

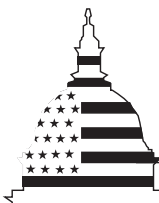
GAO

Report to the Ranking Minority Member
Committee on Small Business and
Entrepreneurship, U.S. Senate

December 2001

REGULATORY REFORM

Compliance Guide Requirement Has Had Little Effect on Agency Practices



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| <p>Abstract</p> <p>Section 212 does not appear to have had much of an impact in the agencies and years that we examined, and its implementation has varied across and sometimes within the agencies. The statute gives agencies broad discretion to decide which of their rules require compliance guides, what has to be in the guides, how they are developed, when they have to be published, and how they are distributed to affected small entities. Using that discretion, an agency could legally exclude all of its rules from coverage by the statute, designate a previously published document as its small entity compliance guide, or develop and publish a guide with no input from small entities years after the covered rule takes effect. Some of the ineffectiveness and inconsistency in the implementation of section 212 are traceable to the broad discretion provided to agencies in the RFA regarding the term significant economic impact on a substantial number of small entities. Although a single, rigid definition of this term may not be feasible, we believe that some additional clarity can be provided. Other problems with the compliance guide requirement are traceable to section 212 itself. We offer suggestions on how Congress may wish to amend the statute to make clear when agencies must prepare a compliance guide under section 212 and the meaning of key terms in the statute.</p> | | |
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United States General Accounting Office
Washington, DC 20548

December 28, 2001

The Honorable Christopher S. Bond
Ranking Minority Member
Committee on Small Business and Entrepreneurship
United States Senate

Dear Senator Bond:

Small businesses comprise a significant portion of the United States' economy, accounting for 99 percent of all businesses, about 50 percent of the gross domestic product, and about 53 percent of the private industry's workforce. However, small businesses and other small entities (small governments and small nonprofit organizations) can be disproportionately affected by federal agencies' regulatory requirements, and agencies may inadequately consider the impact of those requirements on small entities when the requirements are implemented. In March 1996, Congress passed the Small Business Regulatory Enforcement Fairness Act (SBREFA) (5 U.S.C. 601 note), which was intended to, among other things, "simplify the language of Federal regulations affecting small businesses" and "develop more accessible sources of information on regulatory and reporting requirements for small businesses." Section 212 of SBREFA requires agencies to publish one or more compliance guides for each rule or group of related rules for which the agency is required to prepare a final regulatory flexibility analysis (FRFA) under the Regulatory Flexibility Act (RFA). The relevant sections of the RFA (codified at 5 U.S.C. 604 and 605) generally require agencies to prepare a FRFA for every final rule for which a general notice of proposed rulemaking (NPRM) is required unless the head of the agency certifies that the rule will not have a "significant economic impact on a substantial number of small entities."¹

You asked us to examine the implementation of section 212 of SBREFA in selected agencies. Specifically, you asked us to (1) determine whether the agencies have published small entity compliance guides for each covered rule published in selected years, and (2) describe how the agencies

¹In this report, we will refer to rules that the agencies have determined will not have a significant economic impact on a substantial number of small entities as rules that will not have "a significant impact on small entities."

developed the guides and made them available to small entities affected by the rules. We focused our review on final rules published during calendar years 1999 and 2000 by six federal agencies: the Department of Commerce (DOC), the Centers for Medicare and Medicaid Services (CMS)² and the Food and Drug Administration (FDA) within the Department of Health and Human Services (HHS), the Environmental Protection Agency (EPA), the Federal Communications Commission (FCC), and the Securities and Exchange Commission (SEC). All of these agencies except EPA were selected based on the frequency with which they prepared FRFAs.

Results in Brief

Section 212 does not appear to have had much of an impact in the agencies and years that we examined, and its implementation has varied across and sometimes within the agencies. The statute gives agencies broad discretion to decide which of their rules require compliance guides, what has to be in the guides, how they are developed, when they have to be published, and how they are distributed to affected small entities. Using that discretion, an agency could legally exclude all of its rules from coverage by the statute, designate a previously published document as its small entity compliance guide, or develop and publish a guide with no input from small entities years after the covered rule takes effect. Some of the ineffectiveness and inconsistency in the implementation of section 212 are traceable to the broad discretion provided to agencies in the RFA regarding the term “significant economic impact on a substantial number of small entities.” Although a single, rigid definition of this term may not be feasible, we believe that some additional clarity can be provided. Other problems with the compliance guide requirement are traceable to section 212 itself. We offer suggestions on how Congress may wish to amend the statute to make clear when agencies must prepare a compliance guide under section 212 and the meaning of key terms in the statute.

None of the agencies in our review provided us with guidance documents that met all of the statutory requirements for all of their 1999 and 2000 final rules that they said were covered by section 212. The agencies said that they did not provide documents for some of the rules because they had no compliance requirements, the requirements had not taken effect, or the rules were so clear that a compliance guide was not needed. The documents that EPA and FDA provided to us for their covered rules with active compliance requirements met all of the nondiscretionary provisions

²Prior to 2001, CMS was the Health Care Financing Administration.

in section 212. However, almost 90 percent of the documents that the other agencies provided for their covered rules with compliance requirements did not meet all of the statute's requirements. Specifically, many of the documents were not designated as small entity compliance guides and/or did not explain what small entities had to do to comply with the associated rule. Some of the documents appeared to have been prepared for reasons unrelated to section 212, and the agencies identified those documents as small entity compliance guides only in response to our inquiry. Notably, the agencies varied widely in the types of rules they considered covered by section 212. Some of the agencies (e.g., FCC and SEC) established low coverage thresholds and included rules that they viewed as having little or no effect on small entities. EPA, on the other hand, established a high coverage threshold, excluding virtually all of the agency's final rules from coverage by section 212. Some of the agencies had difficulty determining which of their previously issued rules were covered by the compliance guide requirement.

The responsibility for developing the compliance guides was decentralized to the rule-writing units in all of the agencies that we contacted. The agencies generally indicated that they attempted to put their compliance guides in "plain language"—just as they have for all of their regulatory materials. The guidance documents that the agencies gave us were often published on the agencies' web sites. In other respects, though, the development, timing, and distribution of the guidance documents varied among the agencies. Some agencies consulted small entities during the development of their guides, but others did not. Some of the documents were published before the final rules were published, while others were not published until after the rules had taken effect. In addition to the agencies' web sites, modes of distribution included direct mailing, electronic list servers, use of agency/regional offices, and workshops.

Background

The basic elements of the federal rulemaking process are spelled out in the Administrative Procedure Act (APA), as codified in section 553 of title 5, United States Code. The APA generally requires agencies to (1) publish an NPRM in the *Federal Register*, (2) allow interested persons an opportunity to participate in the rulemaking process by providing "written data, views, or arguments," and (3) publish the final rule 30 days before it becomes effective. However, the APA allows agencies to issue final rules without the publication of an NPRM in certain situations, such as for rules dealing with foreign or military affairs; interpretative rules; and rules of agency organization, procedure, or practice. It also permits non-NPRM rulemaking when the agency determines for "good cause" that notice and comment

procedures are “impracticable, unnecessary, or contrary to the public interest.” When agencies use the good cause exception, the APA requires them to explicitly say so and provide an explanation for the exception’s use. Two specific applications of the good cause exception are known as “direct final” and “interim final” rulemaking.³ In August 1998, we estimated that about half of the nearly 4,700 final regulatory actions published during 1997 were published without NPRMs, and that some of the agencies’ explanations for why the good cause exception was used were not clear or understandable.⁴

Congress has added requirements to the federal rulemaking process several times during the past 25 years. For example, the RFA was enacted in 1980 in response to concerns about the effect that federal regulations can have on small entities. The act (5 U.S.C. 604 and 605) requires agencies to prepare regulatory flexibility analyses when publishing proposed or final rules—but only for rules that require an NPRM. In our August 1998 report on non-NPRM rulemaking, we estimated that in more than 500 final rules published in 1997 without a notice, the agencies specifically stated that a regulatory flexibility analysis was not required because the action was not preceded by an NPRM.⁵ Also, an agency does not have to prepare an analysis when the agency certifies that the rule will not have a significant impact on small entities. (See 5 U.S.C. 605(b).) However, the statute does not define the terms “significant economic impact” or “substantial number of small entities.” As a result, agencies have broad discretion in defining these terms, and their definitions vary widely.⁶ Under the RFA (5 U.S.C. 612), the Small Business Administration’s (SBA) Chief Counsel for Advocacy is responsible for monitoring agencies’ compliance with the act. We have recommended several times in the past 10 years that SBA or some other entity be given the authority and responsibility to

³Direct final rulemaking involves agency publications of a rule in the *Federal Register* with a statement that the rule will be effective on a particular date unless an adverse comment is received within a specified period of time. If an adverse comment is filed, the direct final rule is withdrawn and the agency must publish the rule as a proposed rule. In interim final rulemaking, the agency issues a final rule without an NPRM that is generally effective immediately, but with a post-promulgation opportunity for the public to comment, and an opportunity for the agency to be persuaded by those comments and revise the rule.

⁴*Federal Rulemaking: Agencies Often Published Final Actions Without Proposed Rules* (GAO/GGD-98-126, Aug. 31, 1998).

⁵See GAO/GGD-98-126.

⁶*Regulatory Flexibility Act: Inherent Weaknesses May Limit Its Usefulness for Small Governments* (GAO/HRD-91-16, Jan. 11, 1991).

define key terms in the RFA.⁷ Legislation currently under congressional consideration—the Agency Accountability Act of 2001 (S. 849)—could provide some of the definition that we believe is needed. It directs the SBA Chief Counsel for Advocacy to promulgate a rule defining the terms “significant economic impact” and “substantial number of small entities.”

One of the reasons that SBREFA was enacted in 1996 was to strengthen the implementation of the RFA. As previously noted, section 212 of SBREFA requires federal departments and agencies to publish one or more small entity compliance guides for each rule or group of related rules for which the agency is required to prepare a FRFA. Because this provision in SBREFA was built on the FRFA determination, all of the discretion inherent in the RFA regarding whether to do an analysis also applies to whether compliance guides must be developed. Section 212 requires the guides to (1) be published, (2) be designated as “small entity compliance guides,” and (3) explain the actions a small entity is required to take to comply with an associated final rule. However, it gives agencies broad discretion in other areas. For example, it says agencies “may” prepare separate guides covering groups or classes of similarly affected small entities, and “may” cooperate with associations of small entities to develop and distribute the guides. Agencies are given “sole discretion” in the use of plain language in the guides. The statute does not indicate when the guides must be developed or how they must be published.

The small entity compliance guides developed pursuant to section 212 of SBREFA are only one part of a wide range of compliance assistance provided by federal agencies. Earlier this year we issued a report describing, among other things, agencies’ efforts to use information technology to provide compliance assistance.⁸ For example, we noted that EPA has partnered with industry associations, environmental groups, universities, and other government agencies to create 10 compliance assistance centers for specific sectors, many of which are heavily populated with small entities. Agency officials told us that other statutes also require compliance assistance efforts, and that many of their compliance assistance efforts predate SBREFA. Also, section 213 of

⁷See GAO/HRD-91-16; *Regulatory Flexibility Act: Status of Agencies’ Compliance* (GAO/GGD-94-105, Apr. 27, 1994); and *Regulatory Reform: Implementation of the Small Business Advocacy Review Panel Requirements* (GAO/GGD-98-36, Mar. 18, 1998).

⁸*Regulatory Management: Communication About Technology-Based Innovations Can Be Improved* (GAO-01-232, Feb. 12, 2001).

SBREFA requires agencies regulating the activities of small entities to establish a program for responding to inquiries from small entities concerning compliance with the agencies' statutes and regulations.

Objectives, Scope, and Methodology

The objectives of our review were to (1) determine whether the agencies we included in our review have published small entity compliance guides for each covered rule published in selected years, and (2) describe how the agencies developed the guides and made them available to small entities affected by the rules. Federal agencies issue thousands of final rules each year, and SBREFA had been in effect for more than 5 years at the start of our review. Determining whether each rule issued during this 5-year period required a section 212 compliance guide would have been an extremely difficult and time-consuming effort. Therefore, as agreed with your office, we decided to focus our review on the final rules issued by certain agencies during calendar years 1999 and 2000. We selected those years because they were the most recent complete years for which data were available, and because agencies could reasonably be expected to have put their section 212 procedures in place by the start of this period (more than 2 years after the passage of SBREFA).

