



SAFE MEDICAL DEVICE ACT IN-SERVICE

NEIGHBORHOOD HOME
HEALTH SERVICES, INC.



SMDA 1990

- APPLIES TO ALL
- HOSPITALS
- AMBULATORY SURGICAL FACILITIES
- NURSING HOMES
- HOME HEALTH AGENCIES
- REHABILITATION FACILITIES



HEALTHCARE FACILITIES MUST

- “SUBMIT A WRITTEN REPORT WHENEVER THEY RECEIVE OR OTHERWISE BECOME AWARE OF INFORMATION ,THAT FROM ANY SOURCE, THAT REASONABLY SUGGESTS THAT A DEVICE HAS OR MAY HAVE “CAUSED OR CONTRIBUTED” TO THE DEATH OR SERIOUS INJURY.”



WHAT IS A MEDICAL DEVICE

- ANY PRODUCT DEVICE, OR INSTRUMENT OR MACHINE THAT IS USED TO DIAGNOSE, TREAT OR PREVENT DISEASE.
- INCLUDING BUT NOT LIMITED TO, IMPLANTS, INFUSION PUMPS, CATHETERS, MONITORS, SCOPES AND GAUZE PADS.



SERIOUS ILLNESS OR INJURY

- ANY EVENT THAT:
- IS LIFE THREATENING
- RESULTS IN PERMANENT IMPAIRMENT OF A BODY FUNCTION OR DAMAGE TO THE BODY STRUCTURE
- NECESSITATES TIMELY MEDICAL OR SURGICAL INTERVENTION TO PRECLUDE DAMAGE OR IMPAIRMENT



REPORTING

- ANY NHHS EMPLOYEE SHOULD CALL THE MAIN OFFICE AT (786) 693-9600
- FILL OUT INCIDENT REPORT
- EMPLOYEES WILL BE GIVEN SIMPLE INSTRUCTIONS TO ENSURE PATIENT SAFETY AND ISOLATE THE DEVICE, THE CALLER WILL ALSO BE INSTRUCTED TO LEAVE THE DEVICE INTACT, WITH PACKAGING IF POSSIBLE



REPORTING CONT'

- THE CALLER WILL BE INSTRUCTED TO DOCUMENT ON AN INCIDENT REPORT FORM THE EVENT AS SOON AS POSSIBLE.
- ADMINISTRATOR AND OPERATIONS DIRECTOR COMPLETE FILING REPORTS AND WARN USERS AND PROVIDERS.



NEVER, NEVER, NEVER

- ALLOW YOURSELF TO DIAGNOSE AND CORRECT ANY MEDICAL DEVICE PROBLEMS.
- FIND YOURSELF USING DEFECTIVE EQUIPMENT.



ALWAYS! ALWAYS! ALWAYS!

- TAKE ALL NECESSARY STEPS TO PROVIDE A SAFE ENVIRONMENT.
- EXECUTE ALL STANDARDS OF SAFETY.