

FDA BAR CODE RULE: AIDC SOLUTIONS FOR COMPLIANCE

Executive Summary

A number of government-sponsored and independent reports on medication error rates in US medical facilities have clearly identified that a problem exists with the administration of medication, and it can effectively be addressed with the use of bar code technology. In response, the FDA has issued a rule outlining a means of standardizing the application of a machine-readable bar code on single-dose medication packaging, and a method by which this code is to be used. This white paper is intended to provide a basic understanding of the rule and establish a framework from which a bar code system could be designed and implemented within medical facilities.

Background

In 1999, the Institute of Medicine (IOM) issued a report entitled, "To Err is Human: Building a Safer Health System" which consolidated published articles and studies and reported that:

- An estimated 44,000 to 98,000 Americans may die each year due to a range of medical mistakes made by health care professionals.
- In 1993 alone, an estimated 7,000 deaths were attributable to medication errors.
- Between 1983 and 1993, death rates attributable to inpatient medication errors showed a 2.57 fold increase, and outpatient medication errors showed nearly an 8 fold increase.

In 2001, the Agency for Healthcare Research and Quality (AHRQ) issued its own report entitled, "Reducing and Preventing Adverse Drug Events to Decrease Hospital Costs." The report showed that more than 770,000 people are injured or die each year in hospitals from adverse drug events. The report cited a variety of studies showing that 28 to 95 percent of adverse drug events could be prevented by reducing medication errors through the use of computerized monitoring systems.

An article published the same year by Ernst and Grizzle estimated the direct cost of preventable drug-related mortality and morbidity to be \$177.4 billion annually, with drug-related hospital admissions accounting for much of the cost. Another article estimated the cost of preventable adverse drug events in hospitalized patients to be \$5,857 for each adverse drug event, such that the estimated annual costs for preventable adverse drug events for a 700-bed hospital is \$2.8 million.

Although there has been much controversy among government agencies and task forces as to the veracity of the claims in these reports and articles, the underlying messages appear to be well accepted. They include:

- Medication errors account for more adverse events within US medical facilities than is expected and can be tolerated.

- Medication errors result in substantial direct costs.
- Medication error rates are on the rise.
- Medication errors can be prevented (for the most part).

Armed with this new understanding of the magnitude of the medication error problem, the Department of Health and Human Services proposed measures that address the issue. This step was taken at the urging of The American Society for Health System Pharmacists (ASHP). The ASHP asked the DHHS to “develop regulations that mandate that drug manufacturers provide a standardized machine-readable code (bar code) on all drug product containers, including single unit containers, which are essential for hospital unit dose drug distribution systems.” The National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) also played a role in urging the FDA and United States Pharmacopeia (USP) to establish and implement a uniform bar coding program for drugs. The result of these requests and proposals – as well as others – resulted in the FDA- ruling entitled, “Bar Code Label Requirements for Human Drug Products and Blood.”

FDA Rule: Bar Code Label Requirements for Human Drug Products and Blood

HHS Secretary Tommy Thompson comments on new FDA proposals, “These proposals are key steps in reducing medication problems through using state-of-the-art technology.”

