Medical Device Reporting for Mandatory Reporters

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Hello, my name is Anike Freeman and I am a Senior Consumer Safety Officer within the Division of Industry and Consumer Education. In this module, I will inform you of Medical Device Reporting requirements for mandatory reporters. Medical device reporting is a fundamental postmarket activity monitored by FDA.

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Here are our learning objectives. First, we will explain and establish the regulatory basis for medical device reporting. Next, we will define key medical device reporting terms, identify mandatory reporters and go over their specific reporting responsibilities. Finally, we will determine how, when, and where those reports are submitted and discuss the voluntary malfunction summary reporting program.

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Let's discuss FDA's regulatory authority.

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The regulatory authority for the Medical Device Reporting program comes from the United States Food, Drug, and Cosmetic Act. Section 519 pertains specifically to records and reports on medical devices. It grants FDA the authority to require medical device reports from manufacturers, importers, and device user facilities. The specifics of these requirements can be found in Title 21 of the Code of Federal regulations (or CFR), part 803.

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21 CFR part 803 supplements the provision of the quality system regulation, 21 CFR 820, and contains detailed information on how to meet mandatory reporting requirements. It establishes the critical elements for a firm's medical device reporting system which includes: a standardized complaint review process, timely and effective identification and communication of reportable events, and proper documentation and recordkeeping.

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As I mentioned earlier, Medical device reports, or MDRs, are also called out in the Quality System regulation. If you are a medical device manufacturer, you are likely already familiar with this regulation. 21 CFR 820.198 specifically details the requirement for manufacturers to maintain a system for collecting and reviewing complaints about their devices. These are considered complaint files. These complaints must be assessed to determine whether they should be submitted to FDA as an MDR. This diagram illustrates an important point— all MDRs are considered complaints, but not every complaint must be reported to FDA through the MDR program.

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Before we go further it is important to identify some of the key medical device reporting terms

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The first term is "MDR reportable event". The regulation states reportable events reasonably suggest a marketed device may have caused or contributed to a death or serious injury OR

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that a marketed device malfunctioned and likely would have caused or contributed to death or serious injury if it recurred. This is important distinction. Sometimes, medical device users are fortunate, and no harm is sustained during a device malfunction. However, that same malfunction could have triggered dramatically different results if, perhaps, the users were in a different position or less vigilant. These issues must be reported.

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The next term is “malfunction”. A malfunction is the failure of a device to meet its performance specifications or otherwise perform as intended. These performance specifications DO include any and all claims made in the labeling for a device.

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Finally, let’s define a serious injury. A serious injury means an injury or illness that: Is life-threatening, Results in permanent impairment of a body function or permanent damage to a body structure, OR Necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure. The term permanent means irreversible impairment or damage to a body structure or function, excluding trivial impairment or damage.

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Now let’s identify our mandatory reporters and their responsibilities.

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There are three categories of mandatory reporters. Manufacturers, importers, and device user facilities. You may read the complete descriptions for each of these reporting groups using the links provided on this slide.

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Common responsibilities for all mandatory reporters include establishing and maintaining MDR procedures and event files, clearly identifying these files in their records, and permitting FDA employees to access, copy, and verify those records upon request. This most often happens during an FDA inspection.

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Now we will define each type of reporter and their additional responsibilities. Let’s start with manufacturers.

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A manufacturer is any person who manufactures, prepares, propagates, compounds, assembles, or processes a device

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This also includes those who repackage or initiate specifications for a device, or manufactures components or accessories that are ready to be used and intended for commercial distribution

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If you are a manufacturer, you are required to investigate each event to determine its cause. You must also obtain and submit any missing information from other reporters. When reporting, you should provide as much information as can be reasonably known about the event.

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Reasonably known information includes information collected after contacting the person who reported the issue to you, information from your own internal testing and evaluation (if possible), and any information already in your possession (such as trends you've noticed with a specific device type).

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The next category of mandatory reporters are importers.

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Importers are people who bring devices into the United States from a foreign country. They also further the marketing of that device from the place of original manufacture to the person who conducts final sale of the device to the ultimate user.

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Please note importers do not repackage devices. They do not change the container, wrapper, or label of the device in any way nor do they change the device package.

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Importers are not required to investigate reportable events. However, they must establish and maintain their own MDR procedures and event files. Their responsibilities do not extend further than those required of all mandatory reporters.

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The final category of mandatory reporters are user facilities.

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A device user facility may be a hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment facility.

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They are NOT physician's offices, school nurse offices, or employee health units.

