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Client Alert

FDA and Life Sciences

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FDA Releases Draft Guidance on Medical Device Reporting *Will Supersede 1997 Guidance*

On July 9, 2013, the U.S. Food and Drug Administration (FDA or "the Agency") released a draft guidance document titled *Medical Device Reporting for Manufacturers* (hereinafter "Draft Guidance").[1] FDA has not updated its formal guidance on the medical device reporting (MDR) regulation since the final guidance the Agency issued in 1997 (hereinafter "1997 Guidance"),[2] which the Draft Guidance will supersede once it has been finalized. Although the Draft Guidance is not final and the 1997 Guidance remains in effect, the Draft Guidance represents the Agency's current thinking on MDR requirements and is "intended to update FDA's policy and to further clarify FDA's interpretations of the [MDR] regulation requirements . . . ." Given that the 1997 Guidance is more than sixteen years old and in some ways out of date, manufacturers should become familiar with the contents of the Draft Guidance and should consider complying with or commenting on its recommendations prior to its finalization. FDA is accepting comments on the Draft Guidance until October 7, 2013 (docket number FDA-2013-D-0743).

Draft Guidance Overview and Comparison to 1997 Guidance

The Draft Guidance is written in a question-and-answer format, addressing: manufacturers' reporting requirements; requirements for written procedures, recordkeeping, and public disclosure; specific issues and situations; and completing the Form 3500A used to report MDRs to FDA. Much of the content in the Draft Guidance closely tracks the language in the MDR regulations contained in 21 C.F.R. Part 803 and provides a general overview of manufacturers' responsibilities for reporting adverse events to FDA. The Draft Guidance leaves much of the advice from the 1997 Guidance intact and expands upon that guidance, with a few notable changes.

First, FDA has abandoned what has come to be known as the "two-year rule"—that is, the two-year time period for removing the presumption that a malfunction will cause or contribute to a serious injury or death. Both the 1997 Guidance and the Draft Guidance include a statement that once a malfunction has in fact caused or contributed to a death or serious injury, future occurrences of the malfunction are presumed to be likely to cause or contribute to a death or serious injury and are reportable as MDRs. The 1997 Guidance, however, stated that if the malfunction does not cause or contribute to any deaths or serious injuries for two years, then the presumption is lifted. In the Draft Guidance, FDA has eliminated this time

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period for lifting the presumption; rather, "once a malfunction causes or contributes to a death or serious injury, [manufacturers] have an obligation to file MDRs for additional reports of that malfunction."[3] However, the Draft Guidance does state that documentation that a device has not caused or contributed to additional deaths or serious injuries can be submitted to FDA to support a request for an exemption from further MDR reporting for the malfunction.

Second, the Draft Guidance omits the references to baseline reports and annual certification requirements that were included in the 1997 Guidance. The annual certification requirement was stayed by FDA and was never enforced, but it nevertheless remained in the 1997 Guidance. The requirement to provide baseline reports was removed from the regulations by FDA through a direct final rule that was effective as of October 27, 2008. FDA, however, did not update the 1997 Guidance to eliminate references to the baseline reports. FDA has remedied these discrepancies and removed the discussion of baseline reports and annual certifications from the Draft Guidance.

Key Provisions of the Draft Guidance

In the Draft Guidance, FDA reiterates and expands upon key statements from the 1997 Guidance regarding manufacturers' MDR responsibilities and also adds new recommendations. Some key provisions are summarized below, but manufacturers should review the complete Draft Guidance for provisions relevant to their business.

- ***Malfunction reporting continues to apply to all devices.*** Section 2.1 of the Draft Guidance notes that, in 2011, FDA published a notice in the Federal Register responding to statutory changes contained in the Food and Drug Administration Amendments Act of 2007 (FDAAA) that would have required only summary or quarterly reports for malfunctions of Class I devices and Class II devices that are not permanently implanted, life-sustaining, or life-supporting. The Federal Register notice clarified, and the Draft Guidance confirms, that until FDA issues a rule to establish malfunction reporting requirements for such devices, manufacturers of all these products must provide malfunction MDRs as required in 21 C.F.R. Part 803. Neither the Draft Guidance nor the 2011 Federal Register notice provides an estimated timeline for the issuance of such a rule.

