Medical Device Reporting for Manufacturers (MDR) Adverse Event Reporting; New Guidance for Industry as of July 9, 2013

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Weeding through current literature, guidance documents and government websites can prove be a daunting and time consuming task when staying current with FDA regulations. To help simplify the new medical device reporting changes, written here is a summary article to assist with your understanding of the upcoming changes related to the MDR requirements for Medical Device manufacturers.

The purpose for the MDR

Medical device reporting (MDR) regulations mandate the submission of adverse event reports to the FDA. These reports are intended to keep regulators (and the public) informed of potential or existing problems with medical device products. This reporting mandate is meant to push device manufacturers into making prompt changes or removing risks from medical devices when the risk removal is possible.

What is an "MDR reportable event"?

"These are events that manufacturers become aware of that reasonably suggest 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 [see 21 CFR 803.3[8]] (see Chapter 2 of this guidance document for a description of "serious injury" and "malfunction" and information for determining when a device malfunction must be reported to the FDA as an "MDR reportable event)".

(*eCFR data part 803-FDA guidance medical device reporting).

The purpose for new FDA guidance:
The new draft guidance document describes and explains the FDA's current regulation and thinking about reporting and recordkeeping requirements applicable to manufacturers of medical devices for certain device-related adverse events.

[1] These requirements are contained in the Medical Device Reporting (MDR) regulation at Title 21, Code of Federal Regulations (CFR), part 803[3], as authorized by section 519 of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Much of the 2013 MDA draft guidance remains consistent with the finalized version published in 1997.

However, listed here are some of the most pronounced changes that will be of interest to medical device manufacturers.

- **"Removal of the "Two-Year Rule" for malfunctions:**
  The FDA took the position that once a malfunction has caused or contributed to a death or serious injury, future malfunctions of the same type are presumed to be reportable. The 1997 guidance stated that the presumption would cease if the malfunction did not cause or contribute to any more deaths or serious injuries for a period of two years.

  The 2013 guidance states that manufacturers who wish to stop reporting a malfunction that previously caused or contributed to a death or serious injury would need to submit a request to FDA for an exemption. This can be supported by evidence that the malfunction had not caused or contributed to any further deaths or serious injuries.

  Unfortunately, it is not clear in the new draft guidance how much data the FDA requires to support such an exemption.

- **Contract manufacturer/supplier agreements:**
  The 1997 guidance stated that, for contract manufacturer agreements, "FDA would expect only one report from either the specifications developer or the contract manufacturer for one reportable event.

  There must be a written agreement clearly identifying the responsible party for completing Form 3500A.

  Although not stated in the 1997 guidance, FDA's policy in recent years has been to require an exemption when only one entity will be reporting in a contract manufacturer arrangement.

The 2013 draft guidance states that both the specifications developer and contract manufacturer must submit MDR reports unless an exemption is obtained from FDA allowing reporting from one entity.

- **MDR Obligations when your 510(k) is sold:**
  When a 510(k) is sold from one manufacturer to another (with the buyer taking over the manufacture of the devices under the 510(k) after the sale), the draft guidance (and FDA) states that the seller remains responsible for submitting MDRs for all of the devices that it manufactured prior to the sale, even if the agreement between the parties states that the buyer will assume this responsibility, unless an exemption is obtained from FDA.

- **Reporting Events Found in Literature:**
  The new draft guidance outlines the FDA's expectations and recommendations for investigating adverse events identified in scientific articles and other literature.

  The draft guidance suggests that manufacturers may need to contact the authors of these materials to obtain additional information during their investigation.

  The draft guidance also allows for the reporting of multiple events in one report when a manufacturer is unable to obtain sufficient information to provide a complete report for each reportable event, but FDA recommends submitting a separate report for each event type (if multiple event types are identified) and for each device (if more than one generic device type is implicated)."

  (Morgan, Lewis & Bockius LLP, law flash news, July 10, 2013, M. Bierman & M. Buenafe).

The draft guidance makes additional recommendations concerning the information that should be submitted in the different blocks on the MedWatch Form 3500A. The guidance also discusses reporting requirements around extenuating circumstances such as:

- a delay in surgery
- the failure of a diagnostic device; and
- incorrect treatment with a radiation therapy device.

The draft guidance makes clear that certain changes to MDR reporting proposed by Congress in the Food and Drug Administration Amendments Act of 2007 have not been implemented by the FDA. The result is that malfunction reporting requirements for class I and those class II devices that are not permanently implantable, life supporting or life sustaining, continue to be subject to the MDR reporting requirements of 21 C.F.R. part 803.

(*eCFR data part 803-FDA guidance)

Additional points of interest to manufacturers:
The FDA has identified the 12 most common errors it sees in MDR reports.
The points are listed in order of frequency.

1 Duplicate report sequence numbers provided in the Manufacturer Report Number box and Block G-9. Each report must have its own sequence number to avoid confusion.

2 Multiple devices or events are included in the same report.

3 The blocks in B-2 (Outcomes Attributed to Adverse Event) and B-5 (Description of Event or Problem) do not match or do not accurately represent the text contained in H-1 (Type of Reportable Event), H-10 (Additional Manufacturer Narrative), or H-11 (Corrected Data). If any information in Block B conflicts with the information in Block H, then you should provide an explanation in Block H-11 to address the conflict.

4 Block D (Suspect Medical Device) is left blank or specific items within Block D are left blank.

5 An importer submits a report on behalf of the manufacturer without requesting an exemption.

6 The contact name and telephone number are not provided in Blocks G-1 and G-2, respectively.

7 A 5-day report is submitted for an event that does not meet the 5-day report criteria.

8 A report is marked as a “follow-up” report, but no follow-up sequence number is provided.

9 No box is marked, or more than one box is marked, in Block H-1 (Type of Reportable Event).

10 Codes required to be entered in Block H-6 (Evaluation Codes) are put in boxes on the wrong row. For example, an evaluation method code might be entered in the space for evaluation results codes or evaluation conclusion codes.

11 Block H-7 information (If Remedial Action Initiated, Check Type) is not provided when the event relates to a remedial action.

12 Event problem codes (patient problem codes and/or device problem codes) are not provided in Block F-10.

(Regulatory Focus, RAPS online publication, July 8, 2013, A. Gaffney)

Your feedback and comments about the MDR draft guidance can be submitted electronically to the FDA at www.regulations.gov through October 7, 2013.
You may also submit your comments in writing to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.