FOOD AND DRUG ADMINISTRATION

MEDICAL DEVICE REPORTING (FDA MEDICINE MANUFACTURERS)

USER Facility Reporting

Issue No. 17 *A quarterly bulletin to assist hospitals, nursing homes, and other device user facilities* Fall 1996

APPLYING THE SAFE MEDICAL DEVICES ACT TO NURSING HOMES

By Marvin Shepherd and Mary Ann Wollerton

The Safe Medical Devices Act (SMDA) of 1990 explicitly identified nursing homes as device user facilities subject to medical device reporting (MDR) requirements. As a result, nursing homes are required to report deaths and serious injuries "caused or contributed to" by medical devices. The final regulation for reporting adverse events was effective July 31, 1996, although user facilities have been required to report since November 1991. Another provision of SMDA that affects nursing homes is the tracking requirement for certain medical devices that could prove harmful to patients; this became effective on August 29, 1993.

This article describes how nursing homes can comply with medical device reporting and tracking requirements. Since nursing homes perform few invasive procedures and are not as "device intensive" as other device user facilities, they generally submit fewer MDR reports. This situation may change, as a result of emerging patterns of healthcare – in the future, nursing homes will use a greater number and variety of devices as they accept more patients who rely on complex medical devices. These devices will be used by staffs with less device experience than hospital staffs. The end result may be an increase in the number of adverse device events in nursing homes.

Which medical devices are used in nursing homes?

Nursing homes often use pressure manometers, thermometers, oxygen administering apparatus, and infusion pumps; they occasionally use cardiac monitors. Since most patients tend to be older and/or disabled, they frequently use such devices as walkers, canes, crutches,

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FDA BEGINS TRAIN-THE-TRAINER COURSES

The Food and Drug Administration has designed a "train-the-trainer" course on medical device reporting that will be presented this fall. The course will familiarize trainees with current medical device reporting (MDR) requirements for user facilities and manufacturers, which became effective July 31, 1996. The overview of the MDR regulation will be structured into learning modules to provide trainees with an educational package that is flexible in both content and instructional method. Course "graduates" will be able to give presenta-tions and to train additional trainers.

The first trainees will be Public Affairs Specialists and Small Business Represent-atives from FDA's 21 District Offices, as well as some Headquarters staff. This course will be held Sept. 25-26, 1996, in Rockville, Maryland. Additional courses will be held in Rockville and in a number of FDA District Offices around the country. For more informa-tion about the courses, contact your District Office or write to the Editor of this Bulletin.

FDA has invited healthcare and professional associations to send a representative to a 1-day "train-the-trainer" course in Rockville, Maryland, on October 16, 1996. The course will prepare attendees to offer MDR training for their members. Trainees will receive instructional materials to use in their own training. If you are interested in having additional sessions pre-sented, contact Mary Lou Pijar, by FAX at 301-594-0067.❖

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Applying The Safe Medical Device Act to Nursing Homes

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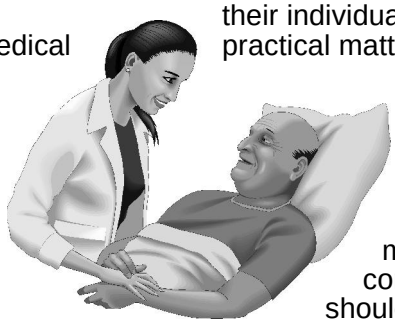
wheelchairs, hospital beds, and physical therapy equipment. The definition of "medical device" also includes bandages, heating blankets, cotton swabs, and tongue depressors.



Which device-related adverse events are reportable?

Reportable adverse events include only those incidents or reports that the nursing home "has received or otherwise becomes aware of that reasonably suggest that a device has or may have caused or contributed to a death or serious injury ." FDA expects you to use professional judgment in making your determinations of reportable events. The process by which you make these decisions should be included in your policies and procedures (P&P) documents.

Numerous articles have been written on how to decide when an adverse event is reportable, so we will not elabo-rate here. The final MDR regulation requires reporting (within 10 days) of deaths and serious injuries in which a medical device caused or contributed to the event because of device failure, malfunction, improper or inadequate device design, manufacture, labeling, or user error.

What is necessary to comply with the medical device reporting requirements?

Nursing homes must have written procedures for internal MDR systems as well as for documentation and recordkeeping. They must also maintain adverse event files.

- ***Written procedures***

Written procedures for complying with MDR requirements do not have to be separate from other policies and procedures (P&P) and may be integrated into the nursing home's existing incident reporting system. The P&P should designate who is responsible for implementa-tion and who is the official MDR "contact person" for the nursing home. The P&P must detail how facility staff will investigate possible adverse events, determine reportability and file the required reports. The location of investigation files should be identified, along with the department or position responsible for maintaining them. Since most nursing home staffs are relatively small, the P&P should be brief, understandable, and readily available to all staff. If a nursing home is part of a larger system, the corporate office may incorporate MDR procedures into the nursing home's overall P&P.

- Training of staff. Although not required by the MDR regulation, the training of nursing home staff about MDR obligations can be addressed in the P&P. The entire nursing home staff needs to be aware of their individual responsibilities related to MDR. As a practical matter, members of the professional staff are most likely to encounter, identify, and report adverse events. Therefore, a special effort should be made to ensure that the professionals understand the P&P and their role in MDR. It is a good idea to keep records of which staff members have been trained and the content of the training. Periodic retraining should be provided.

