

a. *Why Cover Prescription Drug Products, Including Vaccines, But Not Physician Samples?* The comments from the public meeting agreed that prescription drug products should have a bar code, although a small number of comments suggested that only prescription drug products used in institutions should be subject to a bar code requirement and that prescription drug samples should not be included.

We decided to cover all prescription drug products, rather than limit the rule to prescription drug products used in institutions, because we are unaware of any prescription drug products that are not used in hospitals. Our primary focus is to help reduce the number of medication errors occurring in hospitals, and, as we consider "prescription drugs used in institutions" as being the same as "prescription drugs" generally, the proposal refers to "prescription drugs."

However, with regard to prescription drug samples, we decided to omit prescription drug samples from a proposed bar code requirement because most samples are given to patients at physicians' offices, and we do not believe that physicians or patients would have or be inclined to buy bar code scanners for their own use in the immediate future. We recognize that an argument could be made for including samples. We know that some samples are donated to charitable organizations, such as free clinics, for distribution to patients without charge (Ref. 34). These samples could be subject to the same medication errors as marketed prescription drugs, and those medication errors could be prevented through the use of bar codes. In addition, Congress and FDA have been concerned about illegal sales of prescription drug samples, the potential diversion of samples to illegal drug trafficking, and the entry of counterfeit drugs into the wholesale distribution system. Requiring bar codes on samples could help identify diverted or counterfeit drug products that enter distribution through illegal channels, and this could result in benefits that are not directly related to the prevention of medication errors.

We recognize that the vast majority of prescription drug samples are usually given to patients at physicians' offices and are not administered in hospitals. Because we have no evidence to suggest that physicians' offices are likely to be equipped with bar code scanners in the immediate future, the benefits associated with preventing medication errors through bar codes on prescription drug samples are unlikely to be realized in this health care setting. We also

recognize that it is unlikely that charitable institutions, such as free clinics, would have the resources to buy bar code scanners to prevent medication errors. As a result, we have decided to omit prescription drug samples from the rule at this time. We do, however, invite comment on whether to require bar codes on prescription drug samples. Comments should address the costs and benefits associated with requiring bar codes on prescription drug samples.

The proposal would apply to vaccines. The National Childhood Vaccine Injury Act of 1986 (Public Law 99-660) (42 U.S.C. 300aa-25(a)) requires each health care provider who administers a vaccine set forth in the Vaccine Injury Table to any person to record, in that person's permanent medical record or in a permanent office log or file, the date of administration of the vaccine, the vaccine manufacturer, the vaccine's lot number, and other information. A bar code on vaccines could help ensure the accuracy of those records insofar as identification of the vaccine, its manufacturer, and date of administration are concerned, and, for those vaccines administered in health care facilities, help ensure that the right vaccine is administered to the right patient at the right time. However, we are sensitive to the vaccine manufacturers' concerns, particularly as they relate to possible adverse impacts on vaccine production or availability, and we invite comment on the risks and benefits of including vaccines in a bar code rule.

As for those comments that suggested an exemption for certain products or small containers, we decline to create an exemption mechanism and explain our reasons in section II.F of this document.

b. *Why Cover OTC Drugs That Are Dispensed Under an Order and Commonly Used in Hospitals?* The public meeting notice asked whether we should require bar codes on all OTC drugs. After reviewing the comments, we decided against requiring all OTC drugs to carry a bar code because it is unlikely that putting bar codes on all OTC drugs would have a significant impact on reducing medication errors and offset the large costs associated with requiring bar codes on all OTC drugs. Most OTC drugs are used outside hospitals and other health care facilities and are used by consumers who purchase the OTC drugs at retail. At this point, it is unlikely that individual consumers would buy, use, or have access to bar code scanners or use such scanners before taking an OTC drug.

We recognize, however, that some OTC drugs are administered to patients in hospitals and that bar codes would

enable health care professionals to check whether they are giving the right OTC drug in the right dose and right route of administration to the right patient at the right time. In addition, we recognize that OTC drugs could interact with prescription drugs administered at that hospital or affect another drug's performance. Thus, we propose to require bar codes on OTC drugs that are dispensed pursuant to an order and are commonly used in health care facilities. For example, the bar code on an OTC drug dispensed pursuant to an order and commonly used in a hospital may allow a hospital's database to identify any potential interactions between the OTC drug and any prescription drugs prescribed for the patient, or may alert a health care professional to the patient's allergies relative to the OTC drug's ingredients. The proposal would apply to any manufacturer, repacker, relabeler, or private label distributor who sells a specific package of an OTC drug product to hospitals. It would not apply to all packages of a specific OTC drug product. An example of a specific package of an OTC drug product sold to hospitals would be an individual product, such as an aspirin tablet, packaged in a unit-of-use container.

We would interpret "commonly used in hospitals" to include OTC drugs that are sold to hospitals, packaged for institutional use, labeled for institutional use, or marketed, promoted, or sold to hospitals through drug purchasing contracts or catalogues. For example, if an OTC drug product manufacturer sends its catalogues to hospitals to solicit orders from them, the OTC drug products described in the catalogue would be "commonly used in hospitals" because the manufacturer is marketing its OTC drugs to hospitals. If a distributor relabeled an OTC drug "for institutional use," then that OTC drug would be "commonly used in hospitals" because it is intended for hospital use.

We expect that manufacturers, repackers, relabelers, and private label distributors would know which of their products meet the definition of OTC drug products commonly used in hospitals. For example, we believe that when manufacturers, repackers, relabelers, and private label distributors label or package their OTC drugs for institutional use, they know that the products will likely be sold to hospitals. Manufacturers also know that their OTC drug products will be sold to hospitals when they market or promote those OTC drugs to hospital staff through detailing the products or other means, enter into hospital purchasing contracts, or sell to hospitals through catalogues.