

- Each drug would have a bar code. The bar code would provide unique, identifying information about the drug that is to be dispensed to the patient.

- In hospitals, health-care professionals, such as pharmacists and nurses, would use bar code scanners (also called bar code readers) to read the bar code on the drug before dispensing the drug to the patient and use bar code scanners to read a bar coded wrist band on the patient before giving the drug to the patient. In an outpatient setting, the health care professional (such as a pharmacist) could scan the bar code on the drug and compare the scanned information against the patient's electronic prescription information before giving the drug to the patient.

- The bar code scanner's information would go to the computer where it would be compared against the patient's drug regimen information to check whether the right patient is receiving the right drug (including the right dose of that drug in the right route of administration). The system could also be designed to check whether the patient is receiving the drug at the right time.

- If the identity of the health care professional administering the drug was desired, each health care professional could also have a bar code. The health care professional would scan his or her own bar code before giving the drug to the patient.

Bar codes could also complement other efforts to reduce medication errors.

- In computer physician order entry (CPOE) systems, a physician enters orders into a computer instead of writing them on paper. The order can be checked against the patient's records for possible drug interactions, overdoses, and patient allergies (Ref. 26).

- The retail pharmacy community is beginning to use a bar-coded NDC number to verify that a consumer's prescription is being dispensed with the correct drug. These pharmacy-based systems compare a bar code that the pharmacy's computer prints on the consumer's prescription against the bar code on the drug's label. If the computer detects an error, the computer alerts the pharmacist to the problem.

In addition, bar codes could make it easier to enter medication order entries into a patient's electronic medical records, help in inventory control and billing, and help conserve hospital or health care staff resources or free those resources so that they can be devoted to patient care.

#### *E. Can Bar Code Use Reduce the Incidence of Medication Errors?*

Published articles and other information submitted to FDA suggest that bar coding can reduce medication error rates significantly.

- One New Hampshire hospital reduced its medication error rate by 80 percent after it adopted a bar coding program (Ref. 15).

- A medical center in Colorado lowered its medication error rate by 71 percent between 1992 and 1994 (Ref. 16).

- A Department of Veterans Affairs (VA) hospital in Kansas had no medication errors when its computerized, bar coding system was used properly; the hospital estimated that the system prevented over 378,000 medication errors in a 5-year period (Ref. 17).

- Other published articles have discussed how bar coding can reduce medication errors, including missed doses, or increase drug dispensing accuracy (Refs. 18 through 23).

At a public meeting that we (FDA) held on July 26, 2002 (67 FR 41360, June 18, 2002), the VA gave a presentation on its use of bar codes at the VA Medical Center in Topeka, Kansas. The VA stated that a comparison of medication error data from 1993, the last year before the VA implemented the bar code system, to data for 2001 showed that the Topeka medical center reduced its reported medication error rate by 86.2 percent (Ref. 24). The improvements included:

- 75.5 percent improvement in errors caused by the wrong medication being administered to a patient;

- 93.5 percent improvement in errors caused by the incorrect dose being administered to a patient;

- 87.4 percent improvement in wrong patient errors; and

- 70.3 percent improvement in errors caused when medications scheduled for administration were not given. (Ref. 24 at p. 14).

One comment submitted in response to the public meeting indicated that a bar code scanning system, in conjunction with a robotic system for pharmaceutical distribution, reduced dispensing errors at the University of Wisconsin from 1.43 percent to 0.13 percent and that the university realized a return on its investment in 2 years (Ref. 25). The comment also stated that there was an 89 percent reduction in medication administration errors due to point-of-care bar code scanning (Ref. 25 at p. 6).

We discuss the public meeting in greater detail in section II of this document.

#### *F. Is There Support for Putting Bar Codes on Drug Products?*

In recent years, many organizations have either commented favorably on or recommended the adoption of bar coding to reduce medication errors. These organizations include the QuIC Task Force, NCCMERP, ASHP, and Premier, Inc., an alliance of not-for-profit hospital and health care systems (Refs. 27 through 29).

We also saw considerable support for bar coding at the July 26, 2002, public meeting we held to discuss a possible rule to require bar code labeling. Nearly 400 individuals attended the meeting, and they represented a broad range of interests, including:

- Nurses, including the American Academy of Nursing;

- Pharmacists, including the American Society of Health-System Pharmacists;

- Physicians, including the American Medical Association;

- Hospitals, including the American Hospital Association, the VA, which already has a bar code program in place for drugs used in VA hospitals, and the Hospital Corporation of America, Inc., which intends to have bar coding technology in place in its hospitals by the end of 2005;

- Pharmaceutical manufacturers, including the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Generic Pharmaceutical Association (GPhA);

- Over-the-counter (OTC) drug manufacturers, including the Consumer HealthCare Products Association (CHPA);

- Medical device manufacturers, including the Advanced Medical Technology Association (also known as AdvaMed);

- Blood centers and blood organizations, including the American Association of Blood Banks, America's Blood Centers, and the American Red Cross;

- The Vaccine Identification Standards Initiative (VISI), a collaborative effort between public health agencies and private organizations involved in immunization practices and whose purpose is to establish voluntary, uniform guidelines for vaccine packaging and labeling and recording identifying information;

- Bar coding and other "automatic identifier" interests, including the Uniform Code Council and the Health Industry Business Communications Council (two standards development organizations that have established bar code standards);

- Health or medical product distributors, including McKesson