- Reports. An individual report using Form 3500A is required for each device-related event that has or may have caused or contributed to a serious injury or death. If a death resulted from the event, submit a report to both the manufacturer of the device and FDA. If a serious injury resulted, notify only the manufacturer. These reports are due no later than ten days after you become aware of the event. If the identity of the manufacturer is not known, submit the report to FDA. In your next semiannual report to FDA (due January 1 and July 1), include a summary of all events reported during the previous six months. In lieu of submitting a summary of all events, you can attach copies of the original reports to Form 3419. Form 3500A can also be used to report adverse events related to drugs, biologics, and nutritional products and may simplify your paperwork. If you made no MDR reports during the 6-month period, do not submit a semiannual report.

- MDR contact person. The nursing home should designate a staff member to sign all MDR reports sent to manufacturers or FDA. The agency will always contact this person if it needs additional information or visits the nursing home. In your P&P, however, you may wish to identify the MDR contact person by position title rather than by name, because position titles tend to stay the same, while personnel change constantly.

- ***Adverse event files***

All reports of incident investigations should be filed in a specific location where they are readily accessible to FDA inspectors. Reports of device-related adverse events, as well as events that were investigated but not found to be reportable, must be kept in this location. An FDA inspector may ask to see these event files at any time and may wish to copy some of them. FDA began inspecting selected facilities in May 1995.

When should a voluntary report be made?

Incidents sometimes occur that a clinical professional recognizes as a "near miss." For example, a respirator malfunctions during the day; the staff discovers and responds to the unexpected event

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and the patient survives. If this had happened during the night shift, the malfunction might have gone unnoticed. In other words, under slightly different circumstances, a serious injury or death could have occurred. When a potential hazard is recognized, corrective action should be taken. This is the responsibility of all healthcare professionals. To help prevent similar incidents (and perhaps avoid serious injuries or deaths) in your facility and other facilities, FDA encourages you to voluntarily report "near misses" to the device manufacturer. When reporting this type of event to the manufacturer, use mandatory FDA Form 3500A.

Are civil money penalties possible?

It is unlikely that a civil money penalty would be imposed on a user facility. FDA has authority to enforce user facility reporting with a variety of administrative and legal measures. After an MDR inspection, FDA will present an FDA Form 483, Inspec-tional Observations, if any deficiencies are found. Nursing homes should promptly correct any deficiencies to avoid further actions by FDA. If the deficiencies are not corrected within a specified time, FDA may issue a letter informing the facility of its obligation to remedy the problems or a warning letter that is a precursor to legal action. One option FDA has for legal actions is civil money penalties; these are reserved for serious, deliberate, or repeated violations.

Must nursing homes track medical devices?

SMDA requires tracking of certain critical medical devices, so that users can be notified if a hazard develops. The tracking section of the law and its implementing regulation became effective on August 29, 1993. Presently 26 devices must be tracked (*Bulletin*, Issue 6, Fall 1993). The manufacturer of a tracked device bears the primary responsibility for tracking the device through the distribution chain to the end user. All parties (manufacturer, distributor, user facility, and patient) must cooperate to assure an effective tracking system. Of the 26 tracked devices, 22 are implantable. Since nursing homes neither implant nor explant devices, the details of this part of the law have little significance to nursing homes. However, nursing homes have a role in tracking the four non-implantable durable medical devices.

The four durable medical devices that must be tracked are breathing frequency monitors (apnea monitors and ventilatory effort monitors), con-tinuous ventilators, defibrillators and paddles, and electromechanical infusion pumps. Upon purchase of any tracked device, a nursing home must report certain information to the manufacturer. Nursing homes must also keep a tracking record each time they distribute a tracked device to a patient for use outside the nursing home, e.g., for use in the patient's home. At the present time, this possibility may be quite remote. However, as functions of nursing homes become more complex and as healthcare networks evolve, this situation may occur.

The fourth device listed above, electromechanical infusion pumps, is not uncommon in nursing homes. Upon purchase of a pump, a nursing home must report to the manufacturer that it has received a tracked device, when, and from whom. When a pump is permanently retired from use or sold, the nursing home must notify the manufacturer. To comply with the tracking part of the regulation, the manufacturer and the user facility need only know that an infusion pump is in the facility and not the exact location of the pump at every moment. If a recall occurs, FDA, the manufacturer, or the distributor of the pump will notify the nursing home, identify the infusion pump involved, and advise the nursing home what actions to take. Tracking guidelines apply whether the device is owned, leased, or rented by the nursing home.❖

Marvin Shepherd is a Professional Safety Engineer. Since his retirement from the University of California Medical Center in San Francisco, he has continued his educational and consulting activities relating to medical device safety. For questions relating to this article, you may write to Mr. Shepherd at P.O. Box 3504, Walnut Creek, CA 94598; call (510) 945-0137; or send e-mail to marvins523@aol.com.

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ASSOCIATIONS OFFER MDR MATERIALS

Several healthcare and professional associations offer MDR materials free to their members or for a nominal charge. To obtain a list of these organizations through FDA's Facts on Demand (FOD), call 800-899-0381 or 301-827-0111 and ask for document #4799. FOD is a 24-hour automated FAX system. The Summer 1996 *User Facility Reporting Bulletin* tells how to obtain MDR materials through NTIS, Internet/World Wide Web, and FDA's FOD.

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User Facility Reporting
A Quarterly Bulletin

The User Facility Reporting Bulletin is an FDA publication to assist hospitals, nursing homes and other medical device user facilities in complying with their statutory reporting requirements under the Safe Medical Devices Act of 1990 and the Medical Device Amendments of 1992.

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