

protect patients and to promote safety. In February, 2000, he announced a plan to reduce preventable medical errors by 50 percent within 5 years.

- In February 2000, the Quality Interagency Coordination (QuIC) Task Force (a group composed of the Department of Health and Human Services (DHHS) and other Federal agencies) issued an action plan that highlighted steps for Federal agencies to take to reduce medical errors and to improve patient care.

- In March 2001, the Agency for HealthCare Research and Quality (AHRQ) issued a report entitled "Reducing and Preventing Adverse Drug Events to Decrease Hospital Costs." The report stated that more than 770,000 people are injured or die each year in hospitals from adverse drug events and that studies had suggested that 28 to 95 percent of adverse drug events could be prevented by reducing medication errors through the use of computerized monitoring systems, especially computerized medication ordering systems (Ref. 6).

- In April 2001, the Secretary of Health and Human Services, Tommy G. Thompson (Secretary Thompson), announced the establishment of a new Patient Safety Task Force within DHHS. Secretary Thompson named FDA as one of the Federal agencies leading this new effort (Ref. 7).

Congress also focused its attention on patient safety by holding hearings in 2000 and 2001 on patient safety and medical errors. On May 24, 2001, Secretary Thompson appeared before the Senate Committee on Health, Education, Labor, and Pensions' Subcommittee on Patient Health and stated that new technology, such as bar coding, could help save lives and money. Secretary Thompson noted that other industries used bar coding and that the same technology could be used to track drug dispensing and use and to prevent medication errors (Ref. 8).

Shortly thereafter, the American Society for Health-System Pharmacists (ASHP) wrote to Secretary Thompson to urge that FDA "develop regulations that mandate that drug manufacturers provide a standardized machine-readable code (bar coding) on all drug product containers, including single unit containers, which are essential for hospital unit dose drug distribution systems" (Ref. 9). ASHP mentioned a June 26, 2001, recommendation by the National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) urging FDA and the United States Pharmacopeia (USP) to establish and implement a uniform bar coding program for drugs (Ref. 9 at

pp. 1 and 2). Secretary Thompson later asked FDA to begin working on a bar coding proposal, thereby putting in motion the events that led to this proposed rule.

B. What Are Medication Errors?

NCCMERP¹ defines a medication error as:

* * * any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Such events may be related to professional practice; healthcare products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use. (Ref. 10)

For purposes of this preamble, we will adopt the same definition of "medication error."

Medication errors are a part of the overall "medical errors" problem because medical errors include surgical errors, device failures, and medication errors. Medication errors can occur at several points from the time the physician selects the drug to prescribe to a patient to the time when the patient receives the drug. For example, the physician may write a prescription for the right drug, but in the wrong dose. The pharmacist might misread the prescription and provide the wrong drug, or read the prescription correctly and dispense the wrong drug. The health care professional administering the drug might give it to the wrong patient or give it to the right patient, but at the wrong time or in the wrong dose.

Articles discussing medication errors can be found dating back several decades, and refer to such errors under various names, including "preventable adverse events," "drug misadventuring," and "iatrogenic illness" or "iatrogenic injury." (The word "iatrogenic" refers to "any adverse condition in a patient occurring as the result of treatment by a physician or surgeon" (see *Dorland's Illustrated Medical Dictionary*, 26th ed., at p. 647).) The articles often identify the following types of medication errors:

- Administering the wrong dose,
- Administering a drug to a patient who is known to be allergic,
- Administering the wrong drug to a patient or administering a drug to the wrong patient,

¹ NCCMERP is composed of over 20 national organizations (including FDA) whose objectives are to increase the reporting, understanding, and prevention of medication errors and to recommend strategies relative to systems modifications, practice standards, and guidelines, and changes in packaging, labeling, and product identity.

- Administering the drug incorrectly,
- Administering the drug at the wrong time or missing doses.

(See the Appendix elsewhere in this document for a description of various studies identifying different types of medication errors.)

C. How Frequently Do Medication Errors Occur? What Is Their Impact?

Studies differ as to how frequently medication errors occur. Some studies suggest that the medication error rate is under 7 percent, whereas others suggest a medication error rate at or above 20 percent. The differences may be due, in part, to different definitions of "medication error" or different research methodology that focused on fatalities, injuries, or medication orders. (See the appendix for a summary of medication error rates reported in several studies.)

Although most medication errors do not result in harm to patients, medication errors can result and have resulted in serious injury or death (Ref. 11).

Medication errors also represent a significant economic cost to the United States. In an article published in 1995, Johnson and Bootman estimated the direct cost of preventable drug-related mortality and morbidity to be \$76.6 billion annually, with drug-related hospital admissions accounting for much of the cost (Ref. 12). The authors suggested that indirect costs, such as those relating to lost productivity, might be two to three times greater than the direct costs, making the total cost of all preventable, drug-related mortality and morbidity range from \$138 to \$182 billion. A study by Ernst and Grizzle published in 2001 used updated figures and revised the direct cost estimate to \$177.4 billion (Ref. 13). Another article estimated the cost of preventable adverse drug events in hospitalized patients to be \$5,857 for each adverse drug event and the estimated annual costs for preventable adverse drug events for a 700-bed hospital to be \$2.8 million (Ref. 14).

D. How Would Bar Coding Help Prevent Medication Errors?

Bar codes would be part of a system, along with bar code scanners and computerized databases, that would enable health care professionals to check whether they are giving the right drug via the right dose and right route of administration to the right patient at the right time. Under this model, the system could work as follows:

- A patient would have his or her drug regimen information entered into a computerized database.