Rancho Los Amigos National Rehabilitation Center

ADMINISTRATIVE POLICY AND PROCEDURE

SUBJECT: **MEDICAL DEVICE REPORTING PROCESS**

Policy No.: B600
Supersedes: April 6, 2016
Revision Date: November 1, 2021

PURPOSE:

The purpose of the Medical Device Reporting Process is:

1. To identify medical device related incidents as soon as possible after occurrence.
2. To initiate corrective action intended to prevent further similar occurrences.
3. To ensure that the reporting requirements of the Federal Food, Drug and Cosmetic Act, Safe Medical Devices Act (SMDA) and Food and Drug Administration (FDA) are met.

The goal is to prevent injuries related to the use of a medical device.

POLICY:

1. In compliance with the Safe Medical Device Act of 1990, and revised reporting requirements effective July 31, 1996, it is the policy of Rancho Los Amigos National Rehabilitation Center to report to the Food and Drug Administration (MedWatch) and the manufacturer of the device, all deaths, serious illness or injury occurring to patients, which may be related to use of a medical device.

2. This policy applies to any workforce member who discover, witness, or is notified of a known or suspected medical device related event. Workforce members are expected to sequester the device and notify the immediate supervisor.

3. All incidents in which a medical device may have caused or potentially contributed to a patient's death, illness, injury, or adverse outcome shall be reported to the Office of Risk Management within 48 hours of occurrence or as soon as an incident becomes known. In addition, Safety Intelligence online event notification must be completed.

DEFINITIONS:

1. **Medical Device:** Any instrument, machine, or implant which is intended for use in the prevention, diagnosis, or treatment of disease or intended to affect the structure or any function of the body.

2. **Serious Illness and Serious Injury:** Any condition that is life threatening; results in permanent impairment of a body function or permanent damage to a

body structure; or necessitates medical or surgical intervention to preclude permanent damage or impairment.

3. **Cause or Contributed to**: A device may have "caused or contributed to "a patient's death or serious injury, if death or serious injury was or may have been attributed to the device or the device may have been a factor in the death or serious injury because of device failure; malfunction; improper or inadequate device design; manufacture; labeling; or user error.

PROCEDURE:

EMPLOYEES

1. The following procedure applies when an employee becomes aware of a **medical device** suspected of **causing or contributing** to **any patient injury or illness**. Procedure is the same for any medical device suspected of causing or contributing to any personnel injury or illness.

   A. Immediately remove the device from patient use. Notify appropriate clinical personnel (physician, nursing, etc.) to provide appropriate care.

   B. Label the device with a Red Defective Equipment tag or place a written sign indicating "DO NOT USE. RETURN TO BIOMED." Place the device in a secure location where tampering or access for further use cannot occur. DO NOT DISCARD THE DEVICE.

   C. Notify immediate supervisor or management staff.

   D. Notify the manufacturer if known. Otherwise, refer to Bio-Med Department, Value Analysis Director, or appropriate department to notify the manufacturer.

   E. Provide information to Risk Management and Bio-Medical Department on the location of the sequestered device within 48 hours or as soon as the incident becomes known. Location manager/supervisor is responsible for ensuring Risk Management and Bio-Medical Department are notified.

   F. Enter a Safety Intelligence online event report.

RISK MANAGEMENT/ QUALITY RESOURCE DIRECTOR

1. Coordinates the investigation of event.

2. If the event is deemed reportable to FDA (MedWatch), Risk Management (or Quality Resource Director) or designee is responsible for completing the required notification to FDA (MedWatch) within the required timeframe.

3. Collaborates with appropriate departments to ensure that the required investigation, corrective action(s) and follow-up are completed.

4. Maintains a file containing reports, investigation, and corrective actions of medical device related events reported to FDA (MedWatch).

BIO-MEDICAL DEPARTMENT and VALUE ANALYSIS DIRECTOR

1. Ensures that the medical device is sequestered in the Bio-Medical Department or if indicated in another appropriate department.

2. Provides the Risk Manager device related information, including manufacturer information, model number or lot number, serial number, preventive maintenance and service history information and other information as required.

3. Collaborates with Risk Management in conducting an investigation of the device-related event and in the determination if the device is reportable to the manufacturer and FDA (MedWatch).

4. Responsible for reporting appropriate medical device related events to the manufacturer. Provides Risk Management a copy of documentation regarding manufacturer notification.

SAFETY OFFICER/ FACILITIES MANAGEMENT DIRECTOR

1. Assumes oversight of actions listed under Bio-Medical Department.

2. Provides Risk Manager relevant information regarding previously reported hazards, recalls and pertinent FDA related information.

REFERENCES:
FDA/MedWatch Website (September 2011)
Safe Medical Device Act of 1990; Medical Device Amendments of 1992
DHS Safe Medical Devices Act Policy 311.1

Revised:
CM: 2011
CM:RM June 2013
CM:DD April 2016
CM: November 2021