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Hospitals urge FDA to require bar codes on medical devices

Bar coding of drugs, biologicals, blood products and devices seen as tool for improved patient safety, care quality and more efficient delivery

WASHINGTON, DC, May 9, 2005—On the heels of an internal report critical of the Food and Drug Administration’s post-market safety surveillance of medical devices—as well as its oversight of the manufacturers, themselves—hospital groups are urging the agency to act. They have appealed to the FDA to take swift action on a February 2004 pledge to investigate and ultimately pursue a regulation requiring the bar coding of medical devices.

In an effort spear-headed by Premier, Inc., a national non-profit hospital alliance, seven organizations penned a letter to FDA Acting Commissioner Lester Crawford to inquire about the agency’s progress and intentions on this front. Signing on to the letter in addition to Premier were the American Hospital Association, the Association of American Medical Colleges, the Catholic Health Association, the Federation of American Hospitals, the National Association of Public Hospitals and Health Systems, and VHA.

“As an alliance that helps hospitals achieve high levels of quality and financial performance, Premier strongly advocates the expanded use of bar coding in healthcare,” Premier President and CEO Richard A. Norling said. “Bar coding benefits patients immediately through reduced errors and over the long term through our deepened understanding of the relationships between specific medical devices and patient outcomes.”

In February 2004, the FDA issued a regulation requiring electronically-readable bar codes on the packaging of hospital-administered drugs, biologicals and blood products. The measure was billed by the Bush administration as a key strategy for protecting patients from medication errors, improving overall patient safety, and driving supply chain efficiency, thus reducing the cost of care. Given the predominant support, voiced then by industry shareholders and consumer groups, for extending the bar code regulation to medical devices, the agency announced it would address the issue separately in the

near future. Considering the FDA's concern over weaknesses in device safety surveillance and manufacturer compliance with post-market studies, hospital groups believe the time to act is now.

“Based on the experience of other industries, bar coding applied to medical devices will streamline the supply chain, inventory control and asset processes in the healthcare sector resulting in significantly reduced costs,” said Premier CIO Joe Pleasant.

The 1996 Efficient Healthcare Consumer Response (EHCR) study documented that more than \$11 million in healthcare supply chain costs are avoidable process costs, and that a major contributor to such inefficiency was the absence of bar coding. “More recent findings estimate that a fully automated healthcare supply chain could bring 2 to 10 percent total benefits across manufacturers, distributors, and providers,” he said.

About Premier

Premier Inc., is a healthcare alliance entirely owned by more than 200 of the nation's leading not-for-profit hospital and healthcare systems. These systems operate or are affiliated with nearly 1,500 hospital facilities and thousands of other healthcare sites. Premier provides an array of resources including group purchasing for more than \$21 billion annually in supplies and equipment. Premier also offers supply chain, clinical, and operational performance improvement products and services and insurance programs. Premier has offices in Charlotte, NC; Chicago, IL; San Diego, CA.; and Washington, D.C.