

of \$57,100. As noted, the investment decision to install bar code reading technology is voluntary and would include consideration of patient safety and other cost-savings. We have estimated that potential reductions in resources needed to generate reports and to keep track of records may likely vary between \$27,400 and \$43,700 per year for a small hospital. Other institutional gains, including transfers such as increased revenue capture rates and reduced malpractice awards, may also affect internal decisions. Many industry representatives have indicated their willingness to invest in this technology. Nonetheless, even if some hospitals choose to delay or not to invest, this rule would still produce substantial societal benefits.

O. Small Business Analysis and Discussion of Alternatives

We believe the proposed rule is unlikely have a significant impact on a substantial number of small entities. Despite this, we have prepared an initial Regulatory Flexibility Analysis (IRFA) and invite comment from affected entities. In addition, the regulation is considered a significant economic impact under UMRA and alternatives are examined and briefly discussed here.

1. Affected Sectors and Nature of Impacts

We described the affected industry sectors earlier in this section. The proposal would directly affect manufacturers of pharmaceutical and biological products (NAICS 325412 and NAICS 325414), packaging services (NAICS 561910), and blood and organ banks (NAICS 621991), and indirectly affect hospitals (NAICS 622). We accessed data on these industries from the 1997 Economic Censuses and estimated revenues per establishment. Although other economic measures, such as profitability, may be preferable alternatives to revenues in estimating the significance of regulatory impacts in some cases, any reasonable estimate of profits would not change the results of this analysis. These revenues were updated to 2000 values by using the Consumer or Producer Price Index as appropriate.

a. *Pharmaceutical Manufacturers (NAICS 325412)*. The Small Business Administration (SBA) has defined as small any entity in this industry with fewer than 750 employees. According to census data, 84 percent of the industry is considered small. The average annual revenue for these small entities is \$26.6 million per entity. Small manufacturers of prescription and OTC drug products

dispensed under an order and commonly used in hospitals would be required to generate and label products with bar coded information. We estimate the annualized compliance costs for small entities in this industry at \$1,800 per entity. This is less than 0.1 percent of their annual revenues. We believe this does not constitute a significant impact on a substantial number of small entities in this industry.

b. *Biological Product Manufacturers (NAICS 325414)*. The SBA has defined as small any entity in this industry with fewer than 500 employees. According to census data, 68 percent of the industry is considered small. The average annual revenue for these small entities is \$4.7 million per entity. Small manufacturers of biological products would be required to use standardized bar code information on their products. We estimate the annualized compliance costs for small entities in this industry at \$600 per entity. This is less than 0.1 percent of their annual revenues. We believe this does not constitute a significant impact on a substantial number of small entities in this industry.

c. *Packagers (NAICS 561910)*. The SBA has defined as small any entity in this industry that has less than \$6 million in annual revenues. On this basis, almost 75 percent of the industry is considered small. The average annual revenue for small entities is \$1.7 million per entity. Small packagers would be required to apply bar coded information to all affected products. This would require printing and process improvements to packaging operations. We estimated the annualized compliance cost for small entities in this industry at \$240 per entity. This is less than 0.1 percent of their annual revenues. We believe this does not constitute a significant impact on a substantial number of small entities in this industry.

d. *Blood and Organ Banks (NAICS 621991)*. The SBA has defined as small any entity in this industry with less than \$8.5 million in annual revenues. On this basis, 40 percent of the industry is considered small. The average annual revenue for small entities is \$1.4 million per entity. Small blood banks and collection centers would be required to apply standardized bar coded information on all blood products. This would require printing and process improvements to blood handling operations. We estimated the annual compliance cost for small entities in this industry at \$100 per entity. This is less than 0.1 percent of their annual revenues. We believe this does not

constitute a significant impact on a substantial number of small entities in this industry.

e. *Hospitals (NAICS 622)*. The SBA has defined as small any entity in this industry with less than \$29.0 million in annual revenues. According to census data, 35 percent of the industry is considered small. The average annual revenue for small entities is \$12.6 million per entity. There is no specific regulatory requirement for hospitals to respond to this proposed rule. We anticipate that the rule would make the investment in bar code technology more attractive to hospitals, but the rule would not require such investments. Hospitals that have already installed bar code reading systems and internally affix self-generated information might need to prematurely upgrade or replace currently installed scanners in order to capture bar coded information on small vials or bottles. These hospitals would also achieve productivity gains by avoiding the resources now used to self-generate bar code readable information. The total annual net cost of the proposed rule is estimated at \$3,300 per facility, which is equal to less than 0.1 percent of annual revenues. We believe this does not constitute a significant impact on a substantial number of small entities in this industry.

2. Alternatives

We considered several alternatives to the proposed rule. Each is discussed below. We invite comments and suggestions for additional potential alternatives.

a. *Do Nothing*. This alternative would not result in any change in current labeling or packaging practices. We believe that, in the absence of agency action, hospitals would gradually purchase and utilize independent bar code reading systems, but that it would take 20 years before they were installed in all facilities. We rejected this alternative because of the expected positive net benefits of the proposal. Also, we believe that standardizing bar codes would generate additional health and production efficiencies for a variety of different health care sectors.

b. *Requiring Variable Information*. We considered requiring additional information in bar codes, such as expiration dates and lot numbers. The incremental benefit of this data would include improved inventory control and ease of recalls. In addition, we are aware that some firms are voluntarily applying this information. However, we were unable to quantify potential public health benefits for this additional information, and the estimated additional annualized cost of this