SUBJECT: MEDICAL EQUIPMENT USED BY STAFF	REFERENCE #3001
DEPARTMENT: HOME HEALTH	PAGE: 1 OF: 1
	EFFECTIVE:
APPROVED BY:	REVISED:

PURPOSE:

To promote medical equipment management safety when providing patient care, treatment or services.

POLICY:

- The ongoing maintenance, testing and inspection of equipment used in providing care, treatment and services by_____HHA is delineated for the particular piece of equipment in HHA policy.

- Maintenance, testing and inspection of equipment used in providing care, treatment and/or services by the HHA staff may be the responsibility of the supplier/ home medical equipment company.

- Routine and preventive maintenance of medical equipment is performed at intervals defined by the manufacturer, or if there are no manufacturer's guidelines for the equipment, as per HHA policy in accordance with usual and customary practices.

- The HHA evaluates the performance of analytical equipment and instruments, i.e., glucose monitors owned by the HHA and used by HHA staff to provide patient care, treatment or services.

- The HHA routinely inspects other equipment used for testing, i.e., sphygmomanometers.

- The temperature of refrigerators that house vaccines for administration to patients is monitored on a daily basis during normal business hours.

- Maintenance, testing and inspection logs of equipment used for patient care, treatment and services that have been performed by this HHA are retained in the HHA. Equipment maintenance, testing and inspection records that have been performed by outside organizations, i.e., suppliers, home medical equipment companies, therapy organizations, are retained by those organizations and are available to this HHA upon request, per the contractual agreement.

SUBJECT: INFUSION PUMP SAFETY	REFERENCE #3002
	PAGE: 1 OF: 1
DEPARTMENT: HOME HEALTH	
	EFFECTIVE:
APPROVED BY:	REVISED:

POLICY:

- All IV infusion pumps used by this organization to provide IV hydration, antibiotics, etc., or patient-controlled analgesia shall be equipped with a safety device and/or automatic shut-off valve to prevent free-flow of the infusion.

- As part of the patient's plan of care, patients and family shall be instructed in the use, including troubleshooting, and safety features of the infusion pump in an understandable language.

PROCEDURE:

- Pumps shall be evaluated for their ability to protect against free-flow of the infusion prior to being selected for use by the organization.

- HHA staff shall be trained in the use and safety features of the pump prior to providing care, treatment and/or services.

- Pumps placed in the patient's home shall be accompanied by the manufacturer's instructions.

- The HHA RN shall instruct the patient and/or patient's family in safe operation and troubleshooting of the infusion pump per the manufacturer's instructions.

- The patient's and family's level of understanding, as well as proficiency in use of the pump as evidenced by return demonstration, shall be documented in the patient's medical record.

- Pump maintenance shall be performed and documented according to the manufacturer's instructions.

SUBJECT: DURABLE MEDICAL EQUIPMENT	REFERENCE #3003
DEPARTMENT: HOME HEALTH	PAGE: 1 OF: 1
	EFFECTIVE:
APPROVED BY:	REVISED:

POLICY:

- A list of all equipment and its current location shall be maintained.
- All equipment shall have routine and preventive maintenance tests prior to home delivery, and every _____ months, as indicated by the manufacturer.
- Logs for routine performance testing and maintenance shall be kept by the _____.
- Should equipment malfunction while in use, replacement shall be made the same day.
- Life sustaining equipment, i.e., ventilators, suction machines, shall have back-up systems available in the home in the event of failure.
- All _____ HHA staff shall be cross-trained in equipment for various modalities so potential problems may be recognized and serious injury avoided.

NOTE:

See MCN Healthcare's Durable and Home Medical Equipment Compliance Manual.

SUBJECT: EQUIPMENT DELIVERY AND SET-UP	REFERENCE #3004
DEPARTMENT: HOME HEALTH	PAGE: 1 OF: 2
	EFFECTIVE:
APPROVED BY:	REVISED:

POLICY:

- _____ HHA shall provide quality medical equipment and product services appropriate to patients' needs in a timely manner.

- Staff delivering medical equipment shall demonstrate respect for the patient and his/her property and set-up equipment in a safe, efficient and professional manner. The proper operation of the equipment shall be assured before being released for patient use.

