action to be taken when fraudulent behavior is suspected.

42 CFR 491.7

EVIDENCE OF COMPLIANCE:

1. Written policies and procedures identify steps in the process.
2. Education of employees is documented in personnel file or training files.

UNIVERSAL STANDARDS

CORPORATE COMPLIANCE

COM 5.0 The clinic verifies the license of all licensed Personnel.

42 CFR 491.4

EVIDENCE OF COMPLIANCE:

1. The clinic has a process for the verification of active and valid licensure of all applicable personnel.
 - Examples of compliance include:
 - Verification from State Licensing Board
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.

42 CFR 491.1, 405.2401

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).

ADM 2.0 The clinic is located in an area that meets the criteria for classification as a shortage area.

42 CFR 491.2, 491.5

EVIDENCE OF COMPLIANCE:

1. 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.
2. The area is designated by the Secretary as an area with shortage of personal health services under section 330(b)(3) of the Public Health Service Act.
3. The area is designated by the Secretary as a health professional shortage area under section 332(a)(1)(A) of the public Health Service Act because of its shortage of primary medical care professionals.
4. The area is determined by the Secretary to contain a population group that has a health professional shortage under section 332(a)(1)(B) of that Act or is designated by the chief executive officer of the State and certified by the Secretary as an area with a shortage of personal health services.
5. Designated as a high migrant impact area described in 329(a)(5) of PHS Act

UNIVERSAL STANDARDS

ADMINISTRATION

6. Rural areas are areas not delineated as urbanized areas in the last census conducted by the Census Bureau.
 - Included in the rural area classification are those portions of extended cities that the Census Bureau has determined to be rural.
7. Permanent unit. The objects, equipment and supplies necessary for the provision of the services furnished directly by the clinic is housed in a permanent structure.
8. 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).
9. 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.
10. A private, non-profit facility that meets all other conditions of this subpart except for location in as shortage area will be certified if, on July 1, 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.
11. Exceptions will be made by the Secretary upon application by the clinic.
12. Excluded from the rural area classification are:
 - a. Central cities of 50,000 inhabitants or more;
 - b. Cities with at least 25,000 inhabitants which, together with contiguous areas having stipulated population density, have combined population of 50,000 and constitute, for general economic and social purposes, single communities;
 - c. Closely settled territories surrounding cities, specifically designated by the Census Bureau as urban.
13. Included in the rural area are classification are those portions of extended cities that the Census Bureau has determined to be rural.
14. 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.

UNIVERSAL STANDARDS

ADMINISTRATION

ADM 3.0 The clinic meets the certification procedures.

42 CFR 491.3, 405.2402

EVIDENCE OF COMPLIANCE:

1. A rural health clinic will be certified for participation in Medicare in accordance with subpart X of 42 CFR part 405.
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.
3. A clinic certified under Medicare will be deemed to meet the standards for certification under Medicaid.
4. Must have posted hours of operation.

UNIVERSAL STANDARDS

ADMINISTRATION

ADM 4.0 The clinic must have an organized governing body that has legal responsibility for the conduct of the clinic.

42 CFR 491.7

EVIDENCE OF COMPLIANCE:

1. The clinic has by-laws.
2. Proof of ownership or control listed in by-laws.
3. Disclosure of Names and Addresses of the following:
 - Name and address of the owner(s)
 - Person responsible for directing the clinic's operation
 - Physician(s) responsible for medical direction
4. The clinic must report any change in ownership or medical director.
 - Prompt notice to the Regional office is required. (if change involves Physician in charge, licensing information must be included)
 - Change in ownership reported to TCT within 30 days of the effective date of change.
5. The clinic has an organizational chart.

UNIVERSAL STANDARDS

ADMINISTRATION

ADM 5.0 If the clinic has no governing body then one or more named individuals shall perform leadership functions with clear written authority, responsibility and accountability to direct the total activities of the clinic.

42 CFR 491.7

EVIDENCE OF COMPLIANCE:

1. The clinic has a written policy and procedure designating who is in charge of day-to-day operations.
2. The leadership identifies a designee, who is in charge of the operation in the absence of the owner/President.
3. The clinic has written policies for patient care.
4. There are written administration policies as required for fiscal, purchasing, and maintenance of building and equipment.

UNIVERSAL STANDARDS

ADMINISTRATION



ADM 6.0 The clinic's governance/ownership determine the individual Physician responsible for the medical direction of the clinic.

