

exists is not subject to administrative or judicial review. Moreover, as previously mentioned, the Secretary's authority under section 1128 of the Act, including the authority to assess "good cause," has been delegated to the OIG.

Given the myriad of health care payment and service arrangements, the OIG believes that "good cause" should be interpreted broadly. In general, we are proposing that § 1001.701(c)(1) should apply when there is a reasonable set of underlying facts and circumstances.³ The regulations in § 1001.701(c)(1) currently permit submission of excessive charges or costs that are due to unusual circumstances or medical complications requiring additional time, effort, or expense in individual cases. We are proposing a new exception for cases where the higher charge or cost submitted to Medicare or Medicaid is a result of increased costs associated with serving program beneficiaries. For example, higher charges or costs may result from claims processing or delays and denials in payment associated with serving Medicare or Medicaid beneficiaries. The burden of proof to establish the existence of, and to quantify, the higher charges or costs rests upon the individual or entity relying on the good cause exception.

We believe that there may be other circumstances in which providers should be permitted to submit higher charges or costs to Medicare and Medicaid, including factors specific to certain types of providers. The OIG is interested in comments on its proposed amendments pertaining to "good cause," including any comments identifying other circumstances that may constitute good cause for submitting excessive charges or costs.

In addition to the generic exceptions included in the proposed amendments, a provider may also request, in accordance with 42 CFR part 1008, a formal advisory opinion concerning the application of section 1128(b)(6)(A) of the Act to specific billing arrangements that either are in existence or are arrangements the provider in good faith plans to undertake. In order to receive a binding opinion, the specific regulatory requirements and procedures for official advisory opinions set forth in 42 CFR part 1008 must be followed. In addition, the OIG has created preliminary questions and a preliminary

checklist as a guide to crafting advisory opinion requests. All of these materials can be found on our web page at <http://oig.hhs.gov/fraud/advisoryopinions.html>.

Finally, wholly apart from the "good cause" exception, the determination to exclude a provider is discretionary and must be for a remedial purpose. Accordingly, use of this authority for isolated or unintentional mistakes would be inconsistent with the remedial purpose and inappropriate.

III. Regulatory Impact Statement

A. Regulatory Analysis

We have examined the impacts of this proposed rule as required by Executive Order 12866, the Unfunded Mandates Reform Act of 1995, the Regulatory Flexibility Act (RFA) of 1980, and Executive Order 13132.

Executive Order 12866

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulations are 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 must be prepared for major rules with economically significant effects (\$100 million or more in any given year).

This is not a major rule as defined at 5 U.S.C. 804(2), and it is not economically significant since it would not have a significant effect on program expenditures and there are no additional substantive costs to implement the resulting provisions. This proposed rule is designed to further clarify existing statutory requirements. The statute has been in effect in the absence of these clarifying regulations. We presume that the vast majority of providers have been in compliance with the existing statute and will be minimally impacted, if at all, by these regulations. We hope that these regulations will facilitate compliance by establishing bright line rules that will make it easier for parties to ensure that they are not at risk of being excluded. Thus, we believe that any aggregate economic effect of these regulatory provisions would be minimal and would impact only those limited few who engage in prohibited behavior in violation of the statute. Although these regulations would not require providers to change their charges to the Medicare or Medicaid programs, we anticipate that some providers who are overcharging Medicare or Medicaid may

comply with the statute and regulations by lowering their charges to the programs. While we do not have adequate information at this time to ascertain and quantify the effect of such changes on Federal or State expenditures, we note that a number of OIG and General Accounting Office studies have shown that the Medicare program pays considerably more for some items and services than other payers. Notwithstanding, given the likelihood of substantial current compliance with the statute, we believe that the likely aggregate economic effect of these regulations would be less than \$100 million.

Regulatory Flexibility Act

The RFA, and the Small Business Regulatory Enforcement and Fairness Act of 1996, which amended 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 providers are considered to be small entities by having revenues of \$5 million to \$25 million or less in any one year. For purposes of the RFA, most physicians and suppliers are considered to be small entities.

In addition, section 1102(b) of the Social Security 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 providers. This analysis must conform to the provisions of section 604 of the RFA. While these provisions may have some impact on small entities and rural providers, we believe that the aggregate economic impact of this proposed rulemaking would be minimal since it is the nature of the conduct and not the size or type of the entity that would result in a violation of the statute and the regulations. As a result, we have concluded that this proposed rule should not have a significant impact on the operations of a substantial number of small or rural providers, and that a regulatory flexibility analysis is not required for this rulemaking.

Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4) also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditures in any one year by State, local or tribal governments, in the aggregate, or by the private sector, of \$110 million. As indicated, these proposed revisions comport with congressional and statutory intent and

³ In order to make clear that the changes proposed in this rulemaking do not affect § 1001.701(c)(2) (which relates to a different exclusion authority, section 1128(b)(6)(B) of the Act), we have made a technical change in § 1001.701(c)(2) that does not change the existing substance or language of that provision.