To select the agencies for our review, we initially contacted SBA's Office of Advocacy and asked if they had data showing which agencies published the most final rules with a FRFA. However, SBA officials said they had no such data, and were not aware that such data were available. We then obtained data from the Regulatory Information Service Center (RISC) showing which agencies most frequently reported in recent editions of the Unified Agenda of Federal Regulatory and Deregulatory Actions that their final rules required a FRFA.⁹ Specifically, we asked RISC to identify entries listed in the "completed action" fields in the five editions of the Unified Agenda from April 1999 through April 2001 for which the agencies said a regulatory flexibility analysis was required. According to the Unified Agenda, completed actions are supposed to include all final rules issued since the last Agenda edition 6 months earlier. Therefore, completed actions in the April 1999 through April 2001 editions of the Unified Agenda

⁹RISC is part of the General Services Administration but works closely with the Office of Management and Budget to provide the President, Congress, and the public with information on federal regulatory policies. RISC publishes the Unified Agenda twice each year, which provides for uniform reporting of data on regulatory activities under development throughout the federal government.

should reflect final rules published in calendar years 1999 and 2000, and the regulatory flexibility analyses for those rules should reflect FRFAs.

The RISC data indicated that four departments and agencies—DOC, HHS, FCC, and SEC—accounted for more than 54 percent of the Unified Agenda entries during this period in which the agencies indicated a regulatory flexibility analysis was required. The Unified Agenda entries for DOC were only from the National Oceanic and Atmospheric Administration (NOAA). DOC officials told us that, in general, only two agencies within the department regulate the activities of small entities—NOAA and the Bureau of Export Administration. However, they said that the Bureau of Export Administration’s regulations are not subject to the notice and comment provisions of the APA or any other law because the regulations relate to military and foreign affairs functions, and are therefore exempt from the requirements of the RFA. As a result, our review within DOC focused solely on NOAA. The Unified Agenda entries for HHS were almost all from FDA and CMS, so we considered them separate agencies for purposes of our review. We included EPA in our review at the suggestion of the requester.

We also used the Unified Agenda data to address the first part of objective one—to identify each final rule published by the selected agencies in calendar years 1999 and 2000 that appeared to be covered by the requirements of section 212. If the agency indicated in the Unified Agenda that a regulatory flexibility analysis was required for a completed action, and if the action was a final rule that was published during 1999 or 2000, we tentatively considered it a covered rule. We also did a Lexis/Nexis search to identify any additional final rules for which a FRFA appeared to have been prepared, and obtained a copy of each final rule identified through either the Unified Agenda or Lexis/Nexis to confirm that a FRFA had been prepared and that the rule had been published during the specified time frame. In developing our lists of covered rules, we consulted with staff in SBA’s Office of Advocacy. We then met with officials in the selected agencies, shared our tentative lists of covered rules, and asked the officials to add to or subtract from the lists as they believed appropriate. We accepted any final rule that the agencies indicated was covered as long as it was published during 1999 or 2000 and had an NPRM. We also asked the agencies to provide copies of any small entity compliance guides that they had produced for each covered rule. Finally, we used a GAO database to identify the total number of final rules

and substantive and significant final rules that each agency issued during the covered time frames.¹⁰

Some of the rules that the agencies said were covered by section 212 did not appear to have compliance requirements. Therefore, to determine whether the documents provided for each covered rule met the compliance guide requirements in section 212, we focused our analysis on those rules that appeared to have compliance elements. We examined the documents that the agencies provided for each such rule and determined whether each document met the three requirements in section 212: (1) the agency shall designate such publications as “small entity compliance guides,” (2) the agency shall publish the guide, and (3) the guides shall explain the actions a small entity is required to take to comply with a rule or group of rules. Because key terms in these requirements are not defined in the act, we developed working definitions of those terms.

- We considered a document to be “designated” as a small entity compliance guide if it (1) was entitled “small entity compliance guide” or (2) had been otherwise designated by the agency (e.g., a statement by the agency in the document or elsewhere that the guide was prepared pursuant to section 212 and/or satisfies that section’s requirements).
- We considered a compliance guide to be “published” if it was a written document that was either provided directly to all affected small entities or otherwise made available to all affected small entities (e.g., via the internet).
- We considered a document to have “explained” the actions that small entities are required to take to comply with the related rule if it contained at least some discussion of the rule’s requirements. General background information about a rule or a program would not meet the standard.

¹⁰The Unified Agenda defines a significant rulemaking action as one that the agency anticipates will be reviewed under Executive Order 12866 as well as other rules that are considered important and a priority by the agency head. The executive order defines a significant rule in a number of ways, including rules that have an annual effect on the economy of \$100 million or more, that create a serious inconsistency with an action planned by another agency, or that raise novel legal or policy issues. The Unified Agenda defines a substantive action as one that has substantive impacts but the magnitude of the impact is less than significant. GAO maintains a regulatory database pursuant to its responsibilities under section 801(a)(2)(A) of title 5, United States Code.

We interviewed agency officials in each of the selected agencies to address our second and third objectives of describing how the agencies developed the guides and made them available to small entities. Specifically, we asked what guidance the agencies had developed regarding section 212, what entities within the agencies were primarily responsible for the development and/or review of the guides, and the general procedures that were followed in the preparation and dissemination of the materials developed. We also reviewed any written materials that the agencies provided on these subjects, searched the agencies' web sites for relevant documents, and reviewed some of the guides provided for covered rules in the first objective to identify trends in their development and publication.

This review focused on six selected agencies and cannot be used to characterize implementation practices of section 212 of SBREFA in other agencies. In fact, five of the six agencies in our review (all except EPA) were selected because they appeared to prepare more FRFAs than other federal agencies. Therefore, in that respect, they may be among the best federal agencies in terms of RFA implementation. We focused on these agencies because the trigger for the implementation of section 212 is the publication of a rule that requires a FRFA. Furthermore, we believe these six federal agencies can illustrate any variation in the implementation of section 212 among other agencies.

We generally did not validate the reliability of the information that agencies provided, and we generally did not evaluate the appropriateness of agency decisions of what is a covered rule under section 212. However, during our review we discovered several errors in the information that agencies provided to RISC for the Unified Agenda, and notified RISC of those errors.¹¹ RISC, in turn, notified federal agencies of our concern. Also, our questioning of the agencies' initial determinations of covered section 212 rules led to some modifications of their initial determinations. This report discusses the implementation of the specific requirement in SBREFA that agencies publish small entity compliance guides; it does not discuss the extent to which small entities use those guides or how useful the guides are to small entities that access them. We conducted our work between May 1, 2001, and September 1, 2001, at the headquarters offices of EPA, FCC, FDA, CMS, NOAA, and SEC in accordance with generally accepted government auditing standards.

¹¹*Accuracy of Information in the Unified Agenda* (GAO-01-1024R, July 27, 2001).

We provided a draft of this report to the Secretaries of Commerce and HHS, the Commissioners of FCC and SEC, and the Administrator of EPA for their review and comment. The comments that we received are reflected in the “Agency Comments and Our Evaluation” section and in appendixes I-III of this report.

Agencies Did Not Develop Compliance Guides for Some Covered Rules

The agencies varied in the type of rules they believed required a FRFA and, therefore, a section 212 small entity compliance guide. EPA established a high threshold for when a FRFA was required, and therefore certified all but 5 of the agency’s more than 1,000 final rules published in the target years. FCC and SEC, on the other hand, established a much lower threshold, preparing FRFAs for rules that had little or no effect on small entities or that only had positive economic effects. None of the agencies provided us with guidance documents that met all of the statutory requirements for all of their covered rules. In explanation, the agencies said that the compliance requirements for some of the rules without guides had not taken effect, some of those requirements were clear without compliance guides, and some of the rules did not contain compliance requirements applicable to small entities. The guidance documents that the agencies provided for rules with compliance requirements varied in the degree to which they met the requirements in the statute. Few of the documents provided were designated as small entity compliance guides, many did not explain what small entities had to do to comply, and some were not published.

Agencies Defined “Covered Rule” Differently

The first step in determining whether the selected agencies had published small entity compliance guides for each covered rule was identifying the covered rules in each agency. Section 212 of SBREFA states that a compliance guide must be published for each rule or group of related rules that require a FRFA. The RFA (5 U.S.C. 604) generally requires agencies to prepare a FRFA for all final rules for which they are required to prepare an NPRM. However, the act (5 U.S.C. 605(b)) gives agencies broad discretion in determining which rules they can certify as not requiring a FRFA because they will not have a significant impact on small entities. Because section 212 was built upon the RFA and is triggered by the preparation of a FRFA, the same broad discretion applies to the compliance guide requirement.

The six agencies in our review have very different views regarding the type of rules that required the preparation of a FRFA and, therefore, the development of a small entity compliance guide.

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- FCC and SEC have established a relatively low threshold for what rules required a FRFA, resulting in the preparation of FRFAs for many of their rules. For example, in response to our inquiry, SEC provided us with a list of covered rules published in 1999 and 2000 that included not only rules that the agency believed may have a significant impact on small entities (six rules), but also rules whose primary impact was on large or foreign entities (six rules), rules that were primarily deregulatory or permit voluntary cooperation (eight rules), and rules that were expected to have little or no impact on a substantial number of small entities (seven rules). SEC officials pointed out that the language in the RFA is “permissive” in nature, allowing (but not requiring) agencies to certify rules out of the FRFA process. Therefore, they said, if SEC elects not to certify a rule, the agency is technically required to prepare a FRFA and a section 212 compliance guide. FCC officials said their agency takes a somewhat similar position, electing to prepare a FRFA for rules that have minimal adverse or even positive impacts on small entities—even when certification was possible. A January 1998 internal memo prepared by the agency’s Office of Communications Business Opportunities says that agency staff should prepare a FRFA for every final rule that requires notice and comment that is not certified. The memo states that there is “no case law that identifies the ‘trigger’ level of ‘significant economic impact’ or ‘substantial number of small entities,’” but notes SBA’s Office of Advocacy advises that an analysis should be prepared whenever the rule’s impact cannot be described as de minimis.
 - In contrast to the policies in place at FCC and SEC, EPA has established a relatively high threshold for which of its rules require a FRFA. Although the agency’s guidance on the RFA and SBREFA gives agency staff substantial discretion in determining whether a rule is eligible for certification, it also provides numerical guidelines using different mixes of economic impacts and the number and percent of affected small entities to help them make that determination. For example, the guidelines indicate that EPA staff should prepare a FRFA for any final rule that imposes compliance costs amounting to 3 percent of annual revenues on 1,000 or more small entities. On the other hand, the guidelines indicate that EPA staff can presume a rule is eligible for certification if it imposes compliance costs of less than 1 percent of annual revenues on any number of small entities. Therefore, if a rule imposes \$10,000 in compliance costs on 10,000 small businesses, the guidelines indicate that EPA staff can presume that the rule does not have a significant impact on small entities

and certify it as long as those costs do not represent at least 1 percent of the businesses' annual revenues.¹²

- NOAA's policy on when agency employees should prepare a FRFA changed during the period covered by our review. Until August 2000, NOAA had what appeared to be a relatively high FRFA threshold. Under that policy, NOAA considered a substantial number of small entities to be more than 20 percent of the industry, and said a rule should be considered to have a significant economic effect if it is likely to (1) reduce gross revenues by more than 5 percent, (2) increase total production costs by more than 5 percent, (3) cause small entities to incur compliance costs 10 percent higher than compliance costs of large entities, or (4) cause 2 percent of small entities to cease business operations. However, in August 2000, NOAA established less numerically driven guidelines for making RFA determinations. Those guidelines delineate two general criteria to consider in determining the significance of regulatory impacts—disproportionality and profitability. Specifically, the guidelines state that a rule should not be certified if it places a substantial number of small entities at a significant competitive disadvantage in relation to large entities, or if the rule significantly reduces the profitability of a substantial number of small entities. They indicate that the term “substantial number” depends on the context, but generally means “more than just a few.” The guidelines describe the significance of profit reduction in terms of the affected firms' ability to meet both short-term and long-term obligations. If the costs or reductions in revenue imposed by the regulation cannot be absorbed by the firm or passed on to its customers, the guidelines indicate that the agency should not certify the rule.
- FDA officials told us that the agency has no formal definition or generally accepted numerical criteria regarding what rules require a FRFA. However, they indicated that, in practice, the agency generally uses a relatively low FRFA threshold. When in doubt, the officials indicated that FDA staff will err on the side of doing an analysis.
- CMS officials did not provide us with a clear definition of what the agency considers a covered rule. One CMS official told us that because most of the entities affected by the agency's rules were small, the agency

¹²See *Regulatory Flexibility Act: Implementation in EPA Program Offices and Proposed Lead Rule* (GAO/GGD-00-193, Sept. 20, 2000). As detailed in that report, until SBREFA was enacted in 1996, EPA had established a very low FRFA threshold, preparing the analysis for rules that had any impact on any small entities.

considered every “economically significant” rule (e.g., those with a \$100 million impact on the economy) to have a significant impact on small entities, and therefore to require a FRFA.¹³ However, CMS prepared FRFAs for some rules that were not economically significant, and certified some rules that were economically significant as not having a significant impact on small entities. In several of the agency’s 1999 and 2000 covered rules, CMS said that it considered all hospitals to be small entities, and considered a small entity in the health care sector to be one with less than \$5 million in annual revenues.