STAFF STANDARDS:

- Qualified, trained staff perform equipment set-up

- Staff who deliver and set-up equipment do not assist patients with ambulation, transfers and/or mobility

PROCEDURE:

- Delivery staff shall:

  - Contact patient/family to schedule visit and verify patient's address.
  - Gather required equipment and supplies. Equipment and/or supplies should be packaged or covered to provide protection from adverse weather conditions.
  - Identify him/herself before entering the patient's residence.
  - Assess the home to ensure it is adequate for the installation of the equipment.
  - Set-up equipment, taking care to avoid injury to the patient, self, furniture, environment or equipment.
  - Have the patient/family sign the delivery ticket/visit record form.

- Review appropriate equipment instructions with the patient/family.
- Assess and document the ability of the patient/family to properly use the equipment.
- Instruct the patient/family where to call when equipment problems occur.

- Licensed staff should check and document whether equipment is functioning correctly and meets the patient's needs.

NOTE:

See MCN Healthcare's Durable and Home Medical Equipment Compliance Manual.

SUBJECT: SAFE MEDICAL DEVICES	REFERENCE #3005
	PAGE: 1
DEPARTMENT: HOME HEALTH	OF: 13
	EFFECTIVE:
APPROVED BY:	REVISED:

PURPOSE:

In order to promote the safety of this HHA's patients, visitors and staff and comply with Safe Medical Devices Act of 1990.

POLICY:

- Appropriate corrective action will be taken to protect the safety of all patients, visitors and staff of_____HHA whenever information on a product related hazard or potential hazard is brought to the attention of this facility.

- The_____shall ensure that only Food and Drug Administration (FDA) approved pharmaceuticals and health devices, certified manufactured equipment and qualified hospital prepared products will be used throughout the HHA and that the products and devices recalled by the manufacturer or the FDA are removed when found to be in use within this HHA.

- The Safe Medical Devices Act of 1990 requires that device user facilities (including hospitals, outpatient diagnostic and treatment facilities, nursing homes, ambulatory surgical facilities) report incidents to the device manufacturer when the facility determines a device has or may have caused or contributed to the death or serious injury of a patient. The HHA must also send a copy of the report to the FDA in the case of a death.

- Serious illness or injury as defined by the act is an illness or injury that is life threatening or that either results in permanent impairment of a bodily function or permanent damage to a bodily structure or necessitates immediate medical or surgical intervention to preclude permanent impairment of a bodily function or permanent damage to a bodily structure.

- The FDA defines a medical device as any instrument, apparatus or other article that is used to prevent, diagnose, mitigate or treat a disease or to affect the structure or function of the body, with the exception of drugs. A medical device includes but is not limited to ventilators, monitors, dialyzers and any other electronic equipment, implants, thermometers, patient restraints, syringes, catheters, in vitro diagnostic test kits and reagents, disposables, components, parts, accessories and related software.

- In accordance with Safe Medical Devices Act of 1990, the HHA will establish methods for reporting these events. The HHA shall notify the FDA and the manufacturer (if known) within 10 working days of becoming aware of all incidents that reasonably suggest there is a probability that a medical device has caused or contributed to the death of a patient. In cases involving medical devices where patients are injured or become seriously ill, a report must be filed within 10 working days to the manufacturer or the FDA if the manufacturer is unknown.

  - _____ shall be responsible for ensuring compliance with the reporting requirements.

PROCEDURE:

- With any device failure that has had an adverse outcome, the following procedure must be implemented:

  - To ensure proper follow-up and investigation of the incident, the medical staff who reported the adverse medical incident shall also inform the_____of the following information:

    - Patient's name
    - Name of attending physician notified
    - Type of adverse event
    - Relevant laboratory/test data and patient history
    - Initial reporter of the event
    - Product name
    - Location of product
    - Equipment identification number
    - Serial number of product

  - Model number
  - Name of manufacturer, if known
  - User facility/distributor name, address and contact
  - Event problem codes for device and patient
  - Brief description of incident
  - Where and when report was sent

