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White
Paper

FDA BAR CODE RULE: AIDC SOLUTIONS FOR COMPLIANCE

Intermec

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."

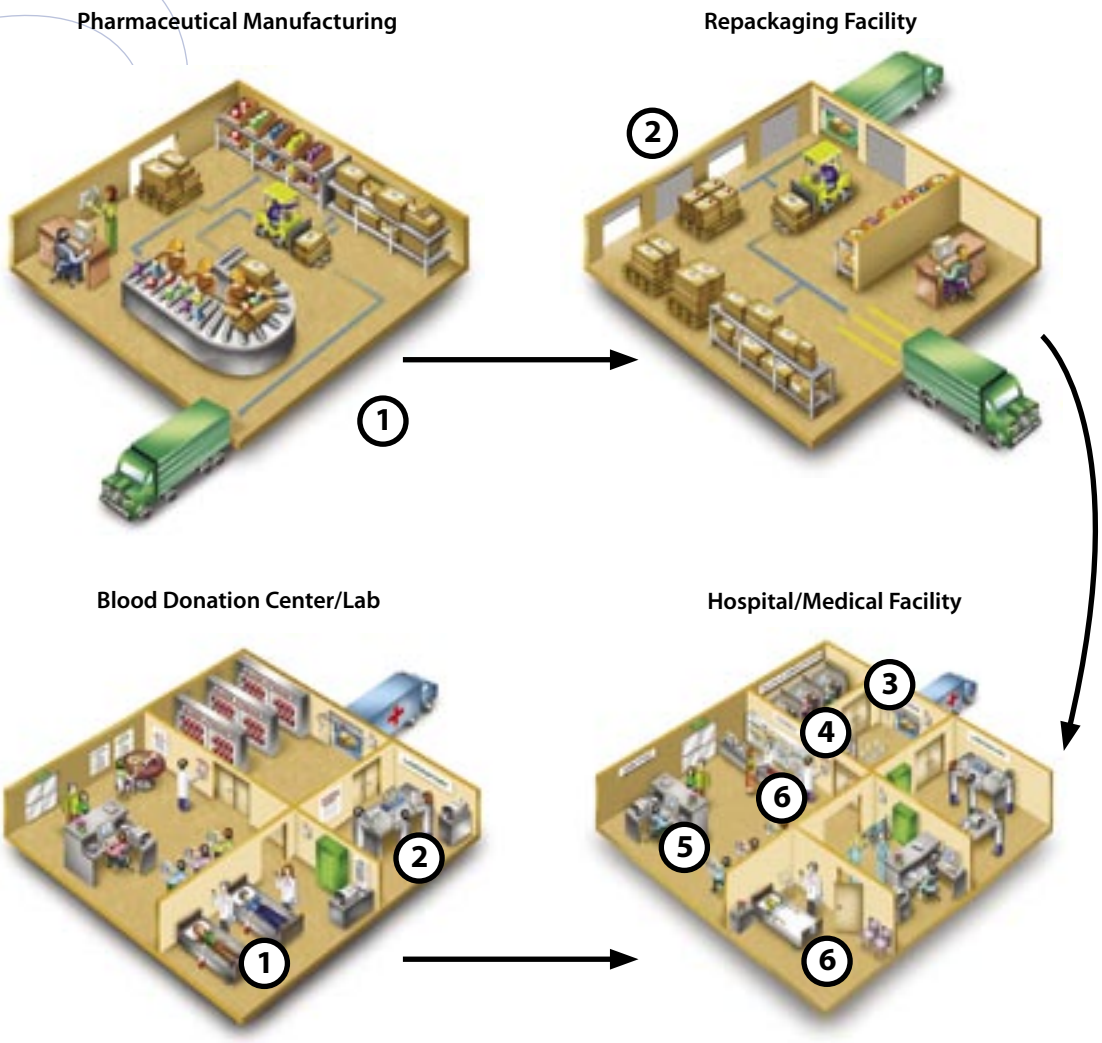
On March 13, 2003, HHS Secretary Tommy Thompson announced the new proposed FDA rules designed to improve patient safety by reducing medication errors, which were later ratified in February 2004. Of particular interest to AIDC industry participants is, "Bar Code Label Requirements for Human Drug Products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