One area in which several of the agencies clearly differed was whether they should prepare a FRFA (and therefore a compliance guide) for a rule that is expected to have a significant positive economic impact on a substantial number of small entities. As previously noted, many of the rules for which FCC and SEC prepared a FRFA were deregulatory in nature, permitting small entities to take actions that they were previously not permitted to take. However, EPA officials said that they did not believe that a FRFA was required when rules are deregulatory and/or have positive economic effects, pointing out that the RFA requires an agency to describe steps it has taken to minimize the impact of the rule on small entities. Why, they asked, should an agency take steps to minimize a positive economic impact on small entities? SBA’s Office of Advocacy’s implementation guide to the RFA states that “Congress apparently considered the term ‘significant’ neutral with respect to whether the impact benefits or harms small businesses, therefore suggesting the need to consider both in an analysis.” However, SBA also notes that “[s]everal agencies have taken issue with the Office of Advocacy’s interpretation of significant economic impact.”

Several of the agencies also differed in whether preparation of a “voluntary” FRFA—i.e., an analysis for a rule that the agency could have certified as not having a significant impact on small entities—triggers the requirement for a section 212 small entity compliance guide. Some officials indicated that their agencies may prepare these voluntary FRFAs to help ensure that the rule won’t be overturned via judicial review and/or to provide greater transparency of the rulemaking process. Both FCC and

¹³The Unified Agenda, referencing Executive Order 12866, defines an economically significant regulatory action as one that “may have an annual effect on the economy of \$100 million or more or will adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities.”

SEC officials viewed these voluntary FRFAs as triggering the requirements of section 212. However, NOAA officials said that voluntary FRFAs do not trigger the requirements of section 212 because the rules do not technically “require” the preparation of a FRFA. There were also differences within one of the agencies with regard to this issue. FDA officials said that in the Center for Food Safety and Applied Nutrition, the preparation of a voluntary FRFA triggers the requirement for a section 212 compliance guide. However, they said that in other FDA centers the preparation of a voluntary FRFA would not trigger section 212.

Agencies Said Many of Their Final Rules Did Not Require Compliance Guides

As table 1 illustrates, the agencies varied widely in the number of their rules that they considered covered by the section 212 compliance guide requirement. The first column in table 1 shows the number of final rules that each selected agency published in the *Federal Register* during calendar years 1999 and 2000. However, some agencies produce a large number of routine or administrative rules that may have little or no effect on small entities.¹⁴ There are no readily available and reliable data on how many of these agencies’ final rules affect small entities. Nevertheless, to provide some perspective, the second column of the table shows the number of final rules that the agencies published during the target years that were substantive or significant—and therefore more likely to have a significant impact on small entities. Finally, the third column shows the number of final rules that the agencies said required a small entity compliance guide under section 212 of SBREFA.

¹⁴The Unified Agenda indicates that “routine and frequent” rules represent recurring applications of a regulatory program and do not alter the body of the regulation. Informational or administrative rules pertain to matters not central to the agency’s regulatory mandate, but inform the public of the actions taken.

Table 1: Number of Final Rules Published in Calendar Years 1999 and 2000 That Agencies Considered Covered by Section 212 of SBREFA

| Agency | Number of final rules published | Number of substantive/significant final rules published | Number of final rules agencies considered covered by section 212 of SBREFA |
|---------------|--|--|---|
| DOC/NOAA | 559 | 176 | 51 |
| HHS/FDA | 222 | 45 | 10 |
| HHS/CMS | 51 | 32 | 8 |
| EPA | 1183 | 100 | 5 |
| FCC | 481 | 121 | 128 |
| SEC | 46 | 35 | 27 |

Source: GAO rules database (final rules and substantive/significant rules) and agency officials (covered rules).

The reasons why the agencies did not consider some of their rules covered by section 212 can be traced back to the requirements in the RFA. For example, some of the rules that the agencies published were interim or direct final rules. Because these rules were published without an NPRM, the issuing agencies were not required to prepare a FRFA. Consequently, because a FRFA was not required, section 212 did not apply to the rules.

Also, the extent to which the agencies considered their rules to be covered varied in direct proportion to the agencies' policies regarding when a FRFA should be prepared. For example, EPA (which established a high threshold for when rules require a FRFA) considered a much smaller proportion of both its final rules and its substantive final rules as requiring compliance guides than any of the other agencies.¹⁵ In contrast, FCC and SEC (which established relatively low FRFA thresholds) considered a substantial portion of their final rules to be covered by the section 212 requirement.

In some cases, only certain components of the selected agencies published rules that they considered covered by section 212. As previously noted,

¹⁵Strict adherence to the numerical guidelines in EPA's guidance document would have resulted in even fewer covered rules. For example, in its December 22, 2000, centralized waste treatment final rule (65 *Fed. Reg.* 81242), EPA estimated that 53 small companies would experience compliance costs amounting to more than 1 percent of sales, and 30 would experience costs of greater than 3 percent of sales. Although EPA could have certified the rule (because fewer than 100 small entities would experience these effects), it elected to use the discretion permitted in the guidance and prepare a compliance guide.

DOC officials said that the only agency within the department whose rules typically could require a FRFA was NOAA. Within NOAA, only the National Marine Fisheries Service (NMFS) published final rules during 1999 and 2000 that the agency said required a FRFA (and thus a section 212 compliance guide). Similarly, within EPA, only two of the four major program offices (the Office of Air and Radiation and the Office of Water) published rules with a FRFA during the target years. The other two major program offices (the Office of Pollution, Pesticides and Toxic Substances and the Office of Solid Waste and Emergency Response) certified all of the hundreds of final rules that they published in 1999 and 2000 as not having a significant impact on small entities.

Agencies Had Difficulty Identifying Covered Rules

Some of the agencies had difficulty determining which of their previously published final rules were covered by section 212.

- In June 2001, we provided FCC with a list of 46 final rules that the agency had published during 1999 and 2000 and that we had tentatively identified as covered by the requirements of section 212. In July 2001, FCC officials indicated that they did not believe 5 of the rules on our list were subject to section 212, thereby reducing the list to 41 rules. In early August 2001, FCC officials compiled a more comprehensive list of 142 rules that they believed were covered, reinstating some of the rules that they had previously eliminated. Later in August 2001, after consultations with us, FCC officials removed 14 rules from the covered rule list. In total, FCC officials changed their minds on at least 18 rules, sometimes two or more times.
- CMS officials were also unsure which of their rules published during the target period were covered by the compliance guide requirement. One agency official initially said that section 212 applied to all of the agency's economically significant rules, but we pointed out that CMS had prepared FRFAs for some non-economically significant rules and had certified some economically significant rules as not having a significant impact on small entities. The official then identified 91 CMS rules as covered, but some of the listed rules were published after 2000, some had been certified, some had no NPRM, and some were not even final rules. After we discussed the problems concerning the list of rules, the official agreed that eight of the rules on the list appeared to be covered by section 212.
- SEC officials initially said that 24 of the agency's final rules published in 1999 and 2000 were covered by section 212, but later amended the total to 27 rules.

Agencies Did Not Provide Guidance Documents for Some Covered Rules

We asked agency officials in each of the agencies to provide copies of any small entity compliance guides that they developed for each rule they considered covered by section 212 of SBREFA. As table 2 shows, by the end of our audit work, most of the agencies provided at least one guidance document (and sometimes numerous documents) for most of the covered rules. However, only the SEC provided documents for all of the agency’s covered rules.

Table 2: Number of Covered Rules for Which Agencies Provided Guidance Documents and Number of Documents Provided

| Agency | Number of final rules considered covered by section 212 of SBREFA | Number of covered rules for which agencies provided at least one guidance document | Number of guidance documents provided for all covered rules |
|---------------|---|--|---|
| DOC/NOAA/NMFS | 51 | 44 | 52 |
| HHS/FDA | 10 | 2 | 2 |
| HHS/CMS | 8 | 0 | 0 |
| EPA | 5 | 3 | 3 |
| FCC | 128 | 125 | 407 |
| SEC | 27 | 27 | 95 |

Note: After our audit work was completed, CMS provided copies of instructions issued to Medicare contractors. An agency official said that these contractors repackage the information for inclusion in their provider bulletins. Also, on September 25, 2001, FDA published a third small entity compliance guide covering the agency’s January 6, 2000, final rule on dietary supplements (65 *Fed. Reg.* 1000)—after our audit work was completed.

Source: GAO analysis of agency submissions.

We asked officials in the agencies why compliance guides were not available for certain covered rules, some of which were published more than 2 years earlier. In some cases, the officials said that guides were not yet necessary because the rules’ compliance requirements had still not taken effect. For example, EPA officials said that compliance guides for two of the agency’s five covered rules were not yet needed because the rules’ requirements did not take effect until 2003 and 2004.¹⁶ Similarly, FDA officials said that the compliance date for its March 1999 labeling rule had been extended to May 2003 for small entities, therefore extending the date

¹⁶The compliance requirements for “Control of Air Pollution from New Motor Vehicles: Tier 2 Motor Vehicle Emissions Standards and Gasoline Sulfur Control Requirements” (65 *Fed. Reg.* 6698 (Feb. 10, 2000)) do not occur until 2004. The requirements for “National Primary Drinking Water Regulations; Radionuclides” (65 *Fed. Reg.* 76708 (Dec. 7, 2000)) take effect in 2003.

by which a small entity compliance guide was needed for this rule as well as three other related rules.¹⁷ In addition, FDA officials pointed out that many of the provisions in the agency's December 1999 rule on prescription drug marketing do not take effect until April 1, 2002.¹⁸

In other cases, the agencies indicated that compliance guides might not be needed for certain rules because their compliance requirements were obvious. For example, NMFS officials said that some of their covered rules were very straightforward (e.g., banning fishing within a particular geographic area, or prohibiting the use of certain types of fishing gear). In those cases, they said, it was unclear what more a compliance guide could do to explain what small entities must do to comply with the rule.¹⁹ Similarly, FDA officials said that the actions required for three of the agency's covered rules were "unambiguously clear." For example, the officials said that FDA's August 2000 topical antifungal rule merely added the word "most" to the indications on the label for these products.²⁰ As a result, the label now is required to say "cures most athlete's foot" instead of "cures athlete's foot."

Although EPA had prepared or was in the process of preparing a compliance guide for each of its covered rules, an EPA official also told us that it was not clear that a small entity compliance guide was useful or necessary for every rule that requires a FRFA. In some cases, the official said, the regulated community is well aware of how to comply with the rule, and the guide is just a restatement of current industry practices. In other cases, the official said the rule simply bans a particular activity, and a guide explaining the ban is unnecessary. For example, one part of EPA's class V injection well rule prohibited the development of new wells.²¹ The

¹⁷For the final rule, see 64 *Fed. Reg.* 13254 (March 19, 1999). For the extension in the compliance date, see 65 *Fed. Reg.* 38191 (June 20, 2000).

¹⁸See 64 *Fed. Reg.* 67720 (Dec. 3, 1999). FDA said the compliance guide for this rule is currently scheduled for publication in December 2001.

¹⁹However, in some straightforward rules, NMFS developed brief guidance materials. For example, NMFS developed a one-page guidance document for a January 27, 1999, rule prohibiting the use of driftnets in Atlantic swordfish fishery (64 *Fed. Reg.* 4055). The document was sent to permit holders, indicated that NMFS had issued the rule, and said "no vessel with a driftnet on board may retain a swordfish."

