
# Exemplary Provider®
# Accreditation Program

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## QUALITY STANDARDS AND EVIDENCE OF COMPLIANCE

# DMEPOS

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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 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 have 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.

# 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 annual training in personnel or training files.
3. Employees agree to abide by the Standards of Conduct and documentation (signed/dated copy) 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…")
- Organization's availability is related to type of equipment provided. (All businesses providing NPWT, Respiratory Equipment, including nebulizers, oxygen or other type of supplies or equipment necessary to the patient's wellbeing 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. 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.

**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 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 or will not fulfill the order, the organization will contact the prescribing physician at a minimum within a 5-day period.
5. Organization maintains ordering and referring documentation consistent with Medicare requirements.

**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
# 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.
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 deliver 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., 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
   - 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 products/services (if applicable)
    - Goals for improving patient outcomes (e.g., patient satisfaction, and equipment failure 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 within 72 hours of delivery of service.
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
   - Equipment breakdown or manufacture defects (if applicable)
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. Incidents are documented on a specific Incident form and include adverse events due to inadequate or malfunctioning equipment, items or services. (e.g., injuries, accidents, infections, hospitalizations).
2. 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.
3. Employees are knowledgeable of process.
4. 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 FOR ALL PRODUCT LINES:

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

**EQP 2.0 The organization stores equipment appropriately and has areas of the warehouse/storage designated and labeled for: "Dirty/Contaminated" "Testing and Repair" "Cleaning Area" "Clean/Patient Ready"**

### EVIDENCE OF COMPLIANCE FOR ALL PRODUCT LINES:

1. The organization needs a written Equipment Management policy and procedures that addresses the equipment provided and follows manufacturer guidelines.
2. Clean equipment is segregated from dirty equipment.
3. Equipment should be stored on palettes, shelves, boxes and off the floor (legs and wheels of equipment may touch the floor as long as the seat or area exposed to patient is covered).
4. Like equipment is stored together.
5. Accessories are grouped together and labeled.
6. Defective and obsolete equipment is grouped together and labeled.
7. Appropriate signage is utilized.
8. If cleaning is contracted out, agreement must state that the cleaner used kills HIV, TB and Hep B, and that the Quality Standards must be followed.

# Specialty Standards
# EQUIPMENT MANAGEMENT
# SECTION 7

## SPECIALTY EVIDENCE OF COMPLIANCE:

### ORTHOPEDIC

1. Soft goods are wrapped in plastic or bagged and stored together.

### WOUND CARE/SUPPORT SURFACES

2. The pressure mattress is rolled up and placed in a clean mattress bag and controller bagged separate.
3. If a State Bedding law exists, state parameters must be followed including documentation to support compliance.

### SUPPLIES /ENTERAL

1. All items with expiration dates should be checked, rotated and destroyed, according to manufacturer guidelines.
2. Nutritional products should be protected from contamination and spoilage, and stored according to manufacturer guidelines. Appropriate lighting, temperature control and humidity should be used to prevent potential mold growth.
3. If temperature control is required, there must be appropriate parameters in place to monitor the environment in which the products are stored (e.g., temperature log is necessary if storage area is not climate controlled as in a LTC facility).

### RESPIRATORY

1. Full tanks are separate from empty or partially full. There is a method to identify and separate quarantined tanks.
2. Storage & trans-filling areas are labeled.
3. Tanks are grouped by size and type of gas, and are stored in a well-ventilated area.
4. Containers are kept away from heat ducts, radiators, steam pipes, combustibles, oil, grease and electrical appliances.
5. Valve caps, covers and plugs are stored together.
6. No Smoking signs are present where Oxygen is kept.

# Specialty Standards
# EQUIPMENT MANAGEMENT
# SECTION 7

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

## EVIDENCE OF COMPLIANCE FOR ALL PRODUCT LINES:

1. Organization has written Equipment Cleaning policies and procedures that adhere to manufacturer guidelines for all equipment provided.
2. Equipment is cleaned with a disinfectant that kills HIV, Hepatitis B and TB, and is applied to the device according to manufacturer directions.
3. Equipment (clean or dirty) is bagged or covered to maintain sanitary conditions and prevent cross-contamination in the warehouse, repair or storage areas.
4. Evidence of cleaning should be noted on tag or checklist and accompany the device.
5. Eyewash present in each area where chemicals are being used and potential for splashing is apparent. Eyewash quantity present should be enough to treat both eyes and not exceed expiration date.