- Retain all packaging materials and disposable supplies.
- _____ shall initially be requested to document the condition of the device upon inspection. Control settings, and any observed physical damage will be noted. Device will be impounded by_____and shall be tagged, bagged and sequestered including identifying number and date. Device shall be logged into an impound log with all pertinent data recorded to show a "chain of evidence."
- Investigation of incident shall be conducted to determine if a device failed or if there was a user error. This investigation shall be carried out by a team consisting of representation from_____, Risk Management and Nursing.
- Device failure investigation shall be carried out as appropriate before repair work is conducted. Investigation may include the following:
  - Team approach (Risk Management, Third Party Manufacturer and Nursing)
  - Testing
  - Visual Inspection
  - Third Party Investigation (may be recommended by HHA insurance carrier)

- All written communication submitted to the FDA or manufacturer shall be reviewed by the HHA Risk Manager prior to submittal. The Risk Manager will determine the appropriateness and that the submitted communication meets the requirements of the Safe Medical Devices Act of 1990.

- Any additional communications with the manufacturer or vendor shall be carefully and completely documented. Written acknowledgments will be requested for all verbal responses given by the manufacturer.

- Copies of all written communications will be forwarded to the HHA Risk Manager.

MEDICAL DEVICE TRACKING:

- The Safe Medical Devices Act of 1990 requires manufacturers and distributors of permanently implantable, life sustaining and life supporting devices used outside a user facility to adopt a method for tracking devices. Manufacturers have been required to provide a system to track certain medical implants and devices. Hospitals are required to comply with the provisions of the tracking rule and are now required to assist manufacturers by providing the manufacturer with information to implement their programs.

- Tracking records must be maintained for the useful life of the device, even if a patient is lost to follow-up.

- Tracking is no longer required when documentation shows that the device is returned, destroyed, explanted or the patient dies. Refurbishers or remanufacturers of tracked devices that remain in domestic commercial distribution are subject to tracking requirements and should be able to ensure that the original manufacturer can promptly locate the device(s).

SAFE MEDICAL DEVICE ACT DESIGNATED TRACKABLE IMPLANTABLE DEVICES:

- ☐ Aortic valve prosthesis, percutaneously delivered
- ☐ Breast prosthesis, non-inflatable, internal, silicone gel filled
- ☐ Defibrillator, automated, external, wearable
- ☐ Defibrillator, automatic, implantable, cardioverter, with cardiac resynchronization (CRT-D)
- ☐ Defibrillator, auxiliary power supply (AC OR DC) for low energy DC defibrillator
- ☐ Defibrillator, DC, high energy (including paddles)
- ☐ Defibrillator, DC, low energy (including paddles)
- ☐ Defibrillator, implantable cardioverter (NON-CRT)
- ☐ Defibrillator, implantable, dual chamber
- ☐ Defibrillator, over-the-counter, automated, external
- ☐ Defibrillators, automated external (AEDs) (non-wearable)
- ☐ Electrode, pacemaker, permanent
- ☐ Electrode, pacing and cardioversion, temporary, epicardial
- ☐ Electrodes, defibrillator, permanent
- ☐ Electrodes, pacemaker, drug-eluting, permanent, right ventricular (RV) or right atrial (RA)
- ☐ Endovascular graft system, aortic aneurysm treatment

- ☐ Heart valve, mechanical
- ☐ Heart valve, non-allograft tissue
- ☐ Heart valve, replacement
- ☐ Mandibular prosthesis, condyle, temporary
- ☐ Monitor, apnea, home use
- ☐ Monitor, breathing frequency
- ☐ Pacemaker battery
- ☐ Pacemaker, lead adapter
- ☐ Pacemaker, pulse generator (NON-CRT) implantable
- ☐ Pacemaker, pulse generator, implantable
- ☐ Pulmonary valve prosthesis, percutaneously delivered
- ☐ Pulmonic valved conduit
- ☐ Pulse generator, dual chamber, pacemaker, external
- ☐ Pulse generator, pacemaker, implantable, with cardiac resynchronization (CRT-P)
- ☐ Pulse generator, permanent, implantable
- ☐ Pulse generator, single chamber, sensor driven, implantable
- ☐ Pulse generator, single chamber, single

