



January 6, 2006

BY ELECTRONIC MAIL

The Honorable John D. Graham  
Administrator  
Office of Information and Regulatory Affairs  
Office of Management and Budget  
New Executive Office Building, Rm. 10235  
725 17<sup>th</sup> Street, N.W.  
Washington, D.C. 20503

Re: Comments on the Office of Management and Budget's "Proposed Bulletin for Good Guidance Practices," 70 Fed. Reg. 71,866

Dear Dr. Graham:

The Office of Advocacy (Advocacy) is pleased to submit the following comments in response to the notice and request for comments published by the Office of Management and Budget (OMB) on its "Proposed Bulletin for Good Guidance Practices," 70 Fed. Reg. 71,866 (Nov. 30, 2005). Congress established the Office of Advocacy under Pub. L. No. 94-305 to advocate the views of small entities before Federal agencies and Congress. Because Advocacy is an independent entity within the U.S. Small Business Administration (SBA), the views expressed by Advocacy do not necessarily reflect the position of the Administration or the SBA.

Advocacy strongly supports OMB's effort to develop a transparent, consistent process for Federal agencies to use when they issue guidance documents. Each year, Federal agencies issue thousands of guidance documents stating their interpretation of often highly complex regulatory and technical requirements, usually without prior notice to the public or the opportunity for public comment. Small businesses and their representative trade and membership organizations have told us that these guidance documents are then often implemented by agencies as if they were regulations having the full force and effect of law. Advocacy believes that the Bulletin will help ensure that agencies use a more transparent process in developing guidance documents. Input from the public should improve the quality and consistency of these documents.

**Background**

Small businesses have long been concerned that Federal agencies have an incentive to issue informal guidance documents that have the effect of expanding regulatory

compliance burdens – rather than formally promulgating rules – in order to avoid having to go through the notice and comment rulemaking procedures required by section 553 of the Administrative Procedure Act (APA).<sup>1</sup> In the absence of the procedural protections of the APA, and without any real-world feedback from affected parties, agencies may issue poorly-conceived and unworkable directives to the regulated community. One of the most important procedural protections bypassed when an agency issues guidance documents rather than promulgating rules is the small business review required by the Regulatory Flexibility Act (RFA)<sup>2</sup> In Advocacy’s experience, agencies benefit tremendously when they hear from small businesses and other interested parties before taking regulatory action. Unfortunately, despite the fact that guidance documents often have the practical effect of expanding the requirements imposed upon a regulated entity, they lack the transparency and agency accountability that administrative procedures demand for rules.<sup>3</sup>

This problem with guidance documents was addressed directly by the U.S. Court of Appeals for the District of Columbia Circuit in *Appalachian Power Co. v. EPA*,<sup>4</sup> wherein the Court found that a guidance document relating to emissions monitoring in fact imposed new substantive requirements on facilities that necessitated notice and comment rulemaking. Noting that “it is well-established that an agency may not escape the notice and comment requirements . . . by labeling a major substantive legal addition to a rule a mere interpretation,”<sup>5</sup> the Court of Appeals sent a clear message that agencies must follow section 553 of the APA (and the requirements of the RFA) when they wish to impose new substantive requirements. Similarly, the Administrative Conference of the United States has observed that “at times policy statements and interpretive rules are barely distinguishable from substantive rules for which notice and comment is required.”<sup>6</sup> Accordingly, the Administrative Conference recommended in 1976 that

before an agency issues, amends, or repeals an interpretive rule of general applicability or a statement of general policy which is likely to have substantial impact on the public, the agency normally should utilize the procedures set forth in [APA section 553] by publishing the proposed interpretive rule or policy statement in the Federal Register, with a concise statement of its basis and purpose and an invitation to interested persons to submit written comments . . . .<sup>7</sup>

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<sup>1</sup> 5 U.S.C. § 553.

<sup>2</sup> 5 U.S.C. §§ 601-612.

<sup>3</sup> In the late 1990’s, for example, the U.S. Environmental Protection Agency issued guidance documents implementing a change in the agency’s longstanding interpretation of permitting requirements under the Clean Air Act’s New Source Review Program. The guidance letters and memoranda, which had the effect of imposing new compliance costs, were issued without the public involvement formalized by the APA and the RFA.

<sup>4</sup> 208 F.3d 1015 (D.C. Cir. 2000). *See also, Chamber of Commerce v. Dept. of Labor*, 174 F.3d 206 (D.C. Cir. 1999) (OSHA Directive found to be a rule requiring notice and comment rulemaking); *United States Telecom Assoc. and Century Tel. Inc. v. FCC*, No. 03-1414 (D.C. Cir., decided March 11, 2005) (FCC “clarification” held to be a substantive change in the agency’s rules requiring notice and comment rulemaking).

<sup>5</sup> 208 F.3d at 1024.

<sup>6</sup> Administrative Conference of the United States, Recommendation 76-5, 1 C.F.R. § 305.76-5 (1976).

<sup>7</sup> *Id.*

Advocacy does not suggest that every guidance document should go through the APA notice and comment rulemaking process. We also recognize that guidance documents can be useful in helping agencies manage their regulatory duties. Nevertheless, we do believe that agencies should be required to be more consistent, transparent and accountable to the regulated community in issuing guidance.

### **The Bulletin Requires Greater Agency Consistency and Transparency**

By requiring agencies to use standardized, comprehensive procedures for issuing “significant guidance documents,” the Bulletin on Good Guidance Practices should result in guidance documents that are more consistent and transparent. The Bulletin calls for the internal clearance of guidance documents by an appropriate senior agency official. Advocacy believes this will yield more consistent documents, as will the inclusion of standard required elements in guidance documents. We believe that it is very important that guidance documents clearly be identified as “guidance” that are non-binding and that do not carry the force of law.