## SPECIALTY EVIDENCE OF COMPLIANCE:

### WOUND CARE/SUPPORT SURFACES

1. Laundering techniques include use of detergents (or additives) that kill HIV, Hepatitis B and TB and are followed in according to instructions. Comforters can be washed on-site or sent out to a laundry service.
2. Washer and dryer bins are labeled for clean and dirty and are segregated.
3. There is an appropriate drying area according to manufacturer guidelines.
4. If a State Bedding law exists, cleaning/disinfecting parameters must be followed including documentation to support compliance.

### RESPIRATORY

1. Oxygen tanks should be wiped off with a damp cloth but no disinfectants should be used (unless approved by manufacturer).

### SUPPLIES

1. All pre-packaged one use items or nutritional products are boxed up for shipping and cleaning is not necessary but items should be kept sanitary per manufacturer guidelines.

### ORTHOPEDIC

1. Soft goods are for one patient only and are normally purchased (or included with the rental).

### NEGATIVE PRESSURE WOUND THERAPY (NPWT)

1. Must be disinfected between uses per the manufacturer specifications.

# Specialty Standards
# EQUIPMENT MANAGEMENT
# SECTION 7

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

## EVIDENCE OF COMPLIANCE FOR ALL PRODUCT LINES:

### ELECTRICAL

1. Organization has written policy regarding the testing of equipment.
2. Documentation of testing exists in the form of log, checklist, electronic record, etc.
3. Manufacturers operating manual(s) 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.

### SUPPLIES/ENTERAL

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

### MOBILITY (POWER CHAIRS/SCOOTERS ETC.)

1. The organization has an organized process for the assembly of a power chair or scooter.
2. The battery is tested and chair is driven to determine working condition.
3. Documentation of assembly and testing exists.

### RESPIRATORY

1. The organization tests Oxygen for Purity and Identity or has written proof from outside supplier.
2. The organization maintains an analyzer calibration log (if applicable).

### WOUND CARE/SUPPORT SURFACES

1. The support surface is inspected for proper inflation and deflation of the sacs.

### ORTHOPEDIC

1. CPM devices are run through the parameters and if recommended by the manufacturer, a weight is sometimes added to mimic the weight of a limb while testing.

# Specialty Standards
# EQUIPMENT MANAGEMENT
## SECTION 7

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

### EVIDENCE OF COMPLIANCE FOR ALL PRODUCT LINES:

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. The repair technician has been trained in all aspects of repair and maintenance procedures and documentation exists in personnel file.
5. Written or computerized list exists of all repairs and maintenance performed by Manufacturer, Model and Serial number.
6. When needed, loaner or replacement equipment is provided to the patient while patient's equipment is being repaired. This does not apply to O&P products.

**EQP 6.0 Preventive maintenance is performed according to manufacturer guidelines.**

### EVIDENCE OF COMPLIANCE FOR ALL PRODUCT LINES:

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).

# Specialty Standards
# EQUIPMENT MANAGEMENT
# SECTION 7

**EQP 7.0 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 to identify the equipment at each location is needed.

## SPECIALTY EVIDENCE OF COMPLIANCE:

### RESPIRATORY

1. Written or computerized list of cylinders exist including:
   - *a. Type and size*
   - *b. Batch number*
   - *c. Lot number*
   - *d. Disbursement*

### SUPPLIES/ENTERAL

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

# Specialty Standards
# EQUIPMENT MANAGEMENT
# SECTION 7

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

## EVIDENCE OF COMPLIANCE FOR ALL PRODUCT LINES:

1. Company vehicle has designated clean and dirty areas.
2. All equipment is bagged during transport.
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 eyewash.

