Bar-Code Rule for Medical Devices May Be Imminent

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As if hospitals didn’t already have enough concerns about the FDA’s changes to its existing bar-code rules for drugs, health systems also have to worry about a first-time FDA regulation mandating a unique device identifier (UDI) system for medical devices. Hospitals that want to take advantage of devices that are likely to be marked with GS1-compatible bar codes will have to upgrade their software systems, a task that could be complicated and costly. GS1 is the international standards group that also prescribes product identification (ID) numbers for drugs.

Yet a number of major benefits of a national UDI program will probably balance out these shortcomings. Advantages include more timely and less costly recalls, better hospital safety records for implanted devices, and the ability to transmit more patient data into electronic medical records (EMRs), thereby allowing hospitals to meet the definition of “meaningful use.”

The upcoming proposed rule for a UDI system, which is similar to a couple of recent FDA initiatives related to the tracking of drug packages, stems from the FDA Amendments Act (FDAAA), which Congress passed in 2007. Under the FDAAA, the FDA requires manufacturers to mark (or identify) their devices; however, the agency has moved very slowly in prescribing UDIs. In September 2011, the FDA held a 2-day workshop, at which Jeff Shuren, Director of Devices and Radiological Health, followed up by saying: “The UDI proposed regulation is close to coming out.”

Since then: nothing.

Before that September meeting, the FDA had sent a proposed rule to the White House Office of Management and Budget (OMB), which is responsible for approving all new proposed rules. The UDI rule is probably politically sensitive; in its regulatory agenda, the FDA rates it as “economically significant.”

Some proponents of the UDI plan suggest that medical device manufacturers might have pressed the Obama administration to water down the proposed rule, but a spokesperson for AdvaMed (Advanced Medical Technology Association), the medical device manufacturer’s organization, denied this.

Hospital executives see many benefits resulting from implementation of the UDI system.

“UDI is essential to maximizing the value of electronic health records,” says Christopher M. Dadlez, FACHE, President and Chief Executive Officer of Saint Francis Hospital and Medical Center in Hartford, Conn. Referring to the 5 years of FDA workshops that centered around the UDI since the FDAAA was passed, Mr. Dadlez emphasized, “The time to act is now. UDI is too important to patient safety to delay any longer.”

In February 2012, a coalition of health care trade associations wrote to Jeff Zients, Acting Director of the OMB. The letter stated:

The great potential for UDIs to increase safety and lower costs for the American health care system means that widespread adoption is sorely needed now. Prompt action is also important because hospitals and physicians are in the process of implementing electronic health records as part of the Medicare and Medicaid EHR Incentive Programs.

One month later, on March 15, a bipartisan group of senators introduced a bill, the Ensuring Safe Medical Devices for Patients Act, which would give the FDA the tools it needs to improve oversight of medical devices. The bill requires the FDA to publish a final rule establishing a UDI program by the end of 2012. Blair Childs, Senior Vice President of Public Affairs at Premier, Inc., located in Charlotte, N.C., says:

Enabling health care providers to track medical devices electronically in the supply chain will improve the speed and accuracy of product recalls, as well as adverse event reporting. In addition to these important safety benefits, automating the new manual process of tracking of medical devices is projected to save the health care industry approximately $16 billion each year from greatly improved efficiencies.

Premier is a performance-improvement alliance consisting of more than 2,500 U.S. hospitals and more than 81,000 other health care organizations.

Although some medical device manufacturers currently place bar codes on medical devices, many manufacturers use a proprietary number on a given device. Distributors use their own number, group-purchasing organizations use another number, and so on. As a result, a hospital at the end of the distribution line has no way of communicating with the device manufacturer because of the variety of device numbering systems used.

A few manufacturers, such as Becton, Dickinson and Company (BD), in Franklin Lakes, N.J., print a Global Trade Identification Number (GTIN) within a linear bar code on the device, the outer packaging, or the case in which it is sold—sometimes on all three. Thus, the GTIN can differ at each packaging level. The GTIN is a data formula prescribed by GS1, the standards group.

BD also prints a second linear bar code on all cases and, in some instances, on shelf packs containing the lot number, expiration date, and other production information. The GTIN becomes the
primary product identifier on purchase orders, invoices, and other electronic data interchange transactions and allows the hospital to communicate electronically with BD. This communication would not be possible without the GTIN. Other manufacturers are also printing GTINs on their devices. The final rule from the FDA, after the OMB loosens its grip, may well require the printing of a GTIN.

Alex Zimmerman, Director of Integrated Business Solutions for Resource Optimization & Innovation (ROI), Mercy Health System’s supply chain division in St. Louis, says about 50% of the medical and surgical products arriving at Mercy have GTINs. Mercy owns 31 hospitals in four states. Mercy and BD have synchronized their software systems so that the two partners can send data back and forth using GTINs to identify specific products.

“We no longer have to make phone calls back and forth for business transactions,” explains Dennis Black, Director of e-Business at BD. “But the electronic data integration does take some heavy lifting.”