**The Safe Medical Device Act**

**What is the Safe Medical Device Act?**

The Safe Medical Device Act (SMDA) is a law that was passed in 1990 and amended in 1992. It is regulated by the US Food and Drug Administration (FDA). The SMDA requires hospice agencies and other health care institutions to report to the FDA any incidents involving medical devices that are reasonably believed to have caused or contributed to the serious injury or death of a patient or employee. The intent of the law is to identify any medical device problems that pose a threat to public health and safety. Since serious injuries and deaths have occurred when a medical device has failed, has malfunctioned, was labeled incorrectly and/or was used improperly, the SMDA seeks to identity “bad” equipment in order that the public be protected from further harm.

**What is a “Medical Device”?**

A “medical device” is any instrument, apparatus, machine, accessory to a machine, or a similar related article that is

* Used or intended for use in the prevention, diagnosis, cure or treatment of a disease in a man or animal
* Used to affect the structure or function of the ody of man or animals.

Some medical Devices used in the hospice may include:

* Hospital Beds
* Wheelchairs
* Oxygen equipment
* Walkers
* Suction equipment
* Wound Vacs
* Air Mattresses
* Hoyer lifts

Insulin pumps and infusion ports are also considered medical devices, however the medication used in these devices is not covered under the act.

**What is meant by “Serious Injury”?**

A serious injury is one that:

* Is life threatening
* Results in permanent impairment or damage to a body structure or function
* Necessitates medical or surgical intervention to prevent permanent impairment or damage

**What is my responsibility regarding Medical Devices?**

Agency clinical staff should inspect the assistive equipment or medical devices that their patients are using on each visit. As an employee, you should know

* Patients should not be using broken equipment until it is replaced or repaired. If a patient reports that equipment is not working properly, call the office immediately. You may be asked to place a tag or label on the piece of equipment that says “DEFECTIVE-DO NOT USE”
* Equipment that is broken or not working properly will be reported by the office staff to the medical equipment company so that it can be repaired or replace
* If you learn that a medical device or piece of equipment has caused, or may have caused the death or serious injury of a patient, the following information must be reported to the office immediately so that the FDA can be notified:
* The patient’s name, address, etc
* A description of what happened to the patient
* The manufacturer of the equipment and the identification of the device you believe caused the problem. Retrieve and report any model or product identification numbers that are visible on the device. Put aside and save, if you are able, the device, and any packaging and all related parts.
* The Director of Performance Excellence will report to the FDA any event where a medical device is suspected as the cause of death in a patient.
* An incident report will be completed by the appropriate agency staff members.

**What are the Agency’s Responsibilities regarding the Safe Medical Device Act?**

* To report any event to the FDA where a medical device is suspected as a cause of patient death
* To keep detailed records according to the Agencies safe medical device act policy
* To educate the staff annually regarding the requirements of the Safe Medical Device Act

**Safe Medical Device Act Quiz**

Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Circle **ALL** correct answers

1. Medical Device problems are tracked and monitored by
2. The Social Security Administration
3. The FDA
4. Medicare
5. The Safe Medical Device Act is intended to:
6. Find ALL broken devices
7. Track how many manufacturers are selling defective medical devices
8. Identify any medical device that poses a threat to public health and safety
9. A Hoyer lift is a medical device
10. True
11. False
12. A Wound Vac is a medical device
13. True
14. False
15. Insulin is classified as a medical device
16. True
17. False
18. Serious Injury causes permanent damage or injury.
19. True
20. False
21. A serious injury is NOT life threatening.
22. True
23. False
24. If I find broken equipment in the patient’s home, I should
25. Call the FDA
26. Instruct the patient not to use the defective equipment
27. Call the office to report the broken equipment to the supervisor
28. Education for employees, including volunteers, on the Safe Medical Device Act must occur
29. Every 5 years
30. Bi-annually
31. Annually