- ***Likelihood of malfunctions to cause or contribute to death or serious injuries.*** In section 2.14, FDA reiterates the types of malfunctions that the Agency considers reportable as MDRs. This list of reportable malfunctions is notable because it provides insight into how FDA interprets the word "likely" in the requirement to report as MDRs malfunctions that would be *likely* to cause or contribute to a death or serious injury if the malfunction were to recur. Examples of reportable malfunctions include:

  i. events in which the chance of death or serious injury is "not remote,"

  ii. malfunctions that affect the device in a catastrophic manner that "may" lead to death or serious injury, and

  iii. failures of the device to perform its essential function which "could" cause or contribute to death or serious injury.

  The terms "not remote," "may," and "could" set a lower bar than what one typically would interpret the term "likely" to mean. These terms are not new in the Draft Guidance (they previously appeared in both the 1997 Guidance and the preamble to the final MDR rule), but their inclusion in the Draft Guidance highlights FDA's conservative interpretation of "likely," and the need to carefully analyze malfunctions for reportability.

- ***Correctable malfunctions may still be reportable.*** In section 2.14, FDA clarifies that even if a malfunction can be corrected during service or maintenance, the malfunction is nevertheless reportable if it would be likely to cause or contribute to a death or serious injury.

- ***Similar devices for malfunction reportability.*** For the first time, FDA provides an explanation of devices it considers similar for purposes of reporting malfunctions (*i.e.*, malfunctions are reportable if the device or *a similar device marketed by the manufacturer* would be likely to cause or contribute to death or serious injury if the malfunction were to recur). In section 2.14, FDA explains that it considers devices similar if they have the same basic design and performance characteristics, intended use and function, and device classification and product code. Additional factors include whether the devices have the same brand name, common name, or were cleared or approved under the same 510(k) or PMA.

- ***User error reportable as an MDR.*** In section 2.6 of the Draft Guidance, FDA reinforces the fact that user error may be reportable as an MDR if the incorrect use of the device causes or contributes to a death or serious injury. This is not a new position: the definition of "caused or contributed" in 21 C.F.R. § 803.3 includes user error. In the Draft Guidance, FDA reinforces this point and provides additional detail, noting that user errors "often reflect problems with the device labeling, the user interface, or other aspects of device design. Thus, FDA believes these events should be reported in the same way other adverse events a device causes or contributes to should be reported."

- ***Delays in surgery and MDR reporting.*** In section 4.1.1 of the Draft Guidance, FDA addresses the common practice in which manufacturers submit an MDR for any situation that causes a delay in surgery. FDA notes that "[a]n event should not be considered to be an MDR reportable event solely on the basis of a delay in surgery." (emphasis added). Device failures that cause a delay in surgery are reportable if the "delay may have caused or contributed to a death or serious injury to a patient . . . ." If no death or serious injury occurs, delays in surgery may still be reportable if the device malfunctioned and the malfunction (and the associated delay) would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

- ***Alarms to signal a malfunctioning device.*** In section 4.13.1 of the Draft Guidance FDA addresses the often confusing situations involving alarms that, if acted upon, may preclude serious injury or death of a patient. If a device malfunctions but an alarm alerts the user to intervene before there is any harm to the patient, FDA expects that the event will still be reported as a malfunction because of the potential to cause or contribute to a death or serious injury should the malfunction recur and either the alarm does not work or there is no one to respond. Manufacturers should investigate the event to confirm and document that, in this instance, the device malfunction did not cause or contribute to any change in the patient's condition that would be considered a reportable serious injury.

