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FDA eyes stricter post-market surveillance for medical devices

Medical device manufacturers will face new and enhanced post-market safety requirements under an updated Food and Drug Administration (FDA) plan. The effort to improve device safety comes in response to concerns about its outdated methods to monitor increasingly complicated devices once they reach patients. For the past several years, members of Congress, the FDA and the Institute of Medicine have been examining how the agency approves and monitors devices in order to ensure patient safety.

Historically, once manufacturers obtain marketing approval from the FDA, they must comply with labelling regulations, good manufacturing practices and safety requirements that are part of the agency's existing post-market surveillance program. That program consists of six main elements, including adverse event reporting (AER) and post-approval studies. Under its recent proposal, the FDA would bolster surveillance capabilities with four key steps.

- **Create a Unique Device Identification (UDI) system and promote its incorporation into electronic health information.** In July 2012, the FDA issued a proposed rule for a UDI system, which was updated in November. The first set of requirements took effect in September 2014 for high risk devices, such as implantable pace-makers. Requirements will be phased in over the next seven years for lower-risk devices. A UDI may contain two types of information: a unique numeric or alphanumeric code and an identifier that includes the production information for that specific device.
- **Promote the development of national and international device registries for selected products.** FDA will host workshops on how to improve the exchange and collection of data from existing patient and product registries. The agency will not create its own centralized registry.
- **Modernize adverse event reporting and analysis.** FDA will focus on the development of automated and electronic AER systems; develop a mobile application for AERs, modernize its device AER database, and improve automated statistical methods that can easily identify patterns in safety signals.
- **Adopt new methods for evidence generation, synthesis and appraisal.** FDA will examine new ways for assessing benefits and risks that account for patient views; promote the adoption of uniform standards for data collection from multiple sources, and a new system to evaluate and prioritize safety signals when they arise.

HRI Impact Analysis -- Manufacturers must confront new rules and procedures around UDIs, as well as a greater level of transparency that could result in increased product liability if safety signals are not properly defined. The collection of more robust product information could improve development and manufacturing capability, as well as speed product reviews and approval. Manufacturers will face new costs in complying with the requirements, which may be passed on to payers and consumers in the form of higher prices. The FDA will also have to find new sources of funding or divert existing resources in order to finance these new activities. Payers and providers may benefit from greater access to information about quality as they make reimbursement and supply chain decisions.

At a glance

FDA focuses on 4 new areas to strengthen post-market surveillance.

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- Modernize adverse event reporting and analysis.
- Adopt new methods for evidence generation, synthesis and appraisal.

Source: FDA

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