System Requirements	Description	Solution for FDA Compliance
Computerized Patient Records 	• Patient records must be stored in a centralized database enabling application programs to call up specific pieces of a patient's record, as well as the record in its entirety. • The host database must accept every bit of patient information that could be collected during the course of medical treatment, as well as category assignments. • Existing patient databases will need to accept NDC (National Drug Code) numbers and any other information relating to a specific patient's drug regiment. • Electronic patient records must be secure.	Most medical facilities already have electronic records and have set up sufficient security measures to satisfy HIPAA regulations. However, for FDA compliance, existing patient databases will need to be modified to accept NDC number and any other information relating to a specific patient's drug regimen (prescribing doctor, administering health care professional, etc.).
Bar Coded Patient ID 	• To call up a specific patient's electronic record, use a patient ID as a unique identifier.	Bar coded wrist bands or patient ID cards are currently made available at most medical facilities today. Retail pharmacies often don't need to scan a patient ID, as they use privileged information supplied by the patient to confirm a patient record. These systems are satisfactory for compliance with the new rule.
Bar Coded Drug/ Blood Product 	• Drugs and Blood Products must be source-coded at the manufacturer.	There are several options: the use of in-line flexographic and offset printing of the NDC on package materials, or on-demand printing using bar code printers when pharmaceutical manufacturers choose to add additional information (lot, expiration).
Bar Code Scanning 	• Use of a product capable of collecting and deciphering information encoded in a bar code.	With implementation of this new rule, the scanning device takes on new importance as the lack of a reliable unit could delay the ability to dispense medication and provide adequate patient care. Whenever possible, rugged mobile computers with integrated scanning should be the primary scanning device, however use of a handheld scanner connected to an existing PC (at a nursing or admitting station) or a laptop (on a powered cart) will satisfy this requirement. Any scanning device selected should be able to withstand moderate bumps and drops without breaking, and it should be comfortable to hold and easy to use for a variety of workers. The scanners should use imaging technology for the increased safety and performance advantages within the standard range. In some cases, they can be cordless employing Bluetooth radio technology.

System Requirements	Description	Solution for FDA Compliance
Mobile Computing 	• Use of a product capable of collecting and/or displaying information based on user-activated commands. • The product must have sufficient processing capability to run necessary application programs as well as a means of communication with the primary database which houses the information.	Mobile computers will enable the user to receive information quickly and in an easy to use format. The medication dispensing application would load a display screen that would prompt the user to scan for a patient ID and then the associated NDC, and it would display a go/no go message that is easy to follow. Doctors can use this device to quickly access patient records, review information, add notes and write orders—all initiated by a quick scan of the patient ID bar code. Like the scanning devices , it should be able to withstand moderate, inadvertent abuse. It should incorporate a battery that is easily changed and supports at least a full shift's work. It should support the operating system of the application developer. It should have an integrated radio that operates on the same frequency as the rest of the WLAN system installed.
Bar Code Printing 	• Use of a product capable of encoding alphanumeric characters into bar codes, and then marking those codes on the desired surface (paper, label, card, etc.).	While laser printers are often used today for patient ID bar codes, it is with mixed results. Bar code printers are specifically designed to quickly and consistently provide high quality bar codes and will be the best bet for high-use environments like patient admitting.
Real Time Communication 	• Immediate communication with the host database. • Host system processing from any location where the information may likely be useful. Generally, this results in the installation of Local Area Network (LAN) across a large area using Radio Frequency (RF) waves so that wireless communication takes place.	A network of access points can be installed to provide RF communication. 802.11 protocols are most widely used and offer the appropriate security measures in support of HIPAA. The access points should support roaming. A site survey should be conducted by professionals in the field to ensure adequate coverage.
Application Programs	• Software installed on a device or system that delivers input or display screens to guide the user through tasks that are often repeated throughout the course of a day or work week.	Application programmers can write specific programs in support of a medical facility's individual processes. They should use standard operating systems to ensure long term support.

Anticipated Benefits

Some of the primary benefits and direct results of an AIDC system within the health care arena include:

- **Reduced Medication Errors.** The overriding objective of the rule is to reduce medication error rates in US medical facilities. The government has installed and used bar code technology in many VA hospitals, and has seen medication error rates decrease by 71% to 86% after implementation. One New Hampshire hospital reduced its medication error rate by 80 percent after it adopted a bar coding program. A medical center in Colorado lowered its medication error rate by 71% between 1992 and 1994. A VA hospital in Kansas had no medication errors when its computerized, bar coding system was used properly — the hospital estimated the system prevented over 378,000 medication errors in a 5-year period. Therefore, with a conservative estimate that 50% of all medication errors are caught at the "dispensing and administration" stages, it is expected that 413,000 fewer adverse events would occur over the next 20 years.

- **Cost Reductions and Positive ROI for Hospitals and other Medical Facilities Impacted.** The new AIDC rule, at full implementation, is expected to result in over 413,000 fewer adverse drug events over 20 years – the present value of avoiding hospital stays and patient pain and suffering is estimated to be about $41.4 billion (versus cost of $7.2 billion). In addition, hospitals are expected to realize a present value of $4.8 billion in savings relating to recordkeeping and reporting activities. Additional upside savings are also possible given the likelihood that hospitals could avoid litigation associated with preventable adverse events, reduce malpractice liability insurance premiums, and increase receipts with more accurate billing procedures.

Conclusion

Manufacturing, Transportation, Retail and other industries have been using bar code and data collection to track and verify items for many years. The FDA regulation suggests that these very same techniques should be employed in health care to track and verify medication. Therefore, the problem within health care could be successfully addressed by pointing to the experiences gained in other industries – industries which also faced compliance issues while focusing on customer ROI.

Incorporating the appropriate AIDC equipment and services will complete the health care medication coding system, and provide a much clearer picture of how the entire system should operate.

For Additional Information:

www.fda.gov– FDA website provides status updates on the rule as organizations move toward implementation.

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AIDC SOLUTIONS FOR COMPLIANCE

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