Issue No. 1 June 1992

FOOD AND DRUG ADMINISTRATION USER Facility Reporting

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SAFE MEDICAL DEVICES ACT OF 1990

The Safe Medical Devices Act of 1990 (SMDA), which became law on November 28, 1990, imposes significant new reporting requirements on facilities that use medical devices. It requires that device user facilities, such as hospitals, outpatient surgical clinics and nursing homes, report to the Food and Drug Administration device-related deaths, serious injuries and serious illnesses within 10 working days of becoming aware of the information. We will then tabulate and analyze the reports, and if they show a pattern common to certain types or models of devices, we will take action to protect the public health.

Before enactment of SMDA, our ability to gather information about a device, once it was in the hands of the user, was limited. Generally, we had to rely on our Medical Device Reporting (MDR) regulation, which requires manufacturers and importers of devices—but not users—to report device-related deaths, serious injuries and serious illnesses. Studies of this system revealed serious under-reporting of problems. For instance, a 1986 GAO study revealed that fewer than 1% of device problems occurring in hospitals were reported to FDA, and that serious problems were least likely to be reported. A followup study conducted 3 years later concluded that the problem still existed, despite full-scale implementation of the MDR regulation.

Recognizing this problem, Congress included mandatory reporting by user facilities in the 1990 device legislation. Although a final user reporting regulation is not in place as we go to press, medical facilities must now comply with the law and report device-related deaths, serious injuries and serious illnesses.

It is important to understand that we do not view this user facility reporting system as just another exercise in paperwork. Your reports are vital to us. We need them to identify serious problems with medical devices and to take action to protect people's lives. We also view this sharing of information as a two-way street. We will periodically report back to you on what we find out about the safety of certain devices, through the pages of this Bulletin and through other sources. By working together, we can help assure that the public health is not jeopardized by unsafe or ineffective medical devices.

James S. Benson, Director
Center for Devices and Radiological Health

ABOUT THE BULLETIN

At the April 1991 Conference on Medical Device Reporting, FDA requested suggestions for providing feedback to the reporting facilities. Most of the participants said they would be eager to report device problems if they could receive feedback from FDA concerning the experience of facilities nationwide. Conference participants felt that such feedback would help each facility to better serve its patients. FDA is publishing this quarterly Bulletin in response to suggestions from participants at six of the seven Conference workshops.

User facilities are invited to submit articles that could help other facilities comply with SMDA. Two possibilities are: (1) how a facility trains its staff to comply with the

In this issue:

Department of Health and Human Services • Public Health Service

A Quarterly Bulletin

Center for Devices and Radiological Health
Food and Drug Administration
Rockville, Maryland 20857

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reporting requirements, and (2) how a facility decides which device-related problems should be reported. FDA is also interested in hearing about problems encountered in reporting and how they were resolved. Plans for the Bulletin also include articles on the FDA perspective.

We encourage you to send suggestions for articles to be included in future Bulletins. As we receive miscellaneous information, we will pass it along in a column entitled "Did You Know?"

We hope you will feel this is your Bulletin—a dynamic publication that can change according to your needs as well as ours.

IT'S THE LAW: USER FACILITY REPORTING UNDER SMDA

Healthcare facilities must now report patient deaths, serious injuries, and serious illnesses related to medical devices. Under SMDA, the requirement for reporting by device user facilities became effective on November 28, 1991. Reports are due no later than 10 working days after the device user facility has determined that the event is reportable. Report patient deaths to both FDA and the manufacturer. Send reports of serious illness or serious injury associated with the use of a medical device to the manufacturer. If you do not know the manufacturer, send the report to FDA.

FDA published in the Federal Register of November 26, 1991, a tentative final rule for implementing the reporting provisions of the law. The proposed regulation provides guidance on FDA's policy for reporting problems associated with the use of medical devices. FDA then mailed copies of a document entitled "Medical Device Facility User Reporting Interim Guidance" to hospitals, nursing homes, ambulatory surgical facilities, and outpatient treatment facilities. (Physicians' offices are exempt from reporting under SMDA.) This document clarifies which types of events are reportable and includes a test reporting form and abbreviated instructions for completing the form.

To further clarify its policy, FDA developed a question and answer booklet entitled "Medical Device Reporting for User Facilities: Questions and Answers Based on the Tentative Final Rule." FDA mailed this booklet to device user facilities in February 1992. If your facility did not receive these mailings, please request a copy by writing to the Office of Training and Assistance (HFZ-240), Food and Drug Administration, Center for Devices and Radiological Health, 5600 Fishers Lane, Rockville, MD 20857, or FAX your request to 301-227-8067.

