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GUIDANCE ON

PROPER CONSIDERATION OF

SMALL ENTITIES IN RULEMAKINGS

OF THE

U. S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Executive Order 13272 (the Order), issued by the President on August 13, 2002, requires that the Department of Health and Human Services (HHS) thoroughly review draft rules to assess and take appropriate account of their potential impact on small business, small governmental jurisdictions, and small organizations, as mandated by the Regulatory Flexibility Act of 1980 (the Act), as amended and as codified at 5 U.S.C. § 601 *et seq*.

Section 3(a) of the Order directs agencies to issue a written statement of procedures and policies to ensure proper consideration of small entities in the rulemaking process. After review of this statement of policies and procedures by the Small Business Administrations's Office of Advocacy, the statement is to be made readily available to the public through the Internet or other easily accessible means. The following guidance, expressed in question- and answer format and reflecting the Office of Advocacy's review, constitutes the Department's compliance with this mandate. HHS components assessing the impact of regulatory proposals will conduct these analyses within the conceptual framework set out below.

What is the Scope of this Guidance?

This guidance provides a framework for complying with the provisions of the Act requiring the preparation of Regulatory Flexibility Analyses (RFAs) as part of the regulations-development process. Other statutes and executive orders also mandate the preparation of various other impact analyses. While this guidance focuses, as directed by the Order, on RFAs, HHS components should, in keeping with Section 605 of the Act, avoid duplicative analyses and, to the extent analytically possible, combine RFAs with other impact analyses that they are required to conduct.

What is the Purpose of the Guidance?

This guidance presents a broad set of principles for performing RFAs and for interpreting the Act. The guidance attempts to highlight areas that call for interpretation and to articulate approaches that reflect the spirit and the letter of the law. The guidance is not intended as a comprehensive "cookbook" for doing RFAs.

Many HHS regulations have a direct impact on small entities. Small entities comprise the vast majority of health care providers, medical group practices, medical equipment manufacturers, food producers, child care centers, social service agencies, and other industries and organizations that HHS regulates. Thus, when planning most regulations and considering policy alternatives, HHS components must assess the potential effect on small entities to ensure compliance with the Act, and must make every effort to minimize the regulatory burden that might be imposed on small entities.

What Rules Are Subject to the Regulatory Flexibility Act ?

The Act states that whenever an agency proposes a rule through the notice and comment process, the agency must either (1) perform an initial RFA and publish the analysis in the Federal Register for public comment, or (2) certify that the regulation will not have a significant impact on a substantial number of small entities. For any final rule for which it has published a proposed rule, the agency must either (1) perform and publish a final RFA, or (2) make a certification that the regulation will not have a significant impact on a substantial number of small entities. These requirements may also apply to proposed and final notices that function as rules, such as notices announcing health care financing information for a specific calendar or fiscal year. Interim final rules with comment, and final rules with comment, are not mentioned in the statute; however HHS components should perform a "voluntary" RFA for these rules, if they have a significant impact on a substantial number of small entities, as defined below.

What are the General Requirements for an Initial RFA?

The Act, at §603, requires (1)identification of the small entities that will be affected by our regulations; (2) analysis of the burden the regulations will impose on small entities; and (3) assessment of whether the burden of the regulations will have a significant economic impact on a substantial number of small entities. If, as an alternative, HHS concludes that a rule WILL NOT HAVE a significant economic impact on a substantial number of small entities, a statement certifying to this effect may be included in the preamble. Such a certification must, under § 605(b) of the Act, be accompanied by a statement of its factual basis. (Further guidance regarding this certification is provided on page 9 below). If, on the other hand, we conclude that a rule MAY HAVE a significant adverse impact on a substantial number of small entities, then the agency must describe significant alternatives to the proposed rule which minimize any significant economic impact on small entities.

What is Specifically Required in the Initial and Final RFA?

