Two Hospitals Pave the Way to Becoming Manufacturers

Hospitals had until May 18 to register and list with the U.S. Food and Drug Administration (FDA) as manufacturers under the medical device data system (MDDS) rule, but so far only three have done so. The regulation classifies hospitals as manufacturers if they create or drastically change an MDDS, which is designed to send or receive data from a medical device. Two of the three organizations share their experience navigating the process.

**ORGANIZATION:** Intermountain Healthcare  
**LOCATION:** 23-hospital system based in Salt Lake City, UT  
**PRODUCTS REGISTERED:** Eight software applications including a software library that accepts device data from different sources, and a program called Storkbytes, which displays fetal monitor data.

Intermountain Healthcare differs from many organizations in that it has an IT department of more than 300 people who develop, test, and support all types of clinical software applications. When Intermountain first heard of the MDDS rule, Rob Hyatt, director of clinical software quality, looked at the hundreds of applications used in Intermountain and determined which ones were an MDDS.

“The rule is straightforward as to what is an MDDS,” says Hyatt, who previously worked in regulatory affairs for a manufacturer. “I created a database of simple questions based on the four main questions about an MDDS product: does it transfer, store, convert, or display medical device data?”

It wasn’t a quick process. “From February to the middle of May, about 75% of my time was just attacking this problem,” he says. Hyatt says the process of registering with FDA wasn’t “super difficult,” but he encountered some problems along the way. It took him three to four hours over two days to go through the agency’s website and register. “The process itself was a little wait-and-see,” he says. “You had to register in one part of the website, pay in another, and then wait for confirmation on the payment before you can sign up.”

The organization is also hard at work on meeting the FDA’s next requirement under the rule: establishing a quality system and medical device reporting (MDR) system. Hyatt says Intermountain is on course to have the systems in place before the FDA’s deadline of April 18, 2012.

**ORGANIZATION:** Partners Healthcare  
**LOCATION:** Nine-hospital system based in Boston, MA  
**PRODUCTS REGISTERED:** Three applications described as “software pipes,” which take data from medical devices and send it to electronic medical records.

Partners Healthcare had some special insight to help it get started with registration. A colleague in the genomics department in one of the hospitals had already registered and listed a product—which was not an MDDS—with the agency.

“We were fortunate in that Partners had already registered,” says Rick Schrenker, systems engineering manager for Massachusetts General Hospital, a part of the Partners system.

Partners formed an ad hoc group that included representatives from the clinical engineering and risk management departments to develop criteria to assist colleagues unfamiliar with the regulation in determining what was and wasn’t an MDDS.

“We reflected the criteria in a form that we distributed to colleagues in Partners whom we believed might be using an MDDS,” Schrenker says. The group analyzed returned forms and determined that three met the MDDS definition.

The organization is also in the midst of creating a quality system. “This is new for us; it’s too soon to know what it will cost to build a quality system that satisfies the regulation. It won’t be $10, and I hope it won’t be $10,000,” Schrenker says.

Schrenker is perplexed at the small number of registered hospitals: Intermountain, Partners, and the Alaska Native Tribal Health Consortium in Anchorage, AK.

“Others may not think it applies to them or may think it is onerous,” he says. “So far it doesn’t appear to be onerous to us, but time will tell.”

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