## SPECIALTY EVIDENCE OF COMPLIANCE:

### RESPIRATORY

1. Oxygen tanks are secured in vehicle (to prevent movement or ejection) during transport.
2. The organization has a policy of No Smoking in the vehicle and signs are present in the cab and at entrance to vehicle (No Smoking and Oxygen on board sign should be visible from the outside of the vehicle).
3. The organization has a fire extinguisher mounted inside the van.
4. Vehicles that transport a combined hazardous material (e.g., oxygen) gross weight (packaging/container +contents=gross weight) of 1,000 lbs or more are subject to Department of Transportation regulations.
5. Anyone who delivers medical oxygen should receive training on proper handling of medical gases and potential risks involved.
6. Adequate ventilation must be maintained.
7. Full, empty and quarantine must be designated while transporting tanks.

### Mobility (Power Chairs /Scooters)

1. The organization has a fire extinguisher mounted inside the vehicle.
2. Ramps or other access present to safely load and unload equipment.

# Specialty Standards
# EQUIPMENT MANAGEMENT
# SECTION 7

**EQP 9.0 The organization has a process in place for handling equipment/product hazards, defects or recalls.**

## EVIDENCE OF COMPLIANCE FOR ALL PRODUCT LINES:

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 warehouse 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 EVIDENCE OF COMPLIANCE

### RESPIRATORY

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

# 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 at risk for exposure to blood-borne pathogens
    - Utilization of Standard Precautions when at risk for exposure to blood-borne pathogens
    - Proper disposal of gloves in the pharmacy, facility, warehouse 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

3. All delivery/service staff are trained on the following infection control techniques and it is 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 warehouse 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 FOR ALL PRODUCT LINES:

1. The Patient Rights and Responsibilities document is given to the patient upon delivery of product/services.
2. The patient/caregiver is instructed on the rights and responsibilities at the start of service and documentation is found in the patient file.
3. All employees of the organization are trained on the Patient Rights and Responsibilities document and how it relates to their individual jobs.
4. There is written documentation of this training in the personnel file.

**PTS 2.0 The organization has written policies and procedures regarding the proper delivery and set-up of equipment.**

## EVIDENCE OF COMPLIANCE FOR ALL PRODUCT LINES:

1. The organization has written policies on the set-up of equipment, including response time for delivery, and is related to type of patient served and equipment provided.
2. All delivery/service staff is trained on proper set-up and it is documented in the personnel or training file.
3. All respiratory equipment such as oxygen concentrators, reservoirs, high-pressure cylinders, oxygen accessories & supplies, oxygen conserving devices, CPAP & nebulizers are delivered and set-up according to the current AARC Practice guidelines. (http://www.rcjournal.com/cpgs/index.cfm)
4. A checklist is utilized to assess competency at orientation and annually and is maintained in the personnel or training file.
5. The organization assesses employee performance when new products are added or if warranted by substandard performance.
6. Delivery document including the date of delivery, company information, patient information, product information (manufacturer, model, quantity and description), patient paperwork provided, and any identifying number (serial/lot) in addition to patient and delivery person's signature (or tracking number receipt) should be used to maintain proof of delivery.

# Specialty Standards
# PATIENT SERVICES & INSTRUCTION
# SECTION 9

**PTS 3.0 The organization educates and instructs the patient/caregiver on the product/equipment use and operations, maintenance and cleaning.**