The Act restates a number of requirements which are also specified in the Administrative Procedure Act and the Paperwork Reduction Act, usually addressed elsewhere in a rule's preamble. The following elements established by §§ 603(b) and 604(a) of the Act, however, should also be included in the initial and final RFAs:

- A succinct statement of the objectives of the rule (if not already included in the regulatory impact analysis), and a citation for the legal basis for the rule;

- A description of the types of small entities affected (for example: hospitals, food processors, physicians), and, to the extent that data are available, estimates of the number of affected small entities;
- A description of reporting, record keeping and other compliance requirements, which includes an estimate of the types of small entities affected, and the types of professional skills (including skill level) and number of personnel that would be required to meet the reporting and other requirements;
- Identification of any overlapping, duplicative, or conflicting Federal statutes or rules; and
- A description of significant alternatives to the proposed rule, which would accomplish stated objectives and minimize economic impact on small entities.

The requirements for an initial and a final RFA are almost identical. Both require:

- a description of the impact of the compliance requirements of the regulation; and
- an analysis of alternatives to reduce burden.

The final RFA must contain the following additional items:

- a summary of the significant issues raised in the comments to the initial RFA and the agency's response to those comments, and any changes made to the rule because of the comments; and
- a description of the steps the agency took to minimize the burden on small entities consistent with the objectives of the underlying statute. The description must include the factual, policy, and legal reasons for the agency's choice and an explanation for why the other alternative considered were not adopted.

How Are the Affected Entities Identified?

The first step, using the definitions presented in §§ 601(3) and 601(4) of the Act, is to identify the industry sectors that the regulations will affect. These include those sectors explicitly identified in the regulation, and other sectors that may be indirectly affected . For example, a food safety regulation that is explicitly directed at food manufacturers may affect other entities in the food distribution or supply channel such as warehouses, packagers, and wholesalers. In addressing the number of small entities a proposed or final rule may affect, the Act identifies and defines three classes of entities:

- A ***small business*** is a for-profit firm that accords with the Small Business Administration's (SBA) size standards for small business. § 601(3) of the RFA defines a "small business" as having the same meaning as "small business concern" under Section 3 of the Small Business Act. This includes any firm that is "independently owned and operated" and is "not dominant in its field of operation." SBA has developed size standards to carry out the purposes of the Small Business Act; those size standards can be found at 13 CFR.§121.201. The current size standards are posted on the SBA web site at http://www.sba.gov/size/ .

  If an alternative size standard would be more appropriate for a particular industry

segment, a modification of the current standard can be sought under § 601(3) of the Act from SBA's Chief Counsel for Advocacy, with public comments then requested in the preamble on the proposed alternative. (If we should seek to change size standards in a general rulemaking context, SBA's Administrator should be contacted.)

- A ***small organization,*** as defined in §601(4), is a not-for-profit organization that is independently owned and operated and is not dominant in its field. (Establishment of an alterative definition of a small organization, appropriate to an agency's activities, is possible under §601(4), using notice-and comment procedures.)

  A decision to consider small members of non-profit chains to be "small organizations" or not, and thus to include or exclude them from the analysis, will depend on particular conditions. For example, many health care provider chains are owned by organizations that provide very limited or no support to the chain member, with the providers operating with a high degree of autonomy. In most respects, these providers experience the same burdens and must manage with the same limited resources as do independently owned facilities.

- A ***small governmental jurisdiction***, as defined in §601(5) of the Act, is any political subdivision (for example, city, town, school district) with a population of less than 50,000 (unless an agency establishes, after opportunity for public comment, an alternative definition based on such factors as location in a sparsely populated area with limited revenues). States, tribal governments and individuals are not subject to the Act. HHS components, however, although not required to analyze the secondary impacts of proposed or final rules in initial and final analyses, should take note that Federal regulations and grants that are administered by States and tribal governments often affect small organizations that receive grants from those States or tribes or have contracts with them.

