



9 January 2006

John D. Graham, Ph.D.
Administrator
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Office of Management and Budget
Washington, DC 20503
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Dear Dr. Graham:

Regulatory Checkbook is pleased to offer comments on the Office of Management and Budget's *Proposed Bulletin for Good Guidance Practices*, which was posted on OMB's website on 23 November 2005. As a Section 501(c)(3) nonpartisan and nonprofit research organization, Regulatory Checkbook does not represent any interested parties.

In principle, OMB's *Proposed Bulletin* may serve a valuable purpose insofar as it reduces uncertainty about the status of guidance and it imparts needed discipline on federal agency regulatory practice. By reducing uncertainty, guidance documents can provide both regulated entities and the general public useful information concerning how existing regulations are (or will be) interpreted and applied. At the same time, all agree that federal agencies should not issue guidance in order to circumvent the informal rulemaking procedures set forth under the Administrative Procedure Act (APA).

We first offer comments on specific sections of the *Proposed Bulletin*. We conclude by offering suggestions with respect to Section III, which we believe is the cornerstone of the effort and where we think OMB ought to focus its efforts.

DEFINITIONS

1. Domain of agencies covered

Regulatory Checkbook agrees that if OMB intends to establish government-wide standards and procedures for good guidance practices

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(GGP), those standards and procedures ought to apply to all government agencies. Therefore, it is entirely appropriate to use the definition of “agency” found in the Paperwork Reduction Act (PRA) at 44 U.S.C. § 3502(1). We do not see any sound policy reason for excluding so-called independent agencies as defined in 44 U.S.C. § 3502(5). Nothing in OMB’s proposal suggests that § 3502(1)- and § 3502(5)-agencies differ in their propensity to issue guidance documents or their need to apply best management practices to the guidance they issue.

In the preamble, OMB does not clearly set forth the statutory (or other) authority under which it proposes to issue this guidance. It appears that OMB is relying on Executive order 12,866 (as amended by Executive order 13258) to provide that authority, and we agree that EO 12866 is sufficient. Section 3(e) of that Order defines a “regulatory action” to include:

any substantive action by an agency (normally published in the Federal Register) that promulgates or is expected to lead to the promulgation of a final rule or regulation, including notices of inquiry, advance notices of proposed rulemaking, and notices of proposed rulemaking.¹

In 2001 OMB explicitly recognized the breadth of this definition:

The [Executive] Order defines ‘regulatory action’ broadly to include all substantive action by an agency that is expected to lead to the issuance of a final rule.²

Guidance documents either modify an existing regulation (which makes them by-products of rulemaking) or they alter the practical effect of existing or future rules. That makes them “regulatory actions” under Executive order 12866.

As we indicate below, OMB should modify its basic agency standards to require agencies to specify both the law(s) under which the guidance is issued and the specific regulatory provision(s) affected by it. The public is ill-served by federal agencies issuing guidance that explains how a regulation is (or will be) interpreted if it fails to clearly state the regulation to which the guidance applies. To set an example of adherence to this basic agency standard, OMB should clearly state the authority it relies upon for issuing its own *Bulletin on Good Guidance Practices*. OMB should not expect federal agencies to comply with procedures from which it has inexplicably provided itself an exemption.

¹ William J. Clinton, 1993. Executive Order 12866: Regulatory Planning and Review, 58 *Federal Register* 51735-51744.

² John D. Graham, 2001. Memorandum for the President's Management Council: Presidential Review of Agency Rulemaking by OIRA [September 21]. Accessed January 9, 2005, from http://www.whitehouse.gov/omb/inforeg/oira_review-process.html.

2. What is a “guidance document”?

OMB has proposed a definition of “guidance document” that is at once overly broad and inappropriately narrow, and which does not home in on the most important issues at stake. The proposed definition in § I(2) would cover any document “prepared by an agency and available to the public to describe the agency’s interpretation of or policy on a regulatory or technical issue,” with the only exception being documents issued pursuant to the APA. The phrase “available to the public” is defined to mean either disseminated by the agency or involuntarily disclosed pursuant to the Freedom of Information Act (FOIA).

We expect that many commenters will strenuously object to the extraordinary breadth of this definition, especially when combined with the cross-reference to FOIA. Neither regulated entities nor the general public can be at all certain what documents are reachable via FOIA, and agency regulatory personnel also may not know because FOIA law itself has become rather complicated. Even without the FOIA cross-reference, the number of agency documents that could be construed as “describ[ing] an agency’s interpretation” of a policy or regulation is difficult to gauge.