## EVIDENCE OF COMPLIANCE FOR ALL PRODUCT LINES:

1. The organization has a process in place for instructing patients/caregivers.
2. The organization has a checklist or Patient Instruction/Plan of Care form which addresses all aspects of patient instruction including:
   - * Use and operation of equipment (written copy must be provided or a pictorial may be provided if it better meets the patient need)
   - * Maintenance, troubleshooting and cleaning of equipment
   - * Infection control tips, safety risk and hazards if appropriate
   - * Goals to be achieved with equipment
3. The patient/caregiver must sign the instruction form and receive a copy of it. The original should be placed in the patient file.
4. All patients /caregivers receiving respiratory equipment such as oxygen concentrators, reservoirs, high-pressure cylinders, oxygen accessories & supplies, oxygen conserving devices, CPAP, IPPB, nebulizers as well as need for suctioning in the home, are trained by the supplier according to the current AARC Practice guidelines.
5. A return demonstration by the patient or caregiver is obtained after instruction has been provided and should be documented and maintained in the patient medical record if applicable.
6. All delivery/service staff is trained in patient instruction at the time of hire, annually, and as new products or services are added.
7. All delivery/service staff has documentation of training in their personnel record.
8. The organization provides the patient with information regarding expected time frames for receipt of delivered items.
9. The organization verifies that the patient has received equipment, items, and services.
10. If a patient in need of instruction speaks a language other than English, the organization needs to make arrangements to have a family member, neighbor or contracted service that can interpret. If the organization services a large percentage (40% or more) of non-English speaking people in their patient population then the following documents should be available in that language:
    - * Patient Agreement/Assignment of Benefits
    - * Patient Instructions
    - * Patient Rights and Responsibilities

# Specialty Standards
# PATIENT SERVICES & INSTRUCTION
# SECTION 9

**PTS 3.1 The organization educates and instructs the patient/caregiver on the product/equipment's use and operation, maintenance and cleaning.**

## SPECIALTY EVIDENCE OF COMPLIANCE:

### WOUND CARE/SUPPORT SURFACES

1. Patient instruction and documentation includes the use of the CPR mode if appropriate.

### ORTHOPEDIC (CPM)

1. Instruction and documentation include proper location of device.
2. Instruction and documentation include how and when to increase or decrease parameters as well as limits in degrees.

### MOBILITY (POWER CHAIRS AND SCOOTERS)

1. Instruction and documentation include charging of the battery.
2. Instruction and documentation on getting in and out of an entranceway, elevator and vehicle when appropriate to the individual needs and goals of the patient.

### RESPIRATORY

1. Patient instruction and documentation includes:
    * Proper placement and storage of oxygen
    * How to transport (including of oxygen)
    * Maintenance of liter flow as prescribed
    * Tank replacement
    * Importance of not smoking and having no smoking signs posted in patient home
    * Fire safety
2. The organization shall comply with current AARC Practice guidelines.

### ENTERAL/PARENTERAL

1. Patient Instruction includes preparation of enteral/parenteral nutrients

### NEGATIVE PRESSURE WOUND THERAPY (NPWT)

1. Clinical services provider should be indicated on delivery document.
2. Written information must be in compliance with current CMS NPWT Interpretive Guidelines.

# Specialty Standards
# PATIENT SERVICES & INSTRUCTION
# SECTION 9

**PTS 4.0 The organization has a process for assessing the patient home for safety hazards as it relates to the type of equipment provided, how the equipment is used, and where it is used.**

## EVIDENCE OF COMPLIANCE FOR ALL PRODUCT LINES:

1. Safety factors and hazards are reviewed with the patient/caregiver at the time of delivery and documented on the patient instruction form/Plan of Care.
2. Delivery/service staff is trained on patient safety and safety in the patient's home as it relates to the type of equipment provided. This is documented in the personnel record or on the training checklist.

## SPECIALTY EVIDENCE OF COMPLIANCE:

Documentation of safety assessment needs to cover the following areas for the type of equipment listed.

**MOBILITY**

1. *Assessment is based on goals for use and whether the chair will be used inside, outside or both.*
   ***Inside assessment*** *would include:*

   * All appropriate rooms
   * Wheelchair accessibility
   * Saddles on doorways in and out of those rooms
   * Bathroom accessibility
   * Pathways
   * Area rugs, furniture, other obstacles
   * Electrical outlet for charging of battery
   * Fire safety (includes exits from home)

   ***Outside assessment*** *would include:*

   * Wheelchair accessibility
   * Need for or presence of ramps
   * Outside terrain

**RESPIRATORY**

2. *Assessment includes the following:*
   * Presence or absence of smoke alarm and fire extinguisher
   * Smokers in house
   * Using oxygen as a drug (not to be mixed with alcohol or sedatives unless authorized by physician)
   * Fire safety and electrical safety (includes exit from home and power outage)

# Specialty Standards
# PATIENT SERVICES & INSTRUCTION
# SECTION 9

**PTS 5.0 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, and written policy and procedure, in place for equipment related follow-up of 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.