After identifying the types of small entities that may be affected, HHS components should check the SBA size standards for the industry in question. Each industry in the North American Industrial Classification System has a size standard, posted on SBA's website at *http://www.sba.gov/size/indextableofsize.html.*

Once the size standard is determined, then estimating the number of small entities that meet the size standard will require collection of data, from both the extensive data bases already maintained within the Department and also from external databases. For example, the SBA's Office of Advocacy has a database that can be used to identify firm size, accessible at *http://www.sba.gov/advo/stats/data/html*. The Census Bureau's Index of Business Establishments maintains annual receipt data by establishments for all industries. The Dunn and Bradstreet company, as well as various trade associations, may provide data useful in identifying the number of small entities. If no useful data can be found, then we should include a brief discussion of the sources examined and the problems encountered.

How is Burden Analysis Conducted?

The burden analysis is the heart of any RFA. Under the Act, the Department is required to analyze the economic impact a regulation will impose on small entities in order to comply with the regulation. The statute specifies personnel record-keeping and reporting costs, but these are only some of the factors that produce additional burden. A complete analysis should examine all the factors required to bring the entity into compliance with the regulation. These may include factors such as:

- training,
- hiring of additional or expert personnel,
- the development of procedures and policies,
- technology migration paths,
- insurance,
- printing,
- debt service,
- rent,
- utilities,
- capital purchases, and
- inventory

Although compliance costs are most often the form in which a regulation will impose burden, a regulation may also impose a burden by forcing reductions in revenues. Medicare and Medicaid rules that specify payment levels for services often result in lower payments to providers, either as a result of a redistribution formula or directly in the form of cuts in payments. In economic terms, the revenue reductions can be seen as opportunity costs, because of the lost opportunity to invest those funds. The burden analysis should, if possible, assess the opportunity costs of revenue reductions along with the other costs of compliance.

Sources As an integral part of the burden analysis, HHS should cite the sources of the data used in the analysis and discuss the limitation of the data, the likelihood of the described outcome occurring, possible alternative outcomes and their likelihood. An explanation of the assumptions made about the distribution of values or about missing values due to incomplete or questionable data should be provided.

The baseline A major analytic assumption is the baseline used as the reference point for determining the incremental burden a regulation will place on the affected entities. In simple terms, the baseline should be the financial and economic state of affairs prior to the promulgation of the regulation. While this concept is simple in form, in practice it can become complex especially if the baseline is changing over time.

For example, a regulation to mandate the use of electronic health transactions that will take effect in three years will have less of an impact than if the same rule were to take effect in a year. Because the industry as a whole is moving toward implementing electronic transaction reporting, the baseline for evaluating compliance costs is shifting in the direction

of the regulation. Over time, the market is pushing the affected entities to adopt electronic claims processing and thus by the time the rule takes effect, many entities will have adopted the provision of the regulation. As is the case with performing the cost analysis, obtaining data on the baseline may be problematic; adoption of reasonable assumptions about the baseline, or consideration of alternative baseline levels, may be necessary.

Causation The key in determining the effects of a regulation is establishing causation. The analysis must, in accordance with §603(b)(4) and §604(b)(4), identify the actions and associated costs that are required to comply with the new regulation. The essential element in determining causation is identifying those effects attributable to the rule as distinct from effects resulting from other causes. As mentioned in connection with analyzing the base line, the general workings of the economy may cause behavioral changes on the part of the affected entities; the rule may advance or retard these secular trends.

Also, causation may be attributable to statutory provisions, rather than to the regulation itself. Statutory provisions may leave HHS with no discretion in interpreting and crafting rules. Statutory language may be explicit enough to permit implementation of a provision without a regulation. An example is a statutorily mandated update factor to a Medicare prospective payment rates, where the law dictates the update factor to be applied to the computed payment rates. In such cases, the point should be made that the statute does not allow the Secretary discretion in applying the update factor, and therefore, the impact is attributable to the statute. However, analysts must distinguish between the update factor established in law and the computation of the rates, which the statute authorizes the Secretary to determine. The effects attributable to the rates as articulated in the regulation should be articulated in the RFA.

