

flaking, which makes them unreliable for long-term bar code printing. Production line speeds may also create problems for bar code resolution levels.

The complexities of bar code scanners have evolved as the codes have become more data intensive. Most scanners in current use are laser-based systems designed to read linear bar codes. In health care settings, scanners are routinely programmed to discriminate among the symbologies they are likely to encounter. Some laser scanners can also read composite or two-dimensional codes, if properly programmed. These scanners are more costly, and some consultants have cautioned that multiple data systems may introduce potential misreading at hospital bedsides. Moreover, in certain situations, health care scanners may not need to use all of the available information. For example, scanners at bedside point of care may only need to capture limited identifying information while the central dispensing pharmacies may require full database capabilities. At this time, the scanning industry is confident that linear standards<sup>8</sup> will be readily accessible, whereas other standards may require additional market research. We believe that scanners will work in conjunction with hand-held personal digital assistants (PDAs) in wards due to their portability and multi-functional characteristics.

## 2. Manufacturers and Packagers of Affected Products

Discussions with staff at two large Veteran Health Administration Comprehensive Mail Order Pharmacies indicate that the large majority of exterior pharmaceutical packages include the NDC number in a bar code. The proposed rule, however, would require this bar coded information on both exterior and interior packaging. In addition, some prescription and OTC drug products are sold in blister packs, where individual pills or capsules are enclosed in a bubble. Prescription products are often repackaged into blister cards for more convenient use in hospitals. While some blister cards may now be labeled with bar codes for specified concerns, many are not. OTC drug products rarely include bar coded information on blisters. Moreover, many bar coded exterior packages cannot be read by hospital or retail scanners, because manufacturers use bar codes for sales promotions and other special offers that have separate and distinct NDC numbers that do not appear in all customer databases.

There are currently approximately 1,218 establishments in the Pharmaceutical and Biologic Preparation industries (NAICS 325412 and 325414). Based on the size distribution of industry establishments, we estimate a total of approximately 3,728 in-house packaging production lines. In addition, an estimated 229 establishments in the Packaging and Labeling Services industry (NAICS 561910) are dedicated to serving the pharmaceutical industry, accounting for an additional 501 packaging lines. Overall, we estimate that 4,229 packaging lines are used in 1,447 establishments for these products.

In addition, we estimate there are 981 blood collection centers in the United States (NAICS 621991). Each of these collection centers acts as a separate packaging line. Consultants have estimated that about 25 percent of these blood collection centers are included in published industry counts. We added blood collection centers to the industry packaging lines for a total of 4,995 affected packaging lines in 2,428 separate establishments.

The number of separate trade and generic named products has increased by over 500 percent since 1990, and now encompasses about 17,000 names. Each of these named products may be marketed in varying strengths or dosage forms. Overall, we estimate there are 78,000 separate prescription unit-of-sale packages, 98,000 OTC drug packages, and 2,000 blood/vaccine packages. Over time, the number of distinct packaging units is expected to continue to increase. The OTC drug industry has suggested that fewer than 10 percent of OTC packages (9,800 packages) are commonly used in hospital settings and would be subject to the proposed rule. For example, OTC analgesics that may be dispensed to a patient pursuant to an order would be subject to the proposed rule, but mouth rinses or toothpastes that may be provided would not. We are collecting data to confirm the proportion of affected OTC drug products. The Consumer Healthcare Products Association (CHPA) estimated that as many as 10 percent of their members' products were regularly dispensed from hospital pharmacies or packaged specifically for sale to hospitals. Other responses include a report from a hospital that only 200 OTC drug products are routinely dispensed. For purposes of this analysis, we have assumed that 10 percent of all OTC drug products would be required to provide bar coded information. We are trying to collect better information for these products. Overall, 89,800 separate unit-of-sale packages are

expected to be subject to the proposed rule.

OTC drug manufacturers frequently redesign labels. Based on discussions with manufacturers, we believe that the majority of OTC labels are redesigned within a 6-year cycle for marketing reasons. Many products have redesigned labels every 2 or 3 years. Prescription drug product labels may be redesigned less frequently, but there is evidence that numerous labeling changes occur. While marketing of prescription products may not be as sensitive to labeling graphics and package design as OTC products, there are many other reasons why manufacturers change their labels. Although we examined NDA files and found that changes to prescription product labels occur an average of more than once per year, for this analysis we have nevertheless assumed that the proposed rule would require significant involuntary actions by the affected industry.

## 3. Retail Outlets

Retail pharmacies currently have the capacity to read linear standardized bar codes at their in-house scanners. However, if we had selected an alternative to the proposed rule that would have required reduced space symbology (RSS), the current stock of scanners may have required upgrades or replacement. These upgrades would not have been directly mandated by the alternative, but would have been necessary for these entities to continue with bar coded activity. The retail sector currently relies on UPC or other symbologies, and a single standard would not require scanner replacements or upgrades. Only OTC drug products dispensed pursuant to an order and commonly used in hospitals would be affected by the proposed rule. Although small vials or bottles may require specific RSS symbology, these items are available to consumers in larger packages that accommodate current standards for retail outlets. According to the National Association of Chain Drug Stores, there are 55,000 community and chain pharmacies (NAICS 446110), and pharmacies in supermarkets and mass merchandisers (NAICS 445110) that utilize over 515,000 scanners. The expected useful life of a retail scanner is 5 years. The proposed rule is not expected to impact this sector, but we have considered alternatives that would affect retail outlets.

## 4. Hospitals

The proposed rule would not require hospitals to introduce the new automated technologies, but the development of consistent bar codes on

<sup>8</sup> A standard refers to a general description of a system of machine-readable languages.