

Based on ERG's discussions with industry consultants, we predict that the rule could double the rate of hospital investment in this technology, thereby achieving the installation of complete systems within 10 years. For example, for those hospitals that now expect to acquire bar code systems within 10 years, we assume the availability of standardized bar codes on medications would accelerate the purchase to within 5 years. The cost to the hospital of this accelerated investment expenditure would be the opportunity cost of the investment capital for 5 years (the difference between making the investment in year 5 as opposed to year 10) as well as the five additional years of maintenance expenses and productivity losses. In addition, industry experts suggest that systems of bar code readers and scanners would require software and equipment upgrades within 10 years of installation. For the example facility, the installed system would require upgrades during the 15th project year under the accelerated investment, whereas upgrades would not occur until the 20th year in the absence of a regulation. We acknowledge that precise estimates of the rate of acceleration of technology acceptance are highly uncertain, but industry experts have indicated that doubling the rate of technology acceptance is a reasonable assumption. Alternative rates of acceptance were analyzed and discussed as a sensitivity exercise. We specifically invite public comment on the feasibility of this assumption.

ERG used a Probit function to estimate the annual rate of acceptance. This function assumes a normal density distribution for the selected period and has been used to describe rates of technology acceptance for other new products. Consequently, over the 20-year period, FDA estimates the PV of the costs of the accelerated investment in bar coding technology by hospitals, including the annual operating expenses and productivity losses, to be \$7.2 billion. The estimated annualized cost is \$680.0 million. Table 4 shows the expected annual incremental expenditures by year for adopting hospitals under the proposed rule.

TABLE 4.—EXPECTED INCREMENTAL HOSPITAL EXPENDITURES (IN MILLIONS) PER YEAR¹

Evaluation Year	Incremental Cost to Hospitals Adopting Bar Codes ¹
1	\$1.2
2	\$18.9
3	\$129.8
4	\$506.9
5	\$1,187.4
6	\$1,823.6
7	\$2,062.7
8	\$1,934.0
9	\$1,617.8
10	\$1,226.8
11	\$834.3
12	\$499.2
13	\$254.5
14	\$102.4
15	(\$15.3) ²
16	(\$29.4)
17	(\$34.5)
18	(\$35.6)
19	(\$36.0)
20	(\$36.0)

¹ Reflects both negative and direct positive fixed productivity changes. Hospitals expected to install bar code systems without the proposed rule would not achieve productivity gains associated with internal repackaging. Therefore, given the different expected rates of technology adoption with the proposed rule, the hospital sector would have net productivity gains beginning in the 15th evaluation year.

² Numbers in parentheses indicate cost reductions from baseline.

H. Reduction in Preventable Adverse Drug Events

The benefits of the proposed rule are focused on the reductions in ADEs that would follow the earlier use of bar code reading technology and bar coded drug products. We have not quantified all of the other institutional benefits of computerized systems and medical informatics, but have estimated a potential range of efficiency gains. Any ADEs avoided during a period are analyzed as if they occur at the end of the period.

ERG determined that, under current conditions, about 1.25 million ADEs occur each year in the United States, of which 372,400 are preventable. As discussed above, the proposed rule would substantially reduce the number of ADEs caused by errors originating in the dispensing and administration of pharmaceutical or blood products in hospitals. Studies of medication errors in hospitals that have installed bedside bar coding and use internally applied

labels show error interception rates of from 70 percent to 85 percent (Malcolm et al., 1999; Yang et al., 2001; Brown, 2002; Rough, 2002; and Churchill, 2002). Other industry experts, however, suggest that those published interception rates would not be as high if the technology were widely dispersed, because of the likelihood of events such as lost wristbands, erroneous bar codes, or intentional system bypasses. Therefore, FDA and ERG have assumed that bar code system use would produce no reduction in prescribing and transcribing errors, but that its use would intercept one-half of 45.1 percent of all preventable ADEs that now originate in the dispensing and administration stages of the medication process. Thus, ERG assumed that if all hospitals adopted bar code systems, the number of preventable ADEs would fall by 22.6 percent (45.1 times 0.5), which would prevent about 84,200 ADEs per year (372,400 times 0.226). This equals a reduction of 12.8 preventable ADEs per year for an average hospital. We believe the assumption that bar code readers could intercept one-half of both dispensing and administration errors is reasonable and conservative, but we specifically invite comment on alternative interception rates. This assumption is tested as a sensitivity analysis.

We estimate that the proposed rule, by stimulating earlier hospital investment in bar code scanning systems, would produce a corresponding increase in the number of avoided ADEs. To project the aggregate number of ADEs avoided due to the proposed rule, ERG calculated the number of ADEs per hospital that would be avoided by bar coding systems and multiplied that number by the additional number of hospitals that would use bar coding reading systems during each year of the evaluation period. For example, during the 10th evaluation year, our model predicts that 3,295 more hospitals would have installed bar code reading systems than would have installed them in the absence of the rule. The additional hospitals using bar codes would intercept an estimated 42,182 errors (12.8 ADEs per hospital times 3,295 hospitals) that would otherwise have resulted in ADEs during that year. Over the entire evaluation period, this methodology predicts that the accelerated investment would avoid over 413,000 ADEs.

I. Value of Avoided ADEs

FDA and ERG estimated two values of avoided preventable ADEs. First, ERG estimated the avoided direct hospital