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For: All Health Care Providers Regulated by the Bureau of Quality Assurance

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Cc: Susan Schroeder, Director
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Voluntary and Mandatory Medical Device Reporting – Food and Drug Administration

The U.S. Food and Drug Administration has a web site dedicated to reporting problems with medical devices. It states that “Medical Device Reporting (MDR) is the mechanism for the Food and Drug Administration to receive significant medical device adverse events from manufacturers, importers and user facilities, so they can be detected and corrected quickly.”

Some health care facilities (e.g. hospitals and nursing homes) are *required* to report suspected medical device related deaths to both the FDA and the manufacturers. Serious injuries need only be reported to the manufacturer. If the manufacturer is unknown, the serious injury is reported by the facility to the FDA. Health professionals should familiarize themselves with their institution's procedures for reporting adverse events to the FDA. The web site is located at: www.fda.gov/cdrh/mdr.html . The form for reporting is located at www.fda.gov/medwatch/safety/3500a.pdf.

Other health care providers (Community Based Residential Facilities, Residential Care Apartment complexes, etc.) are not required to report, but may want to report similar equipment failures to the FDA. The voluntary website is located at: <http://www.fda.gov/medwatch/report/hcp.htm> .

Examples of medical devices include siderails, hoist lifts, feeding tubes, nebulizers, etc. Many other examples can be found on the FDA web site. Reporting adverse events and related problems with medical devices is one additional step in ensuring the overall health and safety of the many individuals who are served by our numerous health care providers.

This memo is informational only.