42 CFR 491.2, 491.4, 491.7, 491.8, 405.2401

EVIDENCE OF COMPLIANCE:

1. The Medical Director, who must be a physician, is accountable for the clinic's quality of care.
2. Lines of authority and responsibilities are in policies and in the organizational chart.
3. The clinic has written policies and procedures for identifying categories of practitioners which contain at a minimum one of the following:
 - a. One or more physicians, one of which may be the owner of the clinic, a clinic employee, or under agreement to carry out the responsibilities required.
 - b. One or more physician's assistants, nurse practitioners, nurse-midwife.
 - c. Clinical social worker, or clinical psychologist.
 - d. Ancillary personnel who are supervised by the professional staff.
4. The staff is sufficient to provide the services essential for the clinic.
5. Direct services means services provided by the clinic's staff.
 - a. A physician, nurse practitioner, physician assistant, nurse-midwife, clinical social worker, or clinical psychologist is available to furnish patient care services at all times during the clinic's posted hours of operation.

ADM 6.0 Standard continued on the next page.

UNIVERSAL STANDARDS

ADMINISTRATION

6. A nurse practitioner or a physician assistant is available to furnish patient care services at least 50 percent of the clinic's operating hours.
 - a. Providing RHC services in the clinic.
 - b. Being physically present in the clinic even though not providing RHC services.
 - c. Providing RHC services to clinic patients outside the clinic. These services must be RHC services.
7. A physician is present at least once in every 2 week period (except extraordinary circumstances), to provide medical orders, medical direction, medical care services, consultation, 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. Extraordinary circumstances are documented in the records of the clinic.
8. If the RHC does not have an NP or PA they must submit a staffing waiver to CMS (established clinics only).

UNIVERSAL STANDARDS

ADMINISTRATION

ADM 7.0 The clinic's professional staff develop, execute and review the clinic's policies and services provided.

42 CFR 491.7, 491.8, 491.9
EVIDENCE OF COMPLIANCE:

1. The clinic has written policies and a mechanism in place for review and approval of policies.
2. Patient records are reviewed on a regular basis by the professional staff, including the physician, to evaluate current orders and treatments used by the practitioners as well as patient outcomes.
3. The clinic has a written policy for referring patients to needed services that cannot be provided.
4. 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.
5. The clinic primarily engaged in providing outpatient health services and meets all other conditions of subpart 491.9 (a)(2).

ADM 8.0 The clinic has written policies & procedures for maintaining patient health records.

42 CFR 491.7, 491.10
EVIDENCE OF COMPLIANCE:

1. Designated member of the clinic's professional staff responsible for the oversight of medical records; responsible for complete and accurately documented, readily accessible and systemically organized.
2. There should be a healthcare record for each person receiving services.
3. Records should be maintained on-site and should be available at any time the patient needs care.
4. The clinic has a mechanism in place that assures that adequate patient health records are maintained and transferred as required when patients are referred.

UNIVERSAL STANDARDS

ADMINISTRATION

ADM 9.0 The clinic has policies in place addressing confidentiality, unauthorized use of information, record release and record retention.

42 CFR 491.7, 491.10 EVIDENCE OF COMPLIANCE:

CONFIDENTIALITY

1. The clinic has written policies and procedures including staff designations for entry, release and removal of medical records.
2. A patient confidentiality statement is signed by all employees and documented on the job description and/or in the personnel file.
3. All staff is trained on confidentiality and it is documented.
4. Confidentiality must be maintained in all aspects of clinic as it relates to patient information or private health information.
5. The clinic has safeguards in place to protect Medical Record Information from loss and destruction.
6. The patient's written consent is necessary before any information, not authorized by law, may be released.
7. The clinic at a minimum retains the records a period of 6 years from the last entry date or longer if required by State statute.

ADM 9.0 Standards continue on the next page.

UNIVERSAL STANDARDS

ADMINISTRATION

HIPAA

1. Written Policies and Procedures in place to meet all HIPAA requirements.
2. Privacy Notice must be posted and given to patients at time of initial contact. Documentation of receipt is maintained in the Medical Record.
3. Business Associate agreements must be maintained according to HIPAA regulations as applicable.
4. All staff is trained on HIPAA requirements annually and it is documented.

UNIVERSAL STANDARDS

ADMINISTRATION

ADM 10.0 The clinic's patient files consist of the following contents and are in accordance with 42 CFR 491.10(a)(3).

42 CFR 491.10

EVIDENCE OF COMPLIANCE:

Complete Medical Records include:

1. Identification and social data.
2. Evidence of consent forms.
3. Pertinent medical history.
4. Assessment of the health care status and health care needs of the patient.
5. Brief summary of the episode, disposition and instructions to the patient.
6. Reports of physical exams, diagnostic labs results and consultative findings.
7. All physicians' orders, reports of treatment and medications, signed and dated.
8. Any information pertinent to monitor the patient's progress.
9. Signature of the physician or other healthcare professional.

UNIVERSAL STANDARDS

ADMINISTRATION

ADM 11.0 Patient Medical Records must meet content requirements as outlined in ADM 10.0

42 CFR 491.8, 491.10, 491.11

EVIDENCE OF COMPLIANCE:

1. Random chart audit performed once a quarter with results documented at QI meetings.
2. Documentation must include number of records reviewed and deficiencies found.
3. If deficiencies are found, additional records must be reviewed. All deficiencies must be discussed with the designated professional responsible for oversight. If required, additional training to be provided to staff member responsible for deficiency.