²⁰See 65 *Fed. Reg.* 52302 (Aug. 29, 2000).

²¹See 64 *Fed. Reg.* 68546 (Dec. 7, 1999).

official said that it was not clear what additional guidance was needed with regard to this type of prohibition.

Other agencies indicated that compliance guides were not appropriate or necessary for some of their covered rules because the rules had no compliance requirements applicable to small entities. For example:

- One CMS official said that four of the agency’s eight covered rules were “rate setting” rules, establishing the rates that CMS would pay for particular services under the Medicare program. For example, a November 2000 rule published revisions to the Medicare physician fee payment schedule for calendar year 2001.²² The official said it was illogical to require CMS to prepare a compliance guide for rules that did not have compliance requirements applicable to small entities.
- At least six of the NMFS covered rules appeared to have no compliance requirements applicable to small entities. For example, the agency stated in one rule that it “has no specific requirements for regulatory compliance; it essentially sets an enforceable performance standard (do not take listed fish) that applies to all entities and individuals.”²³ In another rule, NMFS said that it only established year-long quotas for the purpose of closing for certain types of fish in the northeastern United States, and “does not establish any requirements for which a regulated entity must come into compliance.”²⁴
- Nine of the SEC covered rules appeared to have no compliance requirements applicable to small entities. Five of these nine rules primarily affected large entities (e.g., national security exchanges) or foreign entities (e.g., foreign issuers of securities). Two other rules without compliance requirements were deregulatory in nature or permitted voluntary cooperation. SEC said that the two remaining rules without compliance requirements had little or no impact on small entities. For example, one of the rules amended SEC’s Freedom of Information Act and Privacy Act rules to conform to current statutes, case law, and administrative practice, and, according to SEC, “will not impose any additional reporting,

²²See 65 *Fed. Reg.* 65376 (Nov. 1, 2000).

²³See 65 *Fed. Reg.* 42422, 42473 (July 10, 2000).

²⁴See 64 *Fed. Reg.* 1139, 1141 (Jan. 8, 1999).

recordkeeping, or other compliance requirements.”²⁵

- Fifty-eight of the FCC rules did not appear to have compliance requirements applicable to small entities. For example, FCC stated in the FRFA summary for one of its rules that it “merely clarifies an existing requirement imposed on accounting authorities. It, therefore, does not alter the reporting, recordkeeping or other compliance requirements of certified accounting authorities in the maritime mobile, maritime mobile satellite, aeronautical and other satellite-based radio services.”²⁶

In some cases, the agencies offered other explanations for why compliance guides had not been prepared for covered rules. For example, FDA officials said that, as of September 1, 2001, a compliance guide for its January 2000 final rule on dietary supplements had been drafted and was being reviewed.²⁷ The rule took effect in February 2000. The officials said that resource constraints and other priorities had prevented the preparation of the guide prior to its effective date.

Guidance Documents Provided for Most Covered Rules Did Not Meet All of the Requirements in Section 212

Section 212 gives the agencies broad discretion with regard to the development and content of the required compliance guides. For example, it says that the agency “may” prepare separate guides for groups of similarly affected small entities, and “may” cooperate with associations of small entities in the development and distribution of the guides. However, section 212 does contain three requirements: (1) the agency must “publish” the guides, (2) the agency must “designate” the publications as “small entity compliance guides,” and (3) the guides must “explain the actions a small entity is required to take to comply with a rule or group of rules.” The section does not specify how the agencies should “publish,” “designate,” or “explain” the actions required.

We initially intended to examine each of the guidance documents that the agencies provided to us for each of the identified covered rules in terms of these three statutory requirements. However, as previously noted, some of the agencies’ covered rules had no compliance requirements applicable to

²⁵See 65 *Fed. Reg.* 55180 (Sept. 13, 2000).

²⁶See 64 *Fed. Reg.* 40774 (July 28, 1999).

²⁷As previously noted, a compliance guide was issued for this rule after our audit work was completed.

small entities. Because it seemed inappropriate to include these types of rules in this part of our review, we focused our analysis on the rules that explicitly had compliance requirements applicable to at least some small entities. For each such rule, we determined whether the guidance documents provided to us by the agency:

- had been “designated” as small entity compliance guides (i.e., had been entitled as such, or had been otherwise “designated” by the agency [such as a statement by the agency in the document or elsewhere that a guide was prepared pursuant to section 212 or satisfies its requirements]);
- had been “published” (i.e., was a written document that was either provided directly to all affected small entities or otherwise made available to all affected small entities); and
- explained the actions a small entity (or anyone else) had to do to comply with the rule or group of related rules. We considered any substantive discussion of the rules’ requirements to meet the standard.

Table 3 presents the results of our analysis. Overall, the six agencies provided at least one guidance document during our review that met all three requirements in section 212 of SBREFA for 21 (about 14 percent) of their 153 covered rules with compliance requirements. The documents for 76 of these rules (about 50 percent) were not designated as small entity compliance guides, but otherwise met the statutory requirements.

Table 3: Number of Covered Rules With Compliance Requirements Whose Related Documents Met Section 212 Requirements

| Agency | Number of covered rules published in calendar years 1999 and 2000 | Number of rules with small entity compliance requirements | Number of rules with compliance requirements for which agencies provided at least one guidance document | Number of rules with compliance requirements for which at least one document met all three requirements in section 212 | Number of rules with documents that were not “designated” but met other requirements in section 212 |
|---------------|--|--|--|---|--|
| DOC/NOAA/NMFS | 51 | 46 | 44 | 15 | 25 |
| HHS/FDA | 10 | 10 | 2 | 2 | 0 |
| HHS/CMS | 8 | 4 | 0 | 0 | 0 |
| EPA | 5 | 5 | 3 | 3 | 0 |
| FCC | 128 | 70 | 70 | 0 | 38 |
| SEC | 27 | 18 | 18 | 1 | 13 |
| Total | 229 | 153 | 137 | 21 | 76 |

Note: After our audit work was completed, FCC developed a page on the agency’s Office of Communications and Business Opportunity web site that listed the internet locations of the guidance documents the agency identified to us as their small entity compliance guides for the agency’s covered rules published in 1999 and 2000. On that page, FCC said it had “designated the following educational materials to be “small entity compliance guides” under (SBREFA).” See www.fcc.gov/ocbo/guides.pdf.

Source: GAO analysis of agency submissions.

The table also illustrates that the agencies varied in the extent to which the guidance documents met the three statutory requirements. All three of the documents that EPA provided for three of its five covered rules with compliance requirements appeared to meet all three statutory criteria. Each EPA document was published on the agency’s SBREFA web site (www.epa.gov/sbrefa), each was entitled “small entity compliance guide,” and each described in great detail the steps that small entities and others had to take to comply with the rules’ requirements. Similarly, the guidance documents for 2 of FDA’s 10 covered rules with compliance requirements, although much less detailed than those developed by EPA, also appeared to meet all of the statutory requirements. In contrast, none of the more than 200 FCC guidance documents that the agency provided for 70 covered rules with compliance requirements appeared to meet all of the statutory criteria. The documents for 38 of these rules were not designated as small entity compliance guides, but otherwise met the statutory requirements. The documents for another 32 FCC rules appeared to be deficient in other ways (i.e., were not published and/or did not explain the compliance actions required). The documents that SEC provided were only somewhat more likely to meet the statutory criteria. SEC provided nearly 70 guidance documents for its 18 covered rules with compliance requirements, but the documents for only 1 of the 18 rules appeared to

meet all of the statutory requirements. On the other hand, the documents for 13 of the 18 SEC rules were published and explained what small entities had to do to comply with the related rule. We concluded that the documents for 15 of the 46 NMFS covered rules with compliance requirements met all of the requirements. However, the documents for most of the remaining NMFS rules were published and explained compliance requirements.

Designation

Many of the guidance documents we received from some agencies were not “designated” as small entity compliance guides. They often were not entitled as such, did not reference section 212 or SBREFA, and were not otherwise designated by the agencies. They also often appeared to be generic documents that generally related to the overall topic of the rules, but did not mention the rules specifically and/or were not directed at small entities or any individuals or organizations subject to the rules’ requirements. For example:

- More than 90 of the undesignated documents that FCC provided were news releases, public notices, consumer facts, or consumer information notices. Nine documents were notices or agendas for upcoming meetings or events. Some of the documents did not mention the rule for which FCC associated them as compliance guides, some bore no relation to the rule, and some were published weeks or even months in advance of the rule.
- Many of the undesignated documents that SEC provided were general fact sheets, media briefings, press releases, standard application forms and instructions, speeches, and staff legal bulletins. As was the case with the FCC rules, many of the SEC documents did not mention the associated final rules, and some were published in advance of the rules.
- Some of the documents that NMFS provided were also not designated as small entity compliance guides. NMFS officials noted that most of the entities affected by the agency’s rules are small businesses, and some of those businesses may consider the term “small entity compliance guide” to be derogatory in that they do not consider themselves small.

Publication

Most of the documents that the agencies provided for the covered rules were, in some sense, “published.” For example, all of the EPA and FDA compliance documents, and most of the SEC and FCC documents, had been published on the agencies’ web sites. Many of the documents that NMFS identified as compliance guides were published in the preamble to the final rule or were mailed to all affected entities. However, a few of the

documents that the agencies provided did not appear to have been published in any form.

- SEC provided us with letters about an August 1999 rule involving the Year 2000 problem that were sent to the heads of federal banking regulators. However, there was no indication that these letters were sent to organizations that were affected by the rule. Also, one of the documents that SEC provided for a March 1999 rule revising a part of Regulation D was entitled “4 Town Hall meetings in Seattle, Kansas City.” However, SEC did not indicate that any documents related to these meetings were prepared, much less published.
- Several of the documents that FCC provided to us were forms or application materials. However, FCC did not indicate whether any of these documents were published or were otherwise sent to or made available to all small entities.

Explanation

Most notably, however, many of the documents provided by certain agencies did not accomplish the basic task that is contemplated by section 212 of SBREFA—i.e., explain the actions that small entities had to take to comply with the rules’ requirements.

- The guidance documents that FCC provided for 31 of its 70 covered rules with compliance requirements (136 of the 210 documents) did not explain the compliance actions required. The documents for many of these rules were the previously mentioned public notices, fact sheets, and consumer information bulletins as well as notices of upcoming meetings, workshops, or other events. In some cases, the documents provided did not directly apply to the covered rule. For example, FCC gave us three guidance documents for its October 1999 rule on telecommunications carriers’ use of customer proprietary network information.²⁸ However, all three documents were published before the rule was published, and two were notices of meetings involving different but related rules. None of the three documents explained what actions small entities had to take to comply with the covered rule.
- The documents that NMFBS gave us for several covered rules did not explain small entities’ compliance requirements. As was the case with FCC, some of these documents did not directly relate to the final rules. For

²⁸See 64 *Fed. Reg.* 53944 (Oct. 5, 1999).

example, NMFS provided us with a June 1999 fishery bulletin that agency officials described as the compliance guide for a November 1999 rule on coral reef resources of Puerto Rico and the U.S. Virgin Islands.²⁹ The bulletin predated the final rule by 5 months, and was a request for comments on the proposed rule, not the final rule.

- The guidance documents provided for 5 of the 18 SEC covered rules with compliance requirements did not adequately explain the actions that affected entities were required to take. For example, although the guidance document provided for a November 2000 rule on the delivery of proxy statements and information statements to households contained a brief general description of the scope and content of the rule, it did not identify what actions affected entities needed to take to satisfy the rule's requirements.³⁰

Agencies Varied in Development, Timing, and Distribution of Compliance Guides

Section 212 generally does not require agencies to develop or distribute the small entity compliance guides in any particular way or at any particular time. Although the statute says agencies "may cooperate with associations of small entities to develop and distribute such guides," it does not require them to do so. The responsibility for developing the guides was decentralized in most of the agencies in our review, and some of the agencies developed their guides without substantial input from small entity representatives. The timing of the documents varied, with some published before the final rule was issued and others not published until after the rules took effect. The agencies generally used the same procedures to ensure that their guides were written in plain language as they had for their other regulatory materials, but the agencies varied in how they publicized and distributed the guides they developed.

