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QUALITY STANDARDS AND EVIDENCE OF COMPLIANCE

Pharmacy Services

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Universal Standards
CORPORATE COMPLIANCE
SECTION 1

COM 1.0 The organization has a Corporate Compliance plan.

EVIDENCE OF COMPLIANCE:

1. The organization has a written plan that includes the following:
   - Philosophy
   - Designated Compliance Officer who is in a leadership position of the organization
   - Objectives
   - Annual training of employees on Fraud Waste Abuse, Corporate Compliance, and Standards of Conduct
   - Internal communication system identified
   - Corporate Policies & Procedures that promote a commitment to compliance. These include areas such as: standards of conduct, financial incentives (bonuses to staff/other entities), billing practices, marketing, disciplinary action and corrective action
   - Quality Improvement techniques utilized for problem identification, investigation of problems, monitoring and audits
   - Company Risk Assessment must address areas in which the industry is vulnerable (e.g., areas identified in current OIG Work Plan) or areas where the company has vulnerability

2. All employees must agree to abide by the elements of the Compliance Plan.

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

EVIDENCE OF COMPLIANCE:

1. The organization that participates in the Medicare/Medicaid program has been free of sanctions for a period of at least 2 years.
2. Organization prohibits employment/contracting with individuals or company who has been convicted of a criminal felony offense related to healthcare or who are charged with criminal offenses related to healthcare. Verification and re-verification required through Office of Inspector General (OIG) exclusion database (www.oig.hhs.gov/exclusions) and System for Administrative Management (SAM) (www.sam.gov) and documentation maintained in accordance with applicable state/federal time frames as well as Part D Sponsors/contracts.

Universal Standards
CORPORATE COMPLIANCE
SECTION 1

COM 3.0 The organization has written standards of conduct.

EVIDENCE OF COMPLIANCE:

1. The organization has standards of conduct, including a non-retaliation statement in writing.
2. There is written documentation of training 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 must be posted in employee area.

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

EVIDENCE OF COMPLIANCE:

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

COM 5.0 The organization verifies the license of referring physicians either through a State licensing board or a Hospital Medical Staff office.

EVIDENCE OF COMPLIANCE:

1. The organization has a process for the verification of active and valid State licensure and expiration dates and NPI of all referring physicians.
2. Compliance includes all of the following:
   - Verification from State Licensing Board or List from State Licensing Board
   - NPPES (https://nppes.cms.hhs.gov/NPPES/NPIRegistryHome.do)
3. This information is documented and tracked in an organized format.

Universal Standards
ADMINISTRATION
SECTION 2

ADM 1.0 The organization has one or more individuals who perform leadership functions to direct the organization and its key activities.

EVIDENCE OF COMPLIANCE:

1. An organization must disclose any person having ownership, financial, or controlling interest.
2. An organization must provide complete and accurate information on the application submitted to The Compliance Team, Inc. All changes must be reported in writing to The Compliance Team, Inc., within 30 days of the change.
3. The organization has a written policy and procedure designating who is in charge of day-to-day operations.
4. The organization identifies a leader who is accountable and in charge of the operation. A designee is identified in the absence of the Owner/President. An organizational chart is maintained to document the chain of command.
5. Leadership reviews Policy & Procedure manual and forms annually. Documentation of review is maintained.

ADM 2.0 The organization has a written description of their scope of services, products/services offered and availability.

EVIDENCE OF COMPLIANCE:

1. The organization has written information made available to the public. It is provided to the patient at time of initial service and documentation of receipt is kept in the patient record. The document includes the following:

- Company Contact Information
- Scope of products and services offered
- Hours of availability – CMS DMEPOS Supplier Standards require minimum of 30 hours per week (if applicable)
- The organization has written policies and procedures for Availability of Services including after hour coverage provided by organization. Answering service/voicemail must include medical emergency statement (e.g., "If this is an emergency call 911…"). Additional information to be kept by the organization
- Organization's availability is related to type of equipment provided. (All businesses providing Infusion Pumps and Nebulizers, or other type of supplies or equipment that is necessary to the patient's well-being will mandate 24-hour availability, appropriate back-up equipment, and maintenance of after-hours call log)

2. All Marketing Materials must adhere to all Federal Regulations and Guidelines.

Universal Standards
ADMINISTRATION
SECTION 2

ADM 3.0 The organization maintains patient confidentiality.

EVIDENCE OF COMPLIANCE:

CONFIDENTIALITY

1. The organization 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.
3. All staff is trained on confidentiality and it is documented.
4. Confidentiality must be maintained in all aspects of organization as it relates to patient information or personal health information.

HIPAA

1. Written Policies and Procedures in place to meet all HIPAA requirements including HIPAA Hi-Tech.
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. All staff is trained on HIPAA requirements annually and it is documented.

ADM 4.0 The organization maintains records for all patients receiving products or services. These records are retained for a period of at least 7 years or more in accordance with applicable state and federal regulations. (In the case of a minor they are retained for a minimum of 7 years past the age of 18).

EVIDENCE OF COMPLIANCE:

1. The organization has a Record Retention process in place that addresses HIPAA standards.
2. The organization's staff is knowledgeable.
3. The records are stored in a locked, fireproof cabinet, or are backed-up on electronic disk and stored off site, or in the cloud.

Universal Standards
ADMINISTRATION
SECTION 2

ADM 5.0 The organization has a process for receipt and disposition of orders for medications/products/equipment.

EVIDENCE OF COMPLIANCE:

1. The organization has a process in place.
2. The organization has a documented intake process for use in receiving orders.
3. The organization has a process for the tracking of CMN, LMN or RX.
4. If the organization cannot fulfill the order, the organization will contact another pharmacy for purposes of transferring the prescription. If the drug is not available the prescribing physician is notified.
5. The organization also participates in a prescription drug monitoring program if required by the State Board.

ADM 6.0 The organization has appropriate financial management practices in place that ensure accurate accounting & billing to beneficiaries & the Medicare /Medicaid programs.

EVIDENCE OF COMPLIANCE:

1. Financial records shall be accurate, complete, current, and reflect cash or accrual based accounting practices.

2. Organization shall maintain accounts that link equipment & items to the beneficiary and manage revenues and expenses on an ongoing basis, as they relate to beneficiary services, including the following:
   - Mechanism in place for reconciling charges to patients for drugs/equipment/supplies /services with invoices, receipts and deposits (*as applicable*)
   - Operating budget as appropriate to business size and scope of services
   - Process in place to track actual revenue and expenses

Universal Standards
ADMINISTRATION
SECTION 2

ADM 7.0	**The organization has formal written contracts and agreements with subcontractors, other organizations and/or individuals for the provision of care, products and services to organization clients that detail specific responsibilities of the parties involved.**

EVIDENCE OF COMPLIANCE:

1. Written service contracts with individuals, and/or other entities, are signed and dated by authorized principals of each party and are reviewed annually.
2. The executed document stipulates the terms of the contract which include:
    a. Specific services/products to be provided
    b. Review of any accreditation determinations by other accrediting organizations
    c. Contractor is required to adhere to applicable primary organization policies and procedures
    d. Assurance and documentation by the contractor of the education, training, qualifications and identification of personnel designated to provide care, services and products
    e. Processes for the documentation and submission of contractor activity that verifies the provision of care/services and products
    f. Processes that outline the contractor's orientation and expectation of the care/services and products provided
    g. Procedures for the submission of invoices and reimbursement for care/services and products provided
    h. Effective dates of the contract, including terms for renewal and/or termination.
    i. Contract/Business Associate Agreement must contain patient confidentiality agreement and be maintained according to applicable HIPAA regulations.
3. The written service contracts shall contain processes for (at a minimum) annual review of:
    a. The contractor's policies and procedures
    b. The contractor's performance compliance
    c. The organization's performance compliance with the contractor
    d. Subcontractors are monitored via the quality improvement process

Universal Standards
BILLING/COLLECTION
SECTION 3

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

EVIDENCE OF COMPLIANCE:

1. The organization has written policies outlining billing procedures for all types of billing handled which includes a process for non-pick-up of medications/supplies and credits the claim back to the payer source.
2. A common list of codes billed are documented and utilized for training purposes.
3. There is a policy for billing the patient portion of the bill. This is communicated to the patient and documented in the patient record.
4. The organization has a patient agreement or assignment of benefits form, which outlines the charges and is given to the patient at the time of delivery. This statement must include "I authorize any holder of Medical Information about me to release to <Provider>, my physician (s), caregiver, CMS or its agents" as part of the statement as applicable.

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

EVIDENCE OF COMPLIANCE:

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

Universal Standards
HUMAN RESOURCES
SECTION 4

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

EVIDENCE OF COMPLIANCE:

1. The organization has written Human Resources policies and procedures to specify personnel qualifications, training, experience, certifications/licensures (where applicable), and continuing education requirements consistent with the specialized equipment, items, and services it provides to beneficiaries.

2. Orientation, on-going product and job specific training are documented; summary checklists are maintained in the personnel or training file. Training is performed at time of hire and updated annually. Additional training is provided if new services/ products are added or if employee performance warrants.

3. The organization has a mechanism in place to monitor staff orientation and on-going training.

4. Supplier shall provide copies, upon request, to accreditation organizations and government officials or their authorized agents.

