**PURPOSE**

To ensure that Ohio Living home health and hospice are in compliance with the Safe Medical Device Reporting regulations.

**POLICY**

When it has been determined that a medical device has, or may have, caused or contributed to the serious injury of a patient, the Ohio Living staff will make a report to the manufacturer of the device, if known, and to the FDA when the manufacturer is not known.

When it has been determined that a medical device has, or may have, caused the death of a patient, the organization will make a report to the manufacturer of the device and to the FDA.

The Executive Director/Administrator will be responsible for determining when a reportable event has occurred and will complete all required FDA reports.

**PROCEDURE**

1. A report using FDA Form 3500A will be completed and submitted to the manufacturer of a device when it is suspected or determined that a device has caused serious injury or illness to a patient. The report should be completed within ten (10) working days of discovery of the serious injury to the patient.
2. A report using FDA Form 3500A should be completed and submitted to the manufacturer of a device and the FDA when it is suspected or determined that a device has caused a patient death. The report should be completed within ten (10) working days of discovery of the patient’s death.
3. In addition to individual device reports, an annual report to the FDA will be made, using FDA form 3419, summarizing all reports sent to manufacturers and the FDA in the previous year. The annual report is due by January 1st of each year where a reportable occurrence has occurred.
4. A file will be established and maintained for each reportable event and will include:
   1. Information related to the investigation of the event—including all documentation of the reporting decisions and the decision-making process
   2. Copies of all completed Medical Device Reporting forms and other information submitted to the FDA, distributors, and manufacturers
5. All records will be maintained for a period of two (2) years after the reportable event.
6. Safe Medical Device Reporting education will be provided to personnel on an annual basis. Documentation of education will include:
   1. Dates of sessions
   2. Written curriculum outlines describe training content
   3. Records of attendance