- ☐ Pump, infusion or syringe, extra-luminal
- ☐ Pump, infusion, implanted, programmable
- ☐ Shunt, protosystemic, endoprosthesis
- ☐ Stimulator, autonomic nerve, implanted (depression)
- ☐ Stimulator, cerebellar, implanted
- ☐ Stimulator, diaphragmatic/ phrenic nerve, implanted
- ☐ Stimulator, diaphragmatic/phrenic nerve, laparoscopically implanted
- ☐ Stimulator, electrical, implanted, for Parkinsonian symptoms
- ☐ Temporomandibular joint, implant
- ☐ Transmandibular implant
- ☐ Ventilator, continuous, home use
- ☐ Ventilator, continuous, minimal ventilatory support, facility use
- ☐ Ventilator, continuous, minimal ventilatory support, home use
- ☐ Ventilator, continuous, non-life-supporting
- ☐ Ventilator, mechanical

PATIENT INFORMATION SENT TO MANUFACTURERS FOR TRACKABLE IMPLANTABLE DEVICES:

- The person or institution who owns the device, i.e., a physician or HHA, is considered the final distributor. Final distributors must report to the manufacturer the name of the patient to whom they distributed the device and other required information:
  - Name and address of the final distributor
  - Lot, batch, model or serial number of the device or other identifier necessary to track the device
  - Name, address, telephone number and social security number (if available) of the patient receiving the device
  - Date that the device was provided to the patient
  - Name, mailing address and telephone number of the prescribing physician
  - Name, mailing address and telephone number of the physician who regularly follows the patient
  - The date the device was (when applicable):
    - Explanted, with the name, mailing address and telephone number of the explanting physician
    - Out-of-use due to patient death (date of death)
    - Returned to the manufacturer
    - Permanently retired from use, or permanently disposed of

FOOD AND DRUG ADMINISTRATION (FDA):

- FDA has discretion on whether to order tracking for devices that meet the statutory requirements or to release devices from tracking based on additional guidance factors and other relevant information that comes to the agency's attention. The following additional guidance factors may be considered to determine whether a tracking order should be issued:
  - The likelihood of sudden, catastrophic failure
  - The likelihood of significant adverse clinical outcome
  - The need for prompt professional intervention

- The agency may add or remove devices from the list of tracked devices and may consider the additional guidance factors in conjunction with the review of premarket applications, recall data, medical device reporting, inspections, petitions, postmarket surveillance or other information coming to its attention.

- The Food and Drug Administration (FDA) may add or remove devices from the list of tracked devices. Please check the FDA website at http://www.fda.gov/ for the most current list of trackable devices.

- The following devices have been released from mandatory tracking requirements:
  - Annuloplasty ring
  - Arterial stents (used in coronary or peripheral arteries)
  - Condylar fixation plate, implant
  - Condyle prosthesis, mandibular; bone plate with mandibular condyle prosthesis; locking reconstruction plate with attachable condyle
  - Dura mater

- Electromechanical infusion pumps
- Glenoid fossa prosthesis
- Infusion pumps - designated and labeled for use exclusively for fluids with low potential risks, i.e., enteral feeding, anti-infectives
- Interarticular disc prosthesis (interpositional implant)
- Intraocular Lenses
- Penile inflatable implant
- Silicone gel-filled angel chik reflux valve
- Silicone gel-filled chin prosthesis
- Silicone gel-filled testicular prosthesis
- Silicone inflatable breast prosthesis
- Tracheal prosthesis
- Vascular graft prosthesis of 6 millimeters and greater diameter
- Vascular graft prosthesis of less than 6 millimeters diameter

FDA AND MANUFACTURER HAZARD ALERT AND PRODUCT RECALLS:

- The_____will subscribe to several information services to obtain hazard/recall alert information._____HHA currently subscribes to: _____.
- Additional hazard recalls and alert notifications are received by Administration and other support departments. These product hazard and recall notifications shall be forwarded immediately to the Chief Biomedical Engineer.

- The_____shall receive and review all incoming device hazard/recall alerts, warning letters from manufacturers, product information reports of potential hazards and facility notification reports.

- Each incoming notice will be documented as received in a chronological logbook to track the progress and review status of the distribution of the notice.

- The logbook will document the transmittal of notification, receipt of staff signatures, follow-up with the manufacturer, repair of the device and transmittal of the completed Medical Device Alert form.

- The_____shall determine what action(s) are to be taken by review of the notification. The_____will then notify the appropriate department manager of their required actions.

- The action(s) to be carried out will be documented through distribution of a Medical Device Alert form.