5. Technical personnel shall be competent to delivery and set-up equipment, items & train beneficiaries if applicable

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.

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

EVIDENCE OF COMPLIANCE:

1. The organization has written job descriptions outlining employee responsibilities and accountabilities.

Universal Standards
HUMAN RESOURCES
SECTION 4

HR 3.0 The organization maintains files on all employees and independent contractors.

EVIDENCE OF COMPLIANCE:

1. The organization has personnel files that contain the following:

   - W4, I-9 for employees
   - Application/Resume and references
   - Signed job description or Independent Contractor agreement
   - Orientation/Training /Competency Assessment checklists
   - Signed standards of conduct
   - Verification & copies of professional license, registration and certification is maintained if appropriate to job duties (e.g.R.Ph., PharmD, CPhT, RN, RRT,CRT, ATP and O & P)
   - Driver's License and Driving Record (if driving a company vehicle)
   - Hepatitis B shot record/TB skin test result/Health Status letter (staff with patient or equipment contact). These items maintained in a separate file that are kept secure and confidential.
   - Current CPR certification (if administering injected medications, biologicals and/or immunizations)
   - Background check if required by State

2. The files must be kept confidential.

Universal Standards
QUALITY IMPROVEMENT
SECTION 5

QI 1.0 The organization has a Quality Improvement Plan.

EVIDENCE OF COMPLIANCE:

1. The organization has a written Quality Improvement plan which is developed and implemented by key personnel representing management and all departments of the organization. It includes the following:

   - Plan for new drugs/products/services (if applicable)
   - Goals for improving patient outcomes (e.g., patient satisfaction, medication error and equipment as applicable)
   - Operational areas identified in need of improvement
   - Monitoring of human resources
     - Staff development & training (e.g., competency based orientation and annual checklists)
     - Subcontractor, other organization and individual agreements (if applicable)
   - Patient satisfaction and dissatisfaction (addressed in QI 2.0)
   - Fraud Awareness and Prevention (addressed in COM 1.0-3.0)
   - Input received from employees, customers, and referral sources when assessing the quality of operations and services

2. Quality Improvement/Staff Meeting with key personnel is held a minimum of quarterly and minutes are kept. Areas requiring quarterly attention should be reviewed and documented in minutes. (e.g., Complaints, Incidents, Claims monitoring, Patient Satisfaction Survey, Training)

3. The plan is reviewed and updated on an annual basis and revised if necessary.

Universal Standards
QUALITY IMPROVEMENT
SECTION 5

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

EVIDENCE OF COMPLIANCE:

PATIENT SATISFACTION SURVEY:

1. Patient Satisfaction Survey form is utilized and written responses are collected for patients/clients/facilities served (as applicable).
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 via follow up phone call, and be a representative sample, however, a customer survey card would be acceptable in a community pharmacy location.
3. The organization has a process for reviewing the responses and addressing issues that were noted.

COMPLAINTS:

1. The organization 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 organization is investigating.
2. Organization 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 <company 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 response to patient questions, problems and concerns is monitored.
4. Unresolved 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
SECTION 5

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

EVIDENCE OF COMPLIANCE:

1. Data is collected on the following:
   - Patient satisfaction
2. Once accreditation is obtained, measurement is submitted on a continuous basis. Submission is done via the website login of The Compliance Team, Inc., using the Electronic Benchmarking™ Program.
3. Quarterly summary reports are reviewed within the QI Meeting.

QI 4.0 The organization monitors and audits claims on a quarterly basis.

EVIDENCE OF COMPLIANCE:

1. The organization has a process that the following data is collected quarterly on claims submitted to Medicare/Medicaid and other insurance:

   Patient Record/Claim Review:

   - Number of claims submitted
   - Number of claims on review
   - Number of claims denied
   - Reasons for denial
   - Errors found in records review
   - Patterns of incorrect documentation (if applicable)
   - Patterns of error by the same employee (if applicable)

Universal Standards
RISK MANAGEMENT
SECTION 6

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

EVIDENCE OF COMPLIANCE:

1. There is a process in place for reporting information to the appropriate agency related to adverse events that endanger the health and safety of consumers/clients (e.g., child abuse, elder abuse, suicide threats).
2. Incidents are documented on a specific Incident form and include adverse events due to medication errors, adverse drug interaction, allergic reaction and inadequate or malfunctioning equipment, items or services. (e.g., injuries, accidents, infections, hospitalizations).
3. The organization designates a staff member to review the incidents that occur. Review is initiated within 72 hours if not serious. If resulting in hospitalization or death, refer to Standard REG 3.C.
4. Employees are knowledgeable of process.
5. There is a process in place to identify areas of potential risks and necessary corrective action.

RSK 2.0 The organization 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. Effective January 1, 2015, Pharmacy and DME businesses are exempt from OSHA 300 recordkeeping, but must report to OSHA any workplace incident that results in an employee fatality, inpatient hospitalization, amputation or loss of an eye.
2. The human resources director or designee should review and handle all employee injuries.
3. A process is in place to identify potential risks and necessary corrective action in order to prevent injuries or accidents from occurring.

Universal Standards
RISK MANAGEMENT
SECTION 6

RSK 3.0 The organization maintains a safe work environment.

EVIDENCE OF COMPLIANCE:

1. The facility has uncluttered hallways.
2. Personal protective equipment is provided for employees at risk.
3. Appropriate lighting/heating/ventilation/air conditioning is available where appropriate.
4. In pharmacies/warehouses that store drugs/equipment on high shelves, an appropriate ladder is utilized to prevent injury.
5. Company delivery vehicles are maintained in good working order.
6. No hazards present that would place an employee, customer or patient at risk.

Specialty Standards
EQUIPMENT MANAGEMENT
SECTION 7

EQP 1.0 Equipment is selected according to the specific needs of the patient and the physician's orders when appropriate.

EVIDENCE OF COMPLIANCE:

1. The patient file clearly indicates that the equipment/product ordered was the equipment/product delivered.

EQP 2.0 All supplies are stored according to manufacturer guidelines.

EVIDENCE OF COMPLIANCE:

1. All items containing expiration dates should be checked, rotated and destroyed according to manufacturer guidelines.

EQP 3.0 All equipment is tested and/or working order assessed prior to patient use.

EVIDENCE OF COMPLIANCE:

SUPPLIES

1. The organization checks supplies according to order, lot number and expiration date.
2. Information is documented.

Specialty Standards

EQUIPMENT MANAGEMENT
SECTION 7

EQP 4.0 The organization has an organized process for the tracking of inventory.

EVIDENCE OF COMPLIANCE FOR ALL PRODUCT LINES:

1. Written or computerized list of inventory exists by serial number, manufacturer, model number and disbursement of either patient name or facility.
2. The organization must have proof of purchase of all equipment in inventory and vendor source.
3. Make/model number or other identifier (e.g., lot number) of any non-custom equipment will be recorded in the patient record.
4. If the organization has more than one site to store equipment, a process exists to identify the equipment at each location is needed.

SUPPLIES:

1. The organization maintains a list of lot numbers (or other identifier) with expiration dates.

EQP 5.0 The organization has a process in place for handling equipment/product hazards, defects or recalls.

EVIDENCE OF COMPLIANCE:

1. The organization has a systematic process for the receiving and handling of equipment hazards, defects or recalls. The organization has a method in place to track both serial and lot numbers in the event of a recall.
2. All equipment/product hazards, defects or recalls are documented on the organization's individual equipment history record.
3. There is a process for notifying the delivery/service staff to pick-up,-exchange or repair the equipment if in use.
4. Delivery, service and pharmacy staff are trained on this process and are knowledgeable. Training is documented in personnel or training file.
5. Manufacturer report is kept on file if equipment returns to inventory.

Specialty Standards
INFECTION CONTROL

SECTION 8

INF 1.0	**The organization follows infection control techniques that relate to the type of patient served, equipment provided and staff risk for exposure, as well as protecting the patient and staff, from the spread of infection.**

EVIDENCE OF COMPLIANCE:

1. The organization has a written policy and procedure.
2. The organization practices infection control techniques by utilizing the following:

    - Hand washing before and after each patient contact or use of alcohol based gel
    - Utilization of gloves while handling or cleaning dirty equipment or touching the patient
    - Utilization of Standard Precautions when at risk for exposure to blood-borne pathogens
    - Proper disposal of gloves in the pharmacy, facility or patient home
    - All patients/caregivers are instructed on infection control and aseptic techniques as appropriate to the type of drug/equipment provided and patient's condition
    - Stores equipment /supplies off floor
    - Prevents cross-contamination by segregating clean from dirty in pharmacy/storage areas or delivery vehicle and keeping equipment bagged after it has been cleaned and disinfected

3. All delivery/service staff are trained on the following infection control techniques and documented in the personnel file upon hire and annually.

    - Hand washing techniques
    - Use of Standard Precautions
    - Handling and disposal of waste (e.g., dirty gloves, bags and cleaning supplies)
    - Preventing cross-contamination in the pharmacy and delivery vehicle
    - Patient/caregiver education as it relates to the product/equipment provided

Specialty Standards
PATIENT SERVICES & INSTRUCTION
SECTION 9

PTS 1.0 The organization has a Patient Rights and Responsibilities document which is posted and provided to the patient upon delivery of product/service.

