

report 30 minutes as well. This would total 2 hours per grantee per year, or 40 hours per year (2 hrs. × 20 grantees).

If you comment on these information collection and record keeping requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, DRDI, DRD-B, Attn: Julie Brown, Room C5-16-03, 7500 Security Boulevard, Baltimore, MD 21244-1850.

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Brenda Aguilar, CMS Desk Officer.

## VI. Regulatory Impact Statement

### A. Overall 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, if 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 in any 1 year). Since the amount of appropriations under this rule will not total more than \$40 million per fiscal year, it is not a major rule.

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 government agencies. 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 in any 1 year. Individuals and States are not included in the definition of a small entity. Since this rule is implementing a grant program for the States, this rule will not have a significant impact on small businesses.

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. Again, since this rule is implementing a grant program for the States, it will not have a significant impact on small hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$110 million. Since this rule is strictly an appropriation, there are no unfunded mandates included in the rule.

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 requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this rule is strictly an appropriation of \$80 million to the States to fund losses incurred in the operation of qualified high risk pools, it will have a beneficial impact on State governments since the funds will be used to provide health insurance coverage to uninsured individuals and will not impose any direct requirement costs on State and local governments.

### B. Anticipated Effects

This rule will have a positive impact on approximately 22 States that currently operate qualified high risk pools in that it will make funds available to those States to fund losses incurred in the operation of their high risk pools. Additionally, in order to be eligible for funding, the high risk pools will have to lower or maintain their premium cap at no higher than 150 percent of the standard rate in the private market. These grants, therefore, will serve as an incentive for States to keep their risk pool premiums at a level that will be affordable and accessible to more uninsured individuals. It will not significantly impact upon other entities, including providers, nor will it have any significant impact on the Medicare and Medicaid programs.

### C. Alternatives Considered

The Trade Adjustment Assistance Reform Act of 2002 was very prescriptive in its criteria for eligibility for operation grants to high risk pools.

It also provided a specific definition of a high risk pool and outlined the allocation formula for the grants. In addition to following the statute, we had to comply with the Department grant award procedure requirements. Because of these requirements, and because we wanted to make the money available as quickly as possible, we did not consider other major alternatives on how to award the grants.

### D. Conclusion

For the reasons indicated elsewhere in this section, 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.

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

### List of Subjects in 45 CFR 148

Administrative practice and procedure, Health care, Health insurance, Penalties, Reporting and record keeping requirements.

■ For the reasons set forth in the preamble, the Department of Health and Human Services amends 45 CFR subchapter B part 148 as set forth below:

## PART 148—REQUIREMENTS FOR THE INDIVIDUAL HEALTH INSURANCE MARKET

■ 1. The authority citation for part 148 continues to read as follows:

**Authority:** Secs 2741 through 2763, 2791, and 2792 of the Public Health Service Act (42 U.S.C. 300gg-41 through 300gg-63, 300gg-91, and 300gg-92).

■ 2. A new subpart E is added to read as follows:

### Subpart E—Grants to States for Operation of Qualified High Risk Pools

Sec.

- 148.306 Basis and scope.
- 148.308 Definitions.
- 148.310 Eligibility requirements for a grant.
- 148.312 Amount of grant payment.
- 148.314 Periods during which eligible States may apply for a grant.
- 148.316 Grant application instructions.
- 148.318 Grant application review.
- 148.320 Grant awards.

### Subpart E—Grants to States for Operation of Qualified High Risk Pools

#### § 148.306 Basis and scope.

This subpart implements section 2745 of the Public Health Service Act (the PHS Act). It provides for grants to States