

	Montana Mental Health Nursing Care Center Policy Manual	Policy Number	517
		Original Date	04/19/1994
	Department: Nursing	Revised Date	07/10/2014
	Safe Medical Devices Act		

POLICY:

The facility will report all incidents that reasonably suggest that a "medical device" caused or contributed to a resident death, serious illness or serious injury.

A "MEDICAL DEVICE" is defined as "any item that is used for diagnosis, treatment, or prevention of a disease, injury, illness or other condition that is not a drug".

PROCEDURE:

1. If there were no reportable incidents in the last six months, no report needs to be filed.
2. The semi-annual reports are due on January 31st and July 31st.
3. A report will be sent to the manufacturer at time of incident.
4. A serious illness or injury includes one that results in permanent impairment of a body function, permanent damage to a body structure or necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

If all of the four questions listed below can be answered affirmatively, the incident will be reported to the FDA:

- 1) Was there injury or illness?
- 2) Was a device involved?
- 3) Was the victim a resident or employee working in the facility at the time of the incident?
- 4) Was the injury or illness serious?

Some sample medical devices are: walkers, canes, Hoyer lift, Century tub chairs and lift, Arjo walker, wheelchair, implantable pacemaker pulse generator, cardiovascular permanent pacemaker electrode, replacement heart valve, automatic implantable cardioverter/defibrillator, tracheal prosthesis, implanted cerebellar stimulator, implantable infusion pump, apnea monitors Bpap and Cpap continuous ventilator, silicone inflatable breast prosthesis, silicone gel-filled breast prosthesis, testicular prosthesis, chin prosthesis, infusion pumps . There may be other items as defined by a medical device - blood pressure cuffs, or digital thermometers.

Effective Date: 07/14/2011

Policy Number 517

Safe Medical Devices Act

Form to be filled out and sent to manufacturer of medical device involved in resident or employee death, serious illness, or serious injury.

Name & address of manufacturer: _____

Name of medical device that caused or contributed to resident/employee death, serious illness, or serious injury:

Was a resident injured? _____

Was an employee injured? _____

Describe injuries in detail: _____

Who should the manufacturer contact for more details? _____

Montana Mental Health Nursing Care Center
800 Casino Creek Drive
Lewistown, MT 59457

Effective Date: 07/14/2011

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Safe Medical Devices Act

Form for reporting to FDA, accidents involving a medical device

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Lewistown, MT 59457

Name of medical device that caused or contributed to resident/employee death, serious illness or serious injury: _____

Device serial number: _____

Device model number: _____

Name of manufacturer: _____

Address of manufacturer: _____

Describe the event reported to the manufacturer and/or the FDA.

Person to contact for more information: _____

Send to:

Food and Drug Administration
Center for Devices and Radiological
Office of Health, Compliance and Surveillance
HF2 351
P.O. Box 3002
Rockville, MD 20847-3002