Agencies' Section 212 Guidance Varies

In order to determine how the selected agencies' small entity compliance guides were developed, we asked officials in each agency whether any section 212 guidance or procedures had been developed. The guidance that they identified varies in terms of its specificity, accuracy, completeness, and availability. EPA's guidance is the most detailed, and is located in chapter 5 of the agency's March 1999 revised interim guidance on the RFA and SBREFA. (A copy of this document is available at

²⁹See 64 *Fed. Reg.* 60132 (Nov. 4, 1999).

³⁰See 65 *Fed. Reg.* 65736 (Nov. 2, 2000).

www.epa.gov/sbrefa.) The guidance includes sections describing, among other things, what individuals and organizations should participate in the development of the compliance guides, when the guide should be developed, and questions to ask reviewers. The guidance also includes a template developed by an agency workgroup to help EPA staff in developing the guides, including standard language within certain sections that they can use. Suggested standard headings and subheadings for the guides include “who should use this guide,” “how do I obtain a complete copy of the rule,” “how can I tell if I am subject to this rule,” “when do I need to comply,” and “what do I need to do to comply.”

FDA’s guidance on the preparation of small entity compliance guides is not as extensive as EPA’s guidance and is not available on the agency’s web site. The guidance includes a one-page question-and-answer document that briefly describes, among other things, when the guides are required and the legal consequences of failing to issue a guide. The guidance also includes a one-page “Checklist For Small Entity Compliance Guides” that describes four “requirements” and four “optional” features. However, two of the listed requirements—that the guides be “written in sufficiently plain language that it is likely to be understood by affected small entities” and that they will be “available at the time of publication of the final rule”—are not imposed by section 212 of SBREFA.

Other agencies prepared guidance on section 212 that is even less detailed, or had no guidance at all. For example, NMFS officials said that their agency’s guidance on the statute is contained in the agency’s economic analysis guidelines. The relevant portion of those guidelines essentially repeats the statute, noting, for example, that compliance guides must be prepared when the agency is required to prepare a FRFA for a rule or group of related rules and must explain the actions a small entity is required to take to comply with the rule/rules. The guidelines do not specifically mention that the publications must be designated as small entity compliance guides.

Responsibility For Developing Guides Is Usually Given to Agency Rule Writers

The agencies in our review generally delegated the responsibility for developing small entity compliance guides to the bureau or office responsible for writing the associated rule. For example, EPA’s March 1999 guidance document states that “the lead rule-writing office is responsible for developing the rule-specific compliance guide as part of the rulemaking process.” However, the guidance indicates that numerous other offices (e.g., EPA’s Small Business Ombudsman, regional offices, and the Small Business Advocacy Chair’s staff) can also be called upon to

provide assistance and support, or to develop sections of the compliance guides. In addition, the EPA guidance says that the small entity compliance guides should be reviewed by the agency's Office of General Counsel and the Office of Enforcement and Compliance Assistance.

Officials in the other agencies indicated that they used similarly decentralized guidance development procedures. For example, FCC officials said the agency's bureaus and offices with rulemaking responsibilities develop compliance guide materials. These bureaus or offices determine the nature and level of additional guidance that small entities and the public need to understand and follow the rules. The materials developed are then subject to review at the highest levels of the bureaus or offices. FDA officials said that there is no single approach to developing the guides within the agency, with each of FDA's major centers (e.g., the Center for Food Safety and Applied Nutrition) given great flexibility for the development of small entity compliance guides under their jurisdiction. They said that responsibility for the preparation of the guide generally lies with the original rule writer within those centers. NMFS officials said that each of the service's regional offices has been granted the flexibility to determine their own practices for developing and publicizing the compliance guides. Within those regions, they said the Division of Sustainable Fisheries is primarily responsible for preparing the guides, working in coordination with the Regional Fishery Management Councils and Highly Migratory Species Division at NOAA Headquarters. Ultimately, though, the officials said the guides are developed during the preparation of the final rules by those working on the rules and related documents.

Small Entity Input to Guides Varied Across the Agencies

Section 212 says that agencies "may cooperate with associations of small entities to develop and distribute such guides," but does not require the involvement of small entities in either process. Some of the agencies indicated that they attempt to contact small entities during the development of their compliance guides, sending them drafts and obtaining comments before publication of the guides. For example, EPA's March 1999 guidance states that "[s]mall entity representatives should typically be involved in reviewing the draft compliance guide after the rule is promulgated so that we have the benefit of their comments and advice in preparing the final version of the guide." However, the guidance goes on to say that EPA staff "will need to balance such review with equal concern for timely issuance of the guide." In "unusual circumstances" in which the outline of the guide is clear before proposal, the guidance says that draft compliance guides can be released to small entity representatives prior to

the rule's promulgation. The EPA guidance suggests obtaining input from the small entity representatives who participated in the SBREFA advocacy review panel process during the development of the proposed rule,³¹ and asking such questions as whether the format of the guide is appropriate, whether the guide is clear and easy to read, and whether it accurately describes the rule as published.

EPA officials said that this outreach process was used in the development of the agency's three small entity compliance guides for the covered rules in our review. For one of the rules, EPA officials said they sent formal letters to 11 stakeholder groups soliciting their review and comment on a draft of the compliance guide, 3 or 4 of which responded. One of the groups that responded represented only small entities; the others represented entities of varying sizes, including small ones. On another rule, EPA officials said some small entity representatives were consulted that had been small entity representatives for the SBAR panel. Similarly, NMFS officials said that commercial and recreational groups (e.g., the Maine Lobstermen's Association and the Coastal Conservation Association) are consulted in the development of their guides.

However, some of the other agencies indicated that they did not directly involve small entities in the development of some of their guides. For example, FCC said that most of their compliance guide materials are written without the direct assistance of associations of small entities. However, they said that if small entities file comments in a specific rulemaking proceeding, those comments are taken into account in the preparation of the compliance guide materials. Similarly, FDA officials said that the Center for Food Safety and Applied Nutrition did not consult with small entities during the preparation of the two compliance guides. They said that the input the center had received during the process of developing the rules was sufficient, and additional clarification from small entities was not needed.

Timing of Guides' Publication Varied

Section 212 does not indicate when small entity compliance guides must be published. Although both FDA and EPA have indicated when their guides should be published, the agencies did not publish any of their guides within those timeframes.

³¹The advocacy review panel requirements in SBREFA were codified in 5 U.S.C. 609. For a description of the initial implementation of this requirement, see [GAO/GGD-98-36](#).

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- A checklist that FDA developed at the time SBREFA was passed states that a compliance guide “will be available at the time of publication of the final rule.” However, FDA did not publish compliance guides for any of the agency’s 10 covered final rules by their dates of publication. Notably, the compliance guides that FDA had published at the time of our review for 2 of the agency’s 10 covered rules were both published in July 2001—after we notified FDA that we were beginning our study.³² FDA officials said that the guides had been in development for some time, but their publication was accelerated because of our review.
 - EPA’s March 1999 guidance on the RFA and SBREFA states that agency staff should “make every effort to issue the guide within two months of the promulgation of the final rule.” However, all three of the compliance guides published at the time of our review were issued more than 2 months after the final rules were published. For example, EPA’s interstate ozone transport rule was published in May 1999, but the related compliance guide was not published until August 2000.³³ The agency’s class V injection wells rule was published in December 1999, but the compliance guide was not published until November 2000.³⁴ EPA officials also told us that guides for the other covered rules would not be published until more than 2 months after the rules were published.³⁵ For example, the agency’s tier II motor vehicle emissions rule was published in February 2000, but the small entity compliance guide for the rule is not expected to be published until March 2002.³⁶ The effective dates for four of the five EPA covered rules had passed by the time the related compliance guides were published. However, EPA officials pointed out that the compliance requirements for some of these rules do not take effect until well after the

³²The two rules were FDA’s March 16, 1999, food labeling rule (64 *Fed. Reg.* 12887), and December 5, 2000, shell egg labeling rule (65 *Fed. Reg.* 76092).

³³64 *Fed. Reg.* 28250 (May 25, 1999).

³⁴64 *Fed. Reg.* 68546 (Dec. 7, 1999).

³⁵Although not technically part of our review, EPA’s RFA/SBREFA tracking system indicated that one rule published by EPA’s Office of Prevention, Pesticides and Toxic Substances in August 1996 (prior to the period covered by our review) had a projected small entity compliance guide issuance date of October 2001—more than 5 years after the final rule was published.

³⁶65 *Fed. Reg.* 6698 (Feb. 10, 2000).

rules' effective dates. For example, the emission requirements in the tier II rule (with an effective date of April 2000) do not take effect until 2004.³⁷

The timing of the compliance guides for the covered rules published by the other agencies in our review varied markedly. Some of the documents that the agencies provided were published before the final rules were published—in some cases months or even years earlier. For example, one of the documents that FCC provided for its June 2000 final rule on competitive bidding in the narrowband personal communication services was a “Narrowband Fact Sheet” that was published more than 6 years before the rule was published.³⁸ In contrast, other documents that the agencies characterized as small entity compliance guides were not published until some time after the related rules took effect—sometimes months or even years later. For example, three of the documents that FCC characterized as compliance guides for its April 1999 final rule designed to promote competition in the advanced services market were public notices for the release of FCC Form 477 that were published between 1 and 2 years after the rule's June 1999 effective date.³⁹

Agencies Said Guides Used Plain Language

Section 212 gives the agencies broad discretion to ensure that their compliance guides are written in “plain language.” Officials in most of the agencies told us that they attempt to write all of their regulatory materials (e.g., the rules themselves, guidance documents, and other materials) in plain language. Several of the agencies cited a June 1, 1998, presidential memorandum entitled “Plain Language in Government Writing,” which requires that agencies use plain language in all documents that explain how to obtain a benefit or service or comply with a regulation. For example, FCC said that it adopted a five-step action plan to implement the plain language initiative, including training for FCC staff and identification of regulatory initiatives appropriate for plain language writing. Sometimes the agencies indicated that clarity in guidance is statutorily mandated. For example, FDA noted that the Food and Drug Administration Modernization Act of 1997 required the agency to amend its “good guidance practice” regulations to make the agency's procedures for development, issuance, and use of guidance documents clear to the public.

³⁷EPA delayed the implementation of this rule for small entities pursuant to the recommendation of the agency's small business advocacy review panel.

³⁸65 *Fed. Reg.* 35843 (June 6, 2000).

³⁹64 *Fed. Reg.* 23229 (Apr. 30, 1999).

EPA said that all of its guides were in “plain language” except for the guide prepared for engineers responsible for certifying non-road diesel engines. EPA said that although this guide was more technical than the others, the language was appropriate for the intended audience. In at least one of the rules (the motor vehicle waste rule), EPA used “readability” software and consulted with a plain language specialist. Also, reviewers from outside the agency (e.g., American Trucking Association) were asked for suggestions on how to use language the target audiences could understand.

DOC and NMFS officials told us that each rule writer and compliance guide reviewer is expected to pay attention to section 212’s plain language provisions. They noted that the guides are often drafted in a question-and-answer format that simplifies complicated regulatory text, and include illustrations when appropriate. Similarly, FDA officials said the two guides published at the time of our review were both developed by the Center for Food Safety and Applied Nutrition in a question-and-answer format to ensure readability. However, they emphasized that each center has the flexibility to take whatever steps they believe are necessary to achieve this goal.

Agencies Publicize/Distribute Guides in Various Ways

The agencies included in our review varied with regard to how their small entity compliance guides were publicized and distributed. EPA’s March 1999 guidance states that agency staff should provide copies of the compliance guides to staff of the Small Business Advocacy Chair; the Office of the Small Business Ombudsman; the Office of Regional and State/Local Relations; and the Office of Communications, Education and Public Affairs, who will distribute copies to their small entity contacts. In addition, the guidance says that the compliance guides should be included in the agency’s Enhanced Public Access system, which makes agency guidance documents related to statutory or regulatory requirements electronically available. All three of the compliance guides that have been published for the rules included in our review were available on EPA’s SBREFA web site. Otherwise, though, the specific methods by which EPA distributed the three compliance guides varied. EPA officials provided the following examples.

- Compliance guides for the centralized wastewater treatment rule were distributed to small entities at workshops (250 compact discs) and via e-mail prior to their availability on the agency’s web site.

