

having revenues between \$6 million and \$29 million. Individuals and States are not considered small entities. We certify that this final rule will not have a significant impact on small entities.

Also, 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. That analysis must conform to the revision of section 603 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 certify that this final rule will not have a significant impact on a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandate Reform Act of 1995 also requires that agencies assess anticipated costs and benefits for 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. This final rule has no mandated effect on State, local, tribal governments, or on the private sector that reach the threshold of section 202.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct compliance costs on State and local governments, preempts State law, or otherwise has Federalism implications.

In 1994, we invited all interested parties to a town hall meeting to discuss our plans to set forth regulations to establish a new approach to improving the quality of healthcare provided in hospitals. Parties from the Association of Health Facility Survey Agencies, hospital associations, and other stakeholders were in attendance. These agencies were given the opportunity to provide input and were generally in favor of our plans.

We welcomed comments on our December 1997 proposed rule. We received a number of comments on our QAPI CoP but we did not receive any comments indicating that States would be adversely affected by this rulemaking.

Thus, we have examined this final rule and have determined that this final rule will not have a negative impact on the rights, rules and responsibilities of State, local or tribal governments.

B. Anticipated Effects

In December 1997, we proposed to revise all of the hospital CoPs that emphasized lessening Federal regulations to eliminate unnecessary

structural and process requirements, to focus on outcomes of care, to allow greater flexibility to hospitals and practitioners to meet quality standards, and to place a stronger emphasis on QAPI.

Within this newly revised CoP we proposed to establish a QAPI program that encompasses all hospital services and operations. We solicited comments on the QAPI provisions and received overwhelming support for its establishment. There was consensus among, provider, public, professional organizations, accrediting organizations, and the Congress that supported its establishment. The need again arose for a program due to serious concern regarding patient safety and medical errors after publication of the 1999 IOM's report along with the response to the report. These factors led us to set forth this final rule to ensure high quality of care in a safe environment in our nation's hospitals.

1. Effect on Hospitals

Given the shift to regulatory flexibility, for the most part, we are not prescribing the exact process hospitals must follow to meet the regulatory requirements of the QAPI CoP. However, the following components must be established and maintained in the development of a QAPI program: hospitals will be required to have a QAPI program encompassing all services and operations that focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors.

Some hospitals may need to revise their existing programs to conform to this regulation; however, we do not believe this CoP will impose a significant economic burden above what hospitals are already doing to meet the current quality assurance CoP.

Currently under § 482.21, hospitals must ensure that there is an effective, hospital-wide quality assurance program to evaluate the provisions of patient care. Under the existing requirement hospitals must have a written plan of implementation, this plan must include all organized services and contractors. The hospital is also required to document appropriate remedial actions to address deficiencies found through the quality assurance program, as well as the outcome of the remedial actions. However, as a hospital's QAPI program matures, we expect that hospitals will be engaging in quality improvement activities in an expanding number of areas as resources are redirected from areas of program success to new areas, but existing improvements are sustained.

This QAPI CoP focuses provider efforts on the actual care delivered to the patient, the performance of the hospital as an organization, and the impact of the treatment furnished by the hospital on the health status of its patients. In developing this CoP, we have included structure and process-oriented requirements only where we believe they are essential to achieving desired patient outcomes or preventing harmful outcomes. This approach is intended to incorporate into our regulations current best practices in well-managed hospitals, relying on each hospital to identify and resolve its performance problems in the most effective and efficient manner possible.

This QAPI CoP is in fact an extension and modification of the existing quality assurance CoP found at § 482.21. We anticipate that hospitals, both large and small, rural and urban, will or already use a variety of data to inform their internal QAPI programs. Some of these data may be measures designed by the hospital itself, while others will be developed through research or by consensus groups or other sources outside the hospital. Thus, the impact will vary according to each hospital's current quality improvement activities and programs. The impact will also vary and is subject in large part to their decision-making, current policies and procedures, and level of compliance with existing quality assurance regulations. It is important to note that due to the flexibility of these provisions, the extent of the economic impact of most of these requirements is dependent upon decisions made by the hospital. We believe that this CoP will minimize the administrative burden on hospital's to comply with detailed Federal requirements. Instead, this QAPI CoP will provide hospitals with more flexibility to determine how best to pursue our shared quality of care objectives in the most cost-effective manner.

We expect hospitals to develop different approaches to compliance based on their varying resources, patient populations and other factors. There are several provisions that will impact the hospital's processes to a greater or lesser degree. Specifically, this CoP does introduce a new concept that the hospital will have to develop an internal error prevention and reduction program to ensure optimum outcomes for its patients.

The requirements of the rule effect current industry practice. Therefore, hospitals with QAPI programs already in place that meet these requirements, at a minimum level if not in whole, may see little increased burden. Hospitals