

V. 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 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 annually).

We are unable to provide a specific dollar estimate of the economic impact this proposed regulation would have on State and local governments and participating providers. Because the flexibility permitted under Medicaid allows States to provide audiology under various Medicaid benefits, it is not possible to capture accurate expenditure data.

We have determined, however, that this proposed rule is not a major rule under Executive Order 12866, and the Secretary certifies that this proposed rule would not have a significant economic impact on a substantial number of small entities. We have made this determination because while we believe this rule would permit States to have more flexibility in determining who is qualified to provide audiology services, we do not anticipate any increase in States' use of audiology services due to this regulation. Section 804(2) of title 5, United States Code (as added by section 251 of Pub. L. 104–121), specifies that a "major rule" is any rule that the Office of Management and Budget finds is likely to result in—

- An annual effect on the economy of \$100 million or more;
- A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or
- Significant adverse effects on competition, employment, investment productivity, innovation, or on the ability of United States-based enterprises in domestic and export markets.

In addition, consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612), we prepare and

publish an initial regulatory flexibility analysis for proposed regulations unless the Secretary certifies that the regulations would not have a significant impact on a substantial number of small entities. For purposes of the RFA, we do not consider States or individuals to be small entities.

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. For purposes of the RFA, audiologists that generate total revenues of \$6 million or less in any 1 year are considered to be small entities. The Small Business Administration categorizes small businesses for Audiologists along with physical, occupational, and speech therapists. The total number of providers within this category that have total revenues of between \$5 million and \$7.5 million or less in any one year is 23,823 that they consider small businesses. Those firms and establishments with total revenue above \$7.5 million are not considered small businesses according to the SBA. Therefore, approximately 0.92 percent of audiologist would be considered small businesses. For further information on the SBA size standards see 65 FR 69432. Individuals and States are not included in the definition of a small entity.

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. Such an analysis must conform to the provisions 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 a Metropolitan Statistical Area and has fewer than 100 beds. This rule will not have a significant impact on small rural hospitals. The Medicaid program permits States the flexibility to provide audiology services under a variety of mandatory and optional benefits. The majority of States do so, mainly as either independent practitioner services, as part of a nursing facility service or community-based clinic services, or as part of their home health or school-based services programs. In addition, current Medicaid rules permit States the flexibility to provide audiology services by, or under the direction of, a qualified audiologist. This provider flexibility is

recognized by states and is widely used to provide audiology services to children through school-based services programs. Because the proposed rule retains the ability for audiology services to be provided "under the direction of," the changes proposed in this rule would not have an impact on how States currently provide services to their Medicaid populations. Therefore, small rural hospitals would not be affected.

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 expenditures in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$110 million. We do not anticipate this rule would have an effect on the States, local or tribal governments, or on private sector costs. As we stated earlier, this regulation would give States more flexibility in determining qualified audiologists thereby giving them the ability to choose from a larger provider pool of "qualified" individuals. However, because we expect the primary users of Medicaid audiology services, such as, children and seniors, to remain fairly constant, we do not anticipate any significant increase in the use of audiology services due to this proposed rule. In addition, because Medicaid audiology services are optional for states to provide to their Medicaid populations, many states choosing to do so limit utilization in some manner. In addition, many states limit the use of optional services such as audiology in favor of mandatory Medicaid benefits. States providing audiology services to children under the EPSDT program primarily do so a part of their school-based services program under IDEA. Since all 50 states currently have a school based services program in operation, we do not anticipate this rule to have any significant effect on audiology services provided to Medicaid children. Additionally, recognizing that states currently use the flexibility permitted in the Medicaid law to provide audiology services "under the direction of" a qualified audiologist, we expect states will continue to do so by providing audiology services using individuals working under the supervision of qualified audiologists.

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 a State law, or otherwise has federalism implications.