-
- Compliance guides for the interstate ozone transport rule were sent to the agency's regional offices and cognizant state offices, and they were responsible for making copies available to affected small entities.
 - Compliance guides for the motor vehicle waste rule were provided to the agency's 10 regional offices, which distributed 8,000 copies to small entities, the small business ombudsman, and various industry associations (e.g., the American Trucking Association and the National Automobile Dealers Association). Some regions have provided special training on the rule and guide. At the time of our review, EPA was developing a video as another means of reaching affected small entities.

FCC officials said that the agency uses a number of mechanisms to publicize its compliance guides, most notably a web site maintained by FCC's Consumer Information Bureau (CIB). (See www.fcc.gov/cib.) CIB was established in 1999 and has overall responsibility for ensuring the public's understanding of and compliance with the Commission's regulatory requirements. A comprehensive listing of all FCC consumer documents and pertinent internet links for each document is available on this web site. FCC also said that each bureau and office of the FCC also "prominently" features compliance guide materials on their internet home pages.⁴⁰

SEC officials said that the processes they use to publicize and distribute the guides vary from rule to rule. They said available processes include media briefings, postings of "hot topics" to the agency's web site, mailings to affected small entities, and speeches at meetings and conferences. They said that if the compliance guide is in the preamble to the related rule, the *Federal Register* is the mode of distribution.

FDA officials said the agency generally publishes its designated small entity compliance guides on its web site and includes a notice of availability in the *Federal Register*. They indicated that additional distribution varies among FDA's five centers because of the diverse nature of the industries and small entities that each center regulates. For

⁴⁰As previously noted, after our audit work was completed FCC developed a page on the agency's Office of Communications and Business Opportunity web site that listed the internet locations of the guidance documents the agency identified to us as their small entity compliance guides for the agency's covered rules published in 1999 and 2000. On that page, FCC said it had "designated the following educational materials to be "small entity compliance guides" under (SBREFA)." See www.fcc.gov/ocbo/guides.pdf.

example, we were told that certain guides under development for rules to be issued by the Center for Drug Evaluation and Research will be distributed by electronic mail using an existing list serve database of small entities commonly impacted by the Center's regulations.

NMFS officials said that NOAA Fisheries and Councils keep a registry of all permit holders, industry groups, and interested parties. Using that information, they said compliance guides are generally mailed to all those to whom the rule will apply and to others who have expressed interest. They said the guides are also made available at sites frequently visited by constituents, such as docks, bait and tackle shops, and on web sites.⁴¹ However, our review indicated that NMFS practices with regard to the rules published in 1999 and 2000 varied by region within the agency. For example:

- The Alaska region included a "small entity compliance guide" section in the preamble of some of the final rules. The region usually took no other action to publicize or distribute these guides, relying on small entities and others to find them in the *Federal Register* notices. However, in one case a synopsis of the local area management plan for the halibut fishery in Sitka Sound was reduced to fit on a laminated card suitable for posting on fishing vessels.
- The guides developed for certain covered rules by the Northeast, Northwest, and Southwest regions were standard form letters provided to each holder of fishing permits in certain fisheries. For example, on December 6, 1999, the Northeast regional administrator sent a standard form letter to each permit holder containing a detailed summary of the "American Lobster Fishery Regulations."
- The Southeast region issued guides in the form of notices or bulletins containing a summary of the rule with the phone number, fax number, and e-mail address of an information contact. For example, a June 13, 2000, "Southeast Fishery Bulletin" announced the approval of a new rule prohibiting certain types of fishing in certain areas in the south Atlantic to protect and facilitate the recovery of *Oculina* coral.⁴²

⁴¹NMFS also noted other general outreach efforts, such as public information meetings about new regulations and distribution by NOAA special agents and officers of materials when they board vessels and visit fish dealers.

⁴²65 *Fed. Reg.* 37292 (June 14, 2000).

Conclusions

Section 212 does not appear to have had much of an impact in the agencies and years that we examined, and its implementation has varied across and sometimes within the agencies. Some of the statute's ineffectiveness and inconsistent implementation is traceable to previously identified concerns with the implementation of the RFA—the statute upon which the compliance guide requirement is based. Other concerns with and variations in the statute's implementation are traceable to section 212 itself.

The RFA gives agencies broad discretion to decide which of their rules require a FRFA, and therefore a compliance guide. For example, an agency can decide that there is “good cause” not to prepare an NPRM for a final rule, and thereby avoid having to prepare a FRFA or a compliance guide. If an NPRM was prepared, an agency can also avoid preparing a FRFA or a compliance guide by certifying that the final rule does not have a significant impact on small entities, with agencies allowed to determine when a rule reaches that threshold. Given this broad discretion, it is not surprising that the agencies in our review varied with regard to when a FRFA (and thus a small entity compliance guide) was required. For example, some of the agencies considered rules with a positive impact on small entities to trigger the requirements of the RFA and section 212; other agencies did not consider such rules to require a FRFA or a compliance guide. Some of the agencies indicated that preparation of a voluntary FRFA would trigger the requirements of section 212; other agencies said a compliance guide was required only when a FRFA was required, not when voluntarily provided.

Section 212 also gives agencies broad discretion in how its provisions are implemented. Agencies can decide when compliance guides should be published, how they are developed, what they contain, and how they are distributed to affected small entities. Therefore, an agency could designate a previously published document as its small entity compliance guide for a covered rule, or develop and publish a guide with no input from small entities years after the rule takes effect. Again, given this amount of discretion, it is not surprising that the agencies in our review varied in how section 212 was implemented. For example, some of the documents that the agencies gave us were prepared before the associated rules were published, but others were not published until well after the rules' compliance requirements took effect. Some of the agencies contacted small entities during the development of their guides, while others did not.

The agencies also varied in the extent to which they satisfied the three nondiscretionary provisions in section 212—that the guides be published,

designated as small entity compliance guides, and explain what small entities have to do to comply with the related rule. For example, the agencies with the broadest view regarding the coverage of the RFA and section 212—FCC and SEC—often provided us with documents that they characterized as small entity compliance guides that were not designated as such and, most troubling of all, did not explain the actions small entities needed to take to comply with the covered rules. Many of the documents did not mention the associated rule, section 212, or small entities; they were generic descriptions of the program or topic addressed by the rule. It appeared that many of the documents that these agencies provided were prepared for reasons unrelated to section 212, and the agencies identified those documents as small entity compliance guides only in response to our inquiry. In contrast, EPA—the agency that had the narrowest view of the scope of the RFA and section 212, excluding almost all of its rules from coverage—provided us with documents for three rules that appeared to have been prepared in recognition of the compliance guide requirement and meticulously described how to satisfy the rules’ provisions.

Matters for Congressional Consideration

As we have said many times in the past, we believe that there needs to be greater clarity and consistency with regard to how key terms in the RFA are defined and implemented. Such clarity and consistency becomes even more important when RFA determinations serve as the trigger for requirements such as section 212. The requirement in S. 849 directing the SBA Chief Counsel for Advocacy to promulgate a rule to define the terms “significant economic impact” and “substantial number of small entities” can go a long way toward defining what rules require a FRFA and, therefore, require a small entity compliance guide. Although a single, rigid definition may not be feasible for all agencies or even all rulemaking within a single agency, the rule could establish some reasonable parameters and provide useful examples of what types of regulatory effects should and should not be considered “significant” and how broadly those effects must be felt to be considered affecting a “substantial” number of small entities.

We also believe that changes are needed with regard to the requirements in section 212. For example, to address the question of whether an agency must prepare a compliance guide when it prepares a voluntary FRFA, section 212 could be amended to require a guide whenever the agency does not certify the rule under section 605(b) of title 5, United States Code. Doing so would exclude rules for which a FRFA was prepared (either voluntary or otherwise) but that the agency ultimately certified as not having a significant impact on small entities.

Section 212 could also be clarified regarding its applicability to rules that have no compliance requirements. Some of the rules that agencies issue have no compliance requirements but require a compliance guide because they have a significant impact on small entities and require a FRFA. We do not believe that agencies should be required to prepare compliance guides for these types of rules. Therefore, the language in section 212 could be changed to limit its application to rules that agencies do not certify under subsection 605(b) of title 5 and that have compliance requirements applicable to small entities.

We also believe that Congress can strengthen the implementation of section 212 by clarifying other key terms in the statute, either by directly amending the statute or by directing some other entity to provide such clarity. For example:

- Section 212 currently says that agencies must “designate” the publications prepared under the section as small entity compliance guides. However, the form in which those designations should occur is not clear. If Congress wants agencies to make “small entity compliance guides” part of these publications’ titles, Congress could change the word “designate” in the statute to “entitle.” Consistent use of this phrase in the title could make it easier for small entities to locate the guides that the agencies develop. On the other hand, if Congress envisions another meaning to the term “designate,” it could direct some other entity to clarify the issue.
- Section 212 currently says agencies “shall publish” the guides, but does not indicate where they should be published. At least one agency has published the guides as part of the preamble to the subject rule, thereby requiring affected small entities to read the *Federal Register* to obtain the guides. If Congress does not want agencies to publish the guides in this manner, it could require publication in some venue separate from the rule. Although publication on the agencies’ web sites has certain advantages, other more proactive forms of publication could also be permitted and encouraged (e.g., sending the guides out to affected parties).
- Section 212 also does not indicate when the compliance guides should be published—before the related final rule is published, coincident with the publication of the rule, or even before the rule takes effect. We do not believe that compliance guides should be published prior to the publication of a final rule, as changes to rules are sometimes made at the last minute. Neither do we believe that agencies should wait to publish compliance guides until the compliance requirements for their final rules take effect. Agencies could be instructed to publish the compliance guides

coincident with or as soon as possible after the final rule is published, provided that the guides must be published no later than the effective date of the rule's compliance requirements.

- If Congress decides to limit the applicability of section 212 to uncertified rules with compliance requirements applicable to small entities, Congress could also clarify what is meant by the term "compliance requirements." Part of this clarification could include delineation of how relatively straightforward compliance requirements should be treated. For example, if an NMFS rule simply bans fishing within a particular geographic area, should the agency prepare a compliance guide? If so, the guide could be very short, essentially taking the form of a public notice.

Therefore, if Congress wishes to clarify and strengthen the implementation of section 212 of SBREFA, we recommend that Congress consider amending the language in section 212 to limit its application to rules that the agencies did not certify under subsection 605(b) of title 5 and that contain compliance requirements applicable to small entities. We also recommend that Congress clarify, or give the responsibility and authority to some other entity to clarify, key terms in the section such as "designate," "publish," and, if the previous recommendation is accepted, "compliance requirements."

Agency Comments and Our Evaluation

On November 13, 2001, we sent a draft of this report to the Secretaries of Commerce and Health and Human Services, the Chairmen of the FCC and the SEC, and the Administrator of EPA for their review and comment. EPA officials told us that they had no comments on the report. In a letter dated December 7, 2001, the Secretary of Commerce said that the Department had no substantive comments on the report.

On November 30, 2001, the Managing Director of the FCC provided us with written comments on the draft report, which are reproduced in appendix I. The Managing Director said that "in our view, the FCC has met the goals of section 212," and the agency "goes beyond the requirements of section 212 in offering guidance to small entities." He said that the FCC has long issued guidance on its rules to ensure that all entities understand what is required of them, and noted the agency's use of its web site and other mechanisms to distribute guidance materials. However, the Managing Director's comments did not directly address any of the draft report's findings regarding the FCC's implementation of section 212 or the report's conclusions or recommendations. Also, it is not clear how the Managing Director can contend that FCC "goes beyond the requirements of section

212” when none of the more than 200 guidance documents that the agency provided for 70 of its covered rules met all of the requirements in section 212.

On November 30, 2001, the General Counsel of the SEC provided us with written comments on the draft report, which are reproduced in appendix II. The General Counsel first identified several SEC small business initiatives, and then addressed the draft report’s conclusions and recommendations. He said that they were pleased with the draft report’s conclusion that the preparation of a FRFA may not be the most accurate trigger for determining when an agency should prepare a SBREFA compliance guide, noting that no inference can be drawn about a rule’s impact on small entities simply because an agency prepared a FRFA. The SEC General Counsel also said that they “do not necessarily disagree” with the report’s conclusion that SBREFA may warrant clarification. Nevertheless, he said that agencies should retain flexibility and discretion on how best to formulate small entity guidance and on when to issue guidance. For example, he noted that some rules raise implementation issues only after they go into effect, so an agency should have discretion with regard to the timing of its SBREFA guidance. However, as we said in the draft report, we believe that agencies should not wait to publish compliance guides until after the compliance requirements for their final rules take effect. If agencies were required to publish the guides coincident with the publication of the final rule, nothing would prevent the agency from issuing subsequent guidance in the event that questions arise during implementation.

