

Register and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved, section 3506(c)(2)(A) of the PRA of 1995 requires that we solicit comment on the following issues:

- Whether the information collection is necessary and useful to carry out the proper functions of the agency;
- The accuracy of the agency's estimate of the information collection burden;
- The quality, utility, and clarity of the information to be collected; and
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Section 476.78 of this regulation contains information collection requirements. In summary, § 476.78 requires providers to submit information to the QIO during the conduct of a QIO review. Because this information is collected during the conduct of an audit, investigation, and/or an administrative action, we believe these collection requirements are not subject to the PRA as stipulated under 5 CFR 1320.4.

VI. Regulatory Impact

We have examined the impacts of this 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 rules that constitute significant regulatory action, including rules that have an economic effect of \$100 million or more annually. This final rule is not a major rule in terms of the aggregate costs involved.

The 53 separate QIO contracts are awarded on a staggered 3-year basis. Current sixth scope of work contracts provide photocopy reimbursement costs of 7 cents per page. The total dollars budgeted were \$8.6 million per year and

the 3-year costs were \$25.9 million. We estimate by the time this final regulation is published, 19 QIOs will have completed their sixth round contracts, and the other 34 will have less than 153 months (combined) out of a total of 636 months (for all 53 QIOs) remaining in the final year of their sixth round contracts. This translates to 24 percent of the final sixth round year. As such, we project this regulation will increase the costs in the last (that is, current) year of the sixth scope of work by \$1.5 million above the previous budgeted level of \$8.6 million, to a total of \$10.1 million. However, in future years—based on the full 12 months and all 53 QIOs under contract—the increase will be nearly \$6.2 million annually.

Thus, we have determined that this final rule is not a major rule with economically significant effects because it will not result in increases in total expenditures of \$100 million or more per year.

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 small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$6 million to \$29 million or less annually (see 65 FR 69432). Individuals and States are not included in the definition of a small entity.

We generally prepare a regulatory flexibility analysis that is consistent with the RFA unless we certify that a rule will not have a significant impact on a substantial number of small entities. We have not prepared an analysis for the RFA because we have determined, and certify, that this final rule will have no significant economic impact on small entities. The regulation will not impose any economic or operational regulatory burdens on small entities. The regulation will only assist providers in performing the tasks required under the QIO program sixth scope of work, by increasing the reimbursement for providing copies of documents to the QIOs.

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 have not prepared an analysis for section 1102(b) of the Act because

we have determined that this final regulation will not have a significant impact on the operations of small rural hospitals for the reasons stated above in our discussion of the RFA.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in an expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$110 million or more. We have determined that this final rule will not result in such an expenditure. Rather, the final rule will benefit providers by increasing the photocopy reimbursement rate.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct compliance costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have reviewed this final rule under the threshold criteria of Executive Order 13132 and have determined that it will not have a substantial direct effect on the rights, roles, and responsibilities of States or local governments.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 476

Grant programs—health, Health care, Health facilities, Health professions, Quality Improvement Organizations (QIO), Reporting and record keeping requirements.

42 CFR Part 484

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services is amending 42 CFR chapter IV as follows: