OLIVE VIEW-UCLA MEDICAL CENTER POLICY & PROCEDURE

NUMBER: 301
VERSION: 4

SUBJECT/TITLE: **MEDICAL DEVICE REPORTING PROGRAM**

POLICY: Olive View-UCLA Medical Center will report to the Food and Drug Administration (FDA) and/or the medical device manufacturer on all deaths, serious illnesses, and serious injuries to which a medical device has or may have caused or contributed. Olive View-UCLA Medical Center also will establish and maintain adverse medical device event files.

PURPOSE: To provide clear directions to the Olive View-UCLA Medical Center workforce regarding the identification and reporting of medical device related incidents at the hospital.

DEPARTMENTS: All

DEFINITIONS: Medical Device: A device is defined as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is:

1. Recognized in the official National Formulary, or in the United States Pharmacopeia, or any supplement to them;

2. Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in man or other animals; or

3. Intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

Examples of medical devices include catheters, infusion pumps, hospital beds, patient restraints, suture material, heart valves, ventilators, x-ray machines, bandages, syringes, defibrillators, pacemakers, wheelchairs, etc. Generally, if it is used in medical practice and it is not a drug or biologic, it is a device.

Serious Illness and Serious Injury. The terms are defined as an injury or illness that:

1. is life threatening,
2. results in permanent impairment of a body function, or permanent damage to

a body structure, or
3. requires immediate medical or surgical intervention to preclude permanent impairment of body function or permanent damage to a body structure.

Reportable Information:

1. Information, including professional, scientific, or medical facts, observations, or opinions, which would cause a reasonable person to believe that a device caused or contributed to a death, serious injury, or illness.

PROCEDURE: Employee Responsibility

Any individuals who becomes aware of a medical device event that he or she suspects may have caused death, illness, or injury to a patient under treatment or to an employee shall immediately remove and secure the unsafe device, and notify the Attending physician, the Risk Manager and/or the Safety Officer. After hours, notify the Nurse Administrator and communicate the following information:

- Patient's name
- Room and bed number
- Name of attending physician notified
- Device name
- Location of the device
- Serial number of the device
- Model number
- Name of the manufacturer, if known
- Brief description of the event.

Within twenty-four (24) hours of the suspected adverse medical device event, the personnel who reported the incident shall complete a Safety Intelligence (SI) report.

Risk Manager Responsibility

The Risk Manager, in conjunction with the Safety Officer, shall be responsible for establishing and maintaining a Olive View-UCLA Medical Center-wide system for reporting and documenting medical device events.

The Risk Manager shall ensure that all data collected from the hospital's medical device reporting program shall be incorporated into the hospital-wide incident reporting program, which are communicated to Administration, the Risk Management Committee and others (including regulatory agencies) when deemed necessary.

The Risk Manager is responsible for evaluating all medical device related events to determine whether the events are subject to medical device reporting requirements. All the evaluations shall be properly documented.

The Risk Manager shall gather all reasonably known information and when appropriate, follow-up on the event. The results of the follow-up should be reviewed by the Chief Quality Officer, the Safety Officer, Risk Management Committee and other medical staff committees, which shall adopt recommendations for corrective action if appropriate.

The Risk Manager shall be responsible for timely submission of appropriate reports to the FDA and/or the medical device manufacturer in accordance with federal law and regulation. The Risk Manager shall be responsible for submission of a summary report of the preceding information to the FDA on a semiannual basis.

The Risk Manager shall be responsible for maintaining proper documentation, including the Medical Device Reporting event files, in accordance with federal law and regulation.

For FDA inspection and follow-up on medical device related events, the Risk Manager shall be the contact person and shall ensure the FDA's access to requested information.

Safety Officer Responsibility

Upon notification, the Safety Officer, if applicable, shall immediately impound the medical device pending the outcome of the device-related event. He/she shall determine whether the device should remain impounded, repaired, or returned to services.

References:	
Safe Medical Device Act of 1990, 21 CFR Parts 803 and 807 CMS Conditions of Participation 482.41(c) (2); JC (EC 6.10) Joint Commission Environment of Care Standards DHS Policy 311.1, "Medical Device Reporting Program" DHS Policy 934, "Reporting Incidents"	
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