UNIVERSAL STANDARDS

ADMINISTRATION



ADM 12.0 Emergency Services provided to the patient for life threatening injuries or acute illness.

42 CFR 491.9

EVIDENCE OF COMPLIANCE:

1. Clinic should provide first response in the event of an emergency.
2. Available treatment should include use of drugs & biologicals commonly used in life saving procedures. Examples include: analgesics, anesthetics (local), antibiotics, anticonvulsants, antidotes, emetics, serums and toxoids.
3. The clinic assures the safety of patients in case of non-medical emergencies by:
 - a. Training staff in handling emergencies.
 - b. Placing exit signs in appropriate locations.
 - c. Taking other appropriate measures that are consistent with the particular conditions of the area in which the clinic is located.

UNIVERSAL STANDARDS

ADMINISTRATION

ADM 13.0 The clinic is constructed, arranged, and maintained to insure access to and safety of patients, and provides adequate space for the provision of direct services.

42 CFR 491.6

EVIDENCE OF COMPLIANCE:

1. The clinic has a preventive maintenance program to ensure that:
 - All essential mechanical, electrical and patient-care equipment is maintained in safe operating condition.
 - The premises are clean and orderly.
 - Fire and sanitation inspections are current as required by the State.

UNIVERSAL STANDARDS

BILLING

BIL 1.0 The clinic informs the patient of charges at the start of service and maintains billing practices according to Medicare, Medicaid and private insurance company guidelines.

**42 CFR 405.2401, 405.2403, 405.2410, 405.2411-405.2416,
405.2460, 405.2462-405.2464**

EVIDENCE OF COMPLIANCE:

1. The clinic has written policies outlining billing procedures for all types of billing handled.
2. There is a policy for billing the patient portion of the bill (20%). This is communicated to the patient and documented in the patient record.
3. The clinic has a patient agreement or assignment of benefits form, which outlines the charges and is given to the patient at the time of delivery of services. This statement must include “I authorize any holder of medical information about me to release to my <Provider>, my physician, caregiver, CMS or its agents as part of the statement.

BIL 2.0 The clinic has some type of hardship process in place for the indigent or underinsured.

EVIDENCE OF COMPLIANCE:

1. There is a written policy outlining the criteria for a hardship.
2. Hardship waiver form.

UNIVERSAL STANDARDS

HUMAN RESOURCES

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

42 CFR 491.4 & 491.7, 491.8

EVIDENCE OF COMPLIANCE:

1. The clinic has written Human Resources policies and procedures to specify personnel qualifications, training, experience, and continuing education requirements consistent with the services it provides to beneficiaries.
2. Orientation and on-going training are documented in an organized format and are updated annually and when new services are added or if employee's performance warrants.
3. The clinic has a mechanism in place to monitor the staff's orientation and on-going training.
4. The clinic shall provide copies, upon request, to accreditation organizations and government officials or their authorized agents.
5. Licensed/Certified personnel shall be competent to deliver services & educate beneficiaries.
6. Professional personnel shall be licensed, certified, or registered and function within their scope of practice as required by the State standard under which the professional is licensed.

UNIVERSAL STANDARDS

HUMAN RESOURCES

HR 2.0	The clinic documents the job responsibilities and accountabilities for all employees.
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42 CFR 491.2, 491.4, 491.8, 405.2401

EVIDENCE OF COMPLIANCE:

1. The clinic has written job descriptions or checklists outlining the employee's responsibilities and accountabilities.
2. The job descriptions and employee job functions are in line with the CMS definitions of the practitioner:

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:

- i. Is currently certified as a primary care nurse practitioner by the
 - a) 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
 - b) Has satisfactorily completed a formal 1 academic year educational program that:
 - 1) Prepares registered nurses to perform an expanded role in the delivery of primary care;
 - 2) Includes at least 4 months (in the aggregate) of classroom instruction and a component of supervised clinical practice; and awards a degree, diploma, or certificate to persons who successfully complete the program; or

HR 2.0 Standards continue on the next page.

UNIVERSAL STANDARDS

HUMAN RESOURCES

- 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.

Physician means a doctor of medicine or osteopathy legally authorized to practice medicine or surgery in the State.

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:

- i. Is currently certified by the National Commission on Certification of Physician Assistants to assist primary care physicians; or
 - a) Has satisfactorily completed a program for preparing physician's assistants that:
 - 1) Was at least 1 academic year in length;
 - 2) 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
 - 3) Was accredited by the American Medical Association's Committee on Allied Health Education and Accreditation; or
 - 4) 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.

