

# Medical Device Reporting for Manufacturers; Final Guidance

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Medical Devices and Diagnostics

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On November 8, 2016, the U.S. Food and Drug Administration (FDA) published a final guidance titled Medical Device Reporting for Manufacturers (“Final Guidance”).<sup>1</sup> The guidance explains and clarifies FDA’s interpretations of its regulations under 21 C.F.R. Part 803 for adverse event and malfunction reporting and recordkeeping for manufacturers. On November 30, 2016, FDA explained its reasoning behind certain provisions in the Final Guidance through a webinar. The Final Guidance supersedes the Medical Device Reporting for Manufacturers final guidance published in March 1997, and replaces FDA’s draft guidance on Medical Device Reporting for Manufacturers (“Draft Guidance”) published on July 9, 2013. Following the release of the Draft Guidance, FDA received 33 comments from various stakeholders.

The Final Guidance contains four substantive sections:

1. manufacturer reporting requirements;
2. written procedures, recordkeeping and public disclosure;
3. specific issues and situations; and
4. questions concerning the completion of the medical device reporting (MDR) report.

The Final Guidance reiterates key statements from the 2013 Draft Guidance and makes a number of changes. The significant changes include: (1) reintroducing the “two-year rule” for device malfunctions with a new notification procedure; (2) limiting contract manufacturer adverse event reporting to those contract manufacturers that distribute devices for a specifications developer; and (3) removing the reference to alarms in situations where the device malfunctions, but the user intervenes before there is harm. These changes, along with other notable provisions, are discussed below.

## Significant Policy Changes

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### **FDA Reintroduces the Two-Year Rule for Malfunction Reporting and Incorporates a New Notification Procedure**

Section 2.15 of the Final Guidance reintroduces what had been known as the “two-year rule,” a two-year time period for removing the presumption that a malfunction will cause or contribute to a serious injury or death. FDA’s regulations require a manufacturer to submit an MDR if it

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<sup>1</sup> The final guidance is available [here](#).

becomes aware of an event in which one of its marketed devices malfunctioned and the malfunction would “be likely to cause or contribute to a death or serious injury if the malfunction were to recur.”<sup>2</sup> The 1997 Guidance stated that once a malfunction had in fact caused or contributed to a death or serious injury, FDA would presume that the malfunction was likely to cause or contribute to a death or serious injury until two years had passed during which the malfunction did not contribute to a death or serious injury. FDA’s Draft Guidance had eliminated the two-year period for lifting the presumption, recommending that manufacturers file MDRs indefinitely for additional reports of that malfunction unless FDA approved a request for an exemption from further reporting of the malfunction.

The Final Guidance pulls back from the policy in the Draft Guidance and reintroduces the “two-year rule” with a new notification procedure. If a manufacturer wishes to cease reporting at the end of two years, the agency recommends that the manufacturer submit “a notification to FDA with a summary of the data and rationale to cease reporting at the end of two years.” The manufacturer does not need to wait for FDA’s response before it stops reporting, but “FDA may, in certain circumstances, request additional information about the firm’s decision within 30 calendar days of FDA’s receipt of the notification.” In its November 30 webinar, FDA explained that the agency was worried about malfunctions that continue to occur and are likely to cause or contribute to a death or serious injury even if the malfunction had not in fact caused or contributed to a death or serious injury within the two year period. FDA recommended that the notification contain information about how the manufacturer took corrective action related to the malfunction and how the manufacturer knows that the actions were effective. FDA suggested that it may request additional information in cases where the notification is unclear about whether a device continues to malfunction or whether the malfunction is likely to cause or contribute to a death or serious injury.