## Specialty Evidence of Compliance:

**Negative Pressure Wound Therapy (NPWT)**

1. The supplier shall have an on-going individualized service plan with a defined frequency that addresses, define or confirms:
    a. The ongoing operation and maintenance of the equipment, operation and maintenance of the equipment
    b. The frequency for scheduled/planned delivery or supply of additional supplies
    c. That the beneficiary is using the equipment per the physicians order
    d. The supplier picks up the equipment when it is no longer needed per the physicians orders

**Note**:

*FDA category II or III equipment will be followed-up at minimum within 72 hours of initial set-up and then on an as needed basis either by patient or as regulations require (e.g., CPM support surfaces, nebulizer, oxygen, apnea monitor, infusion pumps, enteral pumps and ventilator).*

# Specialty Standards
# PATIENT SERVICES & INSTRUCTION
## SECTION 9

**PTS 6.0 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 billing is stopped according to the date the patient discontinued use.**

### EVIDENCE OF COMPLIANCE FOR ALL PRODUCT LINES:

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) should be given to the patient and the original placed in the patient file.
4. The billing records should reflect the stop date.
5. Equipment should be handled as dirty equipment, bagged, and placed in the dirty area of the vehicle.

**PTS 7.0 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 delivered and contact information for repairs if maintenance is necessary.

**PTS 8.0 The organization has a process for responding to an emergency in a patient home while delivering or servicing the equipment provided.**

### EVIDENCE OF COMPLIANCE FOR ALL PRODUCT LINES:

1. The organization has a written policy.
2. All delivery/service staff is trained at orientation and are knowledgeable.
3. If the organization has been made aware of a DNR (Do Not Resuscitate) directive by the referral source, the organization has a process for communicating the information to the appropriate staff.

# 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 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) of all of the licenses and expiration dates must be available for review.
3. CMS Supplier Standards 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.

# Specialty Standards
# REGULATORY
# SECTION 10

**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 or training file.
4. Personal protective equipment is available and accessible to the appropriate staff for their use.

**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 and documents if they service a patient population that is at high risk for TB and/or are in a geography that has a higher risk for TB.
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 in-home or facility patient contact
   - All staff with direct patient contact must have a TB skin test annually and a medical evaluation
   - Employees are trained in respiratory protection annually
3. OSHA Tuberculosis (TB) training of at-risk staff is performed annually and documented in the personnel or training file.

# Specialty Standards
# REGULATORY
# SECTION 10

**REG 2.C The organization is in compliance with the OSHA 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's Right to Know and training is documented in the personnel or training 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., cleaning disinfectants, chemicals, lubricants, toner, etc.).
4. The organization contacts OSHA and posts all mandatory posters that are needed.

# 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:

**EMERGENCY PREPAREDNESS:**

1. The organization has a written emergency preparedness plan with an 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 with 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.

**FIRE SAFETY:**

1. The organization ensures Fire Safety requirements are met as below:

   - 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 FOR ALL PRODUCT LINES:

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.

# Specialty Standards
# REGULATORY
# SECTION 10

**REG 3.B The organization is registered with the FDA if equipment is rebuilt to different specifications from the manufacturer or repackaging occurs.**

## EVIDENCE OF COMPLIANCE FOR ALL PRODUCT LINES:

1. Written (or electronic) registration with the FDA is available for review.
2. FDA Registrations must be completed prior to any initial or renewal visits with The Compliance Team, Inc.

