

Corporation, the HealthCare Distribution Management Association, and Cardinal Health; and

- The USP.

In addition, in response to requests to discuss bar code issues in greater detail, we met separately with PhRMA on August 19, 2002, with CHPA, GPhA, and others on September 17, 2002, and with the National Alliance for Health Information Technology on October 9, 2002.

In general, almost all individuals, companies, and organizations attending or commenting on the public meeting strongly supported the use of bar codes on human drug products to help reduce medication errors, but differed in their opinions as to the information that should go into the bar code and whether certain products, such as over-the-counter (OTC) drugs and medical devices, should have a bar code. We discuss various aspects of the public meeting throughout the remainder of this preamble to show how information from the public meeting helped shape this proposal.

II. Description of the Proposed Rule

The proposal would create a new § 201.25 entitled “Bar Code Label Requirements.” The proposal would address:

- Who is subject to these bar code requirements?
- What drugs are subject to these bar code requirements?
- What does the bar code look like?
- Where does the bar code go?

The proposed bar code requirement would also apply to biological products (other than blood and blood components). We cross-reference this requirement in the biologics regulations at new § 610.67.

For blood and blood components, the proposal would amend part 606 (21 CFR part 606) in § 606.121(c)(13) which currently allows, but does not require, the use of machine-readable symbols, approved by the Director of the Center for Biologics Evaluation and Research (CBER), on blood and blood component container labels. The proposal would require the use of encoded, machine-readable information approved by the CBER Director on blood and blood component labels.

A. Who Would Be Subject to the Bar Code Requirement? (Proposed § 201.25(a))

In brief, under proposed § 201.25(a), manufacturers, repackers, relabelers, and private label distributors of human prescription drug products and OTC drug products regulated under the Federal Food, Drug, and Cosmetic Act

(the act) or the Public Health Service Act would be subject to the bar code requirement unless they are exempt from the establishment registration and drug listing requirements in section 510 of the act (21 U.S.C. 360(g)(1)). In practice, this means that pharmacies which are exempt under section 510(g) of the act are not required to put bar codes on drugs they are dispensing. (The requirements in proposed § 201.25 would apply to biological products (other than blood and blood components) and would include a cross-reference at proposed § 610.67. For convenience, this preamble will refer only to proposed § 201.25 alone without repeated cross-references to proposed § 610.67 (see section II.I of this document).) For purposes of this proposal:

- “Manufacturer” means a person or persons who owns or operates an establishment engaged in the manufacture, preparation, propagation, compounding, or processing of a drug by chemical, physical, biological, or other manipulations of the drug. These activities include repackaging or otherwise changing the container, wrapper, or labeling of any drug package in furtherance of the drug’s distribution from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user.

- “Repacker” means a person or persons who owns or operates an establishment that repackages and relabels a drug and does not engage in any other activities performed by a manufacturer.

- “Relabeler” means a person or persons who owns or operates an establishment that affixes or changes labels on a drug and does not engage in any other activities performed by a manufacturer.

- “Private label distributor” means a person or persons who owns or operates an establishment that commercially distributes, under its own label or trade name, any drug manufactured, prepared, propagated, compounded, or processed by a manufacturer, repacker, or relabeler.

For example, if you make a prescription drug product, you would be subject to the bar coding requirement. However, if you are a pharmacy operating in conformance with applicable local laws regulating the practice of pharmacy and are regularly engaged in dispensing prescription drugs upon prescriptions of practitioners licensed to administer such drugs to patients, and do not manufacture, prepare, propagate, compound, or process drugs for sale other than in the regular course of

business of dispensing such drugs at retail, you would not be subject to the bar code requirements. Your pharmacy would be exempt because section 510(g)(1) of the act does not require you to comply with the establishment registration and listing requirements.

We recognize that some hospitals themselves place bar codes on drugs and have reduced their medication error rates significantly. Requiring persons who manufacture, repackage, or relabel human drug products to bar code their own products should be more efficient and result in better quality bar codes. Manufacturers, repackers, and relabelers generally have sophisticated manufacturing processes and labeling machinery, and quality control systems that hospitals cannot afford. Bar coding by third parties (such as hospitals) would be more costly for the facility and would not achieve the economies of scale that larger entities could realize. Having many small entities affix bar codes could increase the possibility of a label error through the attachment of the wrong bar code and could lead to inconsistent bar code quality. For example, one comment from the public meeting stated that an institution administering 2.5 million doses per year, even if operating at 99.9 percent effectiveness at applying its own bar codes, would introduce seven new errors per day from repackaging. Another comment, submitted by an entity familiar with “automatic identification” methods, stated that “on demand” bar code printing, as used in hospitals and clinics, will have a higher error rate compared to bar code printing by manufacturers and that the “use and maintenance of this type of bar code printing is historically haphazard at best.” Another comment from a bar code standards organization estimated the error rate in hospital labeling to be approximately 17 percent nationwide.

More importantly, requiring persons who manufacture, repackage, or relabel human drug products and private label distributors to bar code their own products and to use the same bar coding standard should result in a more uniform bar coding system that can be used regardless of a patient’s or hospital’s location in the United States (Ref. 15). Uniformity should also make it easier for health care professionals to train themselves on bar coding procedures and technique and make it easier and less expensive for hospitals to buy bar coding equipment. Uniformity should also make it easier for manufacturers, repackers, relabelers, and private label distributors to put bar codes on products, because they would not have to customize their symbols or