- ***Investigation of reported events.*** FDA expands upon the 1997 Guidance by providing more detail in section 2.23 about the Agency's expectations for manufacturers' efforts to obtain additional information about reported events. The Agency expects firms to undertake a "good faith effort" to obtain additional information and not rigidly focus on an absolute number of attempts. FDA states that a good faith effort should include at least one written attempt to obtain additional information, but that the "level of effort [manufacturers] make to obtain additional information depends largely on the nature and severity of the event reported." The Draft Guidance reminds manufacturers that attempts to obtain information should be documented in the MDR file and that this

information is subject to FDA review to determine whether the firm made a good faith effort. Section 4.9.1 provides further information on the good faith effort that FDA expects manufacturers to undertake and also explains that when a company does not receive a device back from the reporting facility or individual, the manufacturer must still analyze the reported event. This analysis may include "review of other similar events, device history review, [and] review of appropriate manufacturing processes . . . ." Finally, Section 4.16.2 provides detailed information about FDA's expectations for obtaining additional information about MDR reportable events contained in scientific articles and other literature.

- ***Expected life of devices, as relevant for recordkeeping.*** In section 4.2 of the Draft Guidance, FDA provides new information about how to calculate the expected life of the device, as relevant to the requirement in 21 C.F.R. § 803.18(c) that manufacturers keep MDR files for two years or the expected life of the device, whichever is longer. FDA explains that the warranty period cannot be used to determine the expected life of a device; rather, the expected life of a device "is the time that a device is expected to remain functional after it is placed into use." That time includes the overall lifecycle of the product, including any and all calibration and maintenance cycles. The MDR regulation does not require manufacturers to establish an end of life for their devices.

- ***Reporting of labeled complications and risks.*** Section 4.3.1 of the Draft Guidance explains that even if an adverse event was disclosed as a potential risk or complication in the device labeling, the event is nevertheless reportable as an MDR if the device caused or contributed to a death or serious injury. FDA states succinctly: "Events that were anticipated or intrinsically caused by a device are not exempt from reporting."

- ***Assigning MDR responsibility between two entities.*** In sections 2.17, 2.32, and 4.7.1, FDA provides guidance about requesting MDR reporting exemptions so that two entities are not both responsible for reporting MDRs for the same devices. Section 2.27 lists information that should be included in requests for such exemptions.

    i. *Specifications developers and contract manufacturers.* Under 21 C.F.R. § 803.3, both the firm that develops the specifications for a device which it markets (*i.e.*, spec developers) and the firm that manufactures the device to the first firm's specifications (*i.e.*, contract manufacturers) are considered manufacturers that are responsible for submitting MDRs. If the companies decide that they wish only one of the two companies to submit MDRs for the device, then an exemption from filing must be obtained for one of them. FDA suggests that the two companies submit a joint request for an exemption, specifying which firm will submit the MDRs and which will be exempt from doing so. FDA notes that if the reporting firm fails to file MDRs as required, the Agency may revoke the other company's exemption.

    ii. *Importers and foreign manufacturers*. Similarly, the Draft Guidance states that an exemption must be obtained if a foreign manufacturer and importer decide that they wish only one of the two companies to file MDRs for devices for which they both have responsibility. If, for example, the companies decide that the importer will submit MDRs, then FDA recommends that the entities file a joint request for an exemption that would specify that the importer is responsible for all MDRs and that the foreign manufacturer will be exempt from its reporting requirements.

- ***Commonly-observed problems in Form 3500As.*** In section 5.12 of the Draft Guidance, FDA provides a list of twelve of the most common problems that the Agency has observed in Form 3500As submitted by

manufacturers. Examples include submitting only one MDR report for a series of reportable events, and submitting a 5-day report for an event that does not meet the 5-day report criteria.

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King & Spalding will continue to monitor FDA's guidance on and actions related to manufacturers' MDR responsibilities. If you would like help drafting comments on the Draft Guidance or have questions about how to apply its recommendations to your MDR systems, please let us know.

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[1] The Draft Guidance is available for download from FDA's website at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM359566.pdf.
[2] The 1997 Guidance is available for download from FDA's website at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm094530.pdf.
[3] See section 2.15 of the Draft Guidance on page 12.