FDA Issues Bar Code Regulation

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Today's Action

In an effort to improve patient safety in the hospital setting by reducing medication errors, the Food and Drug Administration (FDA) has published a final rule titled, **Bar Code Label Requirements for Human Drug Products and Biological Products**.

The Final Rule

FDA is issuing a final rule that requires "bar codes" on most prescription drugs and on certain over-the-counter drugs. Bar codes are symbols consisting of horizontal lines and spaces and are commonly seen on most consumer goods. In retail settings, bar codes identify the specific product and allow software to link the product to price and other sales- and inventory-related information. FDA's bar code rule uses bar codes to address an important public health concern -- medication errors associated with drug products.

How Would It Work

The final rule requires linear bar codes on most prescription drugs and on over-the-counter drugs commonly used in hospitals and dispensed pursuant to an order. The bar code must, at a minimum, contain the drug's National Drug Code (NDC) number, which uniquely identifies the drug.

For blood and blood components intended for transfusion, the final rule requires the use of machine-readable information in a format approved for use by FDA. The machine-readable information must include, at a minimum, the facility identifier, the lot number relating to the donor, the product code, and the donor's ABO and Rh.

Bar codes on drugs would help prevent medication errors when used with a bar code scanning system and computerized database. This system would work as follows:

- A patient is admitted to the hospital. The hospital gives the patient a bar-coded identification bracelet to link the patient to his or her computerized medical record.
- As required by the rule, most prescription drugs and certain over-the-counter drugs would have a bar code on their labels. The bar code would reflect the drug's NDC number.

- The hospital would have bar code scanners or readers that are linked to the hospital's computer system of electronic medical records.
- Before a healthcare worker administers a drug to the patient, the healthcare worker scans the patient's bar code. This allows the computer to pull up the patient's computerized medical record.
- The healthcare worker then scans the drug(s) that the hospital pharmacy has provided to be administered to the patient. This scan informs the computer which drug is being administered.
- The computer then compares the patient's medical record to the drug(s) being administered to ensure that they match. If there is a problem, the computer sends an error message, and the healthcare worker investigates the problem.
- The problem could be one of many things:
    - Wrong patient
    - Wrong dose of drug
    - Wrong drug
    - Wrong time to administer the drug
    - The patient's chart has been updated and the prescribed medication has changed

So, for example, a bar code system could prevent a child from receiving an adult dosage of a drug and prevent a patient from mistakenly receiving a duplicate dose of a drug he or she had already received. A bar code system can also allow the computer to record the time that the patient receives the drug, ensuring more accurate medical records.

Improving Patient Safety

The Institute of Medicine and other expert bodies have concluded that medical errors have substantial costs in lives, injuries, and wasted health care resources, and that drug-related adverse events are a major component of those errors.

FDA estimates that the bar code rule, once implemented, will result in more than 500,000 fewer adverse events over the next 20 years. Thus, FDA estimates a 50% reduction in medication errors that would otherwise occur when drugs are dispensed or administered, even though some hospitals that currently have bar code systems in place report a higher error reduction from bar code usage.

Other Benefits

Patients would avoid pain, suffering, and extensions of hospital stays with an estimated value of $93 billion over the next 20 years. In addition, hospitals are expected to avoid litigation associated with preventable adverse events, reduce malpractice liability insurance premiums, and increase receipts from more accurate billing procedures.

Also, the bar coding system could help with inventory control for drug manufacturers, wholesalers and pharmacists, as well as efficiencies in ordering and billing.