FDA May Inspect Hospitals as Part of MDDS Rule

Hospitals that are considered manufacturers under a new U.S. Food and Drug Administration (FDA) regulation can expect a visit from the agency, according to a top FDA official.

“Although in a perfect world an establishment might be inspected every two years, in reality it is a risk-based approach,” said Anthony Watson, director of the division of anesthesiology, general hospital, infection control, and dental devices in the FDA’s Office of Device Evaluation. “Therefore, FDA inspects device establishments on a periodic basis and the selection of the establishment is determined using a risk-based approach, for example, addressing a public health situation or product classification.”

Watson answered questions about the new medical device data system (MDDS) rule during and after an AAMI webinar on June 1.

In February, the FDA issued the final rule regulating MDDS products, which are devices designed to transfer, store, convert, or display device data. Under the rule, any entity that tries to create or significantly modify an MDDS is considered a manufacturer, including hospitals. They must have a quality system in place by Feb. 14, 2012 to ensure their devices are safe and effective.

Watson said that some hospitals have already started registering as manufacturers, and the agency will allow people to come up to speed with a quality system. Watson cautioned that hospitals don’t “have to recreate new stuff. We hope most folks have at least started to track the system they have. Start with that, and build on it to turn it into a quality system.”

Watson also touched on what happens when a multihospital system creates an MDDS product. “The system can decide if an individual hospital reports their own MDDS, or if the parent group could report it as one MDDS,” he said.

Defining an MDDS

Watson clarified what constitutes an MDDS product, saying that it may include software or electrical hardware, such as modems.

“If you look at MDDS, in its basic form it is a conduit for sending and receiving device data to and from devices,” Watson added. “Device data is any electronic data that comes from a medical device. It doesn't necessarily have to be patient data. It could be signal or status information.”

Watson stressed that an electronic medical record (EMR) is not an MDDS because it has more functionality.

“Our goal is not to overburden people,” Watson said.

The AAMI Software Committee is drafting a recommended practice to help hospitals that have been classified as manufacturers set up a quality system.

What Isn’t an MDDS?

The FDA’s Anthony Watson said the following are not generally considered an MDDS:

- Maintenance software that is used to update, diagnose, and determine the operational status (i.e., mode) of medical devices
- “Sniffer” software used only to determine which devices are on the network and their status
- Nursing call stations

Biomed Wary of New 4G Devices

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still waiting to see what makes it to market,” says Rick Hampton, the wireless manager for Massachusetts General Hospital in Boston, MA.

Hampton adds that 4G has the potential to create problems for devices, “but the probability is still yet to be determined.”

John Kidder, the clinical engineering supervisor at St. Elizabeth Regional Health in Lafayette, IN, says that his team is currently investigating the potential impact of 4G, adding that AT&T officials told him they don’t believe the phones will pose any interference issues because of power limitations in the battery.

Regular cell phones can affect devices in different ways. For example, Jim Bruett’s facility in Eau Claire, WI, documented many instances where cell phones interfered with external pacemakers. The pacemaker would completely shut down but appeared to be functional, says Bruett, the biomed supervisor for Luther Midlerefort Mayo Health System.

“We made a video clip of the interference, which we used to convince our patient safety committee to implement a policy called ‘arms length.’ Staff can use cell phones almost anywhere in the facility as long as the phone is kept at least an arm’s length away from other devices,” Bruett says.

Response From Regulators

The U.S. Federal Communications Commission (FCC), which approves licenses for wireless communication, has not changed its rules for 4G phones, but says that the newer phones have the capability for faster data flow and multiple wireless technologies operating simultaneously, according to Donald Witters, an expert on electromagnetic interference (EMI) and a biomedical engineer with FDA’s Center for Devices and Radiological Health (CDRH).

Although the addition of wireless technologies operating simultaneously might make the overall energy levels higher than the current cell phones, these new phones still must meet the same limits, Witters adds.

The international standard IEC 60601-1-2 recommends a separation distance of 1.2 to 2.3 meters between phones and equipment. But CDRH doesn’t give recommendations to healthcare facilities about separation distances, and generally leaves it up to the manufacturer to mitigate any EMI, Witters says.