



**Service Area Clinical Director**

Review form FDA 3500A Medical Watch form, and forward to Chief Medical Officer with copies to the environment of care team and the medical products committee for review.

**Chief Medical Officer**

In the event the device(s) or product(s) has resulted in serious injury or death of a client:

1. Submit device/product related deaths directly to the Federal Drug Administration (FDA) and the manufacturer on a FDA form 3500A AMEDWATCH@ within ten (10) working days of becoming aware of the information.
2. Present the matter to the investigative committee for review.
3. Report serious injuries to the manufacturer within ten (10) working days of becoming aware of the information. Report the information to the Federal Drug Administration if the manufacturer is unknown.
4. Semi-annually, submit summary FDA form 3419 to the FDA and the manufacture(s) relating to all adverse events of medical device/products. This report should include device manufacture(s), and a brief description of event(s).

**Investigative Committee**

Review of relevant information, to include interviewing of employees involved in the incident and forward information to the chief medical officer.

**Approved:**

**This procedure has been approved by the CEO and CMO on 12/09.**