- If required, the device or product will be removed from use until it has been determined that adverse health consequences do not exist.

- Equipment and other medical devices that are removed from use shall be delivered to Biomedical Engineering, unless indicated otherwise on the Medical Device Alert form.

- Medical supply items will be returned to Materials Management unless otherwise indicated on the form. Products that are withdrawn from use shall be retrieved from all areas where they are normally stocked.

RECORD KEEPING:

- User facilities and manufacturers are required by the Safe Medical Devices Act to establish and maintain records related to reportable events. These records must be easily identified, facilitate timely access and must include the following:

  - Information regarding the event or where the information is located. This information shall include all documentation of the reporting decisions and decision making process.
  - Copies of all completed Medical Device Reporting Forms and all information submitted to the FDA, distributors and/or manufacturers regarding the event.
  - Facilities shall keep records related to an event for two (2) years. Authorized FDA staff may have access to all required records at all reasonable times to copy and verify the records.

ANNUAL REPORTS:

- Facilities shall submit to the FDA an annual summary of all reports sent to manufacturers and FDA.

- The following information is to be submitted on the annual report to the FDA (Form FDA 3419):

  - CMS provider number or FDA assigned reporting number
  - Reporting year and report date
  - Complete name and address of user facility
  - Name, title and address of the contact person
  - Lowest and highest report numbers of the reports submitted to the FDA and/or manufacturer during the year
  - A summary of basic information about each reported event or a copy of FDA Form 3500A that was submitted for each event

STAFF EDUCATION:

- Staff shall receive inservice education on the Medical Device Act reporting on an annual basis.

- _____ shall be responsible for developing and implementing the inservice.

  - The inservice shall address the following (not all inclusive):
    - Overview of the Safe Medical Devices Act of 1990
    - Definition of a medical device
    - Patient information sent to manufacturers for trackable implantable devices
    - FDA and Manufacturer Hazard Alert and Product Recalls Process
    - Impounding medical equipment; packaging materials and disposable supplies
    - Reporting requirements and timeframes
    - Investigation process
    - Record keeping
  - Record of attendance shall be maintained by_____.

REFERENCES:

- U.S. Government Publishing Office. (December 15, 2017). Electronic Code of Federal Regulations. 21 CFR Part 821. Retrieved from http://www.ecfr.gov/cgi-bin/text-idx?SID=05cb2e645aea15b7e20868a8bc39c798&mc=true&node=pt21.8.821&rgn=div5

- U.S. Food and Drug Administration (FDA). (March 27, 2014). *Medical Device Tracking; Guidance for Industry and Food and Drug Administration Staff*. Retrieved from http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071756.htm

SUBJECT: MEDICAL DEVICE PROBLEM AND RECALL	REFERENCE #3006
DEPARTMENT: HOME HEALTH	PAGE: 1 OF: 3
	EFFECTIVE:
APPROVED BY:	REVISED:

PURPOSE:

Establish a uniform policy for maintaining medical device hazard and recall information, to ensure that product problem and recall information is properly documented, disseminated and reported, as per the Safe Medical Devices Act of 1990 and any other applicable laws, regulations, standards and federal guidelines.

POLICY:

- _____ HHA monitors and acts on equipment hazard notices and recalls, including notifying patients, staff and prescribing physicians, as appropriate.

- Incidents in which a medical device is connected to death, serious injury or serious illness of any patient are monitored and reported as required by the Safe Medical Devices Act of 1990, and any other applicable laws, regulations, standards and federal guidelines.

- Equipment hazard notices and recalls, and incidents involving medical devices resulting in death, serious injury or serious illness are reported to the Quality Assessment and Performance Improvement (QAPI) Committee and the Governing Body.

PROCEDURE:

- Product hazards may come from the following sources and are to be managed as follows:

  - Patient incidents:
    - Notify QAPI Director
    - Fill out Incident Report
    - Notify Safety Director
  - Staff injuries:
    - Notify Administration
    - Fill out Incident Report
    - Notify Safety Director

- Equipment Malfunctions:
  - Contact Administration and Safety Director
- Product Recalls from Manufacturer:
  - Forward to Materials Manager
- Possible Defective Product:
  - Report problem to Materials Manager
  - Fill out Incident Report
  - Material Manager contacts manufacturer to investigate problem
- Medical Device Action Items from FDA Notices, Corporate Warnings or any other third party:
  - Alerts are received by Administration
  - Administration forwards the Alert to the Safety Director, who reviews all Alerts involving equipment
  - The Safety Director forwards the Alerts to the Materials Manager for review of stock items and filing

 The following steps shall be performed, by the Materials Manager, for all reported product alerts and problems.

