

### *K. Other Benefits of Bar Code Technology*

The availability of standardized bar codes would result in additional benefits to patients and the health care sector. As bar codes are an enabling technology, their adoption for hospital patient care would foster their use in other hospital and nonhospital settings. With automated systems, hospitals would no longer need to repack and self-generate bar codes. Hospital pharmacies and wards would likewise take advantage of the availability of bar coded products to generate new production efficiencies for activities such as reporting, record keeping, purchasing, and inventory controls. For example, integrated scanning systems may allow for electronic versions of daily Medication Administration Records (MARs) and pharmacy reconciliation reports. According to industry experts, if these activities could be avoided by automatically generating the records, an average sized hospital could save as many as 592 hours of pharmacist resources and 4,233 hours of nursing resources each year. The estimated annual efficiency savings of avoiding these opportunity costs equals \$167,000. Moreover, ERG and FDA believe the identified potential gains from electronic MAR and reconciliation reports may account for only between 50 and 80 percent of the potential gains in these areas. If so, the total estimated annual efficiency gains to an average hospital would range from \$209,000 to \$334,000 from use of bar code scanners in pharmacies and patient care wards. These new operation efficiencies would continue beyond the evaluation period. If such gains were obtainable, the PV of these gains for the sector as a whole would be between \$4.8 billion and \$7.6 billion. The average annualized gains of these potential efficiencies are between \$451.5 million and \$721.5 million.

The proposed rule could also increase the use of medical informatics in locations other than hospitals. Other health care facilities, such as physician offices and home health delivery systems, would be more likely to adopt bar coding and scanning systems to safeguard the use of patient medications and achieve additional efficiencies. We could not quantify the value of all of these expected additional uses of bar coding, but note that they are realistic and practical future uses of the technology.

### *L. Distributional Effects of Bar Code Technology*

Bar code usage would likely result in distributional transfers between sectors of society. For example, bar code use could reduce hospital payments due to punitive damage awards from potential lawsuits. According to legal data bases (JVR, 2002), there were approximately 35,000 personal injury and malpractice claims per year between 1995 and 2000 in the health care sector. Approximately half of these claims involved pregnancies with the remainder including surgical claims, misdiagnosis, and medication errors. If these claims are distributed equally by type and sector (inpatient and outpatient), we estimate that approximately 600 legal claims per year are potentially associated with preventable ADEs in hospitals. This implies that only 0.2 percent of all preventable ADEs are likely subject to legal claims (600 divided by 372,400). The average jury award for damages from medication errors was \$636,800 in 2000, although only 40 percent of the cases were decided for plaintiffs. Estimated pre-trial settlements for malpractice claims in 2000 averaged \$318,400. We do not have data on the proportion of settlements, but have assumed that 80 percent of claims are settled before trial. If so, the average likely award per preventable ADE is \$532. Bar code systems are expected to avoid 12.8 ADEs per year in an average hospital. This implies an average reduction in annual legal awards of \$6,800 per hospital and \$43.9 million for all hospitals. Fewer awards would also result in lower malpractice insurance premiums, which would reduce other hospital expenditures. The General Accounting Office (GAO, 1995) reported hospital malpractice insurance rates ranging between \$511 and \$7,734 per bed, depending on location. Recent reports have suggested that annual premiums have increased to approximately \$1,250 to \$18,800 per bed. Although we were unable to quantify average hospital malpractice premiums or precise reductions in hospital liability insurance premiums due to the use of bar codes, the potential exists for industry savings. While reductions in legal settlements or liability insurance premiums represent transfers between hospitals, third-party payers, attorneys, and patients, and are not opportunity gains or losses, such reductions could increase the efficient allocation of resources by sector.

Bar code systems may also increase hospital revenues by improving the

“cost capture rate.” One published study (Lee et al., 1992) reported the cost capture rate (the ratio of billed uncontrolled pharmaceuticals to all pharmaceuticals used) increased from 63 percent to 97 percent after installation of computerized systems in nursing wards. According to the authors, this would imply an increase in revenues of approximately \$65,000 per year for an average hospital. While such accounting improvements are transfers from patients and third-party payers to hospitals rather than reduced opportunity costs, this practice illustrates the potential use of bar code scanning systems in increasing the efficient allocation of resources by sector. Other potential transfers may include avoidance of certain billing errors or increased timeliness of payment.

Although reduced lawsuits and liability insurance and increased cost capture represent transfers, they are also critical in determining whether and at what rate hospitals will adopt bar code technology. Combined with the efficiency gains explained previously, these transfers should allow hospitals to cover a significant portion of their bar code technology investment.

### *M. Comparison of Costs, Expenditures, and Benefits*

The annualized costs of the proposed rule to the manufacturing, packaging, and labeling sectors totals \$3.2 million. Hospitals would incur an annualized cost of \$0.6 million to continue current operating practices. FDA resource costs to support the regulation equal an estimated \$1.3 million per year. Thus, we estimate the annualized regulatory cost of the proposed rule to be \$5.1 million. In addition, we expect the proposed rule to spur earlier investment by hospitals in bedside point-of-care systems that read bar coded labels. The annualized opportunity cost of this accelerated investment in technology is \$680.0 million for the entire industry. Table 6 presents, by sector, the present value of the estimated regulatory costs, the annual costs expected at the end of the 20-year evaluation period, and the annualized costs over the entire evaluation period. The estimated reduction in hospital operating expenses results from the assumption that hospitals could eliminate in-house labeling operations.