Federation of
American
Hospitals™

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Charles N. Kahn III
President

June 10, 2003

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

Subject: Food and Drug Administration's Proposed Rule: Bar Code Label Requirements for Human Drug Products and Blood

Dear Commissioner McClellan:

The Federation of American Hospitals (FAH) is pleased to have the opportunity to comment on the FDA's proposed rule in the March 14, 2003 Federal Register (Volume 68, Number 50, Docket No. 02N-0204) entitled, "Bar Code Label Requirement for Human Drug Products and Blood."

FAH is the national representative of investor-owned or managed hospitals and health systems throughout the United States. Our members include general community hospitals and teaching hospitals in urban and rural America.

The mission of FAH member companies is to provide high quality care to the patients we serve. FAH has taken an active role in advancing policy initiatives to improve the safety and quality of hospital care in this country and to promote patient education regarding care. Our Board of Directors has adopted policy statements regarding principles for patient safety reporting systems; methods for reducing medication errors; requirements for creating effective quality measures; and most recently, the public reporting of such measures.

The use of bar coding medications to reduce medication errors was among the principles adopted by the FAH Board in 2001. We strongly support the FDA's actions to establish uniform bar coding for human drug products and blood. Preventable adverse drug events are a major source of medical errors in hospitals. An estimated one-third of these errors occur during the process of medication administration. Electronic medication

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administration systems have the potential to greatly reduce such errors. However, such systems cannot function well or on a widespread basis unless they are uniform and mandatory for all drug products. The costs of these requirements for manufacturers and hospitals are far outweighed by the benefits that will accrue to patients. Based on empirical research, it is estimated that a hospital with 8,000 admissions per year will have more than 50 errors related to medication administration. (Study citations provided below.)

Only the federal government has the authority to establish such standards and the ability to have a significant impact on reducing medication errors occurring in our health care system today. It is appropriate and well within the scope of the FDA to implement this regulation.

Our specific comments follow below.

1. The FDA regulation should require pharmaceutical manufacturers to label all medications, including unit dose medications, with both human readable and bar coded distinguishing information. Each dose should have a *single bar code* including the National Drug Code (NDC) number, lot number, and expiration date. FAH recommends that vaccines be included within this requirement.

   If incremental steps are necessary, the NDC number is the minimal piece of information that should be included initially. However, the FDA should specify a time table for including lot number and expiration date on the bar code in the final regulation. FAH agrees with the recommendation of the National Alliance for Health Information Technology that if these two pieces of information cannot be included initially, then the FDA should require their inclusion within 5 years from the date of the final FDA rule.

   It is also worth noting that the Department of Health and Human Services Secretary's Advisory Committee on Regulatory Reform recognized that the NDC code is the only currently available system that is standard, updates electronically, and specifically states the product administered.

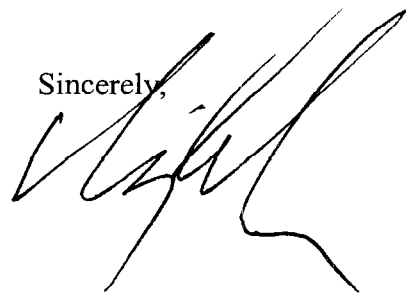
   In terms of an implementation timeframe, FAH recommends that new drugs approved within 2 months following the effective date of the final rule include bar coding, and that existing drugs include bar coding as soon as practicable, but in no instance, later than 3 years after the effective date of the final rule.

2. We generally concur with the FDA's proposed regulation to require bar coding for only those over-the-counter (OTC) medications used primarily in hospitals. Checking administration of these medications and their potential interaction with prescription drugs has significant potential for reducing adverse drug events. However, we would hope that over time, manufacturers would bar code all OTC medications.

3. The FDA regulation should ensure that the bar code print density is designed to provide reliable readability. To maximize the goal of reducing medication errors, it is very important to encourage hospitals to invest in scanner technologies that they are confident will work *well* and work for *all* bar coded drug products. Therefore, we recommend that FDA require the standard symbology be linear Reduced Space Symbology (RSS) for all drug products. By using a standard technology with proven and know effectiveness, hospitals will be able to confidently invest in scanning equipment without having to buy different scanners for different drugs. This situation, in itself, has great potential for creating new errors.

The implementation of standard bar coding is a critical step toward reducing medication errors occurring in the nation's hospitals. Labeling at the manufacturer level provides the highest level of assurance that the bar coding is done accurately. FAH commends the FDA for taking action to improve the quality and safety of care delivered in the nation's hospitals.

Sincerely,



Citations for studies referenced above:

1. Bates, D.W., et al., "The Costs of Adverse Drug Events in Hospitalized Patients", Journal of the American Medical Association, Vol. 277, No. 4, pp. 307-311, 1997.

2. Bates, D.W., et al., et al, "Incidence of Adverse Drug Events and Potential Adverse Drug Events", Journal of the American Medical Association, Vol. 274, No. 1. , pp. 29-34, 1995.