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Device user facilities are responsible for submitting annual reports to FDA using Form 3419. If you are a user facility, please review this form and instructions for completing this annual report using the links provided here.

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Having established the roles and responsibilities of mandatory reporters, we can now discuss the logistics of how, when, and where MDRs are submitted to FDA.

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Manufacturers and importers may only submit their reports electronically through the Electronic Submissions Gateway. This is the result of the electronic medical device reporting (eMDR) final rule which was issued in August of 2015. For more information on this requirement, you are welcome to refer to the eMDR guidance document.

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User facilities, however, while encouraged to report electronically, are not required to do so. They still have the option to submit written reports to FDA by mail using Form 3500A. Please refer to the guidance document on medical device reporting for user facilities for more information.

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FDA expects mandatory reporters to submit MDRs after becoming aware of reportable events and certain malfunctions. This reporting timeline varies and may be within 30 calendar days, 10 working days, or 5 working days. We will discuss this in more detail in just a few slides.

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FDA considered firms to be aware whenever an employee becomes aware of the reportable event or a supervisory employee becomes aware the event requires remedial action.

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The term “remedial action” refers to any action, other than routine maintenance, that must be taken to prevent recurrence of a reportable event.

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The table provided here serves as a consolidated overview of the information we have discussed this far. It explains who reports, what they are required to report, where they must submit those reports, and when that information must be reported. Manufacturers must report deaths, serious injuries, and certain malfunctions to FDA within 30 calendar days of becoming aware. Certain events requiring remedial action, however, must be reported within 5 work days.

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These are considered 5-day reports. They are submitted for events requiring remedial action to prevent an unreasonable risk of substantial harm to the public health. They must also be submitted whenever FDA has made a written request for a specific event involving a specific medical device to be reported within 5 work days.

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Next we will summarize requirements for importers. Importers are required to report deaths and serious injuries to both FDA and the device manufacturer within 30 calendar days. However, they only need to report certain malfunctions to the manufacturer within 30 calendar days. Manufacturers can then investigate these malfunctions to determine whether submission of an MDR would be appropriate.

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Finally, device user facilities are only required to report deaths or serious injuries to FDA within 10 work days. A copy of these reports are sent by FDA to the manufacturer (when known) for their own evaluation.

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Before we close, I’d like to share some information on the voluntary malfunction summary report program for device manufacturers.

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This program came about because of a final rule FDA issued on August 17th, 2018. It specifically grants manufacturers the option to report certain malfunctions in summary format as opposed to individually. These reports would still be submitted electronically but on a quarterly basis. It would apply to malfunctions manufacturers become aware of after August 17th 2018. Please refer the federal register notice linked on this slide for detailed information on this rule.

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There are conditions, however, for the voluntary malfunctions summary reporting program. Manufacturers may not use summary reporting if the reportable malfunction is associated with a 5-day report, is the subject of certain device recalls (such as a Class I recall), or if the device involved has been deemed ineligible by FDA. You can confirm a device's eligibility by searching for it in the product classification dataset linked here. The description page for the device will include a line specifying its summary malfunction reporting status, as shown in this screenshot.

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Summary reporting also cannot be used if FDA has determined individual reporting is necessary for that type of malfunction or that a certain manufacturer may not report in summary format. This would most commonly apply to manufacturers with significant regulatory compliance issues or failures. Finally, summary reporting may not be used for new types of reportable malfunctions for a device.

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You may reference the table provided here to see the timeframe for each quarter of summary reporting and the deadline for submitting reports. The deadlines apply to malfunctions manufacturers became aware of within the corresponding reporting quarter. As you can see, that deadline is always a month after the end of a reporting quarter.

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In summary, understand that MDRS are a regulatory requirement per 21 CFR 803. It is imperative that mandatory reporters understand and comply with their reporting requirements. We cannot emphasize enough how critical MDRs are to public health and safety.

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If you have general MDR questions please contact the Division of Industry and Consumer Education. For assistance with more nuanced or complex questions involving the interpretation of MDR policies, please contact the MDR Policy Group using the contact information provided here.

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As always, we encourage you to refer to CDRH Learn and Device Advice for additional regulatory education. You may also contact DICE directly with any general regulatory questions you may have. We are happy to assist you by phone or email. Please refer to the information provided on this slide for our hours of operation.

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Remember, it is your responsibility to stay current on MDR policies and regulations. This responsibility includes establishing your firm's MDR procedures and being proactive about meeting your reporting deadlines. We hope you've found this presentation helpful and informative. Thank you for watching.

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