# Final Guidance Sheds Light on Medical Device Reporting Requirements

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In November 2016, the U.S. Food and Drug Administration ("FDA") issued a final guidance on medical device reporting for manufacturers ("Final MDR Guidance"). The Final MDR Guidance addresses: (1) manufacturers' reporting requirements; (2) written procedures, recordkeeping, and public disclosures; and (3) questions posed by industry and needed clarifications for manufacturers.

**1. Manufacturers' Reporting Requirements**

Manufacturers must submit reports of adverse events either: (a) no later than thirty days after becoming aware of a death, serious injury, or malfunction ("30-day report")[1]; or (b) no later than five days after becoming aware if either the reportable event requires remedial action to prevent an unreasonable risk of substantial harm to the public health or the FDA has made a written request for a report. The Final MDR Guidance answers questions such as: Who is considered a manufacturer? What does "becoming aware" mean? What constitutes a "serious injury?" What constitutes a "malfunction?" What is "remedial action?" What must be included in the reports?

**a. Serious Injuries**

The definition of a "serious injury" has not changed since the FDA's guidance on medical device reporting in 1997: a "serious injury" is an injury or illness that (1) is life-threatening; (2) results in permanent impairment or damage to a body function or structure; or (3) requires medical or surgical intervention to preclude permanent impairment. But the agency recognized that it may be difficult to define "medical or surgical intervention." So, the Final MDR Guidance suggests manufacturers make a case-specific assessment of the risk to the patient without the intervention to determine if an injury or illness requires reporting.

**b. Malfunctions: Two-Year Presumption Language**

The Final MDR Guidance returns to the 1997 guidance's concept of a "two-year presumption" of recurrence following a malfunction, which had been removed in the 2013 draft. Specifically, once a malfunction has caused or contributed to a death or serious injury, there is a presumption that the malfunction is likely to recur and cause or contribute to a death or serious injury. This presumption continues until either there have been no additional deaths or serious injuries for two years or the manufacturer can show through verifiable data that the likelihood of another death or serious injury as a result of the malfunction is remote.

Regardless, the FDA strongly suggests that a manufacturer submit a notice of intent to cease reporting along with a summary of all data points collected over a two-year period. The agency will likely agree to the cessation of reporting if the data shows that the malfunction *cannot* recur beyond the two years. And the agency leaves the door open for a manufacturer to make a similar showing earlier than two years following an adverse event.

The Final MDR Guidance also eliminates the requirement for a trend analysis to be included in the reporting. But a manufacturer still must conduct a complete investigation on all product complaints. So, a trend analysis should be a routine activity performed and maintained as part of a comprehensive quality plan established at the manufacturer's facility. It is still advisable that adverse trends discovered as part of any investigation be mitigated through a Corrective and Preventive Action program.

**c. User Errors**

Similar to past guidance documents, the Final MDR Guidance defines a "user error" as a device-related error or mistake made by the person using the device. The FDA does not distinguish between deliberate acts and inadvertent acts. Further, the agency believes that user errors often reflect flaws in the device, user interface, or labeling. So, user errors that result in a serious injury should be reported to the agency like other adverse events. If an investigation reveals, however, that the injury was *solely caused* by user error with no device performance or labeling issues, the manufacturer is not required to file a report. The FDA strongly recommends that the investigation and all supporting information be retained in easily accessible files.

**2. Written Procedures, Recordkeeping, and Public Disclosures**

The Final MDR Guidance outlines manufacturers' requirements for developing, maintaining, and implementing written reporting procedures; requirements for establishing and maintaining report files and records; and what information in manufacturers' files is subject to public disclosure.

The Final MDR Guidance also addresses concerns regarding duplicative reporting. All manufacturers of legally marketed medical devices in the United States, including foreign manufacturers who export devices to the United States, are subject to the MDR regulations and must submit required reports. This includes specifications developers (entities that do not manufacture but instead develop specifications for a device distributed under their name). Specifications developers also may arrange for the manufacture of devices labeled with another entity's name by a contract manufacturer. The draft guidance imposed reporting requirements for adverse events on both contract manufacturers and developers, eliciting numerous concerns regarding a redundancy in reporting.

The Final MDR Guidance limits the applicability of reporting requirements to specifications developers and *only* those contract manufacturers that actually market and distribute a medical device. Contract manufacturers that do not market or distribute the product are *not* required to file reports with the FDA. This should appropriately ease the reporting burden on entities that are merely serving as production factories for devices that bear another entity's name. But note that if both a contract manufacturer and the specifications developer market and distribute the device, then *both entities* must file medical device reports.

Many of the comments to the draft guidance suggested that filing responsibility should be determined contractually between the two entities. Though not entirely eliminating double submissions, the Final MDR Guidance encourages both entities to submit a joint request for a reporting exemption that specifies which entity will submit reports (though both should continue to maintain documentation about adverse events). The entity exempted from reporting still may be responsible for ensuring that reports are properly filed. If reports are not submitted by the non-exempt entity, the exemption will be revoked, and both entities will be required to submit.

**3. Specific Issues and Situations**

The Final MDR Guidance answers several questions posed by industry and clarifies manufacturers' obligations in specific scenarios:

- A delay in surgery alone, without any adverse impact on the patient, is not considered a reportable event. But if a malfunction or device failure causes the delay in surgery and it would be likely to cause or contribute to a death or serious injury if it recurred, then it is reportable.

- Manufacturers must maintain MDR files for two years from the date of an event or a period equivalent to the expected life of the device, whichever is greater. The "expected life of a device" is the time that a device is expected to remain functional after it is placed into use. This is not the same as a device's warranty period, or, for devices that require regular maintenance, the time between calibrations or maintenance cycles. Instead, it is a device's overall life.

- Including the risks and complications associated with the use of a device on the device's label does not exempt the manufacturer from reporting adverse events.

- Injuries caused by an approved medical device that is also under an Investigation Device Exemption ("IDE") for another use must be reported under *both* the MDR regulations and the IDE regulations.

The FDA will accept written or electronic comments on the Final MDR Guidance at any time.

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[1] The Food and Drug Administration Amendments Act of 2007 modified malfunction reporting requirements such that manufacturers are only required to submit a quarterly summary of data points for all medical devices (with the exception of Class III and life-supporting, life-sustaining, or permanently implantable Class II devices). Note, however, that this does not change manufacturers' obligation to submit 30-day reports per MDR regulations.