UNIVERSAL STANDARDS

HUMAN RESOURCES

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

42 CFR 491.4, 491.8

EVIDENCE OF COMPLIANCE:

1. The clinic's personnel files contain the following:
 - a. W4, I-9 for employees.
 - b. Application/Resume and references.
 - c. Hep B shot Record/TB skin test result/Health Status letter (Staff with patient contact). These items maintained in a separate file that are kept secure and confidential.
 - d. Signed job description or agreement.
 - e. Orientation/Training /Competency Assessment checklists.
 - f. Signed standards of conduct.
 - g. Verification & Copies of Professional license, registration and certification is maintained if appropriate to job duties (e.g. RN, PA).
 - h. OIG and SAM exclusion list verification.
 - i. Performance evaluations done annually.
2. The files must be kept confidential.

UNIVERSAL STANDARDS

QUALITY IMPROVEMENT

QI 1.0 The clinic has a Quality Improvement Plan.

42 CFR 491.11

EVIDENCE OF COMPLIANCE:

1. The clinic has a written Quality Improvement plan which is developed and implemented by key clinic personnel representing management, including:
 - a. Plan for new if appropriate.
 - b. Goals for improving patient outcomes (e.g. patient satisfaction).
 - c. Operational areas identified in need of improvement.
 - d. Monitoring of human resources including staff development & training (e.g. competency based orientation)
 - e. Annual checklists.
 - f. Patient satisfaction and dissatisfaction (Addressed in QI 2.0).
 - g. Fraud Awareness and Prevention (Addressed in COM 1.0-3.0).
2. The plan is reviewed on an annual basis and revised as necessary.
3. QI meeting conducted at least quarterly by appropriate health professionals and minutes exist to document agenda.
4. Designated member document the results of Patient Chart Audit and discuss at Quality Improvement Meeting.

UNIVERSAL STANDARDS

QUALITY IMPROVEMENT

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

42 CFR 491.11

EVIDENCE OF COMPLIANCE:

PATIENT SATISFACTION SURVEY

1. Patient satisfaction survey form is utilized and written responses are collected.
2. Patient Satisfaction Surveys apply to all products and services provided. The method used should obtain enough results to trend the results that can be evaluated in a QI meeting. It is preferred that the Patient Satisfaction Surveys be conducted at the Point of Care or via follow up phone call with-in 72 hours of service.
3. The clinic has a process for reviewing the responses and addressing issues.

COMPLAINTS

1. The clinic has a written policy and procedure for defining, handling, reviewing and resolving complaints. This includes notifying the patient within 5 calendar days upon receipt of the complaint and that the clinic is investigating.
2. The clinic must include The Compliance Team, Inc statement within written information provided to customers/patients on the complaint process. Documentation is maintained in the Medical Record. 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."
3. Timeliness of provider's response to patient's questions, problems and concerns are monitored.
4. Complaints are documented on a specific form and notification of a written response of the result of the investigation is reported back to the patient within 14 days.

UNIVERSAL STANDARDS

QUALITY IMPROVEMENT

QI 3.0 The clinic submits data to a national database for outcomes measurement.

EVIDENCE OF COMPLIANCE:

1. Measurement is collected on and submitted on a monthly basis:
 - a. Patient satisfaction.
 - b. Medication error and adverse events.
 - c. Patient Incident.
 - d. Other information as required by state or federal government.

QI 4.0 The clinic monitors and audits claims on a quarterly basis

42 CFR 405.2466

EVIDENCE OF COMPLIANCE:

1. The following data is collected quarterly on claims submitted to Medicare/Medicaid:
 - Number of claims submitted.
 - Number of claims on review.
 - Number of claims denied.
 - Patterns of incorrect documentation.
 - Patterns of error by the same employee.

UNIVERSAL STANDARDS

QUALITY IMPROVEMENT

QI 5.0 Clinic conducts an annual evaluation of its overall program.

42 CFR 491.9, 491.10, 491.11

EVIDENCE OF COMPLIANCE

1. Written plan determining who is to do the evaluation, how it is to be done and what is to be reviewed.
2. Evaluation must be performed by the clinic, professional personnel (as described in 24 CFR 491.9 (b)(2) or through arrangement with other appropriate professionals. No part of this evaluation may be replaced with information determined via the state survey.
3. Evaluation must include the following:
 - a. Utilization review of all services provided by clinic.
 - b. Clinic overall organization.
 - c. Review of active policies for administration, personnel and fiscal areas.
 - d. Number of patients served and volume of services.
 - e. Record review of both active and closed clinical records. This must be a representative sample.
 - f. Review of all clinic health care policies affecting patient care.

QI 5.0 Standards continue on the next page.

