FOOD AND DRUG ADMINISTRATION

MEDICAL DEVICE REPORTING (FDA, MEDICINE, MANUFACTURERS)

USER Facility Reporting

Issue No. 13 *A quarterly bulletin to assist hospitals, nursing homes, and other device user facilities* Fall 1995

FDA BEGINS INSPECTIONS OF USER FACILITIES

By Allen T. Wynn and Marje A. Hoban

The Food and Drug Administration (FDA) routinely inspects the industries it regulates to determine compliance with pertinent statutes, regulations, and other requirements. Since user facilities are subject to the reporting require-ments of the Safe Medical Devices Act of 1990 (SMDA), they are subject to site review by FDA investigators. This procedure is similar to an audit by the Joint Commission on Accredita-tion of Healthcare Organizations (JCAHO) or the Health Care Financing Administration (HCFA), but the focus is on SMDA reporting requirements.

As part of FDA's enforcement responsibilities, FDA District Offices began a nationwide inspec-tion of selected user facilities in May. The following types of user facilities are subject to inspection by FDA:

- Hospitals
- Nursing Homes/Residential Treatment Care Facilities
- Ambulatory Surgical Facilities
- Outpatient Treatment Facilities

These inspections will assist the Agency in determining how well user facilities are meeting their reporting requirements under SMDA.

Another objective of the inspections is to collect data on the use of commercial "stand-alone" medical software, the purposes for which such software is used, any problems in its use,

(Continued on page 2)

FINAL CIVIL PENALTIES RULE PUBLISHED

By Joseph M. Sheehan, Esquire

On July 27, 1995, the Food and Drug Administration (FDA) published in the *Federal Register* the final rule to implement the civil penalty provisions of the Safe Medical Devices Act of 1990 (SMDA). The final rule became effective on August 28, 1995.

SMDA gave FDA authority to impose administrative civil penalties for violations of the Federal Food, Drug, and Cosmetic Act. FDA may impose a penalty of up to $15,000 for a single violation and up to $1,000,000 for all violations adjudicated in a single action. In determining the amount of the penalty, FDA may consider the seriousness of the violation, the violator's ability to pay, any history of prior violations, the effect of the penalty on the violator's ability to continue business, and other concerns relevant to the case.

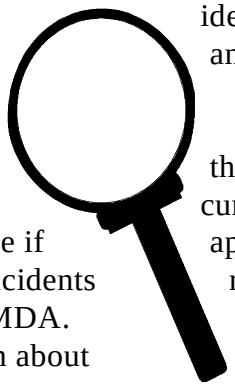
FDA will begin a civil penalty action by filing a complaint with FDA's Dockets Management Branch and serving it on the alleged violator (referred to as the "respondent"). The complaint will state the alleged violations and the amount of penalties sought and will give the respondent an opportunity to request

(Continued on page 2)

FDA BEGINS INSPECTIONS OF USER FACILITIES - *(from page 1)*

and the nature and effect of any defects or "bugs" being encountered.

Upon arrival at the facility, the FDA investigator will issue an FDA Form 482, Notice of Inspection, to the user facility's representative. The investigator will request access to user facility files that contain any information about patient deaths and serious injuries or serious illnesses involving medical devices used within the facility. A review of these files is necessary to determine if the user facility is reporting device-related incidents to FDA and manufacturers as required by SMDA. The investigator will also ask for information about facility use of "stand-alone" medical software. The District Office will forward all inspection reports to the Center for Devices and Radiological Health for analysis.

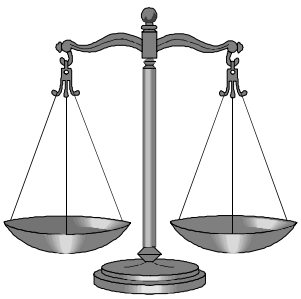


At the conclusion of the inspection, **if** deviations have been observed, the most responsible person present at the facility will be given an FDA Form 483, Inspectional Observations. This form will list any deviations from the SMDA requirements. At the same time, the facility will be given an educational package identifying what it needs to do in order to avoid any sanctions in the future.

User facilities may prepare themselves for these inspections by having their records current and accurate and ensuring that appropriate procedures are in place for reporting device-related incidents as required under SMDA. ✔

Allen T. Wynn is a Consumer Safety Officer in the Field Programs Branch of the Office of Compliance, CDRH. Marje A. Hoban is the Acting Chief of the Branch.

FINAL CIVIL PENALTIES RULE PUBLISHED - *(from page 1)*



a hearing. The hearing is similar to a trial and will be presided over by an admin-istrative law judge who will issue an initial decision. Either party may appeal the initial decision by filing an appeal with the Departmental Appeals Board of the Department of Health and Human Services. The respondent may request judicial review of the Board's decision by filing an appeal in the U. S. Circuit Court of Appeals, District of Columbia Circuit.

