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HOSPICE

SAFE MEDICAL DEVICE TRAINING

SAFE MEDICAL DEVICE ACT

- Requires health-care professionals to report death or injuries caused or suspected to have been caused by a particular medical device to the FDA or the product's manufacturer.
- Designed so the FDA can be quickly informed of dangerous medical products and can then track or recall the product.
- Safe Medical Device Act signed into law in 1990.
- Why created?
  - 1986 Study showed less than 1% of problems with medical devices was reported by hospitals.
  - Also, the more serious the problem, the less likely to be reported.

SAFE MEDICAL DEVICE ACT

- A medical device is defined by the Safe Medical Devices Act of 1990 to include any instrument, apparatus, or other article that is used to prevent, diagnose, mitigate or treat a disease as to affect the structure or function of the body with the exception of drugs.

- A medical device can range from gauze sponges to implanted devices such as pacemakers.

SAFE MEDICAL DEVICES ACT

- What it does:

- Allows regulators to observe operability of a device to make necessary corrections to the functionality if something was wrong.

- FDA quickly informed of dangerous medical products
  - Can track product
  - can recall if needed for repair/replacement
  - Can fine manufacturers up to $15,000 for violating safety provisions of the act

SAFE MEDICAL DEVICE TRAINING

- Our responsibility
- User facilities must report deaths and serious injuries when they become aware of information that reasonably suggests a medical deice has or may have caused or contributed to the adverse event.
- Facility must keep files of adverse events.

REPORTING

- Individual adverse event reports:

- Reports of death and serious injury which are submitted on FDA Form 3500A or electronic equivalent

- Death—must be reported to manufacturer AND FDA
  - within 10 work days from the time any medical personnel of the facility becomes aware of a reportable event

- Serious Injury—must be reported to manufacturer
  - if manufacturer is not known, report should be sent to FDA

Semi-annual report must be submitted in any individual adverse event if a report was submitted during the previous 6-month period.

-reports due on January 1 and July1.

REPORTING

- Include information that reasonably suggests that a medical device has caused or contributed to a medical device reportable event (death or serious injury).

- Include any information such as:
  - professional
  - scientific
  - medical facts
  - observations or opinions

  ...that a device has caused or may have caused or contributed to a reportable event.

REPORTING

- Report should include:

- Patient information
- Type of adverse event
- A description of the event
- Relevant laboratory/test data and patient history
- Manufacturer and identification of the suspect device and certain other information about the device
- Initial reporter of the event
- User facility name, address and contact
- Where and when the report was sent

REPORTING

- Information to be reported annually on Form 3419A will include:

- CMS provider number or FDA assigned reporting number
- Reporting year, reporting period, and report date
- Complete name and address of the user facility
- Name, title, and address of the contact person
- Lowest and highest report numbers of the reports submitted to the FDA and/or manufacturer during the reporting period
- Basic information about each reported event or a copy of the FDA Form 3500A that was submitted for each event

RECORDKEEPING

- A file will be established and maintained for each reportable event and will include:

- Information related to the event—including all documentation of the reporting decisions and the decision-making process

- Copies of all completed Medical Device Reporting forms and other information submitted to the FDA, distributors, and manufacturers

- All records will be maintained for a period of two (2) years after the reportable event.

REPORTING

- Facility must provide all information that is reasonably known to them such as:
  - Information found in documents in the possession of the user facility and any information that becomes available as a result of reasonable follow-up within the facility.
  - Facility is not required to evaluate or investigate.
  - The FDA may determine that protection of the public health requires additional or clarifying information for a medical device report.
  - Any request will state the reason or purpose for which the information is being requested.

ANNUAL TRAINING

Safe Medical Device Reporting inservice education will be provided to personnel on an annual basis.

- Documentation of inservices will include:
- Dates and times of sessions
- Written curriculum outlines describe training content
- Records of attendance

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THANK YOU!

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12040 Raymond Court
Huntley, IL 60142
(847) 515-1505
transitionshospice.com

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