FDA has also started a series of presentations and exhibits at professional meetings. These educational efforts are to acquaint the users of medical devices with the reporting requirements under SMDA. See the Calendar on the back page for details of meetings where FDA will participate.

FDA plans to publish this Bulletin periodically as part of its educational program. It will provide device user facilities with information about problems commonly encountered in reporting, suggestions for determining what to report, and comments from readers. FDA will also report any trends that it detects from the reports. After publication of the final rule, we will update the question and answer booklet and provide additional guidance through this Bulletin.

Joseph S. Arcarese, Director
Office of Training and Assistance

LOOK FOR THE LOGO!

On all of your recent mail from FDA concerning user facility reporting, you may have noticed a sketch of three hands reaching toward each other. This represents the cooperation FDA has seen (and hopes to continue to see) among the three major players in the implementation of the Safe Medical Devices Act, particularly the user facility reporting requirements.

This is the official User Facility Reporting logo, so look for it when you receive information from FDA about user facility reporting.

FREQUENTLY ASKED QUESTIONS

November 28, 1991, was a big day for all of us. Not only was it Thanksgiving Day but it was the effective date of the user facility reporting provision of the Safe Medical Devices Act of 1990 (SMDA). To implement the reporting provisions of SMDA, FDA published a tentative final medical device reporting rule in the November 26, 1991, Federal Register.

Because of the uncertainty of publishing the tentative final rule before the effective date of user facility reporting, FDA developed a document entitled "Medical Device Facility User Reporting Interim Guidance." In mid-November, we mailed this document to user facilities throughout the United States. It contains a brief description of the requirements of the law and a test reporting form with abbreviated instructions.

User facilities should use the proposed rule and the Interim Guidance to determine which incidents to report and what information to submit to the manufacturer or to FDA.

Judging from the calls and letters that we have received, many user facilities are still developing the internal processes necessary to report medical device events. Following are the most frequently asked questions about user facility reporting:

Q. If a user facility made no reports during the previous 6 months, should it file a semiannual report?

A. No, file a semiannual report only for reported events during the previous six-month reporting period.

Q. Can a facility use its six-digit Health Care Finance Administration (HCFA) number as the user facility reporting number?

A. Yes, the six-digit HCFA provider number is acceptable for the first part of the user facility reporting number. The proposed rule and Interim Guidance document state that facilities should use the seven- or ten-digit HCFA number. We will correct that statement in the final regulation.

Q. What is a medical device?

A. The Food, Drug, and Cosmetic Act [21 USC 321(h)] defines a device as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes."

Q. Are reporting forms necessary to submit an incident or to file a semiannual report?

A. The November 1991 Interim Guidance document contains a test reporting form which user facilities are encouraged to use. We have not printed a form for a semiannual report. After publication of the final rule, FDA will develop mandatory reporting forms. The Office of Management and Budget must also approve the final forms. We will then mail these final approved forms and instructions to all facilities on our mailing list.

Q. Are facilities required to report user errors?

A. No, not at the present time. In the tentative final rule, FDA proposed that an error in the use of a medical device (user error) that results in a patient death, serious injury, or serious illness be a reportable MDR event.

Q. Must a facility report under SMDA an event attributed to a drug or a biologic?

A. No, report only medical device events under SMDA. There are other reporting programs that facilities can use to report problems with drugs and biologics.

Q. Why are physicians' offices exempt from reporting?

A. Congress exempted physicians' offices from the reporting requirements under SMDA; therefore, FDA cannot require that they report. Anyone who experiences a problem with a device may report it to the voluntary Product Problem Reporting Program (PRP). Call 800-638-6725 or write to FDA's contractor, the United States Pharmacopeia, 12601 Twinbrook Parkway, Rockville, MD 20852. Do not use the PRP program for reports required by SMDA.

Susan Ellen Bounds
Office of Compliance and Surveillance

A LOOK AT THE FIRST 50 USER FACILITY REPORTS

At the April 1991 FDA Conference on Medical Device Reporting, attendees requested feedback about the medical device reports submitted under SMDA. As a result, we looked at the first 50 user facility reports sent to FDA after November 28, 1991. Since then, we have received over 700 reports, but the same reporting patterns continue.