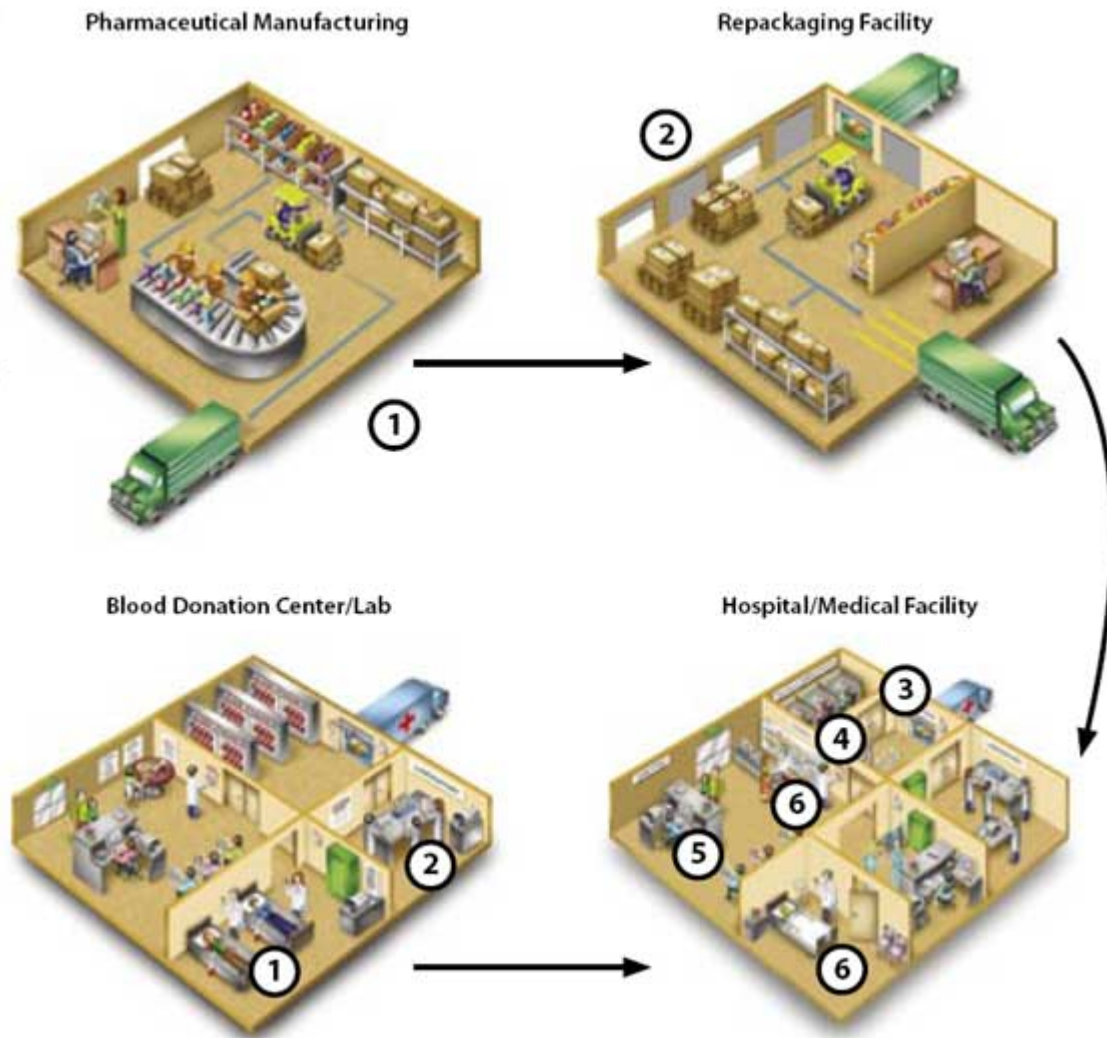
On March 13, 2003, HHS Secretary Tommy Thompson announced the new proposed FDA rules designed to improve patient safety by reducing medication errors, which were later ratified in February 2004. Of particular interest to AIDC industry participants is, “Bar Code Label Requirements for Human Drug Products and Blood.” It stipulates, in part, that:

- All blood products, prescription drugs and OTC drugs commonly used in hospitals and dispensed pursuant to an order are source-coded with a linear bar code.
- The bar code contains the National Drug Code number. It may also include other information (lot, expiration date, etc.) at the discretion of the manufacturer.
- The bar code on blood products contains a unique facility identifier, lot number relating to donor, product code and blood type of donor. • The bar code is visible on single dose packaging and all outer packaging.
- This bar code will be part of a system that enables health care workers to check whether they are giving the right drug via the right dose and right route of administration to the right patient at the right time.
- New drugs must comply with the rule within 60 days of approval, and existing drugs must comply by February 25,2006.

