

by its administrator or chief financial officer certifying the accuracy of the electronic file or the manually prepared cost report. We believe that these electronic filing requirements will initially increase the burden by approximately 40 hours and cost approximately \$5000 for each cost reporting period. We expect that this burden will decrease as the providers become familiar and proficient in electronic filing.

However, as currently approved, these providers may request a delay or waiver of the electronic submission requirement in paragraph (f)(4)(ii) of this section if this requirement would cause a financial hardship.

As noted above, while all the above reporting requirements are subject to the PRA, they are currently approved under OMB approval numbers 0938-0050, "Hospital/Healthcare Complex Cost Report," with a current expiration date of November 30, 2005, 0938-0463; "Skilled Nursing Facility Cost Report," with a current expiration date of May 31, 2004; 0938-0022, "Home Health Agency Cost Report," with a current expiration date of May 31, 2004; 0938-0758, "Hospice Cost Report," with a current expiration date of March 31, 2005; 0938-0102, "Organ Procurement Agency/Laboratory Statement of Reimbursable Costs," with a current expiration date of October 31, 2003, which is currently at OMB awaiting re-approval; 0938-0107, "Independent Rural Health Clinic/Freestanding Federally Qualified Health Center Cost Report," with a current expiration date of October 31, 2005; 0938-0236, "Medicare Independent Renal Dialysis Facility Cost Report," with a current expiration date of August 31, 2004; and 0938-0657, "End Stage Renal Disease Network Cost Report," with a current expiration date of December 31, 2003, which is currently in the re-approval process.

## VI. Regulatory Impact Statement

We have examined the impacts of this final rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), 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 (as amended by Executive Order 13258, which merely reassigns responsibility of duties) 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 effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more annually). This rule will not have a significant economic impact on hospices, OPOs, RHCs, FQHCs, CMHCs, and ESRD facilities, and, therefore, is not a major rule. There are no requirements for hospices, OPOs, RHCs, FQHCs, CMHCs, and ESRD facilities to initiate new processes of care, and reporting; to increase the amount of time spent on providing or documenting patient care services; or to purchase computer software.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having annual receipts of \$6 million to \$29 million or less annually (*see* 65 FR 69432). For purposes of the RFA, all providers and small businesses that distribute cost-report software to providers are considered small entities. We do not believe that this rule will have a significant impact on these providers as no or low utilization providers already have the ability to file for a waiver of the electronic filing requirement. In demonstrated cases of financial hardship, however, we will provide free software. With computers so common in the work place today it is hard to imagine that a provider does not already access to a computer and, in the rare instance when a provider would have to purchase a computer, we believe the cost would be negligible. In addition, the providers have a period of almost two years to familiarize themselves with the electronic filing requirements, since the first cost reports will not be due until May 31, 2005. Our intermediaries are not considered small entities for the purposes of the RFA. Individuals and States are not included in the definition of small entities.

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 of

a Metropolitan Statistical Area and has fewer than 100 beds.

We are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and we certify, that this rule will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

As stated above, under § 413.20(b) and § 413.24(f), providers are required to submit cost reports annually, with reporting periods based on the provider's accounting year. This final rule requires hospices, OPOs, RHCs, FQHCs, CMHCs, and ESRD facilities, like hospitals, SNFs and HHAs, to submit their Medicare cost reports in a standardized electronic format. This requirement will take effect for cost reporting periods ending on or after December 31, 2004, meaning that the first electronic cost reports will be due May 31, 2005.

Currently, approximately 55 percent of all hospices, OPOs, RHCs, FQHCs, CMHCs, and ESRD facilities submit a hard copy of an electronically prepared cost report to the intermediary. We believe that the provisions of this final rule will have little or no effect on these providers, except to reduce the time involved in copying and collating a hard copy of the report for intermediaries. Under this rule, instead of submitting a complete hard copy of the report, providers will be required to submit only hard copies of a settlement summary, statement of certain worksheet totals, and a statement signed by the administrator or chief financial officer certifying the accuracy of the electronic file or the manually prepared cost report. In addition to the 55 percent of providers that currently use electronic cost reporting, this rule will not affect those providers that do not file a full cost report and, as stated above, would not be required to submit cost reports electronically.

This rule may have an impact on those providers who do not prepare electronic cost reports, some of whom may have to purchase computer equipment, obtain the necessary software, and train staff to use the software. However, as discussed below, we believe that the potential impact of this final rule on those providers who do not prepare electronic cost reports will be insignificant.

First, a small number of the 45 percent of providers that do not submit electronic cost reports may have to purchase computer equipment to comply with the provisions of this rule. These providers are generally owned