UNIVERSAL STANDARDS

QUALITY IMPROVEMENT

4. Evaluation results are reviewed to determine the following:
 - a. Utilization of services was appropriate.
 - b. Established policies were followed.
 - c. Identify changes needed.
 - d. Findings are reviewed by staff and corrective actions are taken as determined by the results of the review.
 - e. Documented follow-up indicating that the clinic has initiated/completed corrective action.
 1. Evaluation can be broken into parts and performed separately. There may not be more than 1 calendar year difference between the evaluations of each section.

UNIVERSAL STANDARDS

RISK MANAGEMENT

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

EVIDENCE OF COMPLIANCE:

1. Incidents are documented on a specific incident form and includes adverse events due to inadequate or malfunctioning equipment, items or services. (e.g. injuries, accidents, hospitalizations).
2. The clinic designates a staff member to review the incidents that occur and should be initiated within 72 hours if not serious. If resulting in hospitalization or death, it must be reported to TCT within 48 hours of the event.
3. Employees are knowledgeable of process.
4. There is a process in place to identify areas of potential risks.
5. There is a process in place to take corrective action.

UNIVERSAL STANDARDS

RISK MANAGEMENT

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

EVIDENCE OF COMPLIANCE:

1. Employee incidents, injuries or exposure is documented on an Incident form and if the clinic has greater than 10 employees is listed on an OSHA 300 log.
2. The human resources director or designee should review and handle all employees injuries.
3. A process is in place to identify potential risks and prevent injuries or accidents from occurring.

RSK 3.0 The clinic maintains a safe work environment.

42 CFR 491.6

EVIDENCE OF COMPLIANCE:

1. The facility has uncluttered hallways.
2. Appropriate lighting/heating/ventilation/air conditioning is available where needed.
3. In areas that store supplies on high shelves, an appropriate ladder is utilized to prevent injury when necessary.

SPECIALTY STANDARDS

EQUIPMENT MANAGEMENT

INFECTION CONTROL

PATIENT SERVICES AND INSTRUCTION

PHARMACEUTICAL SERVICES

DIAGNOSTIC SERVICES

REGULATORY

SPECIALTY STANDARDS

EQUIPMENT MANAGEMENT

EQP 1.0 The clinic has a written Equipment Management policy and procedure.

42 CFR 491.6

EVIDENCE OF COMPLIANCE:

1. The equipment management policy and procedure clearly states the process for cleaning, maintaining and storing all equipment.

SPECIALTY STANDARDS

EQUIPMENT MANAGEMENT



EQP 2.0 The clinic stores equipment appropriately and has areas of the storage area designated for and labeled:

- | | |
|----------------------|-----------------------|
| * Dirty/contaminated | * Cleaning |
| * Testing and repair | * Clean/Patient ready |

42 CFR 491.6

EVIDENCE OF COMPLIANCE

1. Clean equipment is segregated from dirty equipment.
2. Equipment/supplies should be stored on shelves, in cabinets or boxes and off the floor.
3. Defective and obsolete equipment is appropriately labeled.
4. Appropriate signage is utilized.

SPECIALTY EVIDENCE OF COMPLIANCE:

RESPIRATORY

1. Full tanks are separate from empty or partially full.
2. Tanks are grouped by size and type of gas, and are stored in a well-ventilated area.

SPECIALTY STANDARDS

EQUIPMENT MANAGEMENT



PATIENT PROTECTION ZONE™
PROCEED WITH CAUTION. The healthcare delivery procedure identified in the following Quality Standard is prone to Preventable Medical Errors that directly cause harm to patients and others.

EQP 3.0 All equipment is cleaned, disinfected and kept sanitary prior to each patient’s use.

42 CFR 491.6 EVIDENCE OF COMPLIANCE

1. The clinic has written equipment cleaning policies and procedures.
2. Equipment is cleaned with a disinfectant that kills HIV, Hepatitis B and TB, and is applied to the device according to the manufacturer’s directions.
3. Equipment is handled appropriately to maintain sanitary conditions.
4. Evidence of cleaning should be documented.

SPECIALTY STANDARDS

EQUIPMENT MANAGEMENT



PATIENT PROTECTION ZONE™
PROCEED WITH CAUTION. The healthcare delivery procedure identified in the following Quality Standard is prone to Preventable Medical Errors that directly cause harm to patients and others.

EQP 4.0 All equipment is tested and in working order and assessed prior to patient use.

42 CFR 491.6 EVIDENCE OF COMPLIANCE

1. The clinic has written policy regarding the testing of equipment.
2. Documentation of testing exists in the form of log, checklist etc.
3. Manufacturer’s operating manual and testing requirements are available for reference.
4. Staff members are trained on testing and training is documented.

SPECIALTY STANDARDS

EQUIPMENT MANAGEMENT



PATIENT PROTECTION ZONE™

PROCEED WITH CAUTION. The healthcare delivery procedure identified in the following Quality Standard is prone to Preventable Medical Errors that directly cause harm to patients and others.

EQP 5.0 All equipment maintenance/repairs and preventative maintenance are performed and documented by the clinic or by contracted vendor.

