

## Medical Device Reporting for manufacturers: Assessment of FDA's 2013 draft guidance

Roshana Ahmed, MA, RAC  
roshana.ahmed@optum.com

Sr. Manager Regulatory Affairs – Medical Devices

Like the rumblings of thunder heard on the horizon, a July 2013 guidance<sup>1</sup> issued by the U.S. Food and Drug Administration (FDA) sparked concern in the medical device industry about a possible storm ahead. As it attempted to provide clarification about its Medical Device Reporting (MDR) regulation (21 CFR part 803)<sup>2</sup>, FDA raised a number of new questions and left others unanswered.

What does the guidance mean to you as a medical device manufacturer? Here's a look at some of the key elements in the guidance, how you should react to it, and why this is a good time to examine the way you do business.

### The industry speaks

When — and if — the 2013 guidance becomes final, it will replace the previous guidance issued in 1997. Will the new guidance be finalized in its current form? It's not likely. When FDA sent the guidance out for comment, it received extensive feedback about the negative impact some of the new thinking in the guidance could have on the industry. FDA is now considering that feedback and how it might incorporate it into the guidance. Some of the thorniest issues are discussed below.

#### Duplicate reporting

Many in the industry expressed concern that certain provisions in the guidance might bog down the industry — and FDA for that matter — with a large volume of additional work.

Take the example in which Company A develops specifications for and distributes a device manufactured by Company B. According to the guidance, both companies are required to submit their own reports when an MDR reportable event involving one of their medical devices occurs. (See definition of MDR reportable event at right.) Not only does this create an overall duplication of effort for each report for both the industry and FDA, it impacts the patient, user and/or facility as well.

FDA states it will allow companies to jointly request an MDR reporting exemption for one of the companies and assign the responsibility for the reporting to the other company. However:

- Even the exemption paperwork could be burdensome to the companies involved and overwhelming to FDA.
- The guidance does not provide a time frame in which FDA will respond to exemption requests, creating uncertainty.
- Once an exemption is granted, FDA can revoke or modify it, causing additional uncertainty.
- FDA may still hold the exempted company responsible and revoke its exemption if the reporting company fails to submit an MDR report for some reason. That places a substantial burden on the exempted company that many feel it shouldn't

---

#### MDR reportable event

For manufacturers, FDA's MDR regulation defines MDR reportable events as 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.
-

Similar exemption request burdens are placed on importers and foreign manufacturers who are working together. In addition, the guidance explains that manufacturers of legally marketed devices being studied under an approved Investigational Device Exemption (IDE) would have to report an adverse event under both the MDR regulation and IDE regulation, leading to duplication of reports and skewed data.

### **“Two-year rule” removed**

FDA assumes that once a device malfunction causes or contributes to a death or serious injury, the malfunction is “likely to” cause or contribute to another death or serious injury if it were to recur. Therefore, a manufacturer has an obligation to file reports for additional incidences of that malfunction.

The 1997 guidance included what is often referred to as the “two-year rule,” which lifted the reporting requirement if the malfunction was not linked to a death or serious injury after two years. By removing this rule, the 2013 guidance creates the potential for manufacturers to have to provide reports over the long term for device malfunctions that may not present a likely threat to patients. This could cause a tremendous drag on the efficiency of large manufacturers, as well as add substantially to FDA's workload.

As with the redundant reporting discussed above, companies can request an exemption from reporting these subsequent malfunctions.

### **All devices still included**

The Food and Drug Administration Amendments Act of 2007 (FDAAA) mandates a reduction in the malfunction reporting requirements for Class I devices and Class II devices that are not permanently implantable, life supporting or life sustaining so that those devices would be subject only to MDR reporting in summary form on a quarterly basis. However, to take effect, that change required further action by FDA, including identification of those devices that would still need to be reported under 21 CFR part 803. FDA has yet to take action, and the 2013 guidance confirms that manufacturers must continue to submit medical device reports for all devices until it does so. No time frame was provided in the guidance for FDA action on the change.

### **“Not remote” vs. “likely to”**

As stated above, the definition of an MDR reportable event per the regulation includes events in which a device malfunction “would be *likely to* cause or contribute to a death or serious injury if the malfunction were to recur.” In Section 2.14 of the guidance, FDA states a malfunction is reportable if “the chance of a death or serious injury occurring as a result of a recurrence of the malfunction is *not remote*.”

The inconsistency in terminology between the regulation and guidance causes confusion because the phrase “not remote” may lead some to identify more events as reportable than “likely to” would. As with the issue of redundant reporting, this ambiguity could lead to the use of valuable resources to perform unnecessary reporting. At the same time, it could skew the public's perception of device safety. Some device users and patients may view certain devices as not safe when they actually are.