EVIDENCE OF COMPLIANCE:

1. The Patient Rights and Responsibilities is posted in a public area and provided to clients upon request.
2. All employees of the organization are trained on the Patient Rights and Responsibilities document and how it relates to their individual jobs.
3. There is written documentation of this training in the personnel file.

PTS 2.0 A medication assessment is made by the pharmacist prior to dispensing.

EVIDENCE OF COMPLIANCE:

1. The pharmacist performs an assessment, per each prescription, that includes at a minimum:

    - Potential drug interaction
    - Potential for Poly-Pharmacy
    - Appropriate dose and frequency
    - Appropriate time of administration
    - Appropriate route and method of administration

Specialty Standards
PATIENT SERVICES & INSTRUCTION
SECTION 9

PTS 3.A **Immunization Services are provided and developed by the Pharmacy under the guidance of the Pharmacist. Evidence-based guidelines and best practices are followed (if provided by the pharmacy).**

EVIDENCE OF COMPLIANCE:

1. The organization has written policy and procedures for an Immunization Services Program.
2. The organization practices infection control techniques by utilizing the following:
   - Hand washing before and after each patient contact
   - Utilization of gloves and aseptic technique while preparing and administering shots
   - Utilization of Standard Precautions when at risk for exposure to blood-borne pathogens
3. Immunization services shall adhere to Recommendations and Guidelines developed by:
   - American Pharmacists Association Immunization Guidelines
   - http://www.pharmacist.com/pharmacy-based-immunization-delivery
   - Centers for Disease Control Immunizations Recommendations and Guidelines
   - http://www.cdc.gov/vaccines/
   - State Board of Pharmacy (as applicable)
4. Must have emergency kit available in accordance with state immunization guidelines.

Specialty Standards
PATIENT SERVICES & INSTRUCTION
SECTION 9

PTS 3.B **Medication Therapy Management (MTM) Services are provided and developed by the Pharmacy under the guidance of the Pharmacist. Evidence-based guidelines and best practices are followed (if provided by the pharmacy).**

EVIDENCE OF COMPLIANCE:

1. The organization has written policy and procedures, and documentation of training, for a Medication Therapy Management (MTM) Services Program which is focused on improving patient therapeutic outcomes.
2. The organization's services, if contracted with a Part D plan for Medicare beneficiaries, must meet CMS qualifying criteria for receiving MTM services:
   - Patient has multiple chronic diseases
   - Patient is taking multiple drugs
   - Annual cost of Part D drugs meets criteria
3. The organization follows the Core Elements of an MTM service:
   - Medication Therapy or Comprehensive Therapy Review (MTR/CMR)
   - Personal Medication Record (PMR)
   - Medication Related Action Plan (MAP)
   - Intervention & Referral and Documentation & Follow-up
4. The pharmacy conducts comprehensive medication reviews to obtain a complete medication history, assess the appropriateness of medication therapy, and create a reconciled medication list and care plan for the patient.

PTS 3.C **Patient Care Services are provided and developed by the Pharmacy under the guidance of the Pharmacist. Evidence-based guidelines and best practices are followed for the following programs (if provided by the pharmacy).**

EVIDENCE OF COMPLIANCE:

1. The organization has a process in place for any other patient services program such as the following:
   - Health Screening/Tests (e.g., lipids, blood pressure, glucose testing)
   - Medication Reconciliation
   - Care transition services

Specialty Standards
PATIENT SERVICES & INSTRUCTION
SECTION 9

PTS 4.0 The organization has a process for informing the patient of their rights regarding the purchase of equipment.

EVIDENCE OF COMPLIANCE FOR ALL PRODUCT LINES:

1. The organization utilizes a form to explain the capped rental, inexpensive, or routinely purchased product categories.
2. The patient/caregiver is given information on the warranty of product as applicable.

PTS 5.0 Automated clinical record systems ensure consistent on-going protection of data.

EVIDENCE OF COMPLIANCE:

1. The organization has a written policy describing signature authentication, in accordance with individual state laws.
2. The organization has safeguards to prevent unauthorized access to inputted information.
3. The pharmacy has unique and protected access codes that are assigned to individuals designated to enter data.
4. The organization has an automated program that designates and controls areas of access by authorized personnel based on a personal identifier and position in the organization.
5. The computer internal clock designates date and time of entries.
6. The automated controls prevent a change in entry, allowing only corrections.
7. Hard copies of automated data are retrievable by designated personnel.
8. The organization has a system for validation of inputted data.
9. An automated system for backup and storage of data is controlled, and the data is stored in a safe environmental place.

Specialty Standards
PATIENT SERVICES & INSTRUCTION
SECTION 9

PTS 6.0 Communication to patients/clients shall address cultural diversity verbally, as well as in writing.

EVIDENCE OF COMPLIANCE:

1. If a patient in need of instruction speaks a language other than English, the organization shall make arrangements to have someone interpret. If the organization services a large percentage (40% or more) of non-English speaking people in their patient population, then the following documents (at a minimum) should be available in that language: Assignment of Benefits/ Patient Instructions/ Patient Rights and Responsibilities.

Specialty Standards
REGULATORY
SECTION 10

REG 1.0 The organization is in compliance with all local, State, and Federal regulatory agencies and has the legal authority to operate.

EVIDENCE OF COMPLIANCE:

LICENSING/FACILITY:

1. Supplier shall have a physical location and display all licenses, certificates and permits to operate. These must be posted in an area accessible to all customers. Upon request, copies shall be provided to government officials or their agents (including The Compliance Team, Inc.).
2. Licenses for State Board of Pharmacy and DEA Narcotic Registration must be present for each State where the company is doing business (unless not required by the State). If mail order, a spreadsheet (or copies) with all of the licenses and expiration dates must be available for review.
3. CMS Supplier Standards (if providing DME) must be posted in public view. Required Federal and State posters must be posted in employee visible area.
4. Facility must be American Disability Act compliant.
5. Provider is in Compliance with all Medicare and Medicaid Standards.
6. All building exits are marked with signs and an exit floor plan is posted in appropriate locations.

REG 2.A The organization is in compliance with the OSHA blood-borne pathogen standard as it relates to the type of patient served, equipment provided and staff risk for exposure.

EVIDENCE OF COMPLIANCE:

1. The organization has a written work-exposure plan. Environmental Housekeeping Schedule is posted in the cleaning area.
2. Staff members who are identified as being at risk for exposure have been offered Hepatitis B vaccinations and have either accepted at the employer's expense, or have signed a letter of declination. If employee declines initially, they can accept at a later date at the employer's expense.
3. The staff members who are at risk for exposure receive annual training on the OSHA standard and have written documentation in their personnel file.
4. Personal protective equipment is available and accessible to the appropriate staff for their use.

Specialty Standards
REGULATORY
SECTION 10

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

EVIDENCE OF COMPLIANCE:

1. The organization determines if they service a patient population that is high risk for TB and/or are in a geography that has a higher risk for TB and documents.
2. If at risk, the organization does the following:
   - Develops and implements a respiratory protection plan
   - Has Hepa-filter (N-95) fit tested masks available for those employees with direct patient contact
   - All staff with patient contact must have a TB skin test and a medical evaluation
   - Employees are trained annually in respiratory protection
2. OSHA Tuberculosis (TB) Training of at-risk staff is performed annually and documented in the personnel files.

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

EVIDENCE OF COMPLIANCE:

1. The organization develops a written plan specifying all hazardous materials or chemicals in the workplace including location of Safety Data Sheets (SDS).
2. The organization provides annual training to all employees on OSHA Right to Know and training is documented in the personnel file.
3. Safety Data Sheets (SDS) are current and available for all hazardous material in the organization's workplace and employees are knowledgeable of the location (e.g., medications, cleaning disinfectants, chemicals, lubricants, toner, etc.). See link to the NIOSH List of Anti Neoplastic and hazardous Drugs in Healthcare Settings: http://www.cdc.gov/niosh
4. The organization contacts OSHA and posts all mandatory posters that are received.

Specialty Standards
REGULATORY
SECTION 10

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

EVIDENCE OF COMPLIANCE:

1. The organization has a written emergency preparedness plan and organized process for handling an on-site emergency, (e.g., fire) addressing the following:
   - How employees will be notified of emergency
   - Staff responsible for calling the Fire Department
   - Emergency use of Fire extinguishers if warranted
   - Location of where employees should meet outside the building
   - Staff person designated to do head count upon evacuation of the building
2. The organization has a written emergency preparedness plan and has an organized process for handling an off-site emergency, (e.g. snowstorm, flood, etc.) addressing the following:
   - How employees will be notified of emergency
   - Staff responsible for notification and triaging of patient services
   - If product or equipment is necessary for sustaining patient's health or life, emergency services are arranged to ensure continuation of services
   - Contingency plan includes alternative provider in the event that the organization cannot service its own customers
3. The personnel or training records reflect documentation of annual training of staff on emergency preparedness.
4. Fire Safety:
   - Fire extinguisher is mounted and has been checked and approved for use.
   - An in-service for all employees on Fire Safety and how to operate an extinguisher is performed annually and documentation is maintained either in the personnel or training file.
   - All staff has written documentation of attendance at annual Fire Safety in-service.

