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FDA Regulatory ▪ Health Care

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# FDA Examining Role of Hospitals in Medical Device Surveillance

On October 25, 2016, FDA announced an upcoming public workshop entitled, "The Role of Hospitals in Modernizing Evidence Generation for Device Evaluation: Harnessing the Digital Revolution for Surveillance." FDA's notice of this workshop is published in the Federal Register here.

The workshop, to be held on December 5, 2016, will remind hospitals of their reporting obligations under current FDA regulations and explore potential opportunities for changing those requirements to enhance national device surveillance in the future. In light of recent hospital-based disease outbreaks associated with the use of contaminated medical devices, as well as multiple initiatives by FDA to create a more comprehensive national device surveillance program, FDA is soliciting feedback from hospital stakeholders and others on a broad range of questions covering current requirements and future opportunities to improve postmarket device surveillance.

This Alert summarizes the key aspects of FDA's announcement and the significance for regulated stakeholders.

## Hospital Reporting of Adverse Events

A primary objective of the public workshop is to educate hospitals and other user facilities about the current FDA reporting obligations applicable to user facilities of medical devices. Under FDA regulations, "device user facilities," including most hospitals, ambulatory surgical facilities, nursing homes, outpatient diagnostic facilities, and outpatient treatment facilities, are required to submit medical device reports (MDRs) to FDA or the device manufacturer upon becoming aware of certain reportable events.[1] Specifically, device user facilities are required to report to FDA and the manufacturer (if known) within 10 work days of becoming aware of a device-related death, or to the manufacturer (if known) or FDA (if the manufacturer is unknown) within 10 work days of becoming aware of a device-related serious injury.[2] A user facility also must submit an annual report to FDA if it submitted any individual MDRs during the applicable reporting period.[3]

In addition to reporting adverse events, hospitals and other user facilities are required to develop, maintain, and implement written MDR procedures that ensure: (i) timely and effective identification, communication, and evaluation of events that may be subject to MDR requirements; (ii) a standardized review process or procedure for determining when an event meets the criteria for reporting; and (iii) timely transmission of complete medical device reports to manufacturers or to FDA, or to both if required. Such procedures must address, among other things, documentation and recordkeeping requirements related to the evaluation of information to determine whether an event is reportable and retention of all MDRs submitted to manufacturers and to FDA.[4]

In the Food and Drug Administration Modernization Act (FDAMA) (Pub. L. 105-115), enacted in 1997, Congress sought to shift from FDA's universal device user facility reporting requirements to an alternative system limited to a "subset of user facilities that constitutes a representative profile of user reports" for device-related deaths and serious injuries. Although FDA has developed the Medical Product Safety Network (MedSun), which currently includes approximately 300 hospitals nationwide that are active, voluntary partners with FDA in the assessment and reporting

[1] 21 C.F.R. § 803.3.
[2] 21 C.F.R. § 803.30.
[3] 21 C.F.R. § 803.33.
[4] 21 C.F.R. § 803.17.

of device-related events, the agency has not yet established the program limiting reporting to a subset of user facilities envisioned in FDAMA.

As an FDA-regulated entity, device user facilities are also subject to FDA inspections.[5] FDA has informally stated that it generally does not enforce reporting requirements against hospitals and other user facilities, and instead seeks to educate hospitals and work collaboratively to achieve voluntary compliance.[6] However, depending on the nature, frequency, and severity of MDR noncompliance, FDA can exercise its statutory and regulatory authority to pursue stringent administrative and enforcement actions. In fact, FDA's recent inspections of a number of hospitals, chosen because of reports of hospital-based pathogen infections related to the use of certain medical device types, resulted in multiple Form FDA 483 observations issued to hospitals alleging noncompliance with FDA reporting regulations. According to the 483s, some hospitals did not have MDR written procedures in effect, hospital staff were not always aware of or trained to comply with FDA's MDR requirements, and required reports had not been submitted.[7]

As part of the upcoming workshop, FDA has asked whether the current reporting requirements should remain, be modified, or be eliminated in light of modern tools, such as software tools that could be used to conduct active surveillance of electronic health records that include unique device identifier (UDI) information.

## Strengthening National System for Medical Device Surveillance

FDA has been working for several years to try to strengthen the national system for medical device postmarket surveillance. Most recently, and as part of CDRH's 2016-2017 Strategic Priorities, CDRH committed to building a National Evaluation System for Health Technology (NEST), designed to generate better evidence for medical device regulatory decision-making through the use of real-world evidence and advanced data analytics.

FDA has stated that hospitals are uniquely positioned to contribute to a robust device surveillance system because of the growing availability of new tools, methodologies, and electronic data sources, as well as the implementation of FDA's UDI program. Current hospital-based surveillance efforts include participation in registries, patient safety organizations, and electronic health records-based surveillance projects. A comprehensive national device evaluation system may also directly benefit hospitals and other user facilities by helping to address broader issues of improved quality of care and efficiencies. However, FDA acknowledges the limitations and challenges facing hospitals, including the potential for considerable costs to be diverted from patient care.

## Public Workshop Topics

The Federal Register notice lists eight topics for discussion at the public workshop. These are:

- An overview of the role of hospitals and potential benefits from a national evaluation system;
- The role of hospitals in evidence generation and how this fits into the national system;
- Current hospital-based surveillance efforts;
- The role of hospitals in medical device reporting activities and current challenges hospitals face in complying with these requirements;
- An exploration of FDA's MedSun program;
- Future surveillance opportunities for hospitals in the national system, including use of non-traditional sources of hospital data and capabilities;

[5] *Id.*
[6] FDA Voice Blog, J. Shuren, "FDA is working with hospitals to modernize data collection about medical devices," October 24, 2016.
[7] *Id.*

- A review of the potential benefits to hospitals of a national surveillance system and UDI implementation to modernize hospital surveillance; and
- How all stakeholders can work together to improve hospital-based medical device surveillance.

FDA intends for the workshop to foster a dialogue about the value, costs, and challenges of current hospital-based reporting and surveillance, and whether the existing regulatory framework appropriately facilitates the creation of more robust surveillance capabilities and the development of a national device evaluation system.

## Implications of the Announcement

During the workshop, FDA will review the regulatory requirements applicable to hospitals and other user facilities, and those stakeholders are expected to share with FDA the challenges, burdens, benefits, and limitations in complying with such obligations. While FDA has informally announced a general intent not to enforce the user facility reporting requirements, recent instances of medical device problems occurring in the hospital setting have led to FDA inspections of hospitals, FDA Form 483 observations, regulatory meetings between FDA and hospital management teams, and regulatory and congressional inquiries into the roles and obligations of hospitals in reporting device-related adverse events to manufacturers and FDA.

Importantly, FDA has requested that hospitals and other user facilities comment on the appropriateness of current regulatory requirements for adverse event reporting. Stakeholders should thoroughly evaluate their internal FDA compliance programs and the costs, burdens, and benefits associated with adverse event reporting and developing and implementing MDR written procedures, and determine what, if any, changes or alternate regulatory frameworks would be appropriate for user facilities at this time considering the overarching objective of ensuring a robust and complete medical device surveillance program.

Hospital and other user facility stakeholders seeking to present at the public workshop must register by November 15, 2016. Persons interested in attending must register online by November 28, 2016. FDA also is soliciting comments on all aspects of the public workshop topics, which must be submitted to the agency by January 6, 2017.

If you would like to discuss the workshop or your regulatory obligations, please contact any member of Ropes & Gray's FDA regulatory or health care practices or your usual Ropes & Gray advisor.