Most facilities used the **test** form from the "Medical Device Facility User Reporting Interim Guidance" of November 1991. This was good news for FDA, because it allowed us to analyze the information more efficiently. The first 50 reports included:

- 11 patient deaths - 9 of these were also reported to the manufacturers; 2 were not, although the names of the manufacturers were known. (Note: Report a death to **both** FDA and the manufacturer.)

- 12 injuries - 9 of these were also reported to the device manufacturers. The 3 that were not appear to have been the result of user errors rather than defective medical devices. (Note: Report a serious injury related to the use of a medical device to the manufacturer. If the manufacturer is unknown, report to FDA.)

- 3 illnesses - 2 of these were also reported to the manufacturers; 1 was not, because the manufacturer was not known. (Note: Report a serious illness related to use of a medical device to the manufacturer. If the manufacturer is unknown, report to FDA.)

Remember, the law requires that facilities report to the manufacturer incidents in which a medical device contributed to or caused a serious injury or serious illness. If the manufacturer is unknown, report the incident to FDA. Patient deaths contributed to or caused by a medical device must be reported to **both** FDA and the manufacturer.

After receiving an incident report, a manufacturer must investigate the event and report to FDA. FDA periodically inspects the manufacturers for conformance with manufacturing and reporting requirements. Thus, if a facility incorrectly reports an illness or injury to both FDA and the manufacturer, the agency wastes its resources to verify the report.

There were 24 malfunction reports in the first 50 reports received by FDA. Facilities also sent most of these reports to the manufacturers. There is no requirement that user facilities report device malfunctions that do not result in patient death, injury, or illness. We do, however, encourage facilities to report malfunctions to the device manufacturers. Manufacturers must investigate all problem reports and then report to FDA. Historically, FDA has found that device malfunction reports are important. They can result in product recalls and other types of corrective action.

Frequently, user facilities encounter device malfunctions that do not adversely affect patients, but they want to inform FDA about the incidents. To report device malfunctions to FDA, use the voluntary Product Problem Reporting Program (PRP). Call 800-638-6725 or write to FDA's contractor, the United States Pharmacopeia, 12601 Twinbrook Parkway, Rockville, MD 20852. Do not use the PRP program for reports required by SMDA.

We are investigating several facility reports, but FDA policy does not allow us to discuss them now. In future issues of the Bulletin, we plan to include articles about followup and device problem resolution resulting from user facility reports. One incident resulted in a corrective action which we will describe briefly.

A hospital reported the death of a pediatric patient as a result of obstructed tubing. The tube connecting the oxygen source and the patient endotracheal tube did not allow gas exchange because of an obstruction. FDA began its investigation upon receipt of the information. Three days after the facility reported the incident, the firm recalled several lots of the product.

As this incident shows, facility reporting makes a difference!

Susan Ellen Bounds
Office of Compliance and Surveillance

Your
First
Semiannual Report
is due in July

(see next page) ➤

FIRST SEMIANNUAL REPORT DUE BY JULY 31

If your facility filed with FDA and/or a manufacturer or distributor any reports of death, serious illness, or serious injury between November 28, 1991, and June 30, 1992, you are required to submit a semiannual report to FDA by July 31, 1992. Please send a copy of each report submitted as well as the following information, excerpted from the November 26, 1991, Federal Register (submitting this information will take the place of completing FDA Form 222, which was mentioned in the Federal Register but is not yet available).

1. Facility name and complete address
2. User facility identification number
3. Reporting year and period, e.g., November 28, 1991-July 1, 1992
4. Lowest and highest report number of MDR reportable events for the semiannual reporting period, e.g., 0001-1000
5. Total number of reports attached, by type, i.e., (a) death, (b) serious injury, and (c) serious illness
6. Name and complete address of the facility contact responsible for reporting device problems to FDA and to manufacturers and distributors

Please write "Semiannual Report" in the lower left corner of the envelope and send the report to:

Food and Drug Administration
Center for Devices and Radiological Health
MDR User Reporting
P.O. Box 3002
Rockville, MD 20847-3002.

Questions about filing your semiannual report should be sent to:

Food and Drug Administration
Center for Devices and Radiological Health
Division of Product Surveillance (HFZ-340)
Medical Device Reporting Inquiries
1390 Piccard Drive
Rockville, MD 20850

FAX (301) 881-6670

*U.S. Government Printing Office: 1992 — 623-997