Specialty Standards
REGULATORY
SECTION 10

REG 3.A The organization shall provide only Drugs/DMEPOS and other items that meet FDA regulations and medical device effectiveness and safety standards.

EVIDENCE OF COMPLIANCE:

1. The organization shall obtain manufacturer copies of the features, warranties, and instructions for each type of non-custom-fabricated item.
2. Organization has a mechanism in place to prevent using drugs/products that are non-adulterated, counterfeit, suspected of being counterfeit and have been obtained by fraud or deceit and to ensure that the drugs/products are not misbranded.
3. All drugs/products are appropriately labeled for their intended distribution channels

REG 3.B The organization files a medical device report with the FDA if an injury occurs while using equipment provided and further medical intervention is required, as applicable.

EVIDENCE OF COMPLIANCE:

1. The organization investigates serious patient incidents within 24 hours and documents.
2. There is further documentation if a Medical Device Report has been sent to the FDA.
3. Appropriate employees are trained on such policies and knowledgeable.

Specialty Standards
REGULATORY
SECTION 10

REG 3.C	**The organization shall comply with all Federal and State regulations related to Hazardous Pharmaceutical Waste.**

EVIDENCE OF COMPLIANCE:

1. There are policy and procedures established that address the Resource Conservation and Recovery Act (RCRA) regulations that establish basic hazardous waste management standards for persons who produce hazardous waste, called hazardous waste generators. These standards are found in title 40 of the Code of Federal Regulations (CFR) in part 262 and at 40 CFR §261.5.
2. There is documentation that staff training on Hazardous Pharmaceutical Waste occurs at least annually.

REG 3.D	**The organization shall comply with USP <800> regarding the handling of Hazardous Drugs in accordance with the State Board(s) of Pharmacy that applies.**

EVIDENCE OF COMPLIANCE:

1. The organization shall perform a risk assessment regarding the use of hazardous drugs. It is documented and includes at a minimum the following:
   a. Identify the drugs on the NIOSH list (www.cdc.gov/niosh) that the pharmacy currently has in inventory or plans on dispensing.
   b. Identify how those drugs are handled.
      - Receipt and storage
      - Compounding
      - Labeling and packaging
      - Dispensing
      - Shipping / delivery
      - Administering
      - Disposal
      - Handling of spills
        (a) Identify the route of exposure e.g. injection, inhalant, eye, skin, ingested etc.
        (b) Identify the employee(s) job functions that are at risk for exposure

2. The organization has written policies and procedures regarding the handling of these drugs.
3. There is documentation that staff training on Hazardous Drugs occurs at least annually.

Specialty Standards
PHARMACEUTICAL MANAGEMENT
SECTION 11

DRG 1.0	**The organization must have pharmaceutical services that meet the needs of the patients.**

EVIDENCE OF COMPLIANCE:

1. The pharmacy has a process in place for interpretation and evaluation of each prescription order.
2. The pharmacy has a process in place for drug product selection, compounding, dispensing, and storage according to drug manufacturer guidelines and Board of Pharmacy requirements.
3. Distribution of drugs and devices are documented appropriately.
4. The Pharmacist has the responsibility and knowledge to advise the prescriber and other health care professionals as to therapeutic actions, utilization and possible adverse reactions and interactions in order to encourage a positive client outcome.
5. The Pharmacist also instructs the client and/or caregiver as to therapeutic actions, utilization and possible adverse reactions and interactions in order to encourage a positive client outcome.
6. The organization has written policies and procedures regarding the receipt, preparation and dispensing of all Medications.
7. The pharmacy has a process for promoting drug adherence thru synchronization of medications if needed by patient population served.
8. Appropriate staff has documented training on the above.
9. Staff is knowledgeable upon interview.

Specialty Standards
PHARMACEUTICAL MANAGEMENT
SECTION 11

DRG 2.0 Pharmacy services are provided by, or under the direction and supervision, of a qualified pharmacist.

EVIDENCE OF COMPLIANCE:

Professional pharmacy service is provided by a licensed pharmacist and includes:

1. There is a process for overseeing the drug control system including:
   - Receipt of prescription drugs and prescription orders
   - Storage of medications
   - Packaging of medications
   - Preparation and dispensing of prescriptions
   - Labeling
   - Preparation of prescriptions for delivery
2. There is a process and documentation of instruction/counseling clients and caregivers regarding specific drug therapy, including possible adverse reactions and/or interactions.
3. There is a process in place for providing information regarding the safe and appropriate use of medications to other health care professionals.
4. Identifying appropriate outcomes of drug therapy.
5. There is a process for consulting on drug therapy and coordinating with other health care professionals.
6. There is a process for monitoring and documenting on-going drug therapy including the assessment of:
   - Therapeutic appropriateness of the choice of drug(s)
   - Therapeutic duplication in the client's drug routine
   - Appropriateness of the dose, frequency and route of administration
   - Adherence to drug regimen
   - Potential drug, food or diagnostic test interactions of disease limitations to drug use
   - Laboratory or clinical monitoring methods to detect drug effectiveness, side effects, toxicity or adverse effects
7. Preparing and maintaining clinical records
8. Prescribing activities consistent with state/federal regulations.
9. Pharmacy technical services are provided by pharmacy technicians who have been trained for all tasks performed in compliance with state law, job description and organizational policy.

Specialty Standards
PHARMACEUTICAL MANAGEMENT
SECTION 11

DRG 3.0 The organization has a licensed Pharmacist in Charge that has the authority and responsibility for the overall management of the pharmacy organization.

EVIDENCE OF COMPLIANCE:

The licensed Pharmacist in Charge is a graduate of a pharmacy program accredited by the American Council of Pharmaceutical Education, or has passed a Foreign Pharmacy Graduate Equivalency Examination, given by the National Association of Boards of Pharmacy, and is currently licensed as a Pharmacist in the state.

A qualified pharmacist with appropriate knowledge, expertise and experience is responsible for the management, direction, coordination and general supervision of all professional services.

The licensed Pharmacist in Charge is responsible for the following areas either directly or by clear delegation:

1. Organizing and directing Pharmacy program operations to assure the availability of services and products provided.
2. Assuring adequate inventory of pharmaceuticals and supplies necessary to compound and dispense prescriptions appropriately, including periodic inspection for outdated products.
3. Assuring all equipment utilized in the delivery of the organization's products and services is properly maintained.
4. Assuring pharmacy services are provided in compliance with applicable laws, regulations, accreditation standards and ethical standards of practice.
5. Assuring adequate and appropriate staffing, including recruitment, orientation, in-service education and completion of annual performance appraisal.
6. Coordinating with other program areas and managers as appropriate, consistent with organizational structure.
7. Assuring the implementation of a pharmacy Quality Improvement program services.
8. Assuring Drug Control system is consistent with policies and regulatory requirements mandated by the DEA and the State.
9. Assuring Drug Dispensing system is consistent with policies and regulatory requirements and in compliance with State Prescription Drug Monitoring (PDM) program as applicable.
10. Assuring there is appropriate pharmacy supervision at all times.
11. Assuring safe and appropriate service policies are developed and implemented.
12. A qualified individual is designated in writing to act in the absence of the licensed Pharmacist in Charge.

Specialty Standards
PHARMACEUTICAL MANAGEMENT
SECTION 11

DRG 4.0 The organization has operational policies and procedures covering the scope of services provided at the pharmacy.

EVIDENCE OF COMPLIANCE:

1. The organization maintains written policies and procedures for the following areas:

- Storage of final pharmaceutical products
- Client/caregiver instruction
- Timely assessment of client eligibility and provision of service
- Delivery of services/products, as appropriate
- Acquisition, storage, disposition & dispensing of controlled substances
- Client identification confirmation
- Prescription labeling
- Materials/Inventory Management
- Dispensing Records
- Clinical competency testing
- Medication Error / Monitoring for Medication Errors
- Drug / Device Recall, FDA or Voluntary by Manufacturer

DRG 5.0 All patients/caregivers are educated on medication indications for use, dosage, administration, frequency side effects, contraindications, storage, requirements, drug interactions, food interactions, long term toxicity, identifying characteristics (oral) and medication adherence factors.

EVIDENCE OF COMPLIANCE:

1. Appropriate staff has documented training on the above.
2. Staff is knowledgeable upon interview.
3. Documentation can be found in the patient medical record.
4. Written information is given to the patient/caregiver.

Specialty Standards
PHARMACEUTICAL MANAGEMENT
SECTION 11

DRG 6.0 A medication record is maintained for all patients.