## SPECIALTY EVIDENCE OF COMPLIANCE:

### RESPIRATORY (IF TRANS-FILLING)

1. The organization is registered with the state (if applicable).
2. The organization has a written policy and procedure for the following:
   - * Inspection, use and storage of oxygen both liquid and gas
   - * Testing for bulk delivery from supplier, for vehicle mounted cryogenic vessels, for Dewars delivered by the supplier to the HME, for refilling of cryogenics home unit, for cryogenic home units and for compressed gases.
3. Oxygen analyzers are calibrated according to manufacturer guidelines and a log is maintained.
4. A separate consumer complaint file for Oxygen is maintained.
5. The organization trains the staff responsible for the transfilling annually and training is documented in personnel file.
6. The organization has a written recall procedure.
7. The organization is able to reconcile the batch or lot number and the purity test completed on each batch or lot.
8. The organization has the following Personal Protective equipment available:
   - * Face shields (liquid oxygen filling)
   - * Leather gloves (liquid oxygen filling)
   - * Protective footgear if lifting oxygen cylinders or LOX tanks

# Specialty Standards
# REGULATORY
# SECTION 10

**REG 3.C 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 on related policies and are knowledgeable.

# Specialty Standards
# CLINICAL RESPIRATORY
# SECTION 11

**RES 1.0 The organization has written policies and procedures describing the following:**
- **Initial Assessment & follow-up criteria**
- **Qualifications of staff performing assessments**

## EVIDENCE OF COMPLIANCE:

1. Documentation of assessments, delivery and follow-up in patient record.
2. Documentation of staff training in personnel file or training file.
3. Clinical license (and verification from issuing authority), RRT, CRT or RN and job descriptions that outline specific clinical functions to be performed are present for a minimum of one W-2 employee in personnel file.
4. The organization shall comply with the current AARC Practice guidelines.

**RES 2.0 The organization performing clinical respiratory services provides appropriate medical management rendered by a qualified physician.**

## EVIDENCE OF COMPLIANCE:

1. Ongoing communication between clinical staff and physician are documented.
2. A progress report regarding respiratory care is sent to the physician at a minimum of every 3 months and a copy is placed in the patient file.
3. The organization shall comply with the current AARC Practice guidelines.

# Specialty Standards
# CLINICAL RESPIRATORY
# SECTION 11

**RES 3.0 The organization that provides in-home mechanical ventilator, IPPB & Respiratory Assist Devices (RAD) has written protocols.**

## EVIDENCE OF COMPLIANCE:

1. Written policies and procedures address the following:
   * Patient selection criteria
   * "Care" support system is assessed
   * Home environment is assessed
   * "Medical management" support system in place
2. Written policies and procedures address
   * Airway management
   * Ventilator management
   * Emergency back-up procedures
3. Documentation of staff training and qualifications are in personnel file.
4. Job responsibilities/accountabilities checklist is appropriate for equipment provided.
5. The organization shall comply with the current AARC Practice guidelines.

# Specialty Standards
# CLINICAL RESPIRATORY
# SECTION 11

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| **RES 4.0** | **The organization that provides in-home apnea monitors for infants have written protocols** |

## EVIDENCE OF COMPLIANCE:

1. Written policies and procedures address the following:
   - * Patient selection criteria
   - * "Care" support system is assessed
   - * Home environment is assessed
   - * "Medical management" support system in place
2. The organization has a written protocol that addresses monitor settings, appropriate follow-up and criteria for discharge.
3. Patient information and assessment is found in the patient file.
4. Staff training and qualifications are found in the personnel file or training file.
5. The organization shall comply with the current AARC Practice guidelines

# Specialty Standards
# REHAB TECHNOLOGY
# SECTION 12

**RHB 1.0 The organization shall employ at least one qualified Rehab Technology Supplier that is certified as a CRTS or AT per location for Complex Rehab & Assistive Technology.**

## EVIDENCE OF COMPLIANCE:

1. Evidence of the appropriate credentials exist for a minimum of one W-2 employee in the personnel file and are as follows:
   - * Certified Rehab Technology Supplier (CRTS)
   - * Assistive Technology Professional (AT) (effective 1/1/09)
   - * Assistive Technology Practitioner (ATP)
   - * Documentation of education specific to Rehab technology to maintain credentials per Rehabilitation Engineering and Assistive Technology Society of North America (RESNA)
2. Appropriate credentials are required for Complex Rehabilitative Wheelchairs. This includes Group 2 power wheelchairs with power options, Group 3 and higher power wheelchairs and manual wheelchairs that can accommodate rehabilitative accessories and features (e.g., tilt in space).

