

MEDICAL DEVICE DEFECT REPORTING EDUCATION

For nurses, therapists, dieticians, and social workers



To protect the safety of our clients and in accordance with federal regulations, BAYADA Home Health Care has established guidelines to ensure the timely and appropriate reporting of potential or actual client illness, injury, or death related to defective medical devices. As a BAYADA caregiver, you are responsible for detecting and reporting any problems with your client's medical devices. Therefore, it is critical that you read the following information very carefully and ask for additional information if anything is unclear.

1. Definition of medical devices

Medical devices are supplies or equipment used during client care. Examples include ventilators and other respiratory equipment; wound VAC; PT/INR and blood glucose monitors; intravenous cannulas, solution containers, administration sets, and electronic infusion pumps or controllers; mechanical lifts, air mattresses, and hospital beds.

2. Action to take if you notice a problem

Immediately notify your clinical manager if a defect in a medical device has caused, is suspected as the cause, or has the potential to cause illness, serious injury, or death to a client. Any medical device that is not working properly has the potential to cause harm to the client so it is important to report any strange noise, smell, or other suspected malfunctioning of equipment.

3. What happens after you report the problem

Your clinical manager will complete and file all necessary forms and, depending on the seriousness of the client injury, will notify the manufacturer and or the Food and Drug Administration (FDA).

Reports of serious injury related to a medical device will be sent to the manufacturer of the device. A serious injury is defined as any injury that is life-threatening, results in permanent impairment of a body function or permanent damage to a body structure, or requires medical or surgical intervention to prevent permanent impairment or damage.

Reports of a death caused by medical device problems must be submitted to the manufacturer and the FDA within 10 working days. In addition, your clinical manager must report any incidents of serious injury or death to the durable medical equipment or medical supply company that is providing the equipment to your client.

Your office maintains a file with copies of all reports filed with equipment manufacturers and/or the FDA. Copies of all reports are also submitted to the BAYADA Nursing office. The Nursing office sends a summary report of all reported device problems to the FDA annually.

All medical device problems are reviewed quarterly as an integral part of the BAYADA Home Health Care Performance Improvement (PI) program.

4. Training (initial and annual)

Because of the importance of the medical device defect reporting policies and procedures, you will receive education upon hire and re-education each year. Reading this notice and completing and signing the post-test fulfill this year's re-education.

5. Getting more information

If you have any questions about these policies and procedures, please call your **clinical manager**.

For additional information on medical device defect reporting, visit the following website:

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/ucm124082.htm>