Medical Device Reporting

Home Care Division of the Bureau of Home and Community Services Annual Required In-service

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Faculty

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Medical Device Reporting

- **Each year, the FDA receives several hundred thousand medical device reports of suspected device - associated deaths, serious injuries and malfunctions**

Medical Device Reporting

- **Medical Device Reporting (MDR) is one of the tools the FDA uses to monitor device performance, detect potential device - related safety issues, and contribute to benefit - risk assessments of these products**

Medical Device Reporting

- **Manufacturers, device user facilities, and importers are mandatory reporters for any adverse events and product problems to the FDA concerning medical devices**
- **FDA also encourages health care professionals, patients, caregivers and consumers to submit voluntary reports**

Medical Device Reporting

- **These reports along with data from other sources can provide critical information that helps improve patient safety**

Our Policy – Accident / Injury

- Safe Medical Device Act requires Home Health Agencies to report adverse events related to medical devices under a uniform reporting system
- All medical device incidents, which result in serious injury, illness or death are reported to the Home Care Director

Our Policy – Accident / Injury

- Within 24 hrs the HCD will report the results of investigation to the Bureau Compliance Coordinator
- The Bureau of Compliance Coordinator will consult with the State Compliance Coordinator

Our Policy – Accident / Injury

- The State Compliance Officer reviews and reports to the FDA and follows FDA regulations and completes all required documents within 10 working days
- The Bureau Compliance Coordinator will maintain a file on all Medical Device investigations and reports
  - Records are retained for 35 years

Reporting

- For questions about Medical Device Reporting and interpretation of MDR policy, call (301) 796-6670 or email MDRPolicy@fda.hhs.gov

Reporting

- Voluntary reporting for Patients, Health Professionals and Consumers (Form FDA 3500) are encouraged to report medical device adverse events or product problems to FDA through MedWatch, the FDA Safety Information and Adverse Event Reporting Program

References

- ADPH.org / Homecare Accident / Injury Policy
- Medical Device Reporting U.S. Food and Drug Administration; www.fda.gov

Questions

- **Please refer to your supervisor for any questions you may have**