

1998, and Senst et al., 2001). The reported incidence rates of hospital admissions with ADEs ranged from 2.4 percent to 6.5 percent with a mean rate of 4.3 percent. According to AHRQ, there were 29.1 million nonobstetric hospital admissions during 2000. We multiplied these admissions by 0.043 and found that approximately 1.25 million ADEs occur annually in United States hospitals. The same four studies reported that between 15 percent and 49 percent of all ADEs are preventable. We used the mean of these studies to estimate that about 372,400 (30 percent) of these ADEs were preventable. Based on published reports (Bates et al., 1998, and Leape et al., 1998), we also estimated that 1,046,000 potential ADEs⁵ are either intercepted before reaching the patient or do not cause an injury. According to projected increases in hospital expenditures and population demographics that imply future increases in hospital admissions, the annual number of ADEs could triple within 20 years.

ERG searched the public health literature to identify stages in the hospital medication process in which errors occur and concluded that the medication stages of prescribing, transcribing, dispensing, and administration provide a useful analytic structure. The most common reported ADE symptom was cardiac arrhythmia followed by itching and/or nausea. Relatively few fatalities have been documented as preventable ADEs, but several published studies conclude that as many as 2.8 percent of all preventable ADEs probably result in fatalities. Another study has asserted that as many as 2.7 percent of all "negligent" (as defined in the study) ADEs have resulted in permanent disability. We used these estimates in our analysis.

D. The Proposed Rule

We propose to require machine-readable information on all prescription drug and biological products (including vaccines), all OTC drug products dispensed pursuant to an order and commonly used in hospitals, and all human blood products. This information would include the NDC number identifying the dosage, strength, nature, and form of each administered product and would be portrayed in a standardized linear bar code⁶ and

include product-specific and package-specific NDC numbers. We would maintain a database of all unique NDC numbers and ensure these data are available for use in commercial computerized systems that can provide bedside bar code identification. The bar code requirement would, if finalized, be effective within 3 years after we have published a final rule.

We are proposing this regulation because private markets have failed to establish the standardized bar codes that are needed to motivate hospitals to adopt an important health-saving technology. In particular, we believe that the private market's failure to develop standardized bar codes has impeded the growth of the technological investment necessary to reduce the number of ADEs in the nation's hospitals. We find that a regulatory intervention to establish a standardized system of bar codes is needed to address this market failure.

The proposed rule would increase costs to the manufacturers, marketers, and packagers of the affected products by requiring changes in manufacturing, packaging, and labeling processes. It would also increase costs to some hospitals by requiring a change in some bar code readers associated with these products. The proposed rule would also require FDA resources to ensure industry compliance with the bar coding requirement and additional resources to maintain a computerized database of NDC numbers. Once bar codes are standardized, the proposed rule would enable hospitals to take advantage of the coded information that would permit hospitals to reduce ADEs, while achieving other operational cost efficiencies. The proposed rule would also enable other sectors to use machine-readable technology in ways that would benefit public health (for example, accessing up to date labeling information from home computers).

E. Description of Affected Sectors

1. Current Machine-Readable Technologies

Before developing the proposed rule, we contracted with ERG to examine the current machine-readable technologies available for use by the health care sector and report on trends. The resulting report is included in the docket (Ref. 47) and summarized here.

Bar coding is currently the most widely used machine-readable technology and is also the technology most likely to see increased acceptance in the near future. Healthcare companies have sponsored two organizations that have each developed

different bar code symbologies;⁷ the Uniform Code Council's Universal Product Code (UPC) and the Health Industry Bar Code Council's Health Industry Bar Code (HIBCC). UPC codes are more widely used in retail stores while HIBCC is specially designed to safeguard against errors. However, although the HIBCC code has been more effectively used by medical device manufacturers, it has not won wide acceptance within the pharmaceutical markets. Within these symbologies, the groups have defined acceptable linear (or one-dimensional) codes, two-dimensional codes, and composite codes (a combination of one- and two-dimensional symbology). The advantage of two-dimensional and composite codes is that they can include additional information in the same area. Potential disadvantages of two-dimensional and composite symbologies are the higher costs for readers and scanners and the additional risk of uncertain data recovery by misinterpreting coded information.

While these organizations' bar codes are widely used, their use for the prevention of ADEs remains limited. Most pharmaceutical and OTC manufacturers use bar codes to move shipping cases through their distribution chain, but relatively few pharmaceuticals are sold with the specific bar codes that would be required by this proposed rule. Some hospitals use computer-controlled technology to add their own bar codes to incoming products.

Bar code systems require printers, scanners, and software to ensure that correct information is communicated. According to discussions with consultants, pharmaceutical manufacturers prefer to label products as late as possible in the manufacturing process in order to maximize their flexibility. Printing technology advancements have allowed more printing options to be available. Manufacturers currently use contract label printers or packagers along with in-house operations. Contract printers are commonly used for preprinted labels that do not carry customized data. Currently, ink jet and thermal printers may be appropriate for production line printing of bar codes, although ink jet printers may cause difficulties in media compatibility, print speed, and resolution. Water-based inks can streak or blur, but nonwater soluble inks produce a shine that reflects to the scanner and affect how the bar code is read. Laser printers are subject to toner

⁵ A potential ADE is a medication error that could have caused an ADE, but did not. Potential ADEs include medication errors that were intercepted before reaching the patient. Potential ADEs include any errors that do not involve patients.

⁶ A bar code is a graphic representation, in the form of bars and spaces of varying width, of numeric or alphanumeric data.

⁷ A symbology refers to a distinct technological, machine-readable language.