



THE BAR CODING OF MEDICAL DEVICES

Background

Bar Codes for Drugs:

In a move long advocated by Premier, the U.S. Department of Health and Human Services (HHS) issued a February 24, 2004 final rule requiring electronically-readable bar codes on the packaging of hospital-administered drugs, biologics and blood products. The measure was billed by the department as a key strategy for protecting patients from preventable medication errors, improving overall patient safety, and reducing the cost of healthcare by driving greater delivery and supply chain efficiency.

Over the next 20 years, the Food and Drug Administration (FDA) estimates the new regulations will help prevent nearly 500,000 adverse events and save an estimated \$93 billion through quality of care and patient safety improvements as well as from reduced hospital utilization.

This rule is a major step forward in the federal government's efforts to harness information technology to promote higher quality care. In particular, the bar code rule was designed to support and encourage widespread adoption of advanced information systems that, in some hospitals, have reduced medication error rates by as much as 85 percent.

Bar Codes for Medical Devices:

The Center for Devices and Radiological Health (CDRH) at the FDA held several stakeholder meetings on this issue last year. On October 27, 2005, provider groups were invited to meet with them to discuss unique device identification. A final summary of the meeting is now posted on the CDRH's web site. It includes comments made by CDRH staff regarding their desire to pursue an Advance Notice of Proposed Rulemaking and includes the text of a hospital coalition letter led by Premier. It can be accessed on the CDRH website at the following link: <http://www.fda.gov/cdrh/ocd/uidevices011606.html>

The CDRH has also been working on recommendations to improve its postmarket surveillance ability of medical devices. On January 18, 2006 the CDRH released its report and an executive summary of the Medical Device Postmarket Safety Program and included several references to the need for the unique identification (IUD) of medical devices. The summary states, "We will champion the development of a system to provide unique device identification, a standardized and globally accepted nomenclature for devices, and mechanisms and incentives for device users to include this information in healthcare records." The press release on the FDA's website and link to the report can be found at: <http://www.fda.gov/cdrh/postmarket/mdpi.html>

Discussion

A compelling patient safety interest lies in requiring identification technology (such as bar codes or radio frequency identification tags) for medical devices, especially implantable items like hip/knee prosthetics, stents and cardiac rhythm management pacers. Unique identification technology would facilitate and improve upon the tracking of these devices, especially in the event of a recall or other safety concern. Clearly, UID technology can improve risk management through reductions in supply chain and medical errors.

Hospitals are moving forward on the adoption of technology, but given the current lack of a national standard, they have had to invest millions of dollars to create internal tracking systems for devices. According to a recent American Hospital Association survey of its members, more than half of all hospitals have adopted bar coding technologies for at least one purpose (i.e., match patients to their laboratory specimens and drugs, better management of supplies). And while it is clear this investment improves quality and supply chain efficiency for the hospital, a national unique identifier system would accelerate these efforts that ultimately benefit patients. Due to strong hospital interest in this issue, Premier has led a collaborative effort with all the major hospital associations in Washington to promote the UID of medical devices.

Additionally, the electronic patient medical record (EMR) will require that data standards are in place and used by all institutions in order to transfer information. While much of the EMR discussion has centered on clinical procedures and orders, the ability for clinicians to read and interpret the supplies and devices utilized during a patient's treatment will be required. Therefore, having a standard identification (Product Number) for the supply items and medical devices is a basic requirement that must be in place before automated identification systems are effective.

Recommendations

Premier strongly supports the mandatory unique identification of medical devices as the transmission and translation of critical data has vast potential for improving patient safety and supply chain efficiency.

- Premier recommends the federal government, through regulation or legislation, require standardized bar code labeling on all appropriate hospital-administered/implemented medical devices and implantables. Specifically, Premier strongly encourages the FDA to move toward a mandatory approach for the UID of medical devices through the Advance Notice of Proposed Rulemaking regulatory process.