## Your MDR to-do list

As important as it is to stay abreast of FDA's possible intentions so you will not be blindsided by any changes, it's just as important not to overreact. If when reading the guidance you see something that requires action you believe will improve your processes and business, by all means consider doing it. However, if you're currently in compliance with the regulation, you don't want to make any big changes now based on the draft guidance. It's better to avoid the cost and wait for the guidance to be finalized.

Having said that, the rumbling created in the industry by the 2013 guidance should not be ignored. Consider it a call to action. Follow these steps to make sure your MDR reporting processes are compliant and running smoothly:

**Conduct ongoing training** – As with anything you do, employee knowledge and expertise is critical to satisfying FDA reporting requirements. By making MDR training a priority, you can avoid reporting snags that can ultimately affect your bottom line.

**Stay alert** – Remember, you must file a report when you become aware of an MDR reportable event. Be sure your employees understand their responsibilities if they receive information that may trigger MDR reporting.

**Review your data collection methods** – When an MDR reportable event occurs, it's vital that you are able to collect the proper data in a timely fashion.

**Audit your reporting procedures** – You should regularly review your reporting procedures to make sure they are being followed and are working properly. Ask yourself:

- Do your procedures enable you to satisfy FDA's reporting requirements efficiently and effectively?
- Are your reportable events properly documented?
- Are your MDR files complete?
- Are you submitting reports within the time frames required?
- Have any issues arisen that exposed problems with your procedures that need to be addressed?

**Check your contracts** – If you have an agreement with another company regarding medical device reporting, make sure it's clear who is responsible for which tasks. Also, audit their procedures to ensure they are handling all their reporting responsibilities as defined contractually.

**Strive for perfection** – In Section 5 of the 2013 guidance, the FDA lists the 12 most common problems it sees when manufacturers fill out Form 3500A, which is the form used by manufacturers to submit MDR reports. Review this section so you can avoid those mistakes.

**Prepare for electronic submission** – Beginning August 14, 2015, manufacturers will be required to submit MDRs to FDA in an electronic format that FDA can process, review and archive per a final rule on Electronic Medical Device Reporting (eMDR) FDA published on February 13, 2014<sup>3</sup>. The two options for submitting eMDRs are eSubmitter and Health Level 7 Individual Case Safety Reports (HL7 ICSR). Information on how to prepare for eMDR is provided on FDA's website<sup>4</sup>. If you are unable to meet the date of August 14, 2015, you must request and obtain an exemption from electronic reporting.

---

### Reading between the lines

Overall, FDA takes a more stringent view of MDR reporting requirements in the 2013 guidance. This may indicate a shift in how FDA plans to enforce the regulation and should prompt manufacturers to revisit their reporting procedures.

---

## Getting the job done

The complexities of the MDR regulations — plus the ramifications of not following those regulations in both human and financial terms — puts substantial pressure on manufacturers. At Optum™, we can ease that pressure with our Global Regulatory Affairs group, one of the largest regulatory consulting groups in the world. Our team of regulatory and quality specialists can help you take a rigorous, systematic approach to regulatory affairs with a wide range of MDR support, including:

- U.S, Canadian, and European regulatory compliance services
- Training
- Contract auditing
- Procedures development or review
- Report execution

## Take a deep breath

Anyone who has read government regulations knows how difficult it can be to understand and comply with them. FDA's 2013 guidance on MDR reporting was a long time coming, but left many wondering what is next. For now, the best approach you can take as a medical device manufacturer is to examine your current reporting systems and make sure you are comfortable with how they are running. Once armed with that assurance, you will be in the best position to respond once the latest guidance becomes final.

---

**Ask the experts.** To learn how Optum can help you interpret and comply with MDR regulations, contact us today.

**Call:** 1-866-306-1321

**Email:** [connected@optum.com](mailto:connected@optum.com)

**Visit:** [optum.com/device](http://optum.com/device)

---

---

<sup>1</sup> **Draft Guidance for Industry and Food and Drug Administration Staff, Medical Device Reporting for Manufacturers, July 9, 2013.** Available at: <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM359566.pdf>

<sup>2</sup> **FDA Medical Device Reporting (MDR) regulation, Title 21, Code of Federal Regulations (CFR), part 803.** Available at: <http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&sid=20300bf7673514cf49d530123bc9d8e9&rgn=div5&view=text&node=21:8.0.1.1.3&idno=21>

<sup>3</sup> **Medical Device Reporting: Electronic Submission Requirements.** Available at: <https://www.federalregister.gov/articles/2014/02/14/2014-03279/medical-device-reporting-electronic-submission-requirements>

<sup>4</sup> **eMDR – Electronic Medical Device Reporting.** Available at: <http://www.fda.gov/medicaldevices/deviceregulationandguidance/postmarketrequirements/reportingadverseevents/emdr%E2%80%93electronicmedicaldevicereporting/default.htm>