In addition, under the Final Guidance, a manufacturer wishing to cease reporting a malfunction before two years have elapsed since the malfunction last caused or contributed to a death or serious injury, should request an exemption under 21 C.F.R. § 803.19(d). A manufacturer could consider requesting such an exemption if data suggest that the malfunction has not “caused or contributed to” further deaths or serious injuries and that “the likelihood of another death or serious injury” due to the malfunction is remote. The exemption request should include information “such as the characteristics of the device, incidence rate for the malfunction, and assurance that the complaints were investigated to support the rationale for the decision to cease reporting.” The firm should continue reporting to FDA until the agency responds and grants the exemption request.

### **MDR Reporting Requirements Not Applicable to Certain Contract Manufacturers**

The Final Guidance takes a different approach from the Draft Guidance in specifying that certain contract manufacturers will not need to submit MDR reports. The MDR reporting regulations, including 21 C.F.R. § 803.50, apply to any device “manufacturer,” which is defined as “any person who manufactures, prepares, propagates, compounds, assembles or processes a device by chemical, physical, biological, or other procedure.”<sup>3</sup> However, section 2.17 of the Final

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<sup>2</sup> 21 CFR § 803.3(o).

<sup>3</sup> 21 CFR § 803.3(l).

Guidance makes it clear that a contract manufacturer that does not “distribute or market the devices it manufactures for a specifications developer” would not need to submit MDR reports. This is a change in approach as compared to the Draft Guidance, which would have required reporting by all contract manufacturers.

Under the Final Guidance, if the contract manufacturer “distributes or markets” the devices that it manufactures for the specifications developer, both the specifications developer and the contract manufacturer would need to submit MDR reports. If the two firms want only one firm to file the reports for the device, the two firms should file a joint request for an exemption from filing, specifying which firm will submit the reports. The request should provide “a description of any agreement between the firms pertaining to MDR reporting for events involving the device.” FDA makes clear that an agreement for one firm to file MDR reports for both firms does not negate the other manufacturer’s responsibilities to maintain information about events, “including information about root cause and corrections.”

## Other Policy Highlights

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### Malfunction Reporting Applies for All Devices

Section 2.1 of the Final Guidance reaffirms that malfunction reporting continues to apply to all devices. Title II, section 227 of the Food and Drug Administration Amendments Act of 2007 amended section 519(a) of the FDCA to require only quarterly or summary reports for class I and class II devices that are not permanently implantable, life supporting, or life sustaining.<sup>4</sup> However, in 2011, FDA published a notice stating that it intended to promulgate a rule establishing malfunction reporting criteria for devices subject to quarterly reporting and, until such rulemaking is finalized, all manufacturers must continue to comply with Part 803 requirements.<sup>5</sup> The Final Guidance reaffirms this position, stating that pending FDA’s final rule for malfunction reporting criteria for devices subject to quarterly or summary reports, all device manufacturers and reporters must comply with 21 C.F.R. Part 803. In 2015, FDA released a pilot program for manufacturers interested in submitting malfunction reports for certain devices in a summary format on a quarterly basis.<sup>6</sup> However, FDA has not issued a proposed rule for devices subject to section 519(a)(1)(B)(ii) of the FDCA and has not announced when it intends to do so.

### Not All User Errors Need MDR Reports

As with the Draft Guidance, section 2.6 reiterates that events caused or contributed to by a “user error” should be reported in the same way as other adverse events. FDA clarifies that a manufacturer does not need to submit an MDR report where a device malfunction is solely the result of a user error “with no other performance issue, and there has been no device-related death or serious injury.” However, the manufacturer should retain supporting information in its complaint files. Commenters to the Draft Guidance had pointed out that if user error is involved, the device still may have functioned properly and performed as intended.

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<sup>4</sup> FDCA § 519(a)(1)(B)(ii).

<sup>5</sup> 76 Fed. Reg. 12743 (Mar. 8, 2011).

<sup>6</sup> FDA, Pilot Program for Medical Device Reporting on Malfunctions (Aug. 18, 2015), available [here](#).