In a similar manner, for notices and regulations that merely implement congressionally mandated spending levels, as in the State Child Health Insurance Program, the impact of the spending levels for each State is attributable to the statute and a RFA is not necessary. However, if a notice or regulation deviates from the spending formula specified in law, presumably under statutory authority granting the Secretary discretion, then the effects of those provisions that deviate from the law must be analyzed.

How Is It Determined that a Rule Will Have a Significant Economic Impact on a Substantial Number of Small Entities?

The Act does not define the terms "significant economic impact" or "substantial number." . SBA advises that this absence of statutory specificity allows what is "significant" or "substantial" to vary, depending on the problem that is to be addressed in the rulemaking, the rule's requirements, and the preliminary assessment of the rule's impact.[1]

[1] *The Regulatory Flexibility Act An Implementation Guide for Federal Agencies, pages 17-19.* Issued by SBA's Office of Advocacy, and accessible at *www.sba.gov/advo.*

Substantial Number With a view to ensuring that a broad range of impacts are fully considered in the analysis, we should understand "Substantial Number" to mean 5 percent or more of the affected small entities within an identified industry.

Significant economic impact A 1984 HHS *Handbook On Developing Low Burden And Low Cost Regulatory Proposals* set forth the following definitional narrative for the term "significant economic impact". This narrative has been serviceable in implementing the statute and is still applicable:

> "Significant economic impact": A rule has a significant economic impact on the small entities it affects, if it significantly affects their total costs or revenues. If the economic impact is expected to be similar for all affected small entities, and if those entities have similar costs and revenues, then an average impact can be calculated. If the average annual impact on small entities is 3 - 5% or more, it is to be considered significant.
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> Moreover, if the rule will result in a disproportionate economic impact on a subset of affected small entities (for example, hospital-based as compared with free-standing skilled nursing facilities), a determination must be made as to whether the impact on them will be significant. A low average impact on all small entities should not be used to disguise a significant impact on a subset.
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> A significant negative impact always requires an analysis; regulatory actions having a significant positive impact do not necessarily require an analysis.

In selecting either total revenues or total costs for the denominator for determining the significance of an impact, the goal is to make the analysis as simple and straightforward as possible. Revenue data are often available from internal agency sources and from reliable third party sources, and, in general, these data are less prone to manipulation than other variables. Cost data, although harder to obtain and subject to more accounting manipulations, are available from CMS for health care entities and health plans, and may be available from other government agencies or private sources.

In analyzing the impact of a regulation that may both reduce and increase burden on the same small entities, HHS's intended practice would be to consider an RFA to be mandatory only if the net impact exceeded thresholds described above. For example, if one regulatory provision resulted in a burden increase of greater than 3 - 5 % for all the affected entities, but another provision moderated the increase so the net effect was to actually increase burden on small entities by less than one percent, then, all other things being equal, it is possible that one could certify that the rule would not have a significant impact on a substantial number of small entities. If the different provisions have differing effects on sub-groupings of small entities, however, then the impacts of the various provisions have to be separately analyzed on each of the sub-groupings.

Although revenues or costs are the recommended indicators for measuring significance of a regulatory impact, there are other measures that could also be used at the discretion of the component in contexts where highly reliable data is available. Examples of such other

measures are: profit margins, operating margins, capital investment, rate of return, and cash flow analysis. Moreover, applying these measures should be done with an understanding of the accounting principles used and of the various reporting options allowed under these principles. For example, under IRS rules for sole proprietorships, the owner's salary is classified as income along with "profits" because there is no distinction between the owner and the business. Thus, in computing profit margins for sole proprietorships, the owner's salary should be included as profits.

When should a Voluntary Analysis be Conducted

In addition to these threshold criteria for performing a mandatory RFA, the Department considers that there are four circumstances under which performing a *voluntary* RFA should be contemplated. These are: (1) when a rule is unusually controversial as to possible burdens or may appear to be significantly burdensome even though it is not; (2) when the rule approaches but does not meet the 3 - 5 % threshold (or is clearly above the threshold but in our view still not "significant"), but there is some possibility that public comment will show that there was an error in certifying that an RFA was not required; (3) when the significant impact is created by the statute and our rule has no independent effect on the magnitude of the impact; or (4) when the rule has a positive impact that is significant and affects a substantial number of small entities.

