

On October 24, 2016, the US Food & Drug Administration (FDA) reported [on its blog](#) that it had issued Form 483s to 15 of 17 hospitals it inspected in December 2015. Form 483 is a report issued at the time of an FDA inspection that identifies observed deficiencies with respect to FDA regulations. The FDA selected the hospitals based on knowledge of high-profile safety issues occurring in hospitals and reports of medical device adverse events without corresponding reports from the selected hospitals. Based on the findings of the 17 inspections, the FDA decided it would work with the hospital community on the role hospitals should play in ensuring the safe use of medical devices. On October 25, FDA [announced](#) it will hold a public workshop on the role of the hospital in reporting device-related adverse events in device surveillance.

Hospital Reporting Requirements

User facilities, as well as manufacturers, must report certain adverse events regarding medical devices to the FDA. Hospitals, ambulatory surgical facilities and nursing homes are all “user facilities” under the Food, Drug and Cosmetic Act.¹ The types of adverse events a user facility must report are those for which the user facility has information that reasonably suggests a device may have caused or contributed to a death or serious injury (an MDR Report).² A user facility has up to 10 working days to submit an MDR Report to the manufacturer and the FDA if the device may have caused or contributed to a death; and to the manufacturer, or the FDA if the manufacturer is unknown, if the device may have caused or contributed to a serious injury.³ In addition to the initial MDR Report, a user facility must submit an annual summary of all the MDR Reports submitted to both FDA and the manufacturer.⁴

During the inspections, the FDA found that the hospitals did not submit all required MDR Reports and did not have adequate procedures in place for reporting device-related deaths or serious injuries. Even where there were procedures, the FDA found that hospital staff often was not trained to follow a reporting procedure or the FDA’s medical device reporting requirements. FDA regulations require user facilities to develop and maintain written procedures to determine if an adverse event is reportable and to generate the necessary documentation.⁵ In addition to developing the documentation, a user facility must establish and maintain reportable event files.⁶

The FDA acknowledges that sometimes it is difficult to determine that a specific medical device contributed or may have contributed to a patient’s death or serious injury. In an acute care setting where a number of devices may be used on one patient with a serious condition or injury, it may be difficult for the healthcare providers to determine whether a particular device contributed to a patient’s death or serious injury. To address such situations, the regulations permit a user facility to not submit an MDR Report if the available information would “lead a person who is qualified to make a medical judgment reasonably to conclude that a device did not cause or contribute to a death or serious injury...if it were to recur.”⁷

User Facility Reporting Programs

The reporting requirements may be news to hospitals and other user facilities because the FDA has yet to broadly enforce the regulations. Indeed, collecting and acting on information from all types of user facilities is a challenge for any health product regulator, including the FDA. In recognition of this challenge, Congress passed the Food and Drug Administration Modernization Act (FDAMA) in 1997 that required the FDA replace the current universal reporting system to one that is limited to a subset of user facilities. This requirement prompted the creation of the Medical Product Safety Network (MedSun). There are currently about 300 hospitals that are voluntary reporters to MedSun. Even with MedSun, the FDA has yet to limit the regulatory requirement for universal reporting.

In recent years, the FDA has focused on leveraging real-world data, developed through routine clinical practice, to quickly identify devices that do not perform correctly and to disseminate information about device performance and the benefit-risk profile of marketed devices. Tools such as electronic health records and the requirement for unique device identifiers (UDIs) have increased the amount of available information about devices that the FDA can provide to clinicians. This focus has also led to new programs and organizations such as the Medical Device Epidemiology Network (MDEpiNET) and the National Evaluation System for Health Technology (NEST) that the FDA plans to use in the coming years to improve the collection of real-world data on medical devices.

1 21 U.S.C. § 360i(b)(6)(A).

2 21 C.F.R. § 803.20(c)(1).

3 21 C.F.R. § 803.20(b)(1).

4 21 C.F.R. § 803.33(a).

5 21 C.F.R. § 803.17.

6 21 C.F.R. § 803.18.

7 21 C.F.R. § 803.20(c)(2).

Public Workshop for User Facility-Stakeholders

Realizing that gathering more comprehensive surveillance data for medical devices would require a better approach for user facilities to report on adverse events, the FDA will hold a public workshop on December 5, 2016. The goal of the workshop is to foster dialogue between user facilities and the FDA regarding the value, cost and challenges of current hospital-based reporting and surveillance, and what the role of hospitals should and could be. The topics for discussion at the public workshop include:

- An overview of the role of hospitals and potential benefits from a national evaluation system
- The role of hospitals in evidence generation and how it fits within the national system
- Current hospital-based surveillance efforts, including participation in registries, patient safety organizations, electronic health records-based surveillance projects and other surveillance projects
- A review of the role of hospitals in medical device reporting activities and current challenges hospitals face in complying with these requirements
- An exploration of MedSun
- Future surveillance opportunities for hospitals in the national system, including use of non-traditional sources of hospital data and capabilities
- A review of the potential benefits to hospitals in the national system and UDI implementation to modernize hospital surveillance
- A discussion of how all the stakeholders can work together to improve hospital-based medical device surveillance

Registration for the workshop is free, and the deadline to register is November 28, 2016. The FDA is also soliciting electronic and written comments on all aspects of the workshop topics. The deadline for submitting comments is January 6, 2017. Comments should include Docket No. FDA-2016-N-1380. Electronic comments may be submitted through regulations.gov, and written comments may be sent to Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Our lawyers have significant expertise advising user facility clients on medical device and healthcare regulatory issues. For more information about these regulations, or for help, contact your principal firm lawyer or any of the lawyers listed in this alert.

Contacts

John Wyand

T +1 202 626 6676

E john.wyand@squirepb.com

Sarah Stec

T +1 202 457 6304

E sarah.stec@squirepb.com

The contents of this update are not intended to serve as legal advice related to individual situations or as legal opinions concerning such situations nor should they be considered a substitute for taking legal advice.

© Squire Patton Boggs.

All Rights Reserved 2016