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FDA Working to Modernize Medical Device Reporting in Hospitals

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Recent medical device adverse events prompted ***FDA*** to take a fresh look at the ways it collects data related to medical device adverse events from hospitals. FDA examined some high-profile adverse events, such as the spread of uterine cancer from the use of morcellators and the spread of infections by contaminated duoendoscopes, and found it never received the corresponding adverse event reports from the hospitals themselves. To this end, on October 24, FDA reported on its blog that it had issued 483s, or violations of FDA's medical device regulations, to a number of hospitals after inspections in December 2015. Additionally, 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.

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Reporting Requirements

"User facilities" are required to report certain adverse events with respect to medical devices within ten days of becoming aware of the information. Hospitals, ambulatory surgical facilities, and nursing homes are all considered to be "user facilities" according to the Food, Drug, and Cosmetic Act. User facilities are also required to submit an annual summary of the adverse event reports it submitted to both the manufacturer and to FDA.

These requirements may be news to hospitals and other user facilities, as FDA reported that it had yet to enforce these provisions and accompanying regulations. In addition, the Food and Drug Administration Modernization Act (FDAMA) requires that FDA replace the universal system to one that is limited to a subset of user facilities. This requirement prompted the Medical Product Safety Network (MedSun) to be created. There are currently about 300 hospitals that are voluntary reporters to MedSun. Even with MedSun, however, FDA has yet to limit the requirement for universal reporting in regulation.

Public Workshop

Realizing that gathering more comprehensive surveillance data for medical devices would require a better approach for user facilities to report on adverse events, FDA will hold a public workshop on December 5, 2016. The goal of this workshop is to foster dialogue between user facilities and 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; and
- 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. 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.

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