**RHB 2.0 The organization shall have at least one or more trained technicians available to service each location appropriately depending on the size and scope of its business.**

## EVIDENCE OF COMPLIANCE:

1. Evidence of training exists in the personnel file of the following:
   - * Training from the manufacturer on products offered by the organization
   - * On the job training with experience working with rehab client, products and services
   - * Documentation of 10 hours of continuing education specific to Rehab Technology (annually)
   - * Experience with programming and repair of power wheelchairs, alternative drive controls and power seating systems

# Specialty Standards
# REHAB TECHNOLOGY
## SECTION 12

**RHB 3.0 The organization coordinates services with the prescribing physician and other members of the healthcare team (e.g., PT, OT, etc.)**

### EVIDENCE OF COMPLIANCE:

1. Evidence of a face-to-face evaluation, performed by the prescribing physician, is documented in the patient record in addition to the assessment.
2. Verification that seating, positioning and specialty assistive technology have been evaluated and documented in the patient record.

**RHB 4.0 The organization provides equipment for trial and simulation when appropriate.**

### EVIDENCE OF COMPLIANCE:

1. Documentation exists of the equipment used for trial and simulation.

# Specialty Standards
# REHAB TECHNOLOGY
## SECTION 12

**RHB 5.0 The organization has procedures for assembly and set-up of equipment.**

### EVIDENCE OF COMPLIANCE:

1. Written policies and procedures (including any necessary forms) for initial assessment, set-up and delivery follow up for each product category provided.
2. Prior to set-up the final product is measured against the original product recommendation for verification.

**RHB 6.0 The organization that includes a facility for on-site evaluations must be appropriate.**

### EVIDENCE OF COMPLIANCE:

1. The facility must be clean, private and safe for fittings and evaluations.
2. Repairs are either done on-site or in another location in close proximity for assembly and modification of product.
3. Repair areas should be organized and kept clean.

# Specialty Standards

# CUSTOM FABRICATED, CUSTOM FITTED, CUSTOM MADE ORTHOTICS, PROSTHETIC DEVICES, SOMATIC PROSTHETIC & THERAPEUTIC SHOES & INSERTS

## SECTION 13

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| **CF 1.0** | **The supplier shall be trained in a broad range of treatment options to ensure that the items prescribed are optimal for the patient's condition.** |

### EVIDENCE OF COMPLIANCE:

1. Evidence of the appropriate credentials (license or certification), education, experience and specialized training is present in the personnel file. Applicable State licensure requirements must be met for all states where business is conducted.

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| **CF 2.0** | **The provision of customized items and device services (other than off the shelf items) require access to a facility with the equipment necessary to fulfill the supplier's responsibility to provide follow-up treatment and fabrication/modification of the specific device.** |

### EVIDENCE OF COMPLIANCE:

1. The facility has appropriate equipment to provide the services offered.
2. The facility is able to do fabrication & modification of devices as needed.
3. Supplier is responsible to provide follow-up treatment. This includes modification, adjustment, maintenance and repair of the item.

# Specialty Standards

# CUSTOM FABRICATED, CUSTOM FITTED, CUSTOM MADE ORTHOTICS, PROSTHETIC DEVICES, SOMATIC PROSTHETIC & THERAPEUTIC SHOES & INSERTS

## SECTION 13

**CF 3.0 The supplier performs a diagnosis-specific clinical examination for the use of the item as appropriate.**

### EVIDENCE OF COMPLIANCE:

1. In person assessment performed by trained personnel.
2. Assessment documentation should include: comprehensive history, pertinent medical history, allergies to materials, skin condition (color, integrity, temperature), diagnosis, previous use of O&P devices, results of diagnostic evaluations and beneficiary expectations, sensory function, range of motion, joint stability, presence of edema and/or wounds, vascularity, pain, manual muscle testing, compliance, cognitive ability (as appropriate to type of device ordered). The findings are documented in the patient file.
3. Pre-treatment photographs are taken if appropriate to the type of device provided.
4. Appropriate device is based on patient need, optimum therapeutic benefits and appropriate strength, durability and function as required for the patient.