EVIDENCE OF COMPLIANCE:

1. The organization maintains a medication profile for all patients and is given to patient/caregiver to complete with current meds and over the counter drugs included at initial encounter with the pharmacy.
2. Appropriate staff has documented trained on the above.
3. Staff is knowledgeable upon interview.
4. Documentation can be found in the patient medical record.
5. Adequate and appropriate pharmacy records are maintained:

   a) Drug profiles are maintained for all clients and include the following information:
      - Name, gender, birth date and weight (when appropriate)
      - Address and client identification
      - Allergies or sensitivities
      - Diagnosis, when appropriate
      - Current drug regimen
      - Dosages
      - Relevant clinical information regarding drug therapy
      - Physician name

   b) Dispensing records are maintained for pharmaceuticals which include:
      - Client identification, name and address
      - Name of medication
      - Strength and dosage form
      - Quantity dispensed
      - Physician name
      - Dispensing pharmacist/technician identification
      - Prescription number
      - Date dispensed
      - Directions for use
      - Expiration date
      - Number of refills authorized

Specialty Standards
PHARMACEUTICAL MANAGEMENT
SECTION 11

DRG 7.0	**Adequate shipping containers and shipping processes are used in accordance with regulations and manufacturer guidelines to assure drug stability and potency.**

Evidence of Compliance:

1. The organization documents the Cold Chain process of receipt, stability and potency of the medication products being shipped.
2. Temperature control is maintained according to manufacturer specifications.
3. Shipping containers utilized by the organization assure non-exposure to light and contaminants.
4. Packaging of medications in a tamper evident manner are processed according to organization's policy, applicable regulations and manufacturer guidelines.

Specialty Standards
PHARMACEUTICAL MANAGEMENT
SECTION 11

DRG 8.0 The licensed prescription area of a pharmacy may not be open without a licensed pharmacist on duty at all times.

EVIDENCE OF COMPLIANCE:

1. The pharmacy will remain open while the pharmacist is on break and on the premises in case of emergency.
2. Patient related services may still be delivered during this time period such as:
   - Receipt of new prescriptions
   - Preparation of prescriptions waiting for verification by the pharmacist
   - Delivery of prescriptions to patients that have already been checked and verified by the Pharmacist
3. Pharmacies located within retail establishments whose business hours differ, shall adhere to the following standards:
   - The pharmacy can be securely sealed off from the remainder of the retail establishment
   - The barrier devices which seal off the pharmacy must be capable of providing security for the pharmacy
   - The barrier devices must reach from floor to ceiling, shall be impenetrable by hand, or the use of a reach extender, and be securely locked whenever a licensed pharmacist is not present and on the premises

DRG 9.0 A pharmacy shall maintain a supply of drugs and devices adequate to meet the needs of the health professions and the patients it is intended to serve.

EVIDENCE OF COMPLIANCE:

1. The pharmacy maintains agreements with licensed wholesalers or manufacturers to obtain drugs devices and equipment for inventory purposes.
2. The pharmacy inventory of non-proprietary drugs is maintained at required state board of pharmacy minimum levels (if applicable).

Sub-Specialty Standards
NON-STERILE COMPOUNDING
SECTION 12

NSC 1.0 The Pharmacy that compounds non-sterile preparations maintains an environment that provides for an area that allows minimal interruptions and any potential for contamination of the compounded preparation.

EVIDENCE OF COMPLIANCE:

1. Non-sterile compounding area meets current USP <795> standards.
2. The pharmacy has policies and procedures for the cleaning and maintaining of equipment. There are documented records to demonstrate compliance.
3. There are written procedures and documentation that demonstrates surfaces and equipment are cleaned and/or sanitized before and after each compounding preparation

NSC 2.0 The Pharmacy that compounds non-sterile preparations meets the official compendial standards, including current USP-NF Standards and has a certificate of analysis that documents the strength, quality, purity and integrity of the drug substance.

EVIDENCE OF COMPLIANCE:

1. There are policies and procedures demonstrating the acquisition of all chemicals, components and drug products from reputable sources.
2. The pharmacy documents the source of all bulk chemicals used in compounding non-sterile preparations.

Sub-Specialty Standards
NON-STERILE COMPOUNDING
SECTION 12

NSC 3.0 The Pharmacy that compounds non-sterile preparations maintains records that assure the strength, quality, purity, integrity of the compounded preparation.

EVIDENCE OF COMPLIANCE:

1. The pharmacy maintains records that document all aspects of the compounded preparation. There shall be evidence of a Master Formulation Record for all compounded products.
2. The name, strength and dosage form of all compounded preparations is documented and recorded.
3. There are written policies / procedures that provide for the determination and assignment of Beyond Use Dating (BUD) for all compounded preparations.

NSC 4.0 The Pharmacy that compounds non-sterile preparations will adhere to all State, Federal and Compendial requirements related to packaging, labeling, dispensing for administration of preparations.

EVIDENCE OF COMPLIANCE:

1. Documentation records demonstrate that the pharmacy complies with State, Federal and Compendial dispensing requirements.
2. Staff interviews will show knowledge required to demonstrate evidence of compliance.

Sub-Specialty Standards
SPECIALTY PHARMACY

SECTION 13

SP 1.0 The specialty pharmacy offers services that support and assist patients with availability and access to high cost medications.

EVIDENCE OF COMPLIANCE:

1. The organization has comprehensive reimbursement services.
2. The organization provides access to therapy through co-pay foundations, patient assistance programs and/or other local sources.
3. The organization provides comprehensive coordination with patients, physicians, hospitals and payer networks.
4. The organization assists with patient registration for special protocols with manufacturer assistance programs.

SP 2.0 The specialty pharmacy will assure that patients are following medication instructions and management of any potential side-effects.

EVIDENCE OF COMPLIANCE:

1. The organization maintains availability 24 hours a day, seven days a week to assist patients.
2. The organization educates and manages patients on the therapy protocols that will be instituted.
3. The organization has written policies and procedures in place identifying how often patients receive follow-up. (Patients receiving infusion or specialty medications should receive a follow-up call at a minimum of 72 hours after initial treatment)
4. Appropriate staff is trained in the above and it is recorded in their training records.
5. Staff is knowledgeable upon interview.
6. Documentation can be found in the patient medical record.
7. The pharmacy establishes and maintains regular contact between patients and their health care providers.
8. The organization has written policies and procedures in place addressing reporting and outcomes.
9. Appropriate staff is trained and knowledgeable upon interview.

Sub-Specialty Standards
SPECIALTY PHARMACY
SECTION 13

SP 3.0	**The specialty pharmacy will assure that coordination of care for patient services are met with other health care professionals and entities.**

EVIDENCE OF COMPLIANCE:

Care coordination shall include the following at a minimum:

1. Development of a plan of care according to:
    - Drug manufacturer clinical protocols
    - Establishment of therapy specific goals
    - Determination of expected outcomes
    - Determination of educational needs to patient/caregivers
    - Establishment of a monitoring plan
    - Ongoing evaluation and documentation
2. Documented verbal, telephonic or electronic communication with other health care professionals related to:
    - Medication(s) prescribed and dispensed
    - Precautionary information such as side effects, adverse reactions
    - Identifying and communicating the responsibilities of care amongst all service providers

SP 4.0	**The organization follows the drug protocol for data reporting according to drug manufacturers, payors and referral sources as applicable**

EVIDENCE OF COMPLIANCE:

The high cost of Specialty Drugs requires programs that may encompass documentation and reporting of the following:

1. Patient adherence to prescribed medications (e.g., Medication Possession Ratio reporting)
2. Evidence based patient outcome information.
3. Programs that measure performance and effectiveness for the specific populations for:
    - Clinical processes and/or outcomes based upon established objectives
    - Compares performance data to program outcomes goals
    - Documents and measures patient program results in order to determine overall program effectiveness
4. The results of these programs are monitored via the organization's Quality Improvement process.
5. The organization has written policies and procedures in place addressing reporting and outcomes.
6. Appropriate staff is trained and upon interview can address the program.

Sub-Specialty Standards
SPECIALTY PHARMACY
SECTION 13

SP 5.0	**The specialty pharmacy assures coordination, packaging and tracking of all medications to patient home or other facilities that provide care.**

EVIDENCE OF COMPLIANCE:

1. The organization documents the Cold Chain process of receipt, stability and potency of the medication products being shipped.
2. The organization has a mechanism in place to handle and rectify a lost or delayed shipment, arranging for an alternate source of medication supply to assure no disruption in therapy.
3. The pharmacy maintains packaging controls for temperature and, when required, refrigeration for medications.
4. The pharmacy has a process to assure a shipment or delivery is received by patient and/or caregiver and not left unattended.
6. Appropriate staff is trained and upon interview can address the program.

Sub-Specialty Standards
LONG TERM CARE PHARMACY
SECTION 14

LTC 1.0 There are written policies / procedures for patients / residents that reside in assisted living, residential care, adult foster, community-based and nursing homes who receive medications related to delivery, storage, access, records and information.

EVIDENCE OF COMPLIANCE:

1. The organization has policies cover the following:
   - Prescriber medication orders
   - Use of Medication Administration Records (MARS)
   - Non-prescription (over the counter) medications
   - Controlled substances
   - Medication labeling
   - Patient / resident counseling and education
   - Pharmacy hours and delivery schedule
   - Emergency Pharmacy services
   - Consultant Pharmacy Services (if applicable)
   - Medication product recalls
2. Staff had documented training regarding above policies.
3. Staff is knowledgeable upon interview.

LTC 2.0 There are written policies / procedures that address verbal, electronic and faxed medication orders by physicians identifying which personnel are authorized to accept such medication orders according to State Board of Pharmacy, State and Federal regulation.

