SANDLER, TRAVIS & ROSENBERG, P.A.
International Trade, Customs & Export Law

Working with Hospitals: Issues in Reporting Patient Harm Tied to Medical Devices and FDA's Goal to Modernize Data Collection

FIME

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About Shelly Garg

Shelly Garg is an attorney with Sandler, Travis & Rosenberg's FDA Practice Group.

She represents clients across a broad range of FDA-regulated product categories, including food, beverages and dietary supplements, over-the-counter drugs, medical devices, and cosmetics. She advises in strategic business planning, product development, testing and approval, labeling, advertisement and promotion, liability risk, inspections, responding to regulatory enforcement matters, and related issues.

Her keen insights into the FDA and its inner workings have proven to be of significant value to her clients in successfully resolving matters before the agency.

Requirement to Report

- "Device user facilities" – includes most hospitals, ambulatory surgical facilities, nursing homes, outpatient diagnostic facilities, and outpatient treatment facilities
  - have 10 days to report serious injuries potentially caused by devices to the manufacturer and notify both the manufacturer and the FDA about any deaths that may have resulted.
- Manufacturers are required to file reports to the FDA within 30 days of learning about an injury or death that may have been caused by a device
- For the most serious problems that require immediate action to prevent major public health harm, companies have 5 days to report to FDA

Other Reporting Requirements

- Hospitals and other user facilities required to develop, maintain, and implement written MDR procedures to ensure:
  - timely and effective identification, communication, and evaluation of events that may be subject to MDR requirements
  - A standardized review process for determining when an event meets the criteria for reporting
  - Timely transmission of complete medical device reports to manufacturers or to FDA, or to both if required
  - Procedures must address documentation and recordkeeping requirements related to evaluation of information to determine whether an event is reportable. Must keep all MDRs submitted to manufacturers and to FDA.

The Problem

- Passive Surveillance: relies on people to identify that a harm occurred or risk is present, recognize that the harm/risk is associated with the use of a particular device, and take time to report it
- Hospitals fail to promptly report patient deaths or injuries linked to medical devices
- Hospitals not trained to comply with all of FDA's medical device reporting requirements
- At Mass Gen – FDA investigators found reporting delays of 10 months and 18 months in 2 separate patient deaths related to devices.
- FDA's spotty oversight (EX: infections and deaths related to tainted medical scopes); arguments that FDA's surveillance system for devices is inadequate and relies too heavily on manufacturers to report problems with their own products.

Contaminated Duodenoscopes: An Example

- December 2015, FDA initiated inspections at 17 hospitals, because of reports at the facilities related to the spread of uterine cancer or the spread of infections associated with contaminated duodenoscopes.
- While events subject to MDR, FDA didn't see corresponding adverse event reports in adverse event database (MAUDE).
- What FDA learned
  - Hospitals did not submit required reports for deaths or serious injuries related to devices used at their facilities; lack of adequate procedures for reporting device-related death or serious injury events to FDA or to the manufacturer
  - Hospital staff not trained or not aware of MDR requirements
  - Given electronic health information, better ways to work with hospitals

Example

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Written MDR procedures have not been developed and maintained and implemented .

Specifically, the policies and procedures related to medical device reporting (including: (1) the *Quality and Patient Safety Plan*; (2) the *Clinical Manual Policy for Adverse Events and Medical Error*; and (3) the *Regulatory Agencies: Reportability Criteria*) do not address the following:

A. Timeframes for reporting medical device reports to manufacturers or to FDA.
B. Complete documentation and record keeping requirements for medical device reports.

Example

OBSERVATION 4

MDR event files do not contain or refe nformation in the possession of the reporting entity, including documentation of the deliberations and decision making process used to determine if an event was or was not reportable.

Specifically, hospital Medical Device Report (MDR) files consist only of MedSun reports; they do not include references to or copies of evaluations conducted by various hospital departments such as the Biomedical Engineering department, or root cause analyses as required by the *Adverse Events and Medical Error* policy, or determinations regarding reportability as required by the *Quality and Patient Safety Plan*.

Ongoing efforts

- Working with facilities to improving hospital-based surveillance systems, and broader role of using hospitals to evaluate how well devices work in the clinical setting
- Ongoing participation in registries, patient safety organizations and electronic health records-based surveillance projects.
- Incorporation of Unique Device Identifiers (UDIs) into electronic health records to aid surveillance – adequately identify devices through distribution and use

Questions?
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