In a letter dated December 7, 2001, the Inspector General of HHS transmitted the Department’s comments on the draft report, which are reproduced in appendix III. In those comments, the Department thanked us for pointing out its inconsistent application of the FRFA requirements in the RFA and acknowledged that CMS does not publish the small entity compliance guides required by section 212. Nevertheless, the Department suggested “that it would be of more value to assess the efforts and actions of the Federal agencies included in GAO’s study to...develop more accessible sources of information on regulatory and reporting requirements for small businesses.” The Department also said that it would be “more beneficial and useful to assess the small entity community’s awareness of, reaction to, and assessment of information that CMS makes available to them.” The Department described a number of CMS efforts to apprise regulated entities of their responsibilities, and said it “believes these efforts go well beyond the simple publication of a compliance guide.” However, as requested, our objectives were to (1)

determine whether the agencies have published small entity compliance guides for each covered rule published in selected years, and (2) describe how the agencies developed the guides and made them available to small entities affected by the rules. Therefore, the Department's suggestions are beyond the scope of our review.

The Department also said that it believes that FDA is using appropriate definitions of the terms "significant" and "substantial" as triggers for section 212, and that it would be difficult to develop definitions that work for different agencies with vastly different types of rulemaking. We did not indicate in our draft report that FDA was using inappropriate definitions of those terms. We did say that, although a single, rigid definition for these terms may not be feasible for all agencies or all rulemaking, a definition could establish some reasonable parameters that the agencies could use. In the absence of those parameters, agencies can conclude that rules that impose thousands of dollars in compliance costs on thousands of small entities do not represent a "significant" economic impact on a "substantial" number of small entities, thereby avoiding the requirements in the RFA and SBREFA.

Finally, pursuant to a suggestion from the Department, we changed the draft report to note that a statement that FDA's compliance guides should "be available at the time of the publication of the final rule" was contained in a "checklist" developed at the time SBREFA was passed, not in the agency's official, one-page "guidance document." However, we did not accept the Department's suggestion that we eliminate other portions of the draft report indicating that FDA did not publish any of its covered rules by the dates the rules were published, and that the publication dates for two guides were accelerated because of our review. In its comments on the draft, the Department agreed that congressional clarification of section 212 might be useful with regard to when the compliance guides should be published.

As arranged with your office, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days after the date of this report. At that time, we will send copies of this report to the Chairman, Senate Committee on Small Business; the Chairman and Ranking Minority Member, House Committee on Small Business; the Secretaries of Commerce and Health and Human Services; the Administrator of EPA; and the Chairmen of the FCC and the SEC. We will also make copies available to others on request.

If you have any questions concerning this report, please call me or Curtis Copeland at (202) 512-6806. Key contributors to this assignment were John Tavares and Matthew Ebert.

Sincerely,

A handwritten signature in black ink, appearing to read "Victor S. Rezendes". The signature is fluid and cursive, with the first name being the most prominent.

Victor S. Rezendes
Managing Director, Strategic Issues

Appendix I: Comments From the Federal Communications Commission

FEDERAL COMMUNICATIONS COMMISSION
Washington, D. C. 20554

OFFICE OF
MANAGING DIRECTOR

November 30, 2001

Mr. Victor S. Rezendes
Managing Director, Strategic Issues
United States General Accounting Office
Washington, DC 20548

Dear Mr. Rezendes:

Thank you for the opportunity to review your draft report entitled *Regulatory Reform: Compliance Guide Requirement Has Had Little Effect on Agency Practices* (GAO-02-172, Code 450049).

Section 212 of the Small Business Regulatory Enforcement Fairness Act (SBREFA), 5 U.S.C. § 601 note, requires agencies to publish and make available through a coordinated distribution system easily understood guides to assist small entities in complying with often complex and technical regulations. *See* 142 Cong. Rec. S3242 (Mar. 29, 1996) (Joint Managers Statement of Legislative History and Congressional Intent, offered by Senator Bond); 142 Cong. Rec. E571 (Mar. 28, 1996) (remarks of Representative Hyde). In our view, the FCC has met the goals of section 212.

As your report demonstrates, the FCC publishes a very large number of rules each year. These rules implement complex, highly technical telecommunications statutes regulating a sophisticated, technically knowledgeable community that generally well understands the requirements of the rules. Nonetheless, the FCC has long issued, in many formats, guidance concerning its rules to ensure that all entities subject to the rules understand what is required of them. These materials are presented in plain English, and, under a recent initiative, are also being made available in Spanish. Guidance material is created and made available for rules subject to regulatory flexibility analyses.

The FCC goes beyond the requirements of section 212 in offering guidance to small entities. Guidance materials are made available not only for entities subject to the FCC's rules, but also to entities affected by the rules but who are not included in regulatory flexibility analyses. Thus, for example, not only does the FCC issue guidance for telephone companies that must comply with its truth-in-billing regulations; it also issues guidance to help the general public that receives telephone bills (including small entities).

The FCC is at the forefront of the Federal Government's use of the Internet to make small entity guidance publicly available. Our Internet website, www.fcc.gov, has recently been rated the third best site in the Federal Government. *See* http://www.brown.edu/Departments/Taubman_Center/polreports/egovt01us.html#Overall_Federal_Agency_Ranking. Each component Bureau or Office of the FCC maintains a detailed homepage

**Appendix I: Comments From the Federal
Communications Commission**

with extensive explanatory materials readily identifiable by subject matter. We have found this approach to be the most useful for those interested in understanding telecommunications regulations. Indeed, our Internet site received 41.0 million hits in October 2001 with 8.5 million page views; 28.3 million hits in September 2001, with 7.2 million page views; 31.1 million hits in August 2001 with 8.9 million page views; and 30.4 million hits in July 2001 with 8.1 million page views.

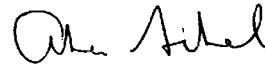
As envisioned by section 212, small entity compliance guide materials are gathered and made available at two locations: the FCC's Consumer Information Bureau page, www.fcc.gov/cib, and the Office of Communications Business Opportunities "Small Entity Compliance Guide" page, www.fcc.gov/ocbo/guides.html. These specialized compilation web pages are heavily relied upon by the public. The CIB pages received 1,155,396 hits in October 2001, 889,299 hits in September 2001, 1,015,706 hits in August 2001, and 677,063 hits in July 2001. The newer special "Small Entity Compliance Guide" page on OCBO's site received 257 page views in October 2001 and 48 page views in September 2001.

In addition to the materials readily available on the FCC's Internet site, the Office of Communications Business Opportunities maintains a mailing list of 3,000 small business and other interested entities that receive informational mailings on communications regulation issues throughout the year.

Finally, should the vast amount of written guidance we make available leave questions unanswered, the FCC's Consumer Center, with its toll-free, 24-hour per day access, provides additional means for small entities to receive guidance concerning FCC rules. The Consumer Center receives an average of 83,272 calls each month.

In short, the FCC endeavors to allow anyone interested in understanding its rules to readily obtain explanations and guidance. We are committed to making available and distributing the comprehensive materials the FCC has long provided to the public, consistent with the requirements and spirit of section 212 of SBREFA.

Sincerely,



Andrew S. Fishel
Managing Director

Appendix II: Comments From the Securities and Exchange Commission



UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

November 30, 2001

Victor S. Rezendes
Managing Director, Strategic Issues
United States General Accounting Office
Washington, DC 20548

Re: Regulatory Reform: Compliance Guide Requirement Has Had Little Effect on Agency Practices (GAO-02-172, Code 450049)

Dear Mr. Rezendes:

Thank you for providing the U.S. Securities and Exchange Commission ("the Commission" or "SEC") with the opportunity to comment on the General Accounting Office's draft report regarding implementation of Section 212 of the Small Business Regulatory Enforcement Fairness Act ("SBREFA"). The SEC has a long-standing commitment to assist small businesses and takes great care to craft regulations that do not disproportionately affect small businesses. To put the report's conclusions in context, we thought it would be useful for the report to have a brief description of our efforts to assist small businesses in understanding and complying with our rules.

The Commission's Small Business Initiatives. The SEC has long been committed to the interests of small businesses. In this regard, the SEC adopted its first simplified disclosure requirements for small businesses in 1935, a year after its own creation. The following are a few of the more recent actions of the SEC to help small businesses comply with SEC regulations:

- In 1979, we created an Office of Small Business that can now be accessed through its own website (www.sec.gov/info/smallbus.shtml) and direct telephone line (202-942-2950). In the last year, it handled nearly 10,000 telephone inquiries for informal guidance.
- Each year since 1982 we have conducted an Annual Government-Small Business Forum with the SBA's Office of Advocacy.
- We have issued small business guides concerning our various regulatory programs, as well as other guidance material to explain our rules, including "Q&A: Small Business and the SEC."
- We have held numerous Small Business Town Hall meetings throughout the country where senior SEC officials and staff explained recent rule changes and heard about the concerns of small businesses.

Mr. Victor S. Rezendes
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In fact, the SEC's compliance with the Regulatory Flexibility Act ("RFA") has been singled out for praise. A 1994 GAO Report [Regulatory Flexibility Act: Status of Agencies' Compliance, GGD-94-105 (April 27, 1994)] quoted the Small Business Administration's ("SBA") Chief Counsel for Advocacy as saying that the SEC "had 'embraced the intent of the Regulatory Flexibility Act' and had done a thorough review of its major laws that 'epitomizes the initiative that all agencies should be taking in this area.'" And, more recently, the SBA Chief Counsel's latest annual report on the Act states that the SEC "continued to maintain high standards in implementing the Regulatory Flexibility Act and reaching out to small entities to participate in the regulatory process."

Additionally, over the years, the SEC has amended its rules to expand the ways that small businesses can raise capital and to reduce the burdens imposed by the federal securities law on small business issuers. A recent report by the General Accounting Office, Small Business, Efforts to Facilitate Equity Capital Formation, GAO/GGD-00-190, noted the SEC's efforts in this regard.

GAO Draft Recommendations. The draft report concludes that SBREFA may warrant clarification; we do not necessarily disagree. We would, however, like to offer the following observations. In our view, the most important question is whether an agency prepares clear, fair rules after receiving input from all potentially affected parties, including small businesses. With virtually every rule it adopts, the SEC seeks comment, consults with those potentially affected by the proposed rule both formally and informally, and takes great effort to publicize significant rule changes – for example, through the press and public conferences (including an annual conference, called SEC Speaks, where the staff discusses the SEC's major initiatives from the previous year). The Commission has also undertaken a major initiative since 1997 to draft all its public documents -- including rule releases and text -- in plain English. If a rule is clear and simple, obviously there is a lesser need for a separate compliance guide.

If Congress takes up this issue, we submit that agencies should retain flexibility and discretion on how best to formulate small entity guidance and on when to issue guidance. We note that SBREFA currently allows agencies to "prepare separate guides covering groups or classes of similarly effected small entities" and requires agencies to publish a compliance guide for "each rule or group of related rules." In 1997, before the scope of the GAO study, the Commission designated six documents covering different groups of regulated entities and the "group of related rules" affecting them as compliance guides and identified them in 17 C.F.R. 202.8. The staff has since created other such general guidance material. These documents explain in plain language the SEC's regulatory scheme for the different types of entities the Commission regulates.

In addition, when a rule is issued, the SEC usually issues a press release and fact sheet to help explain and publicize new rules. For some rules, the SEC anticipates questions and prepares more extensive guidance at the time of a final release. Other rules, however, raise implementation questions only after they go into effect – the staff

Mr. Victor S. Rezendes
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therefore often issues guidance after a rule is effective to answer real questions that have arisen. We recognize that even the clearest rules sometimes raise novel, unforeseen implementation questions. Agencies should retain discretion – which SBREFA currently permits – to formulate the appropriate guidance for affected entities, including small businesses, to address those questions. By not defining when agencies must issue a guide, SBREFA provides needed flexibility.

