

the Regulatory Flexibility Act (RFA) (September 16, 1980 Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) and Executive Order 13132. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year).

We have examined the impact of this final rule and we have determined that this rule is neither expected to meet the criteria to be considered economically significant, nor do we believe it will meet the criteria for a major rule. All entities affected by this rule are considered small entities. Therefore, a final regulatory impact analysis is not required for the same reasons explained in section VI.C of this rule.

We revised our estimate of the regulatory impact of this final rule from \$96,356,599 to \$63 million for the first year and \$17.5 million for each of the next 2 years. The estimate appears lower than the estimate in the October 2001 proposed rule because unlike the October 2001 proposed rule, we are phasing in the requirement to replace all existing roller latches over 3 years. Thus, the cost estimate to replace the roller latches is reduced from approximately \$48 million for the first year to approximately \$16 million per year for 3 years. For a detailed description of our estimates for each provider, section II.C of this final rule outlines our cost estimates in the 2001 proposed rule, and section III.H of this final rule outlines our revised cost estimates for this rule as well as why we revised the estimates.

### *C. Impact on Small Entities and Rural Hospitals*

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$6 to \$29 million in any one year (for details, see the Small Business Administration's regulation that sets forth size standards for health care industries at 65 FR 69432). For purposes of the RFA, all health care facilities affected by this

regulation are considered to be small entities. Individuals and States are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside a Metropolitan Statistical Area and has fewer than 100 beds.

Based on the Small Business Administration (SBA) and CMS data (these data can be found in the April 2002 CMS Statistics Publication No. 03437 or [www.cms.hhs.gov](http://www.cms.hhs.gov)), approximately 4,593 out of 6,650 hospitals are considered to be small businesses or nonprofit hospitals. We do not consider this rule to significantly impact these hospitals because the cost of this rule is less than 1 percent of the total costs for hospitals. According to the CMS 2002 national expenditure data, the total national costs for hospitals in 2002 was \$412.1 billion. We estimate this rule will cost hospitals, including CAHs, approximately \$8,263,848 for the first year and \$4,131,924 for each of the next 2 years due to the phase in of emergency lighting and the replacement of all roller latches.

Based on the SBA and CMS data, approximately 3,064 out of 3,474 ASCs are considered to be small businesses or nonprofit providers. However, we do not consider this rule to significantly impact the ASCs because the cost of this rule is less than 1 percent of the total costs for ASCs. According to the CMS 2002 national expenditure data, the total national cost for ASCs in 2002 was \$286.4 billion. We estimate that it will cost ASCs approximately \$2,511,667 for the first year and \$1,255,833 for each of the next 2 years due to the phase in of emergency lighting and the replacement of all roller latches.

Based on the SBA and CMS data, approximately 17,901 out of 23,500 LTC providers, inpatient hospices, and ICF/MR facilities are considered to be small businesses or nonprofit providers. We do not consider this rule to significantly impact the LTC providers, inpatient hospices, or ICF/MR facilities because the cost of this rule is less than 1 percent of the total costs for these providers. According to the CMS 2002 national expenditure data, the total national costs for LTC providers, inpatient hospices, and ICF/MR facilities in 2002 were \$89.3 billion. Our

cost estimate for compliance with this rule for LTC providers, inpatient hospices, and ICF/MR facilities is approximately \$59,195,736 for the first year and \$5,788,375 for each of the next 2 years due to the phase in of emergency lighting and the replacement of all roller latches. We combined the estimates of LTC facilities, inpatient hospices, and ICF/MR facilities because of the similarities in how the provider types are surveyed for compliance with the LSC and the items that must be upgraded to meet the 2000 edition of the LSC. In addition, most ICF/MR facilities will not be impacted by this rule because the majority of these facilities are fairly new and are considered a residential occupancy rather than the more stringent health care occupancy type. However, there are ICF/MR facilities that care for the more severely impaired. These ICF/MR facilities are similar to an LTC facility and will be impacted by the 2000 edition of the LSC.

Lastly, we do not believe this rule will affect PACE centers or RNHCI facilities because PACE and RNHCI are new programs and they already meet the 1997 edition of the LSC. The changes from the 1997 edition of the LSC to the 2000 edition of the LSC are negligible. For example, PACE centers and RNHCI facilities have 1.5-hour emergency lighting, no vertical opening problems, and do not have any roller latches. Moreover, because both of these providers are new programs, the SBA does not have an estimate as to how many are considered small businesses. We consider all RNHCI to be nonprofit entities.

Please note we also provided a cost estimate for each of the provisions with respect to which we believe that each facility will need to upgrade to be in compliance with this final rule in section III.H.

The cost estimate does not take into account any waivers that may be granted. We will retain the existing authority to waive specific provisions of the 2000 edition of the LSC, further reducing the exposure to additional cost and burden for facilities with unique situations that can justify the application of waivers, and that we determine will not endanger the health and safety of patients.

The cost estimate does not factor in any cost reduction if we accept a State's fire and safety code instead of the NFPA's 2000 edition of the LSC. We have the authority to accept a State fire and safety code in lieu of the NFPA LSC if the State code is imposed by State law, and adequately protects patients.