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ALERTS

Food, Drug And Device Law Alert - Lengthy 'Medical Device Reporting For Manufacturers' Guidance Issued By FDA

November 18, 2016 | Atlanta | Chicago | Columbus | Dallas | Delaware | Elkhart | Fort Wayne | Grand Rapids | Indianapolis | Los Angeles | Minneapolis | South Bend

The Food and Drug Administration (FDA) recently issued a lengthy final guidance titled "Medical Device Reporting for Manufacturers." The guidance updates the July 2013 draft guidance significantly.

Like the related regulations found at 21 C.F.R. § 803, the guidance discusses in a question and answer format the requirements for reporting adverse events related to medical devices. The draft guidance even converts the definitions of 21 C.F.R. § 803.3, which are crucial to understanding the reporting obligations, into a question and answer format. Thus, much of the guidance will be familiar to those who deal with the existing regulations on a regular basis.

For example, the draft guidance identifies the following as basic requirements of manufacturers with respect to device reporting:

- Submit to FDA reports of MDR reportable events involving their medical devices
- Develop, maintain, and implement written procedures for the identification and evaluation of all adverse medical device events to determine whether the event is an MDR reportable event
- Establish and maintain complete files for all complaints concerning adverse medical device events

For these purposes, the draft guidance summarizes the definition of a "reportable event" as an event that "manufacturers become aware of that reasonably suggests that one of their marketed devices may have caused or contributed to a death or serious injury, or has malfunctioned and the malfunction of the device or a similar device that they market would be likely to cause or contribute to a death or serious injury if the malfunction were to recur."

The second half of the draft guidance is likely to be of more interest to those already familiar with the regulations. It addresses what to do in specific situations and specific questions about completing FDA Form 3500A in connection with a report,. Some of the issues addressed in this part of the draft guidance include:

- Whether a delay in surgery related to a device is a reportable event
- How to determine the expected life of a device

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- Whether events already mentioned in the labeling are reportable
- Whether an event indirectly caused by a failed diagnostic device is reportable
- Whether an event is reportable when there is a conflict in medical opinion as to whether the device contributed to the event
- How to report adverse events involving the same patient and device but occurring on different days
- The amount of effort required for a follow-up investigation
- Whether an event is reportable if the device is being used under an IDE
- The reportability of events occurring outside the U.S.
- Whether a manufacturer has an obligation to submit a report when it has ceased marketing the device
- Whether a manufacturer must investigate and submit a report on an event it becomes aware of through literature

There are some significant differences between the final guidance and the draft version that was issued in July 2013. First, under the regulations and prior guidance, once a device malfunctioned and caused or contributed to death or serious harm, it was presumed that it would be likely to do so again unless two years passed without additional incidents. The draft guidance did away with the two-year presumption. The final guidance "recommends" that the manufacturer submit a summary of any data and a rationale for any decision to cease reporting after two years.

Second, according to the draft guidance, both contract manufacturers and specification developers for the same device are subject to the MDR reporting obligations in all cases. The final guidance states: "A contract manufacturer who does not distribute or market the devices it manufactures for a specifications developer would not have an MDR reporting obligation under 21 CFR 803.50 and would not require an exemption." In other words, a contract manufacturer is only subject to the reporting requirement if it also distributes or markets the device.

Finally, both the draft and final versions require the manufacturer to report events resulting from user error "in the same way as other adverse events which are caused or contributed to by the device." The final guidance, however, also states: "If you determine that an event is solely the result of user error with no other performance issue, and there has been no device-related death or serious injury, you are *not* required to submit an MDR report, but you should retain the supporting information in your complaint files" (emphasis added).

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