

VII. Analysis of Impacts

A. Introduction

We have examined the proposed rule under Executive Order 12866, the Regulatory Flexibility Act as amended by the Small Business Regulatory Enforcement Fairness Act, the Unfunded Mandates Reform Act, and the Congressional Review Act. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, distributive impacts and equity). Under the Regulatory Flexibility Act (as amended by the Small Business Regulatory Enforcement Fairness Act), if a regulation has a significant economic impact on a substantial number of small

entities, we must analyze regulatory options that would minimize the impact on small entities. Section 202(a) of the Unfunded Mandates Reform Act requires that agencies prepare a written statement of anticipated costs and benefits before proposing any regulation that may result in expenditure by State, local, and tribal governments, or by the private sector of \$100 million in any one year (adjusted annually for inflation). Currently, such a statement is required if costs exceed about \$110 million for any one year. The Congressional Review Act requires that regulations determined to be major must be submitted to Congress before taking effect.

The proposed rule is consistent with the principles set forth in Executive Order 12866 and the three statutes. We have identified the proposed rule as an economically significant regulatory action, as defined in Executive Order

12866. We believe the proposed rule is unlikely to have a significant impact on a substantial number of small entities. The expected cost of this proposed rule is greater than \$110 million in a single year and therefore is considered a major regulatory action as defined by the Unfunded Mandates Reform Act. The Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB) has determined this proposed rule to be major under the Congressional Review Act.

We contracted with the Eastern Research Group, Inc. (ERG), to collect data, interview industry experts, and analyze the costs and benefits of the proposed rule. The detailed analyses and references in support of the impacts summarized in Table 2 are included in the docket as Reference 46.

TABLE 2.—ESTIMATED IMPACTS OF THE PROPOSED RULE (IN MILLIONS OF DOLLARS)
(OVER 20-YEAR PERIOD AT 7-PERCENT DISCOUNT RATE)

Impacts	Regulatory Costs	Anticipated Hospital Costs ¹	Societal Benefits ²	Potential Hospital Efficiencies ³	Net Benefits (benefits minus costs) ⁴
Present Value	\$53.1	\$7,204.3	\$41,381.3	\$4,783.3–\$7,643.0	\$34,123.9
Annualized	\$5.1	\$680.0	\$3,906.1	\$451.5–\$721.5	\$3,221.0

¹ Costs due to voluntary accelerated purchase and utilization of bar coding systems.

² Benefits to public health due to avoidance of adverse drug events.

³ Potential efficiencies in reports, records, inventory, and other hospital activities.

⁴ Net benefits include only public health benefits of increased patient safety.

Table 2 presents the total expected regulatory costs to manufacturers, repackers, relabelers, retail outlets, and FDA. Most of these costs will occur during the first several years after implementation. Table 2 also shows the estimated opportunity costs of the expected accelerated investment in bar coding systems by the health care sector. These investment expenditures are necessary to achieve the societal benefits expected from the proposed rule. Table 2 also shows our estimated range of possible efficiencies in hospital activities associated with accelerated adoption of technology. Both anticipated hospital costs and societal benefits would occur after hospitals purchase and install the necessary equipment to take advantage of bar codes. The net benefit figure is the societal benefit minus the induced expenditures minus the regulatory costs. This estimate, however, accounts for neither potential hospital efficiencies, nor income transfers to hospitals following fewer awards for medical malpractice.

B. Objective of the Proposed Rule

The objective of the proposed rule is to enable the health care sector to utilize technological solutions to reduce preventable adverse drug events (ADEs)² associated with medication errors³ in hospitals.⁴

C. Estimate of Risk/Risk Assessment

In 1999, the Institute of Medicine (IOM) issued a report that drew public attention to the number of deaths that occur each year in the United States from preventable medication errors in hospitals. A significant proportion of the reported deaths, as well as the additional illnesses and morbidities,

² For this analysis, an adverse drug event (ADE) is an injury from a medicine (or a lack of an intended medicine). (source: American Society of Hospital Pharmacists, 1998)

³ For this analysis, a medication error is a preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. (source: NCCMERP, 2002)

⁴ For this analysis, a hospital is a facility that provides medical, diagnostic, and treatment services that include physician, nursing, and other health services to inpatients and the specialized accommodation services required by inpatients. (source: NAICS, 2002)

were associated with errors involving FDA-regulated products, especially medications. This section briefly describes the agency's efforts to estimate the current number of preventable ADEs.

The public health literature includes many attempts to determine the rate of preventable ADEs in United States hospitals, although these studies typically employed varying methodologies and definitions. Our methodology begins by multiplying estimated hospital admissions by reported rates of ADEs per admission. We combined the resulting number of ADEs per hospital per year with the reported ratio of preventable to total ADEs to estimate the number of preventable ADEs per hospital per year. We first developed these calculations for various hospital size classes and then aggregated the data to present national estimates. We relied on published literature to derive ADE rates for each major stage of the medication process in hospitals.

ERG identified four comparable published studies that reported rates of ADEs per hospital admissions (Bates et al., 1995, Classen et al., 1997, Jha et al.,