42 CFR 491.6

EVIDENCE OF COMPLIANCE

1. Manufacturer guidelines and operating manuals are available.
2. Preventive maintenance due date is located on device.
3. All preventative maintenance performed is documented.
4. Process exists for tracking due dates.
5. The clinic has a process for the documentation of problem, type of maintenance/repair; parts needed and repair technician's initials.
6. If repairs are done by an outside service, a report accompanies the equipment upon return.
7. Written or computerized list exists of all repairs and maintenance performed by manufacturer, model and serial number.

SPECIALTY STANDARDS

EQUIPMENT MANAGEMENT



PATIENT PROTECTION ZONE™
PROCEED WITH CAUTION. The healthcare delivery procedure identified in the following Quality Standard is prone to Preventable Medical Errors that directly cause harm to patients and others.

EQP 6.0 All sterilization equipment and procedures follow manufacturer and CDC 2008 guidelines for use.

42 CFR 491.4, 491.6 EVIDENCE OF COMPLIANCE

1. Manufacturer guidelines and operating manuals are available.
2. All instruments are placed in tray in an open position for optimum sterilization.
3. Preventive maintenance due date is located on device.
4. All preventative maintenance performed is documented.
5. Process exists for tracking individual loads and use of indicators.

SPECIALTY STANDARDS

EQUIPMENT MANAGEMENT



PATIENT PROTECTION ZONE™

PROCEED WITH CAUTION. The healthcare delivery procedure identified in the following Quality Standard is prone to Preventable Medical Errors that directly cause harm to patients and others.

EQP 7.0 The clinic has a process in place for handling equipment/product hazards, defects or recalls.

42 CFR 491.6

EVIDENCE OF COMPLIANCE

1. The clinic has an organized process for the receiving and handling of equipment hazards, defects or recalls.
2. All equipment/product hazards, defects or recalls are documented on the clinic's repair log and the individual device history record or like form.
3. Manufacturer's report is kept on file if equipment returns to inventory.

RESPIRATORY

1. The clinic has a written policy and procedure for the handling of oxygen recalls.
2. The clinic has an oxygen cylinder log or computer access to the same information.

SPECIALTY STANDARDS

INFECTION CONTROL



PATIENT PROTECTION ZONE™

PROCEED WITH CAUTION. The healthcare delivery procedure identified in the following Quality Standard is prone to Preventable Medical Errors that directly cause harm to patients and others.

INF 1.0 The clinic follows infection control techniques that relate to the type of patient served, services provided and the staff's risk for exposure as well as to protect the patient and staff from the spread of infection.

42 CFR 491.4 & 491.9

EVIDENCE OF COMPLIANCE

1. The clinic has a written infection control policy and procedure.
2. The clinic practices infection control 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. Universal Precautions when at risk for exposure to blood-borne pathogens.
 - d. Proper disposal of gloves, sharps and other waste throughout the clinic.
 - e. All patient's/caregivers are instructed on infection control techniques as appropriate to the type of services provided and the patient's condition.
 - f. Stores equipment and supplies off the floor.
 - g. Prevents cross-contamination by segregating clean from dirty in utility and or storage areas.

INF 1.0 Standards continue on the next page.

SPECIALTY STANDARDS

INFECTION CONTROL

3. All service staff are trained on the following infection control techniques and documented in the personnel file.
 - a. Hand washing techniques.
 - b. Use of Universal Precautions.
 - c. Handling and disposal of sharps and waste (e.g. dirty gloves).
 - d. Preventing cross-contamination in the clinic.
 - e. Patient/caregiver education when appropriate.

SPECIALTY STANDARDS

PATIENT SERVICES AND INSTRUCTION

PTS 1.0 The clinic has a patient rights and responsibilities document which is followed and given to the patient upon delivery of service.

42 CFR 491.4

EVIDENCE OF COMPLIANCE

1. The patient or caregiver is instructed on the rights and responsibilities at the start of service, given the document and documentation is found in the patient file.
2. All employees of the clinic are trained on the patient rights and responsibilities and how it relates to their individual jobs.
3. There is written documentation of this training in the personnel file.

SPECIALTY STANDARDS

PATIENT SERVICES AND INSTRUCTION

PTS 2.0 All patient care services are provided in accordance with Federal, State and local laws and are listed in public view.

42 CFR 491.7, 491.8, 491.9, 491.11 EVIDENCE OF COMPLIANCE

1. 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. This should be available for public view.
2. Written policies for each patient care are reviewed annually.
3. All services are provided according to State and local laws.
4. Clinic should have arrangement (in writing) with Medicare/Medicaid participating providers for the following services:
 - a. Inpatient hospital care,
 - b. Physician services
 - c. Additional services furnished through referral are described as: Arrangements have been made with X hospital, provider or supplier for clinic patients to receive the following services if required: specialized diagnostic and laboratory testing, specialized therapy, inpatient hospital care, physician services, outpatient and emergency care when clinic is not operating, referral for medical cause when clinic is operating.
5. There must be evidence that the patients referred are being accepted and treated.

PTS 3.0 Written policies are required for all patient care services.

42 CFR 491.8, 491.9, 491.11 EVIDENCE OF COMPLIANCE

1. Each patient care policy adheres to applicable State laws.

SPECIALTY STANDARDS

PATIENT SERVICES AND INSTRUCTION

2. Advisory group is part of the policy development annual review. At a minimum this group must include a physician, physician's assistant or nurse practitioner and one person who is not a member of the clinic staff and is a professional that is not directly related to healthcare delivery.
3. All current clinical staff must be knowledgeable of the patient care policies.
4. The policies include description of services.

SPECIALTY STANDARDS

PATIENT SERVICES AND INSTRUCTION

PTS 4.0 Written policies for all patient care services must include guidelines for medical management

42 CFR 491.8 & 491.9

EVIDENCE OF COMPLIANCE

1. Policies must include detailed description of services provided.
2. A collaborative agreement must include which procedures may be performed by PA, NP Cert Nurse Midwife and how they are provided specific to scope of medical acts, type of support staff and are compatible with State laws.
3. Criteria is addressed relating to what can be provided directly to patients and what requires physician supervision as it relates to the following:
 - a. Treatment to be followed.
 - b. Identification of condition, signs, illnesses or healthcare management in which consultation or referral is required.
 - c. Descriptions of the criteria for diagnosing and treating various health conditions:
4. It includes the definition of the condition, its etiology, its clinical features, recommended laboratory studies, differential diagnosis, treatment procedures, complications, consultation/referral required, and follow-up.
5. Policies are comprehensive enough to cover most health problems that patients usually see a physician about.

SPECIALTY STANDARDS

PATIENT SERVICES AND INSTRUCTION

PTS 5.0 The clinic has a process for follow-up that is related to the type of service provided and patient's condition.

42 CFR 491.8

EVIDENCE OF COMPLIANCE:

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

SPECIALTY STANDARDS

PATIENT SERVICES AND INSTRUCTION

PTS 6.0 The clinic presents written information to all adult age patients upon admission to services

42 CFR 491.4, 491.10

EVIDENCE OF COMPLIANCE:

1. Information given to patients contains individual rights under State law to make decisions concerning medical care which includes:
 - a. Right to accept or refuse care concerning medical or surgical treatment.
 - b. Right to formulate an advance directive.
2. In the event of a change of law the clinic has 90 days from effective date to amend information:
 - a. The advance directive(AD) document is placed in a permanent place in the patient's medical record.
 - b. Care should not be affected or individual discriminated because of execution of an AD.
 - c. All appropriate staff are trained in proper use of the AD.

SPECIALTY STANDARDS

PHARMACEUTICAL SERVICES



DRG 1.0 Written policies are required for storage, handling and dispensing of drugs & biologicals.

42 CFR 491.6, 491.9 EVIDENCE OF COMPLIANCE

1. Each patient care policy, guidelines for prescribing and dispensing drugs must adhere to all State laws.
2. Policies are reviewed annually as indicated in PTS 2.0.
3. Policies must include:
 - a. Drugs must be stored in original manufacturer containers to assure that they maintain proper labeling.
 - b. Requirements dealing with outdated deteriorated or adulterated drugs and biologicals. These must be stored separately. Disposal must be in compliance with applicable State laws.
 - c. Parameter of storage space needs to address: humidity, temperature and light to maintain quality of drugs and biological.
 - d. Manufacturers' guidelines should be followed and drug references and antidote information on the premises..
4. All schedule II drugs, which are classified under Schedule II of the Comprehensive Drug Abuse Prevention and Control Act of 1970, should be properly secured in a locked compartment. Must comply with requirements dealing with the maintenance of adequate records of receipt and distribution of controlled drugs that account for all drugs in Schedules II, III, IV and V, Diagnostic Services
5. Requirements to meet the provisions in the Poison Prevention Packaging Act of 1970.
6. Temperature monitoring of refrigerated drugs and vaccines including twice daily temperature logs.

SPECIALTY STANDARDS

PHARMACEUTICAL SERVICES

7. Process for complete and legible labeling of all containers used for dispensing to patients.

SPECIALTY STANDARDS

DIAGNOSTIC SERVICES

DGS 1.0 General services provided to the patient shall include diagnostic and therapeutic services and supplies.

42 CFR 491.9

EVIDENCE OF COMPLIANCE

1. General services include:
 - a. Medical History.
 - b. Physical examination.
 - c. Assessment of health status.
 - d. Treatment for a variety of conditions.

