

pharmaceutical and blood products would greatly encourage hospitals to implement bar code based systems to reduce ADEs associated with medication errors. Moreover, unit-dose blister packs and other vials and small bottles might necessitate the use of RSS symbology. In order to scan these products properly, hospitals that currently have installed bar code readers may need to upgrade or replace some scanners. According to the most recent census, there are 6,591 hospitals in the United States (NAICS 622) with a total of over 1.25 million beds. Estimates of personnel in these hospitals include 97,500 pharmacists, 75,500 pharmacy assistants, and almost 1.2 million nurses. Overall, a nurse is responsible for 4.5 beds per shift. An average hospital includes 191 beds and employs approximately 15 pharmacists, 11 pharmacy assistants, and 182 nurses.

Hospitals are currently adopting bar code technology to better control the entire medication process and improve the delivery of care to patients. Virtually all hospital pharmacies use bar code scanners for inventory and stock keeping activities, but only approximately one percent of all hospitals have installed bedside, point-of-care systems that use bar coded information. An additional three percent of hospitals use some form of computerized system in the medication process, but not all use bar codes. Overall, an estimated two percent of all hospitals (131 hospitals) currently use bar codes in everyday operations. Even in the absence of the proposed rule, we expect the remaining 6,460 hospitals to gradually implement computerized tracking systems. Discussions with industry consultants and the American Hospital Association (AHA), however, suggest that without standardization, it would take 20 years for all hospitals to adopt and use systems with bar code readers and utilize in-house overpackaging and self-generation of bar code identifiers. ERG discussed with several consultants whether 20 years is a realistic horizon for acceptance of this technology. While they recognized the uncertainty of future projections in this area, these industry experts felt that 20 years was a reasonable expectation. We examined the impact of alternative acceptance streams as a sensitivity analysis.

We requested comments on the potential uses of bar coded information on drug products at a public meeting held on July 26, 2002. These comments indicated that while patient safety reasons were the primary goals for installation of scanning systems, there are other potential uses. Industry groups

and individual hospitals noted that installation of scanning systems may lead to more efficient inventory control, purchasing and supply utilization, and other potential risk management activities. Other groups noted that an integrated computerized network would assist billing and laboratory systems as well. The AHA stated that bar codes would improve patient care and safety, increase workforce productivity and satisfaction, streamline payment, billing, and administrative systems, lead to efficient management of assets and resources, and meet consumer expectations for service and access to information. We believe these comments indicate that internal investment decisions concerning the acquisition of computerized systems entail additional returns that are in addition to ADE avoidance. While some of these returns to hospitals (such as reduced liability awards and malpractice liability insurance premiums) may be transfers, we believe additional efficiencies are likely.

5. FDA Oversight and Responsibilities

We would be affected in two areas. For successful bar code use, hospitals need access to the unique NDC numbers that identify specific active ingredients, packages, dosage forms, and units. We would maintain the database containing these unique identifiers and arrange access to it for the private sector.

The second area in which our activities would be impacted by the proposed rule is our use of compliance resources. The proposed rule would require the affected products to have bar coded information. Although the exact impact on our compliance resources is not quantified, we recognize that the creation of new regulatory requirements would require additional resources to ensure compliance.

F. Regulatory Costs of the Proposed Rule

1. Introduction

We estimated costs for a 20-year evaluation period to reflect the time that hospitals are expected to take to invest in bar code technology in the absence of the regulation. This summary describes these costs and presents both the present value (PV) and the annualized value of the cost streams. We analyzed costs in the affected sectors over the entire evaluation period using a seven percent annual discount rate. We assume that costs accrue at the beginning of any period. The detailed calculations and references that support the following analysis are available in Reference 46.

2. Costs to Manufacturers and Packagers of Affected Products

The pharmaceutical industry would face compliance costs from this proposed rule because we would require manufacturers, repackers, relabelers, and private label distributors to include NDC numbers in bar code format, using linear standardized symbology, down to the unit-dose level. The proposed rule would require this information within 3 years of the implementation date of the final regulation. The proposed rule would also affect the production processes of the pharmaceutical and biological product industries. Although manufacturers appear to initiate labeling changes fairly often for internal purposes, the proposed rule would necessitate large-scale production line alterations that could affect a manufacturer's entire product line.

a. *Prescription Drugs.* Based on ERG's analysis, we expect the overall investment costs to the prescription drug industry to total \$26.3 million over the first 3 years of the evaluation period. Most costs (\$17.6 million) accrue for modifications to unit-dose interior packaging to include a unique NDC number in a linear standardized format for every product. Exterior packaging modifications that include NDC information would cost \$4.1 million over the 3-year period. Because the capital equipment installed for these packaging modifications would require upgrading and replacement after an average 10-years of productive life, the industry would invest an additional \$3.8 million over the 11th, 12th, and 13th evaluation year for this replacement and upgrade. In addition, the packaging production process would require additional annual operating and maintenance costs reaching \$0.4 million by the third evaluation year. In total, we estimate that the PV of the costs incurred by prescription drug manufacturers, repackers, and relabelers to comply with the proposed rule over the 20-year period is \$30.4 million and the annualized cost is \$2.9 million.

b. *Over-the-Counter Drugs.* The OTC drug industry has estimated that fewer than 10 percent of its products are commonly used in hospitals (CHPA, 2002). We are currently collecting data on the size of this market share. For this analysis, we assume that 10 percent of all OTC drug products would be subject to the regulation and will include bar coded NDC numbers. The industry would either assign internal production processes that allow labeling differentiation for these products, or repackers and relabelers would provide the required labeling. We believe that