**CF 4.0 Quality Control of item is assessed prior to fitting/delivery.**

### EVIDENCE OF COMPLIANCE:

1. Item is assessed for structural safety ensuring that manufacturer guidelines have been followed.
2. Ensure the treatment plan is consistent with the prescribing physician's dispensing order and/or written plan of care in accordance with Medicare rules. The physician is consulted as needed.

# Specialty Standards

# CUSTOM FABRICATED, CUSTOM FITTED, CUSTOM MADE ORTHOTICS, PROSTHETIC DEVICES, SOMATIC PROSTHETIC & THERAPEUTIC SHOES & INSERTS

## SECTION 13

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| **CF 5.0** | **The patient record shall include the following additional items as appropriate to device provided.** |

### EVIDENCE OF COMPLIANCE:

1. Goals and expected outcomes are discussed and established and documented in the Plan of Care (e.g. reduce pain, increase comfort, enhance function and independence, provide joint stability, prevent deformity, increase range of motion, address cosmetic issues and/or promote healing).
2. Feedback is solicited from the patient/caregiver and physician as necessary to determine the effectiveness of the item and is documented appropriately (e.g., effectiveness includes wear schedule/tolerance, comfort, perceived benefits/detriments, ability to don and doff, proper usage and function as well as overall patient satisfaction).
3. All recommended treatment plans, potions and risks/benefits involved are discussed with the patient and/or physician and are documented.
4. If the plan differs from the physician order, the prescribing physician is consulted and documented.
5. The patient will be referred back to the physician if treatment is beyond the supplier's scope of practice and it is documented.

# Specialty Standards

# CUSTOM FABRICATED, CUSTOM FITTED, CUSTOM MADE ORTHOTICS, PROSTHETIC DEVICES, SOMATIC PROSTHETIC & THERAPEUTIC SHOES & INSERTS

## SECTION 13

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| **CF 6.0** | **The supplier shall provide instructions to the patient/caregiver for the specific items and devices as follows:** |

### EVIDENCE OF COMPLIANCE:

1. Use, care and maintenance instructions are reviewed. (topics include: wearing schedules, therapy, residual limb hygiene, don and doff, adjusting closures for proper fit, how to inspect the skin for pressure areas, redness, irritation, skin breakdown, pain or edema, how to utilize appropriate interface to accommodate the device as appropriate, how/when to schedule a follow-up and any other pertinent instructions). This information is documented and maintained in the patient medical record. A written copy of this information is provided to the patient.
2. Supplies that are necessary to attach, maintain and clean the items are provided as applicable (e.g., adhesives, solvents, lubricants). The patient is informed about how to obtain the supplies as well.
3. Inspecting and monitoring for complications.
4. Reporting any problem to the supplier and /or referring physician of changes in condition or general health.

# Specialty Standards

# CUSTOM FABRICATED, CUSTOM FITTED, CUSTOM MADE ORTHOTICS, PROSTHETIC DEVICES, SOMATIC PROSTHETIC & THERAPEUTIC SHOES & INSERTS

## SECTION 13

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| **CF 7.0** | **The supplier shall follow-up as it relates to the following as appropriate to item provided.** |

### EVIDENCE OF COMPLIANCE:

1. Provide appropriate beneficiary follow-up care consistent with the items or services provided, the patient's diagnosis, specific care rendered and recommendations. Review and make changes to treatment plan based on patient's current condition.
2. All follow-up communication is documented in the patient file.
3. The patient/caregiver is informed of the procedures for repairing, replacing, and/or adjusting the device or items, the possible risks, and estimated time involved in the process.
4. Have access to the equipment (or another provider who has it) needed to modify or adjust the item.
5. Patient is advised to contact the prescribing physician as appropriate for the use of the specific items or service.
6. Follow-up is performed within one week of delivery. Follow-up is continued until item reaches optimal level of fit and function.