FDA INSIGHTS

Medical Device Reporting

An overview of the current reporting responsibilities.

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The FDA Medical Device Reporting (MDR) regulations require the reporting of device malfunctions, serious injuries, or deaths associated with medical devices to the FDA. The Code of Federal Regulations, specifically 21 CFR Part 803, defines the entities and circumstances for which the medical device regulations apply. Although the MDR system has been in place since 1984, there have been changes in the system over time. In light of the recent emphasis on proper reporting, it is useful to review the current reporting responsibilities.

The Reporting Systems Monitoring Branch (RSMB) of the Office of Surveillance and Biometrics in the Center for Devices and Radiological Health has the responsibility to assist entities required to report with the proper interpretation and application of the MDR regulations. Deborah Yoder of the RSMB provides some insight regarding these regulations.

What is the purpose of Medical Device Reporting?

There are several uses of MDR, including the identification of newly emerging or recurring device problems, which allow the FDA to interact with the manufacturer of the device to better understand, evaluate, and mitigate these problems.

What are the mandatory MDR requirements for User Facilities?

User Facilities include ambulatory surgical facilities, hospitals, nursing homes, outpatient diagnostic facilities, and outpatient treatment facilities. Of interest is that private doctors' offices are not considered User Facilities and therefore the reporting obligations described below do not apply.

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User Facilities must report device-associated deaths to both the FDA and the device manufacturer. These reports must be submitted within 10 working days after the day the User Facility becomes aware of the event. User Facilities must also report device-associated serious injuries to the device manufacturer within the same time frame. The User Facility must report deaths and serious injuries using the mandatory report Form 3500A. If the User Facility does not know the name of the device manufacturer, the serious injury should be reported to the FDA. User Facilities do not have an obligation to report device-associated malfunctions that are not associated with a serious injury or death, but such reporting is encouraged. When reporting malfunctions, the User Facility should use the voluntary report Form 3500. Both mandatory and voluntary forms, along with instructions for completing the forms, are available at http://www.fda.gov/medwatch/getforms.htm.

What are the mandatory MDR requirements for manufacturers and importers?

Manufacturers must report device-associated deaths, serious injuries, and malfunctions to the FDA within 30 calendar days of becoming aware of the event. When the manufacturer takes an action to prevent significant risk of substantial harm to the public, the report is due to the FDA within 5 work days, excluding federal holidays.

When a manufacturer receives significant new informa-

tion on a reported event, the new information must be filed as a supplemental report. This information should reference the original MDR number and must be submitted within 30 calendar days.

Manufacturers are also required to file baseline reports with the first MDR report on the device or family of devices, with an annual update when there are changes to the baseline data. These baseline data include basic device identification information, such as brand name, device family designation, model number, catalog number, and any other device identification number, as well as information on the shelf life and expected life of the device.

TABLE 1. SUMMARY OF NEW REPORTS (IE, NONSUPPLEMENTAL)

Event Type	Report Source		Total
	Manufacturer	User Facility	
Death	2,225	158	2,383
Serious injury	29,925	959	30,884
Malfunction	47,700	1,785	49,485
Other	6,314	761	7,075
Total	86,164	3,663	89,827

Importers must report, no later than 30 calendar days after becoming aware of device-associated deaths and serious injuries, to both the manufacturer and the FDA. Importers must report device-associated malfunctions to the manufacturer (not to the FDA) within the same time frame.

How many MDR reports does the FDA receive each year?

Last year, the FDA received more than 200,000 MDR original and supplemental reports (Table 1).

Are there unique reporting requirements for devices being used off-label?

Yes, there is a unique aspect to reporting events associated with off-label use. Off-label use is reportable only when it causes or contributes to a death or serious injury. When reporting on off-label use, indicate specifically how the device was used off-label, to optimize the analysis of the event.

What are the reporting requirements for a manufacturer who has a device to treat another manufacturer's malfunctioning device?

Manufacturers are required to report certain events associated with their own devices, once they "become aware." When a manufacturer becomes aware of information that involves a competitor's device, the information known about the event must be forwarded, along with a cover letter, to the FDA. This correspondence does not constitute an MDR because the manufacturer is not required to submit a report on a competitor's event.

Are the reporting requirements different for devices that were implanted under an approved investigational device exemptions application?

MDR obligations apply as soon as the product is approved or cleared for marketing. Events that meet the MDR regulations must be reported under MDR, including patients who were initially treated under the investigational device exemption..

Are the reporting requirements different for devices that are implanted under a postapproval study?

There are no differences in the requirements for reporting when a device is used as part of a postapproval study. MDR requirements define the primary reporting mechanism for PMA-approved and 510(k)-cleared devices. To prevent duplicate reporting, MDR reports should contain all information mandated by the FDA. The MDR reports should then be referenced in any summaries submitted to the FDA in compliance with PMA Conditions of Approval requirements.

What obligation does the manufacturer have when the device is not returned?

The MDR obligations are unchanged, whether or not the device is returned. The MDR regulation requires the manufacturer to investigate and evaluate device-associated adverse events, not just the device itself. Clearly, it is optimal for the manufacturer to be able to evaluate the device to help determine the cause of the event, however, the reporting requirements are independent of the ability to conduct such an assessment.

What type of information is needed in a report?

The required format and content of MDR reports can be found on the FDA Web site at http://www.fda.gov/medwatch/getforms.htm. Specific regulatory requirements are defined within 21 CFR Parts 803.32 (for User Facilities), 803.42 (for Importers), and 803.52 (for Manufacturers). More details can be viewed and downloaded from

www.fda.gov/cdrh/devadvice/351.html.

All persons required to report under MDR must provide information that is reasonably known to them about the event and must complete all applicable sections of the mandatory Form 3500A. With respect for HIPPA requirements, it remains important that as much patient data as possible be provided to the manufacturer, to adequately assess and evaluate the reported adverse events and their relationship, if any, to the medical device.

It is important to provide consistent data that are appropriate for the subject device of the MDR. RSMB welcomes the opportunity to work with all reporters to assist them when completing the Form 3500A. Missing and incomplete data on the 3500A can result in FDA requests for additional information.

What are the ramifications for failing to report?

Every individual with reporting obligations can be penalized for violations of The Federal Food, Drug, and Cosmetic Act. Section 303 defines the penalties that can be applied. Regulatory penalties include, but are not limited to, citations and civil money penalties assessed for failure to properly handle complaints and investigate adverse events. Additionally, failure to provide adequate and consistent data in MDR reports can impede the FDA's authorization of a manufacturer's request to participate in alternative reporting exemptions such as exist under 21 CFR Part 803.19.

Who can I turn to when I have questions regarding MDR requirements?

The Reporting Systems Monitoring Branch, under the Division of Surveillance Systems in the Office of Surveillance and Biometrics, within the Center for Devices and Radiological Health (CDRH), is the official source for MDR regulatory interpretation and reporting determinations.

During normal working hours, an "Officer of the Day" is always available to help you at (240) 276-3464 phone; (240) 276-3454 fax; and rsmb@cdrh.fda.gov. For MDR materials and information online, go to www.fda.gov/cdrh/mdr.html. ■

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