The Bulletin’s requirement that significant guidance documents be available to the public in electronic form, along with lists of significant guidance documents, should allow affected small businesses to be better able to track important developments. Small businesses often cite the difficulty under current agency practice in simply identifying all of the agency guidance that applies to them individually. Providing an avenue for the public to comment on draft agency guidance is also an important feature of the Bulletin. This should add at least some degree of public participation to the guidance dissemination process. The opportunity for the public to review draft guidance and submit comments gives small business representatives and the Office of Advocacy a potential voice in the process. It is clear that OMB has authority to review guidance documents. This authority is grounded in OMB’s inherent role as overseer and coordinator of the Administration’s regulatory policy, as well as OMB’s overall implementation of Executive Order 12866.<sup>8</sup> We are confident that Advocacy will be able to work with OMB’s Office of Information and Regulatory Affairs (OIRA) and the agency in question, pursuant to the Bulletin, to resolve issues arising from controversial guidance documents that impose significant economic impacts upon small entities. Advocacy is also pleased that the Bulletin contains a mechanism to require Federal Register notice and comment procedures for guidance documents that may be reasonably

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<sup>8</sup> Executive Order 12866, *Regulatory Planning and Review*, 58 Fed. Reg. 51735 (October 4, 1993). In determining whether Federal agency actions are “significant regulatory actions” under the Executive Order, the OMB Office of Information and Regulatory Affairs must have the ability to review and evaluate items, including guidance documents, which are in fact actually rules. In addition, OIRA has repeatedly exercised its guidance oversight authority to call for the public to nominate Federal agency guidance documents for revision or deletion through OMB’s rule reform process, and has overseen the actual reform of guidance documents by the agencies. See, e.g., *Informing Regulatory Decisions: 2003 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local and Tribal Entities* (September 2003) at Table 10 “New Reforms Planned or Underway – Guidance Documents,” available at [www.whitehouse.gov/omb/inforeg/2003\\_cost\\_ben\\_final\\_rpt.pdf](http://www.whitehouse.gov/omb/inforeg/2003_cost_ben_final_rpt.pdf).

anticipated to lead to an annual effect of \$100 million or more. Guidance documents of this magnitude are at least functionally equivalent to major legislative rules under Executive Order 12866, and should be given analogous procedural safeguards. Importantly, the Bulletin requires agencies to respond to comments submitted concerning draft guidance. This gives small businesses and Advocacy a role in the guidance issuance process, and an avenue for Advocacy, OIRA and an agency to address problems with an economically significant guidance document that affects small entities.

### **Recommended Improvements to the Draft Bulletin**

The chief concern that small business representatives have expressed to Advocacy about the draft Bulletin is the fear that too many important guidance documents will not be classified as “significant guidance documents” and will therefore fall outside of the purview of the Bulletin. These small business representatives believe that the definition of “significant guidance documents” should be expanded. Advocacy agrees, and recommends that OMB make the following changes to the Bulletin:

- In the definition of “guidance document” in § I(2), insert “, or is otherwise relied upon by an agency to manage the regulatory process.” at the end of the sentence;
- In the definition of “significant guidance document” in § I(3), delete the word “highly” in § I(3)(ii);
- In the definition of “significant guidance document” in § I(3), move subsection (i) to become the fourth and final item in the list.
- In the definition of “economically significant guidance document” in § I(5), change the reference from “Section I(3)(i) of this Bulletin” to “Section I(3)(iv) of this Bulletin.”

OMB should clarify that a guidance document that meets **any** of the listed criteria in Section I(3) must comply with the transparency and accountability requirements of the Bulletin.

In Section II(2) of the Bulletin, beyond explicitly stating that a document is “guidance,” and is not legally binding, Advocacy recommends that an agency be required to include an explicit finding that the new guidance is appropriately guidance and is not a rule. Small business representatives have also suggested that agencies should address the following questions in the guidance document:

- What is the underlying need for the guidance document?
- What alternative approaches have been considered?
- Is there relevant preceding guidance (i.e., Advisory Circulars, Orders, etc.)?
- Who will be administering or enforcing the guidance materials?
- What entities are affected by the guidance?
- What are the economic impacts on the affected parties? Does the agency have data indicating that the guidance will not lead to an annual economic impact of \$100 million or more?

In reviewing the responses to these questions, the public can provide more informed feedback to assist the agency.

In Section III of the Bulletin, OMB should explicitly state that each agency, within a reasonable time, is expected to compile a list of all of its guidance documents that are currently in effect and to make that list available to the public in electronic form. Also, OMB should require agencies to ensure that comments received on draft significant guidance documents are made available to the public in electronic form.

Finally, in Section V of the Bulletin, OMB should add the following language, "Nothing in this Bulletin shall affect or modify the legal obligations of Federal agencies to comply with 5 U.S.C. §§ 553 and 554, and related procedural requirements."

### **Conclusion**

Advocacy shares OMB's objective of bringing improved consistency, transparency, and accountability to agencies' issuance of guidance documents. We believe that the Bulletin on Good Guidance Practices will be an effective tool in meeting that objective. We look forward to working with agencies and with OMB to implement the Bulletin to its full potential.

For additional information or assistance relating to these comments, please contact Keith Holman at (202) 205-6936.

Sincerely,

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Thomas M. Sullivan  
Chief Counsel for Advocacy