

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, we prepare a regulatory flexibility analysis unless we certify that a rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, nonprofit organizations, and governmental agencies. Most hospitals and other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$5 to \$25 million or less annually. Individuals and States are not included in the definition of a small entity.

Section 1102(b) of the Act requires us to prepare a regulatory impact analysis for any proposed rule that 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.

The Unfunded Mandates Reform Act (Pub. L. 104-4) requires that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may result in an annual expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$110 million or more. This rule does not impose any mandates on State, local, or tribal governments, or the private sector that will result in an annual expenditure of \$110 million or more.

Under Executive Order 13132, we are required to adhere to certain criteria regarding Federalism in developing regulations. We have determined that this regulation will not significantly affect States rights, roles, and responsibilities. Section 1903(a)(30)(C) of the Act currently requires an EQR for each contract a State has with a section 1903(m) organization. In accordance with section 4705 of the BBA, this rule will establish requirements and procedures for EQR of Medicaid MCOs. We require States to ensure that an annual EQR is performed by a qualified EQRO for each contracting MCO, the EQRO has adequate information to carry out the review, and that the results of the reviews are made available to interested parties such as participating health care providers, enrollees, advocate groups, and the general public. We also require that these EQR provisions apply to PIHPs and certain entities with comprehensive risk contracts that have been exempted from the requirements of section 1903(m) of the Act. We believe this is consistent

with the intent of the Congress in enacting the quality provisions of the BBA. This rule would not require State agencies to dismantle EQR mechanisms that they have used to meet section 1902(a)(30)(C) of the Act and which they have found to be effective and efficient. Rather, this rule would provide States greater flexibility in the types of entities they may use to conduct EQR.

We worked closely with States in developing this regulation. Specifically, in accordance with section 1932(c)(2)(A)(ii) of the Act, which requires the Secretary to consult with States to establish a method for identifying entities qualified to conduct EQR, we met with States and other stakeholders under the auspices of the NASHP to establish a criteria to identify qualified entities. Most of the recommendations made at this meeting have been incorporated into this rule. For recommendations not accepted, an explanation was provided in the December 1, 1999 proposed rule.

In addition, section 1932(c)(2)(A)(iii) of the Act requires the Secretary to coordinate with the NGA in contracting with an independent quality review organization to develop protocols to be used in EQR. To meet this requirement, we issued a request for proposal for one or more contractors to develop a set of review protocols for EQROs to use in the conduct of EQRs. Two State representatives selected by the NGA were members of the panel that reviewed and rated responding proposals. Moreover, part of the development of the EQR protocols includes convening an expert panel for review and comment of the protocols. State representatives were included in this process.

B. Anticipated Effects

In publishing this final rule, we considered two main alternatives. The first was to allow this final rule to be published, incorporating public comments on the proposed rule. The second alternative was to implement the provisions of the BBA as written, without expanding the regulations beyond the statutory language. We believe this final rule as written was the appropriate alternative to choose. Used in conjunction with the Medicaid Managed Care final rule published June 14, 2002, this final rule is a necessary tool for States to use to create and maintain strong, viable Medicaid managed care programs that deliver high quality health care in their State marketplaces and health care delivery systems. Further, we felt this final rule was necessary to implement the Congress' directive to the Secretary to

establish a method for identifying entities qualified to conduct EQR.

We do not anticipate that the provisions in this final rule will have a substantial economic impact on most hospitals, including small rural hospitals. The BBA provisions include some new requirements on State agencies and MCOs, but not directly on individual hospitals. The impact on individual hospitals will vary according to each hospital's current and future contractual relationships with MCOs. Furthermore, the impact will also vary according to each hospital's current procedures and level of compliance with existing law and regulation pertaining to Medicaid managed care. For these reasons, this final rule will not have a significant impact on the operations of a substantial number of hospitals. The only other small entity affected by these regulations would be the EQROs. However, this rule does not impose additional burdens on them. Instead, the rule offers these organizations the benefit of opportunities for additional revenues. Thus we certify that this rule will not have a significant economic impact on a substantial number of small entities.

We do not anticipate a significant increase in Medicaid expenditures as a result of the publication of these regulations for the following reasons. First, approximately 42 States are currently obtaining 75 percent enhanced FFP for EQR activities carried out by QIOs and organizations that meet the requirements to contract with Medicare as a QIO. Permitting these State agencies to claim 75 percent matching for EQR activities conducted by the additional types of entities allowed by these regulations would therefore not result in increased costs to the extent that State agencies switch from QIO or organizations that meet the requirements to contract with Medicare as a QIO to these other entities. Moreover, we believe that, by expanding the pool of organizations available to conduct EQR, State agencies may be able to negotiate savings compared to current costs of dealing with PRO and PRO-like organizations. Additional savings may be realized through opportunities afforded by the final rule to coordinate EQR activities with quality reviews conducted for other purposes. Additional costs may arise where State agencies currently conduct quality review activities at 50 percent Federal matching rate that would now qualify for 75 percent, and from new EQR activities undertaken as a result of the BBA requirements.

In addition, even though we extend this requirement to PIHPs, again we do