SPECIALTY STANDARDS

DIAGNOSTIC SERVICES



PATIENT PROTECTION ZONE™

PROCEED WITH CAUTION. The healthcare delivery procedure identified in the following Quality Standard is prone to Preventable Medical Errors that directly cause harm to patients and others.

DGS 2.0 The clinic provides basic laboratory services essential to immediate diagnosis and treatment.

42 CFR 491.9

EVIDENCE OF COMPLIANCE

1. Adhere to all areas of 42 CFR 493 f and Section 353 of the Public Health Service Act for all services provided.

Laboratory services include:

- a. Urine and ketones
- b. Hemoglobin or hematocrit
- c. Glucose
- d. Pregnancy tests
- e. Exam of stool for occult blood
- f. Primary culturing for transmit to lab

SPECIALTY STANDARDS

REGULATORY

REG 1.0 The clinic is in compliance with all local, State and Federal regulatory agencies.

42 CFR 491.4, 491.5, 491.6, 405.2401, 405.2402

EVIDENCE OF COMPLIANCE:

1. The clinic shall have a physical location and display all licenses, certificates and permits to operate.
2. Must comply with applicable Life Safety Code (2012) regulations.
3. All exits are marked with signs.
4. Exit doors are never locked from the inside.
5. Means of egress are free and unobstructed and shall be accessible for occupants having limited mobility.
6. Fire extinguisher is mounted and has been checked and approved for use by the local Fire department.
7. The Fire department or equivalent has performed an in-service for all employees on fire safety, including fire extinguisher use and fire drills.
8. All staff has written documentation of attendance at fire safety in-service.
9. Floor plans posted in key locations.

SPECIALTY STANDARDS

REGULATORY



PATIENT PROTECTION ZONE™

PROCEED WITH CAUTION. The healthcare delivery procedure identified in the following Quality Standard is prone to Preventable Medical Errors that directly cause harm to patients and others.

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.

42 CFR 491.4

EVIDENCE OF COMPLIANCE:

1. The clinic has a written work-exposure plan.
2. Staff members who are identified for being at risk have been offered Hepatitis B vaccinations and have either accepted at the employer's expense, or have signed a letter of declination.
3. The staff members who are at risk for exposure have been trained on the OSHA standard and have written documentation in their personnel file.
4. Personal protective equipment has been made available to the appropriate staff and is accessible for their use.

SPECIALTY STANDARDS

REGULATORY



PATIENT PROTECTION ZONE™

PROCEED WITH CAUTION. The healthcare delivery procedure identified in the following Quality Standard is prone to Preventable Medical Errors that directly cause harm to patients and others.

REG 2.B The clinic is in compliance with the OSHA TB standard as it relates to the type of patient served, services provided and staff's risk for exposure.

42 CFR 491.4

EVIDENCE OF COMPLIANCE:

1. The clinic determines if they service a patient population that is high risk for TB.
2. If at risk, the clinic does the following:
 - a. Develops and implements a respiratory protection plan.
 - b. Hepa-filter masks are available as needed.
 - c. All staff with patient contact must have a TB skin test and a medical evaluation.
 - d. Employees are trained in respiratory protection.
3. OSHA TB training of staff at risk is documented in the personnel files.

SPECIALTY STANDARDS

REGULATORY

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

42 CFR 491.4

EVIDENCE OF COMPLIANCE:

1. The clinic provides training to all employees on OSHA's Right to Know and training is documented in the personnel file.
2. Material Safety Data Sheets are filed for all hazardous material in the clinic's workplace and employees are knowledgeable of the location. (e.g. cleaning disinfectants, chemicals, lubricants, toner, etc.)
3. The clinic posts all mandatory OSHA posters for all employees to view.

SPECIALTY STANDARDS

REGULATORY

REG 2.D The clinic has an emergency preparedness plan that addresses an emergency on-site, off-site (natural disaster) and disruption of service.

42 CFR 491.4, 491.6

EVIDENCE OF COMPLIANCE:

1. The clinic has an organized process for handling an on-site emergency, (e.g. Fire) which addresses the following:
 - a. How employees will be notified of emergency.
 - b. Staff responsible for calling the Fire Department.
 - c. Emergency use of fire extinguishers if warranted.
 - d. Location of where employees should meet outside the building.
 - e. Staff person designated to do head count upon evacuation of the building.
2. The clinic has an organized process for handling an off-site emergency, (e.g. Snowstorm, flood etc.) which addresses the following:
 - a. How employees will be notified of emergency.
 - b. Staff responsible for notification and triaging of patient services.
 - c. Contingency plan includes alternative provider in the event that the clinic cannot service its own customers.
3. The personnel records reflect documentation of training of staff on emergency preparedness.
4. Power outage: the clinic must have a policy for how refrigerated medications are handled such as vaccines etc.
 - a. Manufacturer and CDC guidelines are followed
 - b. Clinic has back up generator or other options for keeping drugs patient ready.