EVIDENCE OF COMPLIANCE:

1. The organization has written policies and procedures that address verbal, electronic and faxed medication orders as above.
2. Staff is knowledgeable upon interview.

Specialty Standards
LONG TERM CARE PHARMACY
SECTION 14

LTC 3.0 There are written policies / procedures that address the storage of medication, specialized medication packaging and the use of medication reminder/ adherence devices.

EVIDENCE OF COMPLIANCE:

1. The organization has written policies and procedures that include:
   - Those patients / residents who self-administer their medications
   - Those patients / residents who utilize medication reminder/ adherence devices are labeled in accordance with applicable federal, state regulations and laws.
   - Those patients / residents receiving medications packaged in "Blister Packs" or "Bingo Cards" that contain a 30/31 day supply or 30/31 doses of medication.
2. Applicable staff are trained and it is documented in their personnel/training file.
3. The staff is knowledgeable and follows manufacturer guidelines for storage and packaging of drugs.

LTC 4.0 There are written policies and procedures that address the proper disposal of medications and medication related equipment in a Long Term Care facility.

EVIDENCE OF COMPLIANCE:

1. The organization has written policies and procedures addressing the proper disposal of medications, and medication related equipment, in a Long Term Care facility.
2. Disposal of medications will adhere to State Board of Pharmacy, State and Federal regulations.

LTC 5.0 There are written policies and procedures that address the use and role of a Consultant Pharmacist (if applicable) in a Long Term Care facility.

EVIDENCE OF COMPLIANCE:

1. The organization has written polices and procedure addressing the use and role of a Consultant Pharmacist in a Long Term Care Facility.
2. A written agreement/job description outlines what duties and reviews the Consultant Pharmacist will perform at the facility.
3. The organization has a process for scheduling of visits to the facility.

Sub-Specialty Standards
INFUSION THERAPY
SECTION 15

IT 1.0 The organization has a mechanism for assessing knowledge and skill level of infusion procedures and medication administration.

EVIDENCE OF COMPLIANCE:

1. The organization has written documentation of skill level and competency for all care delivery procedures and medication administration (i.e., written tests, supervised return demonstrations of care procedures).
2. Evidence of annual updates of new medications/procedures exists.

IT 2.0 The organization collects data and monitors for trends in the following areas:

- **Medication error and adverse reactions**
- **Patient incidents unrelated to medication errors**
- **Patient infections that occurred during the length of service**

EVIDENCE OF COMPLIANCE:

1. Measurement is collected and submitted monthly on all of the above.
2. The organization has a mechanism in place to coordinate and monitor the above measurements, either by an incident committee, Quality Improvement director, or management designee.

IT 3.0 The organization has written policies/protocols for the handling, clean up, and disposal of hazardous pharmaceutical and chemical waste.

EVIDENCE OF COMPLIANCE:

1. The organization has written policies and procedures in place.
2. Appropriate staff have documented trained in the above.
3. Staff is knowledgeable upon interview.
4. Hazardous waste spill kit must be available in appropriate areas.

Sub-Specialty Standards
INFUSION THERAPY
SECTION 15

IT 4.0	**The organization stores equipment appropriately and has areas of the warehouse/storage designated for and labeled:** *** Dirty/contaminated** *** Cleaning** *** Testing and repair** *** Clean/Patient ready**

EVIDENCE OF COMPLIANCE:

INFUSION PUMPS /ENTERAL PRODUCTS/SUPPLIES:

1. All items containing expiration dates should be checked, rotated and destroyed according to manufacturer guidelines.
2. Nutritional products should be protected from contamination and spoilage. Appropriate lighting, temperature control and humidity should be used to prevent potential mold growth. Temperature log is maintained for any area that stores products requiring climate control (e.g., refrigerators, special storage areas, etc.).
3. Pumps must be stored according to manufacturer guidelines.

IT 5.0	**All equipment is tested and/or working order assessed prior to patient use.**

EVIDENCE OF COMPLIANCE:

ELECTRICAL:

1. Organization has written policy regarding the testing of equipment.
2. Documentation of testing exists in the form of log, checklist, electronic, etc.
3. Manufacturer's operating manual and testing requirements are available to reference.
4. Staff members are trained on testing and it is documented.

NON-ELECTRICAL:

1. Organization has a written policy regarding checking for working order of equipment.
2. All parts are present, wheels, castors, etc.
3. Manufacturer operating instructions are available.
4. Staff members are trained on testing and it is documented in personnel or training file.

Sub-Specialty Standards
INFUSION THERAPY
SECTION 15

IT 6.0 All equipment maintenance/repairs are performed and documented by the organization or by contracted vendor.

EVIDENCE OF COMPLIANCE:

1. Manufacturer guidelines and operating manuals are available.
2. Organization has a process for the documentation of problem, type of maintenance/repair; parts needed and repair technician's initials.
3. If repairs are done by an outside service, a report accompanies the equipment upon return.
4. Written or computerized list exists of all repairs and maintenance performed by manufacturer, model and serial number.
5. When needed, loaner or replacement equipment is provided to the patient while equipment is being repaired.

IT 7.0 Preventive maintenance is performed according to manufacturer guidelines.

EVIDENCE OF COMPLIANCE:

1. Manufacturer guidelines are available in file.
2. Preventive Maintenance due date is located on device.
3. Process exists for tracking due dates.
4. All preventive maintenance performed is documented (even if performed by an outside vendor).

IT 8.0 While transporting equipment the organization has processes in place that address safety and proper infection control.

EVIDENCE OF COMPLIANCE:

1. Company vehicle has designated clean and dirty areas.
2. All equipment is bagged.
3. There is a process for identifying clean from dirty equipment. (e.g., tag or label)
4. Equipment is secured in vehicle to prevent movement during transport.
5. Ensure surface is non-porous and has the capability to be cleaned and disinfected.
6. If transportation occurs in a personal vehicle, products must be separated from personal belongings.
7. Vehicle must have on board a first aid kit, infection control kit and if curbside cleaning have eye wash.

Sub-Specialty Standards
INFUSION THERAPY
SECTION 15

IT 9.0 **The organization performs a patient assessment that includes the following:**

* Physical status	* Home environment
* Psychosocial	* Proper site selection
* Nutritional	* Equipment/device selection
* Caregiver Support	* Patient/Caregiver learning ability
* Medications	* Need for community resources
* ADL	* Potential safety risks
	* Height & Weight when applicable

EVIDENCE OF COMPLIANCE:

1. The organization has written policies and procedures in place.
2. Appropriate staff have documented trained in the above.
3. Staff is knowledgeable upon interview.
4. Documentation can be found in the patient medical record.

IT 10.0 **The organization has a process for follow-up that is related to the type of equipment provided and patient's condition.**

EVIDENCE OF COMPLIANCE:

1. The organization has an organized process in place for the equipment related follow-up of their patients either by phone or visit. This can be incorporated into the time of survey if done by phone.
2. Upon delivery of product or equipment the patient/caregiver is made aware of the follow-up policy and is documented on the patient instruction checklist.
3. Documentation of equipment related follow-up is found in the patient record. Injuries, accidents, signs & symptoms of infection, hospitalization will be documented on Follow-Up form when known by the provider.
4. As appropriate, the patient's record is reviewed to incorporate any necessary changes in conjunction with the prescribing physician.

NOTE: FDA category II or III equipment (e.g., nebulizer, infusion pump, enteral pump, etc.), is followed-up within 72 hours of initial set-up, and then on an as needed basis either by patient, or as regulations require.

Sub-Specialty Standards
INFUSION THERAPY
SECTION 15

IT 11.0	**The organization has a policy regarding the pick-up of equipment insuring proper infection control methods are followed; equipment is picked up in an efficient manner and that billing is stopped according to the date the patient discontinued use.**

EVIDENCE OF COMPLIANCE:

1. The organization has a written policy and procedure.
2. A document specifying the stop date is utilized (if different from pick-up date). Billing should stop according to stop date.
3. A copy of the pick-up document (including product and serial number and stop billing date information) is given to the patient and the original placed in the patient's file.
4. The billing records should reflect the stop date.
5. Equipment should be handled as dirty equipment and placed in the dirty area of the vehicle.

IT 12.0	**The organization has policies and procedures regarding the need for utilization of informed consent when applicable.**

EVIDENCE OF COMPLIANCE:

1. The organization has written policies and procedures in place.
2. Appropriate staff is trained in the above and it is recorded in their training records.
3. Written information is given to the patient/caregiver.
4. Staff is knowledgeable upon interview.
5. Documentation can be found in the patient medical record.

Sub-Specialty Standards
INFUSION THERAPY
SECTION 15

IT 13.0 The organization has written policies and procedures, or clinical protocols, regarding proper site selection for all types of infusion therapy.

EVIDENCE OF COMPLIANCE:

1. The organization has written policies and procedures in place.
2. Appropriate staff has documented training in the above.
3. Staff is knowledgeable upon interview.
4. Documentation can be found in the patient's medical record.

IT 14.0 The organization has written policies and procedures, or clinical protocols, for follow-up, monitoring and maintenance, and care of the infusion site.

EVIDENCE OF COMPLIANCE:

1. The organization has written policies and procedures in place.
2. Appropriate staff has documented training in the above.
3. Staff is knowledgeable upon interview.