### **FDA Retains Criteria Describing When a Malfunction Would be Likely to Cause or Contribute to a Death or Serious Injury**

The Final Guidance retains criteria in the Draft Guidance describing when a malfunction is reportable because it would likely cause or contribute to a death or serious injury if it were to recur. FDA had introduced the five criteria in the preamble to its 1995 MDR regulation.<sup>7</sup> The Draft Guidance had provided additional guidance on FDA's interpretation of these criteria. Section 2.14 of the Final Guidance retains the language from the Draft Guidance but provides no additional guidance, such as when the chance of a death or serious injury occurring as a result of a malfunction recurrence is "not remote." The Final Guidance retains the list of factors provided in the Draft Guidance to help manufacturers determine whether a device is "similar" to another device for malfunction reporting.

### **Single Reporting Exemptions Pertaining to Foreign Manufacturers and Importers**

The Final Guidance provides additional information for situations in which an importer intends to submit MDRs for the importer and the foreign manufacturer. In section 2.32, FDA reaffirms that even if the importer submits the MDRs, the foreign manufacturer still bears responsibility for ensuring that the importer submits the MDR reports in compliance with all applicable requirements. FDA recommends standard operating procedures for both the manufacturer and importer describe how the firms will handle MDR reporting procedures and how the firms intend to timely transmit MDR reports to FDA.

### **MDR Reports Required Where a Delay in Surgery is Due to a Defective Product**

Section 4.1.1 of the Final Guidance addresses instances where manufacturers will submit a MDR report for an event that causes a delay in surgery. As in the Draft Guidance, FDA reiterates that "[a]n event should not be considered an MDR reportable event solely on the basis of a delay in surgery." FDA clarifies that a delay in surgery due to a defective product, such as a broken suture or other malfunction, may be MDR reportable as a malfunction even where the patient remained stable with no adverse consequences.

### **Events from Incompatible Devices**

Section 4.3.2 of the Final Guidance reiterates that an event resulting from use of incompatible devices would be reportable if the event may have caused or contributed to a death or serious injury. However, the event would not be reportable as a device malfunction if the labeling was clear that the devices should not be used together. FDA recommends that manufacturers submit a voluntary report for the issue using the MedWatch Form FDA 3500.

### **MDR Requirements for 510(k) Transfers Apply to PMA Transfers**

As with the Draft Guidance, section 4.12.2 of the Final Guidance reiterates that where one firm manufactures and distributes a 510(k) cleared device (Firm A), but sold the 510(k) to another firm (Firm B), Firm A must report adverse events for devices it manufactured that are already on the market. If Firm B assumes responsibility for the devices manufactured by Firm A, the arrangement should be documented with a written agreement, and Firm A must request an exemption from FDA to end MDR reporting for the devices it manufactured. The Final Guidance

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<sup>7</sup> 60 Fed. Reg. at 63585 (Dec. 11, 1995).

confirms that these recommendations also apply when a firm transfers ownership of the PMA for a device.

### Device Malfunctions Involving Alarms

Unlike the Draft Guidance, section 4.13 of the Final Guidance omits any mention of alarms in situations where a device malfunctions, but a user intervenes before the patient is harmed. The Draft Guidance had recommended that manufacturers file an MDR report for a malfunction that would be likely to cause or contribute to a death or serious injury but an alarm alerts the user to intervene before there is any harm to the patient. The Final Guidance removes the emphasis on alarms and restates FDA's regulation that a manufacturer must report the event as a malfunction if the manufacturer "concludes that the malfunction is likely to cause or contribute to a death or serious injury if the malfunction recurred." It is unclear why FDA decided to eliminate the reference to alarms in the Final Guidance or whether the change signals any shift in policy.<sup>8</sup>

Covington & Burling LLP will continue to monitor FDA's implementation of the Final Guidance and advise clients on developments. If you have any questions concerning the material discussed in this client alert or other medical device and diagnostic regulatory matters, please contact any of the following attorneys in our medical devices and diagnostics practice, or visit our [medical devices and diagnostics website](#):

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<sup>8</sup> Some commenters requested that FDA remove the reference to alarms.