KING & SPALDING

Client Alert

FDA & Life Sciences Practice Group
Healthcare Practice Group

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FDA Identifies Fifteen Hospitals with Failures to Comply with User Facility Requirements for Medical Device Reporting

FDA issued a Form FDA 483 to fifteen prominent hospitals across the United States following inspections that demonstrated failures to comply with the user facility medical device reporting requirements pursuant to 21 C.F.R. Part 803. These actions were disclosed in a recent official FDA blog post from Jeffrey Shuren, the Director of the Center for Devices and Radiological Health (CDRH).[1] The Part 803 regulations require user facilities, such as hospitals, to have written procedures to ensure the submission of reports no more than 10 work days after the facility becomes aware of information reasonably suggesting that a medical device has, or may have, caused or contributed to a death or serious injury to a patient. User facilities are not required to determine if a medical device malfunctioned or failed to meet its specifications. Reports of medical device-related deaths *must* be submitted to FDA and the manufacturer, whereas reports of medical device-related serious injuries need only be submitted to the manufacturer; however, even these reports must be submitted to FDA if the manufacturer is not known. In addition, medical device report event files must be maintained, which are subject to FDA inspection, including documentation of the deliberations and decision making.

In December 2015, FDA initiated inspections of 17 hospitals in the wake of events related to infections associated with contaminated duodenoscopes or spread of uterine cancer following the use of morcellators. At the end of these inspections, 15 of 17 hospitals were issued a Form FDA 483 with the listing of inspectional observations of noncompliance with the regulations. The FDA post includes a table with a listing of all inspected hospitals and links to each FDA Form 483 that was issued and the deficiencies that were identified.[2]

Director Shuren discloses that in the past, FDA "*has not enforced the reporting requirements for hospital and other user facilities*." He notes that these recent inspections informed FDA that (1) some hospitals failed to submit required reports for device-related deaths and serious injuries and did not have adequate procedures for reporting, (2) hospital staff were often unaware of and not trained to comply with the

For more information, contact:

Beverly H. Lorell, MD
+1 202 383 8937
blorell@kslaw.com

Seth H. Lundy
+1 202 626 5540
slundy@kslaw.com

Mark Polston
+1 626 318 1240
mpolston@kslaw.com

King & Spalding
Washington, D.C.
1700 Pennsylvania Avenue, NW
Washington, D.C. 20006-4707
Tel: +1 202 737 0500
Fax: +1 202 626 3737

www.kslaw.com

medical device report requirements, and (3) there is a need for FDA to work with hospitals to better obtain the information it needs.

Implications of FDA Issuance of a Form FDA 483

A Form FDA 483 is issued at the end of an FDA inspection and presented to senior management when the investigator(s) has identified objectionable conditions that in their judgement may constitute violations of the Food Drug and Cosmetic Act (the Act). It is not an all-inclusive listing of every possible deviation from the law and it is not a final Agency determination that any condition is in violation of the Act. The inspected entity is encouraged to respond with a written corrective action plan and implement the corrective action plan promptly. However, issuance of a Form FDA 483 may be followed by enforcement actions, including issuance of a Warning Letter by FDA, which identifies violations of the Act that must be corrected and is disclosed to the public, as well as other legal actions including fines and penalties.

Separately, non-compliance with user facility medical device reporting requirements may impact hospital accreditation by the Joint Commission.

Implications for User Facilities: Increased FDA Enforcement

Director Shuren's recent communication indicates FDA's intent to explore new methods to obtain postmarket information about medical device performance and product-related deaths and injuries. As example, on December 5, 2016, FDA held a public workshop on the role of hospitals in developing and improving device surveillance capabilities, including the potential use of new tools and methods involving electronic data.[3] Comments on this topic may be submitted by January 6, 2017.[4]

However, these recent actions of FDA also signal that the agency is intent on increasing its enforcement of the legal requirements for reporting of medical device-related deaths and serious injuries by user facilities, including hospitals. Although FDA has not yet issued a Warning Letter to any of the hospitals cited in Director Shuren's communication, he observed that these deficiencies are likely to be found in other hospitals that have not yet been inspected: "*Based on the number of user facilities in the United States and the number of reports we receive, we believe that these hospitals are not unique in that there is limited to no reporting to FDA or to the manufacturers at some hospitals.*"

We suggest that further FDA inspection of multiple user facilities regarding compliance with Part 803, and subsequent enforcement if violations are found, is likely because of new public awareness of the problem and the opportunity for notifications to FDA by hospital staff or other watch dogs of potential deficiencies in the hospital's reporting processes. In addition, further inspection and enforcement may be triggered by nationally publicized device-related adverse events that affect the public health, such as patient infections due to contamination of duodenoscopes.

In the wake of these recent events, counsel and compliance officers of user facilities may wish to review the robustness of their institution's current compliance with 21 C.F.R. Part 803.

- The review should encompass procedures for efficiently identifying medical device-related adverse events that require analysis for reportability, making the determination if the event is reportable,

submitting reports, and compliance with other requirements including record keeping and accessibility for FDA inspection.

- It is also critical for user facilities to appreciate that participation in a federally-listed Patient Safety Organization (PSO), pursuant to the Patient Safety and Quality Improvement Act of 2005, does not obviate the medical device reporting requirements for user facilities.

- In addition, the adequacy of training of hospital employees should be assessed, including training of staff doctors and nurses who may be the initial staff who identify events as well as training for the hospital officers who are accountable for the evaluation of each event and report submission, if applicable.

King & Spalding has extensive experience in evaluating user facility compliance with Part 803, including evaluation of procedures for medical device reporting, and assisting in their modification and update if needed, as well as developing training programs for hospital staff and officers. We would be pleased to assist in helping user facilities, including hospitals, ensure that processes are in place to comply with these requirements and respond to an FDA inspection.

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[1] FDA Voice. "FDA is working with hospitals to modernize data collection about medical devices." Posted on October 24, 2016 by Jeffrey Shuren, Director of FDA Center for Devices and Radiological Health. This blog is accessible at http://blogs.fda.gov/fdavoice/index.php/2016/10/fda-is-working-with-hospitals-to-modernize-data-collection-about-medical-devices/

[2] The table of hospitals that were inspected and links to each Form FDA 483 is accessible at http://www.fda.gov/downloads/MedicalDevices/ResourcesforYou/HealthCareProviders/UCM526194.pdf

[3] 81 Fed. Reg. 73407. October 25, 2016.

[4] Comments should include the Docket No. FDA–2016–N–1380 and may be submitted electronically via Federal eRulemaking Portal at http://www.regulations.gov or written comments may be sent to Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.