

significant economic impact on a substantial number of small entities. The RFA is to include a justification of why action is being taken, the kinds and number of small entities that the proposed rule will affect, and an explanation of any considered meaningful options that achieve the objectives and would lessen any significant adverse economic impact on the small entities. For purposes of the RFA, entities with annual revenues of \$5 million to \$25 million depending on the type of health care provider and non-profit organizations are considered to be small entities. Because of the scope of this rule, all small entities that participate in the Medicare program are considered providers and suppliers and will be affected, but we do not expect that effect to be of a significant nature. As we show in section B of this impact analysis, the annual burden on providers and suppliers for completing the CMS 855 forms would not rise to the level of a significant burden.

The following analysis, together with the rest of this preamble, explains the rationale, purpose, and alternatives considered in the proposed rule. This is an administrative initiative that may result in Medicare program savings but at this time those savings are inestimable. We believe the probable costs providers or suppliers would incur as a result of this rule to be negligible.

#### *A. Rationale, Purpose, and Alternatives Considered*

As noted elsewhere in this preamble, we are responsible for protecting the Medicare trust fund by ensuring that unqualified, fraudulent, or excluded providers and suppliers do not bill the Medicare program. Past experience with a number of program integrity efforts have identified that granting billing privileges to entities that do not exercise sound business practices can result in uncollectable overpayments. The ease of obtaining a billing number in the past has paved the way for unscrupulous businesses to defraud the government deliberately by billing for services never furnished or furnished at inflated prices.

The provisions of this proposed rule supplement, but do not replace or nullify, existing regulations concerning the establishment of provider or supplier agreements, the issuance of provider or supplier billing numbers, and payment for Medicare covered services or supplies to eligible providers and suppliers. Basically, this rule consolidates current regulations found throughout the Code of Federal Regulations and more clearly defines what Medicare expects from providers and suppliers rendering services to the

Medicare beneficiaries. Moreover, we have revised the "Provider Supplier Enrollment Application (CMS 855)" which will greatly decrease the current burden to the provider or supplier when applying for billing privileges. We expect this rule to ensure that the Medicare program has adequate information on those who seek to bill the program for services. Furthermore, it assures us that information will be periodically updated and reviewed. We believe that establishing the foundation for a sound business relationship with providers and suppliers will minimize billing problems and otherwise protect the Medicare trust fund. Similarly, we believe it is necessary for us to impose the requirements of this regulation on existing providers and suppliers and to establish safeguards that enable us to deny enrollment of unqualified providers and suppliers, and to revoke the billing privileges of egregious offenders whose actions place the Medicare trust fund at risk.

The primary goal of this rule, through standard enrollment requirements and periodic revalidation of the enrollment information, is to allow us to collect and maintain (keep current) a unique and equal data set on all current and future providers and suppliers that are or will bill the Medicare program for services rendered to our beneficiaries. By achieving this goal, we will be better positioned to combat and reduce the number of fraudulent and abusive providers and suppliers in the Medicare program, thereby protecting the trust fund and the Medicare beneficiaries. This rule will also allow us to develop, implement, and enforce national provider and supplier enrollment procedures to be administered uniformly by all Medicare contractors. Over time, we strongly believe that any current burden imposed on the providers and suppliers will be greatly diminished through the use of computer storage and web based internet technology.

Studies performed by our contractors, the GAO and OIG have shown numerous instances of fictitious applicants being granted Medicare billing numbers. This proposed rule would integrate the request for enrollment with sufficient data to substantiate an appropriate level of performance on the part of a new or continuing business. In prior studies, the OIG has found applicants who had submitted applications with nonexistent addresses. In some instances suppliers had no inventory of goods to be sold, lacked business licenses, had no financial investment, or lacked any experience in the business venture.

The GAO report concluded: "Weaknesses in CMS' current provider enrollment process have made Medicare vulnerable to dishonest providers. To protect the integrity of Medicare, CMS and its contractors must have effective practices for reviewing applicants to verify that they are eligible for enrollment in the program, as well as the authority to deny or revoke enrollment to those that are not." This report also concluded that, "Periodic revalidation of provider enrollment data should be a valuable means of ensuring that CMS has current, useful data on active providers and that providers no longer eligible to participate in Medicare are dropped from the program." Therefore, based on the above recommendation and our own successes with our 3-year re-enrollment policy currently in effect for DME suppliers, we are seeking to expand this requirement to all providers and suppliers billing the Medicare program.

We have already stepped up our efforts to seek more uniformity in the enrollment process. However, our experience clearly shows that the best means for preventing payment errors and, in worst cases, abuse by providers and suppliers, is to discourage and prevent their entry into the Medicare program through this rule and the authority to deny enrollment or revoke their billing number.

We realize that some entities will perceive our proposed requirements as a barrier to their access to serving Medicare beneficiaries. We do not believe that bona fide businesses will experience any difficulty in obtaining or maintaining a Medicare billing number. We also do not believe that the impact of these proposed requirements would fall any more heavily on underserved areas than on major metropolitan areas. We estimate that furnishing the requested information would require no more than 8 hours of a provider or supplier's time. Most businesses should have the information readily available.

#### *B. Rural Hospital Impact Statement*

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 of a Metropolitan Statistical Area and has fewer than 100 beds. As noted above, there is a minimum amount of time needed to gather data and provide the information requested on the CMS 855