IT 15.0 The organization has a process for assessing the patient home for safety hazards as it relates to the type of care/service provided.

EVIDENCE OF COMPLIANCE:

1. The organization has a mechanism in place to comply.
2. Safety factors and hazards are reviewed with the patient/caregiver at the time of service/delivery and are documented on the Plan of Care.
3. Delivery/service staff is trained on patient safety and safety in the patient home as it relates to the care/service provided.
4. Written information is given to the patient/caregiver.
5. Staff is knowledgeable upon interview.
6. Documentation can be found in the patient medical record.

Sub-Specialty Standards
INFUSION THERAPY
SECTION 15

IT 16.0	**All patients/caregivers receiving infusion therapy are, at a minimum, educated on the following:** *** Care of the IV site and dressing changes** *** Treatment duration and expectations of outcome** *** Prevention of complications** *** Medications /enteral/parenteral nutrients preparation** *** Follow-up care** *** Potential safety risks and adverse drug reactions**

EVIDENCE OF COMPLIANCE:

1. The organization has a mechanism in place to comply.
2. Delivery/service staff are trained on patient safety and safety in the patient home as it relates to the care/service provided.
3. Written information is given to the patient/caregiver (including use and operation of equipment (written copy must be provided or a pictorial may be provided if it better meets the patient needs), maintenance, troubleshooting and cleaning of equipment, infection control tips (if appropriate), and goals to be achieved with use of product/equipment. Documentation can be found in the patient medical record.
4. Return demonstration, by the patient or caregiver, is necessary during instruction and documented.
5. All applicable staff is trained in patient instruction upon hire, annually, and when new service/products added.
6. All staff have documented training in their personnel record.
7. The organization provides the patient with information regarding expected time frames for delivered items.
8. The organization verifies that the patient has received equipment, items and services.

Sub-Specialty Standards
INFUSION THERAPY
SECTION 15

IT 17.0 The organization has a policy regarding the removal of the infusion catheter and/or equipment insuring proper infection control methods are followed, equipment is picked up in an efficient manner, and billing is stopped according to the date the treatments were discontinued.

EVIDENCE OF COMPLIANCE:

1. The organization has written policies and procedures/protocols to follow.
2. A pick-up form is utilized specifying the stop date (if different from pick-up date). Billing should stop according to stop date.
3. A copy of the pick-up form is given to the patient and the original placed in the patient file.
4. Billing records reflect the stop date.
5. Equipment is handled as dirty equipment and placed in the dirty area of the vehicle.
6. All care/service staff are trained and is knowledgeable.
7. Documentation can be found in the patient medical record.

IT 18.0 Drug products are delivered in appropriate packaging to ensure that labeled storage requirements are met during transit.

EVIDENCE OF COMPLIANCE:

1. The organization has written policies and procedures in place.
2. Appropriate staff has documented training on the above.
3. Staff is knowledgeable upon interview.
4. Delivery services are provided directly, or by arrangement, in compliance with laws and regulations to include:
    - Safe and clean transport of pharmaceuticals and supplies to and from client homes/designated sites
    - Timely delivery / shipment of pharmaceuticals and supplies, ability to track medication shipments, ability to notify patients of any delays
    - Record keeping
5. The organization has a process in place for assuring the availability of drug and supplies to clients in their designated sites not available from the organization or if shipment is lost or destroyed.

Sub-Specialty Standards
INFUSION THERAPY
SECTION 15

IT 19.0	**The organization's clinical staff must develop policies and procedures to minimize drug errors and to actively identify potential and actual adverse drug events.**

EVIDENCE OF COMPLIANCE:

1. The clinical staff is responsible for developing policies and procedures that minimize drug errors. The development of policies and procedures to minimize medication errors is based on:
   - Accepted professional principles
   - Development of the organization's formulary
   - External alerts
   - Proactive review of organization's reported and reviewed adverse drug events, including new types of mistakes, and continually improve and refine things, based on what we did wrong

2. Policies and procedures to minimize drug errors include:
   - High-alert medications - dosing limits, administration guidelines, packaging, labeling and storage
   - Limiting the variety of medication-related devices and equipment (*Note: For example; limit the types of general-purpose infusion pumps to one or two)*
   - Availability of up-to-date medication information
   - All elements of the order – dose, strength, units (metric), route, frequency, and rate
   - Alert systems for look-like and sound-alike drug names
   - A voluntary, non-punitive, reporting system to monitor and report adverse drug events (including medication errors and adverse drug reactions)
   - The preparation, distribution, administration and proper disposal of hazardous medications

Sub-Specialty Standards
INFUSION THERAPY
SECTION 15

IT 20.0	**If patient is prescribed medications that warrant specific environmental conditions, patient home is evaluated for appropriateness.**

EVIDENCE OF COMPLIANCE:

1. Appropriate staff have documented training in the above.
2. Staff is knowledgeable upon interview.
3. Documentation can be found in the patient medical record.
4. Written information is given to the patient/caregiver.

IT 21.0	**The organization files a medical device report, with the FDA, if an injury occurs while using equipment provided, and further medical intervention is required.**

EVIDENCE OF COMPLIANCE FOR ALL PRODUCT LINES:

1. The organization investigates serious patient incidents within 24 hours and documents.
2. There is further documentation if a Medical Device Report has been sent to the FDA.
3. Appropriate employees are trained and knowledgeable on related policies.

Sub-Specialty Standards
CHEMOTHERAPY
SECTION 15.1

CHEM 1.0	**The organization has qualified personnel mixing and administering chemotherapy agents.**

EVIDENCE OF COMPLIANCE:

1. The organization has written policies and procedures in place.
2. Appropriate staff has documented training on the above.
3. Staff is knowledgeable upon interview.
4. Documentation of administered chemotherapy agents can be found in the patient medical record.

CHEM 2.0	**The organization has written policies and procedures outlining the preparation and mixture of chemotherapy agents.**

EVIDENCE OF COMPLIANCE:

1. The organization has written policies and procedures in place; at a minimum for the following:
   a. Use of Class 11 or 111 Biological Safety Cabinet (BSC) or Compounding Aseptic Containment Isolator (CACI) for sterile preparations.
   b. The appropriate Personnel Protective Equipment (PPE) inclusive of gloves, gowns, sleeve covers, head/hair cover, shoe cover and eye/face as required for preparation or cleaning.
   c. Spill control of chemotherapeutic agents.
2. Appropriate staff has documented training on the above.
3. Staff is knowledgeable upon interview.
4. Documentation of prepared chemotherapy agents can be found in the patient medical record.

Sub-Specialty Standards
CHEMOTHERAPY
SECTION 15.1

CHEM 3.0	**The organization has written policies and procedures regarding the administration of chemotherapy agents.**

EVIDENCE OF COMPLIANCE:

1. The organization has written policies and procedures in place.
2. Appropriate staff has documented training on the above.
3. Staff is knowledgeable upon interview.
4. Documentation of administered chemotherapy agents can be found in the patient medical record.

CHEM 4.0	**The patient/caregiver is educated on the following:** • **Treatment benefits and risks** • **Duration** • **Side effects** • **Adverse reactions and how to prevent and /or treat** • **Handling and disposal of drug, supplies and linens** • **Potential risk for bleeding**

EVIDENCE OF COMPLIANCE:

1. The organization has written policies and procedures in place.
2. Appropriate staff has documented training on the above.
3. Staff is knowledgeable upon interview.
4. Written information and hazardous waste spill kit are given to the patient/caregiver.
5. Documentation can be found in the patient medical record.

Sub-Specialty Standards
CHEMOTHERAPY
SECTION 15.1

CHEM 5.0 The organization has an organized process for proper disposal of Drugs, Blood, Blood products and Chemotherapy agents, which includes all equipment, dressings, containers, devices are placed in a bag marked "Biohazard" and placed in transport container.

EVIDENCE OF COMPLIANCE:

1. The organization has written policies and procedures in place specific to product disposal.
2. Appropriate staff has documented training on the above.
3. Written information is given to the patient/caregiver.
4. Staff is knowledgeable upon interview.

Sub-Specialty Standards
NUTRITIONAL SUPPORT SERVICES
SECTION 15.2

NUT 1.0	**Enteral or parenteral products are selected and evaluated according to indications, contraindications for use, and appropriateness to the individual patient.**

EVIDENCE OF COMPLIANCE:

1. The organization has a mechanism in place to comply.
2. Appropriate staff has documented training on the above.
3. Staff is knowledgeable upon interview.

NUT 2.0	**The organization has protocols for handling, labeling, and dispensing PPN and TPN solutions.**

EVIDENCE OF COMPLIANCE:

1. The organization has written policies and procedures in place.
2. Appropriate staff has documented training on the above.
3. Staff is knowledgeable upon interview.

Sub-Specialty Standards
NUTRITIONAL SUPPORT SERVICES
SECTION 15.2

NUT 3.0 **Patient assessment & reassessment is specific to the patient's nutritional needs including:**

- **Physical assessment**
- **Dietary history**
- **Lab analysis**
- **Height, weight and percentage of body fat and lean muscle**
- **Intake requirements**

EVIDENCE OF COMPLIANCE:

1. The organization has written policies and procedures in place.
2. Appropriate staff has documented training on the above.
3. Staff is knowledgeable upon interview.
4. Documentation can be found in the patient medical record.

