Premier Tells Medical Device Makers to Adopt GS1 Supply Chain Standards

Premier, an organization that operates a purchasing network for more than 2,000 U.S. hospitals and 53,000 other health-care sites, has announced it will require manufacturers to

support global supply chain standards enabling the identification and tracking of medical devices and products. The standards—set by GS1—could pave the way for the adoption of RFID technology within the medical device supply chain. GS1, a private, nonprofit organization that establishes and promotes global supply chain standards, develops Electronic Product Code (EPC) standards through its EPCglobal branch.

To satisfy Premier's mandate, manufacturers will need to employ a Global Trade Item Number (GTIN) to identify a particular medical product, and a Global Location Number (GLN) to distinguish any parties that have been in contact with that product as it moves through the supply chain—from manufacturer to distributor, then on to hospital and nursing station. The suppliers will have to upload the GTINs, GLNs and associated product data to the Global Data Synchronization Network (GDSN), a network of data pools that stores product information that trading partners (such as hospitals and other health-care organizations) can then access.

Joe Pleasant

Premier is currently phasing in support for the three GS1 standards, with full adoption of the standards within its contracting and operations expected to be implemented within the next five years. The goal, says Joe Pleasant, Premier's CIO and senior VP, is to ensure that the correct products are delivered to the proper place at the right time, ultimately improving patient safety and reducing supply chain costs.

At present, manufacturers, suppliers and hospitals often use their own numbering systems to identify and label products.

“Because there isn’t a standard that everyone agrees to,” Pleasant says, “it makes it next to impossible to locate product recalls.”

The inability to carry out comprehensive product recalls is one reason the U.S Food and Drug Administration (FDA) has been investigating the use of unique device identification (UDI) systems to track and trace medical devices. From the FDA’s perspective, the main purpose of a UDI system would be to reduce medical errors by providing a more automated method of collecting device-related information, such as the manufacturer, make and model, as well as unique attributes, serial numbers, identifying lot and manufacturing numbers, and expiration dates.
In addition, a UDI system could be employed to facilitate device recalls, improve medical device reporting and identify device incompatibilities or potential allergic reactions. By year’s end, the FDA’s Center for Devices and Radiological Health (CDRH) hopes to issue draft specifications for such a system (see U.S. FDA Seeks Research for Medical Device Tracking System).

Neither Premier nor the Food and Drug Administration specify RFID’s use in their initiatives, but the FDA has been studying radio frequency identification. Both Premier’s and the FDA’s initiatives could work with bar codes (which would have the GTINs and GLNs printed on them) or RFID tags (which could have the numbers both printed and encoded on them). RFID tags, of course, would eliminate the need for manual, line-of-sight scanning of each product to collect the product numbers that are uploaded into the GDSN.

According to Pleasant, manufacturers, distributors and hospitals will be able to decide which technology, including RFID, they prefer to use. “We think that there are [applications] where RFID is advantageous and should be the way to go, and we think there are [applications] where bar codes would be just as efficient,” he explains. “There isn’t

one particular statement that you can make—use RFID for this and bar code for that—because it all depends on the applications and processes an organization has set up, and their particular needs."

But by implementing standardized numbering systems and a global repository to store and access data, Pleasant notes, health-care organizations will have a consistent way to obtain information. What's more, the standards should make it easier to leverage RFID technology for automatically tracking and identifying products as they traverse the supply chain.

By requiring suppliers to support GTINs and GLNs on the products they sell to Premier's hospital group, all parties will be working with a consistent numbering scheme to ensure product data matches up across the supply chain, from manufacturers through distributors to customers. And the GDSN aligns those numbers with product and manufacturer information across all supply chain partners. Thus, organizations can easily fold RFID into the mix without having to first establish numbering schemes and a standard, global repository.

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