The rule is relatively vague regarding specific system components and processes; however, system design and development is not the expertise of those writing the FDA rule. That is best left to the vast experience represented in the AIDC market – from within the organizations belonging to equipment manufacturers, software developers and systems integrators. In general, the FDA rule intends to enforce a system as represented below:

Dispensing Medication Using Safe-Patient Practices

The following illustration shows points in the healthcare supply chain where AIDC products will play a significant part in meeting the FDA Bar Code Rule stipulations.



The underlined items below represent the basic system requirements for compliance with the new FDA regulation.

1 - Source Coding. A bar code containing the NDC number is applied to bulk packs and single-dose products, as well as any outer packaging or shipping containers prior to leaving the pharmaceutical manufacturer. Units of whole blood are bar coded prior to leaving the blood

clinic site. Whole blood and single-dose medication may be shipped directly to the hospital/medical facility or retail pharmacy; or alternatively, sent to another facility for packaging. Bar code label printers, label media and scanners communicating to a host system can facilitate these processes.

2 - Re-Packaging Facility / Blood Processing Lab. Bulk packaged medication is converted to single-dose packages at re-packaging facilities. Whole blood is re-processed into a variety of blood products and blood processing labs. In both cases, a new NDC number will need to be created and encoded in a bar code, applied to final product packaging, and verified (inspected). In addition to the AIDC equipment mentioned for Source Coding, handheld and vehicle mounted mobile computers operating on a wireless local area network (WLAN) would expedite the shipping and receiving processes associated with the movement of the medications and blood from facility to facility. Host systems would be updated in real time to accurately reflect stock on hand.

3 - Hospital Receiving. The NDC could be scanned for quick verification that the product ordered is the product shipped; however, the NDC is not likely to be widely used in this function. If bar code labels are not able to carry the amount of information necessary, using radio frequency identification (RFID) tags and readers may be a better alternative. In either case, a WLAN will be necessary to keep the host system up-to-the-minute accurate.

4 - Pharmacy/Medical Supply Stock. Once received, medication is stocked in the pharmacy, or in some cases (e.g. OTC) at the nurses' stations. Simple handheld mobile computers with integrated scanners can be used to record the receipt.

5 - Patient Admitting and Patient Records. An electronic patient file is created at admitting that may include patient-supplied information such as current medications and allergies. A unique ID number or code is associated with that file, and the patient ID bar code is printed and supplied to the patient (e.g. wristband, card). Small bar code label printers and a variety of label media, along with a simple tetherless scanner, can support these activities.

6 - Point of Service. Real-time communication systems enable health care professionals to access patient records as:

- A physician prescribes/orders patient medication using CPOE. He/She can scan the patient ID bar code to access a patient's records to check for allergies and interactions prior to writing a prescription. This may reduce delays in dispensing medication as pharmacists try to reach the physician for consultation later.
- A health care professional dispenses medication. Prior to administering the medication, a bar code scanning device reads the NDC bar code and the patient ID bar code. Application software and/or host system programs direct the processing capability located on the scanning device (thick client) or the host (thin client server) to quickly associate the NDC number and patient record. The health care worker receives basic information back at their mobile computer showing that the drug does/does not match the one prescribed or ordered by the physician, as well as information regarding last dose, next scheduled dose, and other record information (allergies,

patient photo, physician's orders, etc).

- Health care workers have questions about a patient's drug regimen. Unique employee ID numbers can be bar coded on employee badges. Then, these can be scanned at the same time medication is prescribed or administered and immediately associated with a patient record. A quick call up to a patient's record using a handheld mobile computer can help identify the right person to speak with when there are questions about a patient's medication.

Solution Resources Are In Place

The good news is that all of the building blocks – from a product and technology standpoint – are already available in the AIDC marketplace. Furthermore, an expert network of Systems Integrators, Software Developers, and Value Added Resellers has already been established to help those impacted by the new FDA rule to comply.