In theory, civil penalties may be imposed for **any** violation of the user facility reporting requirements. In reality, civil penalties are likely to be imposed only for viola-tions that are significant or knowing. Such penalties would be specifically appro-priate for repeat offenders. In most cases, after detecting a violation of the Act, FDA will issue a warning letter requiring the alleged violator to come into compliance or face further action by FDA. If this warning does not lead to compliance within a reasonable time, civil penalties could follow.

Civil penalties may also apply to violations of the device tracking requirements. However, the Act specifically states that civil penalties do not apply to minor violations of the tracking provisions if the facility shows substantial compliance with the tracking provisions.

Civil penalties can apply to any violation involving devices. FDA may impose civil penalties for violations of the Good Manufacturing Practices (GMP) and Medical Device Reporting (MDR) requirements for manu-facturers and distributors, but

(Continued on page 3)

FINAL CIVIL PENALTIES RULE PUBLISHED- *(from page 2)*

only when the violation involves significant or knowing departure from the requirements or is a risk to the public health.

Since FDA does not expect user facilities to knowingly violate the Act, few civil penalties are anticipated.

Originally, civil penalties did not apply to user facility reporting. Since FDA did not issue a report indicating that user facilities were in substantial compliance with the reporting requirements, civil penalties began to apply to user facility reporting on November 28, 1994 (four years after enactment of SMDA). If at a later date it is found that user facilities are in substantial compliance, FDA could issue such a report and civil penalties would no longer apply to user facility reporting. ✔

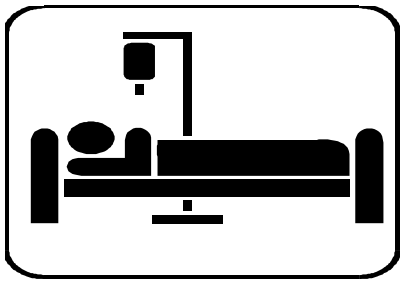
Joseph M. Sheehan is Chief of the Regulations Staff in the Office of Health and Industry Programs, CDRH.

SAFETY ALERT ISSUED FOR HOSPITAL BED SIDE RAILS

By Sherry L. Purvis-Wynn, M.A., B.S.N.

The Food and Drug Administration routinely analyzes information in its databases to detect any trends in device problems. As a result of this trend analysis, FDA staff noticed a gradual increase in the number of deaths associated with the use of hospital bed side rails. This prompted the Agency to mail a Safety Alert entitled "Entrapment Hazards with Hospital Bed Side Rails" on August 23, 1995, to over 94,000 hospitals, nursing homes, hospices, nursing associations, and home healthcare agencies.

Between January 1990 and June 1995, FDA received 102 reports of head and body entrapment incidents involving hospital bed side rails. The reports included 68 deaths, 22 injuries, and 12 entrapments



without injury that occurred in hospitals, long-term care facilities, and private homes. Although one entrapment occurred with a 2-year-old patient, the majority of deaths and injuries involved elderly patients. Patients at high risk for entrapment include those with pre-existing conditions such as confusion, restlessness, lack of muscle control, or a combination of these factors.

FDA recommends that healthcare providers:

- inspect all hospital bed frames, bed side rails, and mattresses as part of a regular maintenance program to identify areas of possible entrapment;
- ensure that hospital bed side rails, mattresses, and bed frames are compatible regardless of manufacturer or distributor;
- check installation of hospital bed side rails to ensure a proper fit;
- follow healthcare facility procedures and manufacturers' recommenda-tions or specifications for installing and maintaining hospital bed side rail protective barriers for the particular bed frame and bed side rails used; and

(Continued on page 4)

SAFETY ALERT ISSUED FOR HOSPITAL BED SIDE RAILS- *(from page 3)*

- do **not** use hospital bed side rails as a substitute for patient restraints.

If you have questions regarding this Safety Alert, please contact the author at:

Office of Surveillance and Biometrics
CDRH, FDA, HFZ-510
1350 Piccard Drive
Rockville, MD 20850
FAX: 301-594-2968

Sherry Purvis-Wynn is a Nurse Consultant in the Office of Surveillance and Biometrics, CDRH.

Editor's Note: This safety alert illustrates why it is important for FDA to receive reports of problems from device user facilities. Events that appear random or unusual in a single institution often identify public health problems when isolated events are reported to a centralized database to permit reviewing for trends. ✔

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.

The publication's contents may be freely reproduced. Comments should be sent to the Editor.

Editor: Nancy Lowe
Assistant Editors: Herb Spark
Mary Ann Wollerton
Graphics Specialist: Edie Plant

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Devices and Radiological Health
Rockville, MD 20857

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
Center for Devices and Radiological Health (HFZ-230)
5600 Fishers Lane
Rockville, Maryland 20857

ATTN: Editor, User Facility Reporting Bulletin

OFFICIAL BUSINESS
PENALTY FOR PRIVATE USE, $300

FIRST CLASS
POSTAGE AND
FEES
PAID
PHS/FDA
PERMIT NO. G-285

Also route to:
- ☐ Biomedical/Clinical Engineer
- ☐ Facility Administrator
- ☐ Nurse Administrator/Manager
- ☐ Quality Assurance Manager
- ☐ Risk Manager