We are pleased to see that the draft report concludes that the obligation to prepare a Final Regulatory Flexibility Analysis (“FRFA”) may not be the most accurate “trigger” for determining when an agency should prepare a small business compliance guide under SBREFA. The obligation to prepare a FRFA depends on whether the rule was promulgated after notice and comment. While the RFA permits agencies to certify a rule – and therefore not conduct a FRFA – if they determine that the rule would not have a significant effect on a substantial number of entities, the mere fact that an agency prepared a FRFA by itself does not establish that the rule will have a significant economic impact on a substantial number of entities. Section 604 of the RFA does not require an agency to make such a finding; rather, an agency is required only to consider the impact of a rule and minimize the impact to the extent possible. Moreover, because “significant economic impact on a substantial number of small entities” is not defined, the SBA Office of Advocacy guidance counsels agencies to “err on the side of caution and perform an IRFA with the available data and information.... Then, if appropriate, the agency can certify the final rule.” The Office “urges the safest course” to prevent “avoidable court challenges.” The Commission has followed this guidance, and therefore, certifies few of its rules. No inference can be drawn, therefore, about a rule’s impact on small entities simply because an agency prepared a FRFA. For many of the rules promulgated in 1999-2000, the SEC found in its FRFA that the impact would be the same for small and large entities and would not likely be significant. For these types of rules, we do not believe it should be necessary to prepare a special “small entity” compliance guide separate from the general guidance issued to the public at large.

Thank you again for the opportunity to comment on the draft. If you have any questions about the SEC’s SBREFA compliance, please feel free to contact me or David Fredrickson (202-942-0968) in my office.

Very truly yours,


David M. Becker
General Counsel

Appendix III: Comments From the Department of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

DEC - 7 2001

Mr. Victor S. Rezendes
Managing Director
Strategic Issues
United States General
Accounting Office
Washington, D.C. 20548

Dear Mr. Rezendes:

Enclosed are the Department's comments on your draft report entitled, "Regulatory Reform: Compliance Guide Requirement Has Had Little Effect on Agency Practices." The comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

The Department also provided some technical comments directly to your staff.

The Department appreciates the opportunity to comment on this draft report before its publication.

Sincerely,

A handwritten signature in cursive script that reads "Janet Renquist".

Janet Renquist
Inspector General

Enclosure

The Office of Inspector General (OIG) is transmitting the Department's response to this draft report in our capacity as the Department's designated focal point and coordinator for General Accounting Office reports. The OIG has not conducted an independent assessment of these comments and therefore expresses no opinion on them.

DEPARTMENT OF HEALTH AND HUMAN SERVICES COMMENTS ON THE GENERAL ACCOUNTING OFFICE'S DRAFT REPORT ENTITLED, REGULATORY REFORM: COMPLIANCE GUIDE REQUIREMENT HAS HAD LITTLE EFFECT ON AGENCY PRACTICES

The Department of Health and Human Services welcomes the General Accounting Office's (GAO) draft report on compliance guides under the Small Business Regulatory Enforcement Fairness Act (SBREFA). We wish to thank GAO for recognizing that the Department's Food and Drug Administration (FDA) met all of the nondiscretionary provisions under section 212 of SBREFA.

GENERAL COMMENTS

The section of GAO's report titled, Timing of Guides' Publication Varied, reads, in part:

"Section 212 does not indicate when small entity compliance guides must be published. Although FDA and EPA have established their own deadlines, the agencies did not meet those deadlines for any of the covered rules in our review.

- Although FDA's guidance states that a compliance guide "will be available at the time of publication of the final rule," FDA did not publish compliance guides for any of the agency's 10 covered final rules by this deadline. Notably, the compliance guides that FDA had published at the time of our review for 2 of the agency's 10 covered rules were both published in July 2001—after we notified FDA that we were beginning our study.¹ FDA officials said that the guides had been in development for some time, but their publication was accelerated because of our review."

As FDA advised GAO's attorney at an exit conference, attended by Department and GAO officials, FDA's official guidance document is a one-page list of questions and answers. This guidance document *does not* contain the language indicated above that states, "...a compliance guide will be available at the time of publication of the final rule..." This language comes from a separate "checklist" developed at the time the law was passed and it is not part of FDA's official guidance. There is no requirement to publish a guide by a certain time. The question and answer guidance document clearly states that the statute does not specify when the guide is required to be published.

The Department recommends that reference to FDA be removed from the above sentence and it should read, "Although EPA has established their own deadlines, the agency did not meet those deadlines for any of the covered rules in our review." if this is accurate from the Environmental Protection Agency's viewpoint. We also recommend that the first bullet in this section, as written above, be removed from GAO's report because it is not accurate.

The section of GAO's report titled, Matters for Congressional Consideration reads, in part, under the first paragraph:

¹The two rules were FDA's March 16, 1999, food labeling rule (64 *Fed. Reg.*12887), and December 5, 2000, shell egg labeling rule (65 *Fed. Reg.*76092).

“The requirement in S. 849 directing the SBA Chief Counsel for Advocacy to promulgate a rule to define the terms “significant economic impact” and “substantial number of small entities” can go a long way toward defining what rules require a FRFA and, therefore, require a small entity compliance guide. Although a single, rigid definition may not be feasible for all agencies or even all rulemaking within a single agency, the rule could establish some reasonable parameters and provide useful examples of what types of regulatory effects should and should not be considered “significant” and how broadly those effects must be felt to be considered affecting a “substantial” number of small entities.”

The Department believes FDA is currently using appropriate definitions of the terms “substantial” and “significant” and it would be difficult to develop definitions that would work for different agencies with vastly different types of rulemaking.

The report states in the third bullet of this section, “Section 212 also does not indicate when the compliance guides should be published—before the related final rule is published, coincident with the publication of the rule, or even before the rule takes effect.” We agree with GAO that some congressional clarification of section 212 regarding time frames may be useful.

The Department’s Centers for Medicare and Medicaid Services (CMS) acknowledges that, for the reasons discussed below, they do not meet the requirements of Section 212, specifically the requirement to publish “small entity compliance guides.” We would suggest that it would be of more value to assess the efforts and actions of the Federal agencies included in GAO’s study to comply with the intent of SBREFA which is to “...develop more accessible sources of information on regulatory and reporting requirements for small businesses.” The simple publication of a “small entity compliance guide” which is written in plain language with some form of input from the affected businesses, does not, in and of itself, ensure a small entity’s understanding of and participation in a Federal program. It would be more beneficial and useful to assess the small entity community’s awareness of, reaction to, and assessment of information that CMS makes available to them.

The CMS is responsible for the administration of the Medicare program, a *voluntary* program that health care providers are *not required* to participate in. By statute, Medicare is a federally-administered program. Medicare contracts with the States for the operation of the Title XVIII survey and certification program to ensure providers’ ongoing compliance with Medicare’s conditions of participation. In addition, in order to effectively utilize their resources and avoid placing redundant burden on providers, Medicare accepts or “deems” accreditation of health care providers by nationally recognized accrediting organizations such as the Joint Commission on Accreditation for Health Care Organizations and the National Committee for Quality Assurance. Medicare contracts with insurance companies for the processing and payment of Medicare claims. Included in the requirements of these contracts are specific expectations regarding provider education and outreach.

As a very large, complex organization that deals with many categories of health care providers, CMS’ operations are necessarily geared to provider type, as opposed to provider size. The uniqueness of provider types, including different governing statutory provisions and payment methods, dictates how CMS deals with each category. Nevertheless, many provider and supplier

categories are predominantly made up of small businesses; for example, physicians, home health agencies, durable medical equipment (DME) suppliers, clinical laboratories, rural health clinics, end-stage renal disease facilities, and nursing and allied health professions. It follows that CMS' dealings with each of these provider types inherently include consideration of the special needs of small businesses.

The CMS continuously engages in activities that benefit small health care providers. In response to feedback from the provider community CMS has eliminated a physician certification form used to ensure that proper Medicare payments was made. The feedback indicated that the required form was overly burdensome to physicians; resulted in billing delays that hurt hospital cash flow; and resulted in less than a .01 percent claim denial rate. In addition, the physician community, through committees established by the American Medical Association and other physician organizations, provides significant input and recommendations on factors that impact annual updates to a physician fee schedule that is published annually.

In 1990, CMS established the Practicing Physician Advisory Council (PPAC). The PPAC consists of 15 physicians from a broad spectrum of practice and specialty areas, including physicians from rural and urban underserved areas, who have submitted claims under Medicare. They advise the Secretary of the Department and CMS' Administrator on certain proposed changes in Medicare regulations and Medicare contractor manual instructions. The PPAC has held more than thirty quarterly meetings since 1992. During these meetings, a wide variety of important issues are addressed, ranging from implementation of significant regulations to issues concerning quality of care, fraud and abuse, billing coding for proper reimbursement, physician education and licensing requirements, and administrative procedures to simplify the Medicare billing process.

The rulemaking process is fundamental to virtually all of the Department's policy-making activities. During the information gathering stage of rulemaking CMS regularly receives information from provider groups. An assessment of the impact on small businesses is a standard requirement in the development of Medicare regulations. In addition, CMS has modified their regulatory approach to ensure that their policies are sensitive to the needs of small businesses. For example, the home health prospective payment system which was recently implemented incorporated many features designed to accommodate the needs of small businesses. Such features as "split percentage billing" and "significant change in patient condition adjustments" were implemented in recognition of the fact that small home health agencies are particularly vulnerable to payment delays or inequities. When CMS has statutory discretion in the promulgation of regulations, they believe their actions reflect a growing sensitivity to the needs of small businesses. Most of the activity surrounding the pricing of DME is based on nondiscretionary, statutory formulas that provide no accommodations for small businesses. However, under a separate authority to modify DME prices that are inherently unreasonable, CMS has made a concerted effort to be sensitive to the needs of the small business community. In an inherent reasonableness survey of retail pricing, CMS was careful to include both small and large entities and then set price changes at the median price for *all* suppliers. The CMS also actively solicited written information from the supplier industry, which includes many small businesses, as regards CMS' implementation of upgraded DME provisions of the Balanced Budget Act of 1997.

As to communication with the provider community, CMS has been especially proactive over the past several years. The CMS encourages the submission of information from providers at all levels on an ongoing basis, from the Administrator to the staff level. In addition to the PPAC mentioned above, CMS encourages communication between physicians and Medicare contractors. All Medicare contractors have trained customer service representatives to facilitate the resolution of provider inquiries and problems. Beginning in Fiscal Year 2001, CMS resumed funding provider toll free telephone lines at Medicare contractors. Physicians can communicate concerns to a regional office with oversight responsibility for their particular contractors. The regional offices provide information on CMS initiatives, receive feedback and provide information of mutual concern to State medical societies.

Providers receive information and education from a number of other CMS-funded and directed sources. These include contractor-published provider bulletins and contractor-maintained web sites. Program manuals explaining the rules and requirements of Medicare are maintained on the CMS web site and available to all providers, along with updates to the provider manuals. The CMS currently is engaged in a 2-year effort to update all of their program and provider manuals on the web and make them more user friendly. In addition, CMS is currently testing the utility to the provider community of a quarterly provider update. The update is designed to bring regularity and predictability to CMS' communication of program changes to the provider community. The provider update will include a listing of previously published regulations, a listing of regulations under development, and a listing of recently released instructions that will be implemented at the beginning of the next calendar quarter. In addition, CMS is testing the utility of publishing their business in the Federal Register one day a month.

One unit within CMS' Center for Medicare Management is dedicated to provider education and training. This unit currently conducts periodic national conference calls with representatives of national, State and local provider associations, providing information on CMS initiatives and soliciting provider feedback. In addition, the unit developed and maintained separate web sites for each new prospective payment system that has recently been implemented, for example, home health, skilled nursing facilities, and outpatient services. Innovative educational efforts are also being developed and piloted. The CMS recently conducted a pilot project to teach over 6,000 medical school residents proper Medicare billing procedures. A former pilot program on Medicare claims documentation and coding requirements was recently expanded nationally. Starting last year, all Medicare contractor local medical review policies are available on CMS and contractor web sites.

The Department believes that through the efforts described above, CMS is actively engaged in an ongoing effort to understand the needs of the small business community and make easily understandable information readily available to the provider community, thereby complying with the *intent* of SBREFA. The Department believes these efforts go well beyond the simple publication of a compliance guide that on the one hand would be duplicative of many of our other efforts, and on the other hand would be limited in its ability to meet the needs of providers at the local level.

**Appendix III: Comments From the
Department of Health and Human Services**

Finally, we thank GAO for pointing out the Department's inconsistent application of the final regulatory flexibility analysis requirements under the Regulatory Flexibility Act. We are working to ensure that appropriate staff understand these requirements and apply them consistently in the future.

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