NUT 4.0 **The PPN and TPN solutions are prepared in a pharmacy, under a laminar flow hood, using strict aseptic technique adhering to <USP 797> guidelines.**

EVIDENCE OF COMPLIANCE:

1. The organization has written policies and procedures in place.
2. Appropriate staff has documented training on the above.
3. Staff is knowledgeable upon interview.

Sub-Specialty Standards
STERILE COMPOUNDING
SECTION 16

SC 1.0	**The organization is in compliance with the "USP 797" standards as it relates to use of medical equipment and pharmacy management. "USP 797 Standards," as mandated, by individual states, in addition to any other state requirements. The compounding pharmacy shall comply, and meet any and all additional state requirements.**

EVIDENCE OF COMPLIANCE:

SC 1.0 A Facilities and Equipment

1. The organization has written policies and procedures addressing the use of Primary Engineering Controls (PEC's) that provides an ISO Class 5 environment for compounding CSP's (Compounded Sterile Products). These may include:
    a. Laminar Flow Workbenches (LAFW's)
    b. Biological Safety Cabinets (BSC)
    c. Compounding Aseptic Isolators (CAI)
    d. Compounding Aseptic Containment Isolators (CACI).
2. The organization has written policies and procedures addressing the physical layout of the sterile compounding area that meet <USP797> current standard inclusive of adequate ventilation, ante and buffer areas.
3. The organization has policies and procedures in place for cleaning and disinfecting the compounding area, as appropriate to the function of each area. Proper documentation of adherence to Environmental Housekeeping Schedule exists.
4. There shall be policies and procedures addressing environmental monitoring and documentation to ensure adequate environmental and personnel controls are in place to prevent contamination of CSP's. Temperature, Pressure differential or velocity across line of demarcation, surface sampling and electronic device sampling of viable particles should be addressed at a minimum.

SC 1.0 B Compounded Sterile Products (CSP's) Preparation and Handling

1. There are policies and procedures addressing the Beyond Use Date (BUD) of all CSP's.
2. The organization has policies and procedures for handling of exposure to hazardous drugs as contaminated compounded sterile products or CSPs.
3. There are guidelines in place for determining specific compounding risk levels of all CSP's
4. There is a process for verification of compounding accuracy and sterility.

Sub-Specialty Standards
STERILE COMPOUNDING
SECTION 16

SC 1.0 C Personnel and Training

1. There is documented evidence of annual personnel training regarding sterile compounding policies and procedures.
2. Annual competency evaluations are performed and documented for applicable personnel.

Sub-Specialty Standards
Patient Centered Pharmacy Home ™
SECTION 17

PCPH 1.0 The Pharmacy provides increased access to its patients.

EVIDENCE OF COMPLIANCE:

1. The Pharmacy offers patient appointments for counseling and medication management sessions for patients with complex care needs.
2. Stakeholders in the community are made aware of additional services and hours of availability.
3. Pharmacy website offers refills, transfers and educational information.
4. Communication with the Pharmacy is available via telephone, walk-in and the website.

PCPH 2.0 Patient assessment is provided for patients in need of complex management of their medications.

EVIDENCE OF COMPLIANCE:

1. The assessment includes an accurate list of current medications, supplements and OTC drugs being taken and pharmacies presently utilized.
2. Any known allergies are discussed and documented.
3. Medication reconciliation is performed.

Sub-Specialty Standards
Patient Centered Pharmacy Home ™
SECTION 17

PCPH 3.0 The Pharmacy creates a pharmaceutical care plan for high-risk patients.

EVIDENCE OF COMPLIANCE:

1. The Pharmacy determines criteria for identifying patients in need of a care plan.
2. A copy of the care plan is sent to the primary care provider, as well as other notable prescribers e.g. for Specialty Drug
3. The plan is discussed and reviewed with the patient and caregiver. A copy is given to the Patient as well as documented in the patient file.
4. The staff is trained on the use of the care plan.

PCPH 4.0 The Pharmacy has a process in place to improve adherence of patients that are high risk.

EVIDENCE OF COMPLIANCE:

1. The Pharmacy have the ability to provide synchronization of refills for patients that take multiple medications if requested.
2. The Pharmacy has a process for refill reminders, as well as available follow up appointment if needed.

Sub-Specialty Standards
Patient Centered Pharmacy Home ™
SECTION 17

PCPH 5.0 The Pharmacy implements care coordination activities among specified high risk patients.

EVIDENCE OF COMPLIANCE:

1. The Pharmacy communicates with the primary prescriber if timely patient refills are not utilized.
2. Medication reconciliation is shared with the primary prescriber.
3. Medication therapy management counseling progress is documented and summary is sent to the primary prescriber.
4. If another pharmacy is involved in care of patient, that pharmacy is notified when appropriate.

PCPH 6.0 The Pharmacy has agreements with other providers to promote better continuity of care, and meet the needs of their patients, relating to enhanced medication management.

EVIDENCE OF COMPLIANCE:

1. The organization must have a written agreement that identifies the Pharmacy's responsibilities for handling patients that are under the care of the primary care provider/prescriber.
2. Scope of services are identified in contract such as:
    a) Immunizations
    b) MTM
    c) Medication adherence
    d) RX Care Planning

Sub-Specialty Standards
Patient Centered Pharmacy Home ™
SECTION 17

PCPH 7.0 The Pharmacy has a plan for improving Rx care management.

Evidence of Compliance:

1. The Pharmacy implements interventions to reduce medication adverse events.

2. The Pharmacy establishes and documents the following medication management initiatives, oriented toward improving efficiency in the delivery of care and reducing costs:
   - Generic medication utilization
   - Reducing avoidable ER visits
   - Reducing hospital readmissions

PCPH 8.0 The Pharmacy has a staff member that functions as the Rx Care Coordinator.

Evidence of Compliance:

1. The Pharmacy has one or more designated staff members providing Care Coordination interdependently with PCMH providers, other healthcare professionals, and other pharmacy services provided externally.

2. The Rx Care Coordinator follows a written protocol which includes:

   a. Utilizing a process to improve the care of high-risk or special needs patients, in need of better medication management, through counseling by appointment.

   b. Utilizing written protocols outlining the referral process and admission/discharge notifications with hospitals.

   c. Providing a transitional Rx care plan for patients transferring from acute care setting back to home or other post-acute setting. This includes the following:

      - Patients' medication history, adherence, and any involvement with medication therapy management.

Sub-Specialty Standards
TelePharmacy
SECTION 18

TeleRX 1.0	**The remote dispensing TelePharmacy site shall be licensed according to the individual state board of pharmacy regulations.**

Evidence of Compliance:

1. The remote TelePharmacy site is staffed by one or more pharmacy technicians as defined by the state board of pharmacy regulations.
2. The remote TelePharmacy site may not be open, unless a Pharmacist is present at the supervising pharmacy. Employees are not allowed access when the supervising pharmacy is closed. If internet connectivity between the central site and remote site is non-operational, then the remote site must be closed.
3. The Pharmacist in Charge of the supervising pharmacy shall be responsible for all operations.
4. The remote TelePharmacy site shall comply with all appropriate federal and state controlled substance regulations if controlled substances are maintained.
5. An organizational chart describing the responsibilities of the remote site staff and central pharmacy shall be present at both sites.
6. All personnel shall be trained on the responsibilities.

Sub-Specialty Standards
TelePharmacy
SECTION 18

TeleRX 2.0	**The organization shall establish written policies and procedures related to the delivery of TelePharmacy services.**

Evidence of Compliance:

1. The Supervising Pharmacist at the central pharmacy shall have the responsibility for documenting the prescriptions filled and patient counseling at the remote pharmacy.
2. There shall be documented regular visits, at least monthly or defined by state board of pharmacy regulations, to the remote TelePharmacy site by the Supervising Pharmacist to review all processes.
3. There shall be documented ongoing review of incident reports and outcomes related to the delivery of TelePharmacy services.
4. All personnel shall be trained and documented on the policies and procedures.

TeleRX 3.0	**The remote TelePharmacy and supervising pharmacy must utilize common electronic technology that confirms the prescription intake, fill and patient counseling process is documented.**

Evidence of Compliance:

1. Electronic records must be available at both the supervising pharmacy and remote pharmacy site.
2. Labeling of prescriptions at the remote site must be unique and identifiable from that of the supervising pharmacy.
3. The common electronic technology shall assure HIPAA compliance with all communications between the remote site and supervising site.
4. The remote TelePharmacy site shall maintain and retain a recording of facility surveillance, excluding direct patient communications.

Sub-Specialty Standards
TelePharmacy
SECTION 18

TeleRX 4.0	**The remote TelePharmacy site that is located in a Rural Hospital, Rural Clinic or Store front location shall have posted signage identifying it appropriately.**

Evidence of Compliance:

1. Posted signage shall identify that this is a remote pharmacy site.
2. Posted signage shall identify the location and phone number of the supervising pharmacy.
3. Posted signage shall inform the patient that a Pharmacist will counsel the patient using an audio and video communication system.