

Approved By: Board of Directors	Adopted Date: 2/13/18
Distribution: Operations	Revision Date(s):
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PURPOSE:

To define the mechanism for oversight of medical equipment acquisition, maintenance, repair, and use.

POLICY:

Medical equipment represents a high risk area for potential patient and staff injury unless it is purchased maintained, repaired, and used in a safe and proper manner. The following guidelines should be used in the management of medical equipment.

- Acquiring Medical Equipment
 - Considerations should include, but not be limited to:
 - Patient satisfaction
 - Provider satisfaction
 - Fits within our scope of service
 - Vendor repair and lifecycle history
 - Cost and return on investment
 - Gaining input from applicable staff such as Providers, Site Administrators, Corporate Services, and/or Finance will be sought before equipment is purchased that meets capital expenditure limits.
- A written inventory shall be kept of all medical equipment.
 - The inventory will be managed by Corporate Services
 - The inventory will include a maintenance history, purchase history
 - The patient incident history is managed by Operations.
 - The inventory log shall be kept in the Health Center.
- Upon receipt of new medical equipment, Corporate Services shall inspect the equipment before patient use. The initial inspection will look for potential electrical issues, cracked or broken housing, instruction manuals, and shipping damage. When the equipment is delivered to the Health Center, Operations will be responsible for arranging installation and coordinating training for all new users.
- All medical equipment shall be inspected and maintained according to manufacturer's recommended service schedule and ODCHC's repair experience
 - Any repairs for the equipment will be coordinated by Corporate Services, upon notification from the Health Center.
 - When equipment is returned to Health Center use it will be inspected for potential electrical issues, cracked or broken housing, manuals, and shipping damage
- Chief Operations Officer or designee will notify the manufacturer of serious injury to patients or staff under the requirements of the Safe Medical Devices Act of 1990.
- When necessary the Chief Operations Officer will notify local, State, and Federal agencies.
 - In the event of a patient death, the Chief Operations Officer will notify Local, State, and Federal agencies including the FDA.
- Notification of Hazard Alerts for medical equipment
 - Notifications can come from a variety sources. FDA, manufacturer, vendor, ECRI, and others.

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- If the organization gets a notification the Notice will be immediately acted upon, regardless of the source.
- All incidents involving medical equipment will be reported via the Consolidated Situation Report.
 - Upon notification an investigation of the incident will commence
 - The investigation will include, but not be limited to;
 - Incident and how it occurred
 - Determination if the equipment was a contributing factor to the incident
 - Sequestering the equipment as necessary
 - Documentation of investigation
 - Identifying deficiencies and how they might impact the future use of similar equipment
- Medical Equipment Orientation
 - Users of new equipment or new users of equipment shall be trained in its use.
 - Operations will coordinate training for all staff using the equipment.
- Medical Equipment Backup
 - In the case medical equipment fails while in use or fails the maintenance inspection, it shall be pulled from service until Corporate Services determines it is safe to use.
 - Corporate Services will work with the Operations Officer on call to determine if it is a high risk piece of equipment needing immediate replacement or if the Health Center can wait for repairs.

REFERENCES:

Safe Medical Devices Act of 1990
Title 22, Division 5, Chapter 7

ASSOCIATED DOCUMENTS:

CLN.010 Sterilization
ODCHC Form #541 New Equipment Evaluation & Deployment Sheet
ODCHC Form #520 Equipment Request
ODCHC Form #521 Equipment Evaluation
ODCHC Form #95 Pharmaceutical & Product Recall
Equipment Management Plan, July 2017

KEYWORD TAGS:

Medical, Equipment, Safety, Repair, Recall