- Determine if the HHA has any of the affected product.
- Notify appropriate department of potential product problem.

- If any of the affected product is in this HHA or in use, take appropriate action. This may include:
  - Removal from service (alternative product available)
  - Modification of product
  - Change in instructions
  - Warning to users
  - Determination of availability of alternate product
- Notify the Product Manufacturer.
- If a medical device has in all probability caused a death, serious injury, or serious illness of a patient, the FDA must also be notified. (See Safe Medical Devices policy)
  - The report to the FDA must be made within 10 working days after the facility becomes aware of the problem. In addition, summaries of user reports must be submitted to the FDA on January 1 and July 1 of each year. The summary report, as well as the initial FDA notification, is the responsibility of the Safety Director.[1]

[1] The Summary shall contain the following information: Facility name; the device's name, serial number and model number, the manufacturer's name and address; and a brief description of the event reported to the manufacturer.

SUBJECT: MEDICAL SUPPLIES	REFERENCE #3007
	PAGE: 1
DEPARTMENT: HOME HEALTH	OF: 1
	EFFECTIVE:
APPROVED BY:	REVISED:

POLICY:

- Medical supplies shall be stored in an area with limited access to maintain cleanliness and intact packaging of supplies.

- Inventory controls shall be maintained on all billable and non-billable supplies.

PROCEDURE:

- All supplies accepted into the organization shall be verified by a signed invoice.

- Supplies shall be stored in delivery cartons until unpacked for placement in the medical supply storage area.

- All packaging shall be checked by Medical Supply personnel when unpacked for intact packaging and reasonable expiration dates.

- Shelf stock shall be rotated on shelves such that older stock is issued before new stock.

- Supplies shall be stored on shelves that are off the floor.

- Syringes and needles shall be stored in controlled, locked cabinets or closets within the Medical Supply Department. A record of the distribution of needles and syringes shall be maintained by Medical Supply personnel.

- When medical supplies are issued, expiration dates shall be checked and any outdated supplies shall be appropriately discarded.

- Supplies maintained as staff car stock shall be checked for expiration dates by the first of each month. Expired items shall be returned to the organization for replacement and to be discarded appropriately.

- The Medical Supply Expiration Checklist must be signed by all staff who maintain medical supplies in their cars and submitted to the Medical Supply Department by the first of each month.

MEDICAL SUPPLIES EXPIRATION CHECKLIST
LICENSED STAFF

❑ No Expired Dates of Medical Supplies

Expired Items	Expiration Date	Date Returned	New Items Obtained	Expiration Date

Name:_____ Title: _____

Signature:_____ Date: _____

MEDICAL SUPPLY DEPARTMENT
EXPIRATION DATE CHECKLIST

Date Checked: _____

Item	Expiration Date (Month/Year)	Checked By
Inner Cannula (all sizes)		
Stomahesive Paste		
DuoDerm 4 x 4		
DuoDerm 8 x 8		
Collagenase Santyl Ointment		
Chronicure		
Sorbsan Dressing		
Povidone Iodine Swab Sticks		
Primapore Adhesive Wound Dressing		
Allevyn Hydrophilic Polyurethane Dressing		
OpSite Transparent Adhesive Film		
OpSite Wound Transparent Wound Dressing		
IntraSite Gel Premixed Hydrogel Dressing		
Keto Stix Reagent Strips		
Chemstrip Test Strips		
Glucofilm Test Strips		
Glucostix Test Strips		
BG Tracer Test Strips		
Lemon Glycerine Swabs		
Isopropyl Rubbing Alcohol		
Hydrogen Peroxide		
Visco Paste Zinc Paste Bandage		
Vacutainers (all sizes/colors)		
Prefilled Irrigation Syringes		
Foley Catheterization Trays		
Dressing Change Kit		
KY Lubricating Jelly		
Fleets Enema		
Phosphate Enema		