The decision to perform a voluntary analysis will be influenced on the one hand by the scope of the regulation's impact on small entities, and on the other, by the workload involved in publishing a compliance guide (under the Small Business Regulatory Enforcement and Fairness Act of 1996, (*P.L. 104-121*)), if a final regulatory flexibility analysis needs to be conducted.

What Alternatives Measures should be Considered?

When the analysis described above suggests that a rule may have a significant economic impact on a substantial number of small entities, the Act requires consideration of alternative measures for reducing the regulatory burden.[2] Options for reducing compliance costs, through small business exemptions, lessening the record-keeping and reporting requirements, delaying effective dates, establishing minimal requirements, or, if possible, waiving certain requirements warrant consideration. Only alternatives that are consistent with the objectives of the regulations need to be considered, and, of those, only those options that could be implemented under the statutory framework authorizing the regulation. As a part of the consideration of the alternatives to the proposed and final rule, we should explain why the rejected alternatives are inferior to the selected option.

For regulations that are essentially implementing statutory provisions with very little or no discretion, the RFA should include under an "Alternative Considered" section a brief statement explaining the lack of administrative discretion in implementing the authorizing

[2] While the statute does not specify that only burdensome impacts require an examination of alternative measures for reducing the impact, it would be counter to the spirit of the Act and would lead to absurd results if we were to explore ways to lessen a positive impact. Therefore we consider alternatives only for reducing burden.

statute. Similarly, if the impact of the regulation is positive, include a brief statement under "Alternatives Considered" that explains the positive effects of the regulation and that alternatives for reducing burden would be inappropriate.

When should a Certification be Used?

If the burden analysis reveals that a regulation will impose either an insignificant burden on small entities or that only very few small entities will be affected, then the Act permits the agency head to certify that the proposed or final rule will not have a significant impact on a substantial number of small entities. This certification should contain a description of the number of affected entities, the size of the economic impacts, and an explanation of how these circumstances support the certification. The agency's reasoning and assumptions underlying its certification should be explicit.

CERTIFICATION SHOULD BE USED WITH CAUTION AND ONLY UNDER CIRCUMSTANCES WHERE AN AGENCY IS CERTAIN THAT A RULE WILL NOT HAVE A SIGNIFICANT IMPACT ON SUBSTANTIAL NUMBER OF SMALL ENTITIES. Using the certification in an RFA commits the Secretary to stating unequivocally that either the rule will not have a significant economic impact or that only very few small entities will be affected. The department can be challenged in court over the accuracy of the certification, and, should the certification be found defective, the rule could be nullified or remanded back to the agency for redrafting. Given that most feasible analyses rely on averaging costs or revenue reductions, the distribution of the factors is often unknown. A cost increase or cut in payments of one percent on average could easily have a distribution that exceeded the 3-5 % threshold.

Furthermore, a certification does not remove the obligation to perform a burden analysis. To reach the conclusion that a regulation will not significantly burden a substantial number of small entities, the analysis must be performed and the findings presented in support of the certification statement.

As was pointed out in the discussion on alternatives, the statutory language with respect to the economic impact of regulation does not distinguish between increasing or reducing burden. Thus, if the RFA reveals a significant decrease in burden on a substantial number of small entities, the Secretary cannot "negatively" certify the regulation. Although the impact is positive, the fact that it meets the thresholds for economic significance and for the distribution of the effects bars us from including a negative certification. A statement to this effect should be included in the RFA.

What if there are no quantitative or financial data available?

The foregoing discussion assumes that some quantitative and financial data are available for performing a RFA. Often, however, there are either no data or the data are of such questionable quality that it is more prudent to avoid relying on the data than to attempt using them for an RFA. The Act makes special provision for such situations. § 607 clearly states that if quantitative data are not available, an agency may provide a more general or descriptive (i.e. qualitative) statement of the effects of a rule and of the available alternatives.