AHA
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June 12, 2003

Dockets Management Branch (HFA-305)
Mark McClellan, MD
Commissioner
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Bar Code Requirement For Human Drug Products and Blood; Request for comments and information on proposed rule (*68 Federal Register 50)* March 14, 2003

Dear Dr. McClellan:

On behalf of our nearly 5,000 member hospitals, health systems, networks and other providers of care, the American Hospital Association (AHA) welcomes the opportunity to comment on the Food and Drug Administration's (FDA) proposed rule to standardize bar coding for drugs and blood. America's hospitals and health systems share the FDA's long-standing commitment to improving patient safety. For this reason, the AHA strongly advocates the use of bar codes on drugs, biologics, and devices used in patient care.

Bar coding is a proven technology that helps doctors, nurses, and pharmacists prevent medication errors. It has been shown to prevent overdoses, the administration of contraindicated drugs, and the use of the wrong drugs.

AHA is one of the founding members of the National Alliance for Health Information Technology (NAHIT). NAHIT is an alliance of nearly 85 organizations representing providers, purchasers, manufacturers and standard-setting organizations that is committed to improving quality and performance through standards-based information systems. Since its inception, NAHIT has strongly encouraged the bar coding of drugs and blood to reduce medication and transfusion errors.

**AHA strongly supports the recommendations included in NAHIT's comment letter, which was sent under separate cover, and offers the following additional comments and clarifications.**

Bar Codes Should Be Universal and Contain All Vital Information

**To be most effective, bar coding must be standardized in its format and application. Bar codes must be affixed to all drugs, blood products, and devices used in the care of patients.**

Excluding any product diminishes the impact of broad-based standardization through bar coding, and its patient safety benefits.

However, because this goal may not be attainable as rapidly as we would like by all manufacturers, there is a need make progress in incremental steps, starting with the bar coding of drugs and blood products. We commend the FDA for taking this step in its proposed rule. Further, we expect that some manufacturers of drugs and blood products may not be ready to implement bar coding immediately, and the FDA should establish a process to approve temporary waivers on a case-by-case basis to ensure continued access to needed pharmaceuticals while bar coding technologies are being adopted.

Bar codes should include all information vital to understanding if the drug, unit of blood, or other product is safe, effective, and appropriate. This information includes the lot number and expiration date, information that would enhance our ability to track and identify a product should there be need for a recall.

Bar Codes for Drugs

**The FDA should mandate the use of the UCC/EAN as the standard symbology on all drug labels.** If the FDA were to require "linear bar code," as proposed in the draft rule, drug companies would be able to use a variety of formats, some of which are not readable by many bar code scanners. Hospitals that have already chosen to purchase scanning equipment might have to update their scanners to be able to read all of the different symbols that pharmaceutical manufacturers might use. This lack of standard symbology would drive up costs and fail to achieve the potential improvements in patient safety.

**Bar code labels encoded with the NDC number should be mandatory for new drug product applications two months after the effective date of the final rule**. Labels on existing drugs should be required to have bar codes as soon as practical, but not later than three years after the effective date of the final rule. The three-year period will enable manufacturers to exhaust their existing stockpiles and make new labels carrying the required information.

The commitment to improving safety should exist regardless of whether a drug is packaged to be sold or as a sample that is given away. The risks of an incorrect dosage or drug-to-drug interactions are the same regardless of whether the drug is for sale or a sample; therefore, the use of bar codes should be the same. Further, safety experts recognize that standardizing processes is a vital step in reducing mistakes. If samples are not bar coded, there would be one process for clinicians to follow if the drug is a sample and another to follow if it is not, which may lead to confusion and mistakes. **The AHA urges the FDA to mandate bar code labels on sample prescription drugs.**

Over-the-counter (OTC) drugs also need to be bar coded if they are to be dispensed safely. To accurately communicate to manufacturers and hospitals which OTC drugs are expected to be bar-coded, the FDA should **use the phrase "non-prescription drugs used therapeutically pursuant to a prescriber's order"** rather than "over-the-counter drug products that are dispensed under an order." Here, the word "therapeutic" is used to exclude OTC drugs such as

fluoride toothpaste or mouth rinse, which are non-curative. In addition, for the sake of clarity and specificity, the phrase "packaged for hospital use, labeled for hospital use, marketed for hospital use, or sold to hospitals" should be used rather than the phrase "commonly used in hospitals."

Bar Coding Blood and Blood Products

**For blood and blood products, the ISBT-128 should be used as the standard symbology.** There are three important reasons:

- The currently used ABC Codabar is outdated and has limited capacity. The ISBT-128 allows for more flexibility; more information can be encoded on a label.
- By adopting this standard, FDA will move the field toward compliance with standards on which there is voluntary international consensus.
- ISBT-128 can be read by the same scanners used on drugs, creating a more standardized process for administering drugs or blood to patients, and minimizing the investment hospitals must make to take advantage of the bar codes for patient safety.

Use of Bar Codes on Vaccines

In the proposed rule, the FDA asked for comments on whether vaccines should also be required to have bar codes. We believe they should. Accurate record keeping that enables patients and providers to know what vaccines were given, when, and whether there was any immediate reaction can be vital in protecting patients throughout their lives. The National Childhood Vaccine Injury Act of 1986 requires that a permanent vaccination record be kept after each inoculation. Including the appropriate information on the bar code label will enable more accurate record keeping and permit easy retrieval of the information. **We urge the FDA to require that vaccines be bar coded, and that the bar code include the lot number and expiration date.**

Bar coding is a critically important technology for improving patient safety. In standardizing bar coding, the FDA has the opportunity to improve the information that health care professionals have so that they can fulfill their aims of giving patients the right drug in the right dose at the right time.

Thank you for the opportunity to provide comments on this proposed rule. If you have any questions about these comments, please feel free to contact Nancy Foster at 202-626-2337.

Sincerely,

Rick Pollack
Executive Vice President