

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.

Section 202 of the Unfunded Mandates Reform Act of 1998 (UMRA) requires that agencies assess anticipated costs and benefits before issuing any rule that may result in an expenditure in any 1 year by State, local, or tribal government, in the aggregate, or by the private sector of \$110 million. The rule does not have an effect on the governments mentioned, and private sector costs are less than the \$110 million threshold.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct compliance costs on State and local governments, preempts State law, or otherwise has Federalism implications. The rule does not have an effect on the governments mentioned.

Although we view the anticipated results of these regulations as beneficial to the Medicaid and Medicare programs as well as to Medicare and Medicaid beneficiaries and State governments, we recognize that some of the provisions could be controversial and may be responded to unfavorably by some affected entities. We also recognize that not all of the potential effects of these provisions can definitely be anticipated, especially in view of their interaction with other Federal, State, and local activities regarding outpatient services. In particular, considering the effects of our simultaneous efforts to improve the delivery of outpatient services, it is impossible to quantify meaningfully a projection of the future effect of all of these provisions on RHC's operating costs or on the frequency of substantial noncompliance and termination procedures.

We believe the foregoing analysis concludes that this regulation does not have a significant financial impact on a substantial number of small entities, such as RHCs. This analysis, in combination with the rest of the preamble, is consistent with the

standards for analysis set forth by the RFA.

Anticipated Effects

Effects on Rural Health Clinics

The total number of participating RHCs under Medicare and Medicaid as of February 1, 2001, was 3,341. Using 2000 Census data, there are approximately 100 urban clinics. At least 20 of these urban clinics do "not" have valid shortage area designations and would lose their RHC status.

With regard to the participating clinics that are still located in rural areas (about 3,200), at least 100 of these RHCs no longer have valid shortage area designations. Based on the above estimates, we know that about 180 would be eligible to apply for exception from RHC disqualification, but it is impossible to accurately predict how many will qualify for an exception. However, the estimated Medicare savings associated with the disqualification of certain RHCs from the Medicare program would be less than \$10 million. Participating RHCs that are no longer located in rural, underserved areas could lose their RHC status and their cost-based reimbursement, which could cause them to reduce services or discontinue serving our beneficiaries. We believe, based on a recent study by the Maine Rural Health Research Center, that approximately 150 clinics will lose their RHC status. However, to minimize the impact of this provision on rural health care, the Congress has authorized us to grant, if needed, an exception to clinics essential to the delivery of primary care in these affected areas. Our criteria in § 491.5 identify the areas and clinics where RHC status and its payment methodology are still needed despite the fact the service area is no longer considered medically underserved.

Implementing the statutory requirement to replace the current payment method used by provider-based RHCs to the payment method used by independent RHCs will establish payment equity and consistency within the RHC program. Before the BBA, payment to provider-based RHCs was made without considering the number of patient visits provided by the RHC, and without a limit on the payment per visit. These criteria are applicable to independent RHCs that furnish the same scope of

services. We have codified the statutory requirement to pay all RHCs under an all-inclusive rate per visit, which will avoid allocation of excessive administration costs to RHCs. We believe that about a thousand RHCs are affected by this rule.

We believe the fiscal impact of limiting payment to provider-based RHCs to the independent RHC rate per visit will result in program savings. Provider-based RHCs that have costs above the all-inclusive cost-per-visit limit required by the law could experience some decrease in their current reasonable cost basis payments. To reduce detrimental impacts of this decrease, the Congress authorized an exception to the annual payment limit to those clinics affiliated with small hospitals, that is, a hospital with fewer than 50 beds.

The QAPI requirement may increase burden in the short term because resources currently used for quality measurement will need to be directed to the development of a quality assessment and performance improvement program that covers the complexity and scope of the particular clinic. However, while the requirements could result in some immediate costs to an individual clinic, we believe that the QAPI program will result in real, but difficult to estimate, long-term economic benefits to the clinic (for example, cost-effective performance practices or higher patient satisfaction that could lead to increased business for the clinic).

Moreover, the QAPI and utilization review requirements replace the current annual evaluation requirement. Resources that the clinics are currently using for the annual evaluation could be devoted to the QAPI program. Therefore, we believe that there is no long-term increased burden to the clinics. Currently, a number of RHCs, primarily provider-based, have some type of quality improvement program in place. To the extent that clinics are familiar with collecting data on their operations and measuring quality, the new requirement will not impose significant additional burden.

Impact of the QAPI Provisions

We estimate that the additional one-time impact for the initial development of the QAPI provisions will be as follows:

Hours/Estimated Salary/Number of RHCs	One-time cost	Annual cost
1 physician/administrator at \$58/hr × 3 hrs × 3,300 clinics for medical direction and overview of QAPI program	\$574,200	
1 Mid-level practitioner (physician assistant, nurse practitioner) at \$28/hr × 32 hrs × 3,300 clinics for program development	2,956,800	