Medical Device Reporting PC.M05

Regulatory Citation(s):	21 CFR 803
L-Tag(s):	None

POLICY: Lifesong Hospice and Palliative Care reports significant adverse events involving a medical device to the manufacturer and/or the Food and Drug Administration (FDA) in accordance with the reporting requirements of the Safe Medical Device Act.

DEFINITION:

Medical Device *- is any item that is used for the diagnosis, treatment, or prevention of a disease, injury, or other condition and is not a drug or biologic. Medical devices include, but are not limited to: ventilators, patient restraints, monitors, hospital beds, wheelchairs, syringes, tongue depressors, infusion pumps, thermometers, oxygen delivery systems, etc.*

Significant adverse event involving a medical device *- an event whereby a medical device has, or may have, caused or contributed to a death or serious injury. This includes, but is not limited to, events resulting from:*

a. device failure;
b. device malfunction;
c. improper or inadequate device design;
d. manufacturing problems;
e. labeling problems;
f. training issues; and
g. use error.

Serious injury *- a serious injury related to a medical device is one that: a) is life-threatening; b) results in permanent impairment of a body function or permanent damage to a body structure; or c) necessitates medical or surgical intervention in order to preclude permanent impairment or damage.*

PROCEDURE:

1. Direct patient care staff are required to complete an incident report for any problems with the use or functioning of medical devices including but not limited to: failure of the device to function or function correctly, poor design of the device, manufacturer defects, or labeling or user errors.

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2. When a problem with the use or functioning of any medical device has or may have caused or contributed to the death of a patient or a serious injury to a patient, the employee must report this information to his/her supervisor immediately.

3. The hospice's Director of Clinical Operations is responsible for determining when an adverse event involving a medical device must be reported to the manufacturer and/or the FDA.

4. When an adverse event with a medical device has caused or may have caused or contributed to a patient's death, a report is sent to the FDA and the manufacturer as soon as possible but no later than 10 working days from the date the event becomes known. The incident is also reported to the state Department of Health or accrediting agency.

5. When an adverse event with a medical device has caused or may have caused or contributed to a serious injury to the patient, the hospice reports the injury to the manufacturer as soon as possible but no later than 10 working days from the date the event becomes known. If the manufacturer is unknown, the injury is reported to the FDA.

6. FDA Form 3500A is used to report deaths and serious injuries to the manufacturer and the FDA.

7. If adverse events related to medical devices have been reported to the FDA, an annual report is submitted to the FDA on Form FDA 3419 by January 1 of each year.

8. The Director of Clinical Operations maintains all documentation related to incident reports involving medical devices and medical device adverse event reports to the FDA and device manufacturers.

9. Any incidents resulting in injury to a patient are included in the hospice QAPI.

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