At the same time, this definition is inappropriately narrow insofar as it is limited to documents “prepared by an agency.” Thus, guidance documents prepared by third parties appear to be exempt. An improvement could be made by borrowing language from the PRA to ensure that documents whose preparation was “sponsored by” an agency are treated as if they were prepared by the agency itself. This may not be enough, however, because agencies can utilize as guidance documents the work products of true third parties. Our view is that OMB should adapt or adopt the language already promulgated in its government-wide information quality guidelines: guidance prepared by an outside party and disseminated by the agency in a manner that reasonably suggests that the agency agrees with it constitutes guidance subject to the GGP.³

We believe OMB’s definition of “guidance document” is too focused on the form of a document and should be more attuned to a document’s function or effect. Guidance documents implicitly amend existing regulatory standards or narrow the range of permissible interpretations of future regulatory standards; that is their function and effect, regardless of what form they

³ Office of Management and Budget, 2002. Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Notice; Republication, 67 *Federal Register* 8452-8460 (hereinafter “OMB Information Quality Guidelines”). A further complication is that information disseminated by an agency pursuant to FOIA is exempt from the information quality guidelines. See § V(8).

take. A document that amends a regulatory standard in nontrivial ways is really a regulation, as is one that limits future agency regulatory discretion; both ought to be promulgated pursuant to the APA. Only if these amendments have a de minimis net effect is there a strong case for foregoing the APA's discipline, which Congress established to ensure that the government followed a consistent set of predictable and reproducible procedures, including procedures for public access and feedback.

3. How does a “significant guidance document” differ from an “economically significant regulation”?

In section I(3) OMB would create a category of “significant guidance documents” that includes documents

- (i) Reasonably be anticipated to lead to an annual effect of \$100 million or more or adversely affect in a material way the economy or a sector of the economy;
- (ii) Raise highly controversial issues related to interagency concerns or important Administration priorities;
- (iii) Set forth initial interpretations of statutory or regulatory requirements, or changes in interpretation or policy; or
- (iv) Concern novel or complex scientific or technical issues.

This definition makes no sense to us. Any document that satisfies the first of these criteria (borrowed from Executive order 12866) is a regulation. Similarly, a document that raises “highly controversial issues” or sets forth “initial interpretations of statutory or regulatory requirements” ought to be subject to the full discipline of the APA. If OMB seeks to establish an orderly system by which regulations and guidance are clearly distinguishable, and guidance deserves a lighter touch of oversight, public accountability and judicial scrutiny, then it should not encourage the practice of issuing as guidance those documents which ought to be promulgated as regulations.⁴

OMB should reconsider its approach before proceeding further. If it concludes that a government-wide definition of “guidance document” is essential or desirable, then it needs to establish a definition such that there is very little (and, ideally, no) overlap with the definition of regulation in the APA. If it concludes that this cannot be done, perhaps because the technology of government has changed too much since the 1940s, OMB ought to recommend that Congress change the law and offer specific suggestions along those lines. Alternatively, OMB could take the principled position that “guidance” that has more than de minimis effect must be subject to the discipline of the APA and be considered a rulemaking.

⁴ The same argument applies to the proposed new term “economically significant guidance document. See § I(5).

BASIC AGENCY STANDARDS

OMB accurately points out that guidance documents ought not to include directive words such as “shall,” “will,” or “must,” because directive language is fundamentally incompatible with guidance. But if OMB is serious about the general goal of “promoting good management practices” and the specific goals set forth in the preamble,⁵ then it ought to make basic agency standards nondiscretionary and not merely hortatory. For example, saying “All offices in an agency *should* follow these policies and procedures” (emphasis added) does little to advance the principle that *basic* standards reflect an appropriate minimum standard of agency conduct. In Section III, OMB proposes to *require* agencies to engage in certain conduct with respect to public access and feedback. Similar language ought to be used with respect to basic agency standards.

1. Full disclosure of statutory authority and the regulation(s) affected by guidance

An essential practice all agencies ought to follow is to specify the statutory authority authorizing the agency to issue the guidance and the specific regulation(s) to which the guidance applies. This is missing from OMB’s proposed basic agency standards, which focus mostly on housekeeping matters.⁶ OMB approaches the edge of the issue by including as a basic element identification of “the activity to which and the people to whom the [guidance] document applies.” Yet this leaves too much room for confusion about the domain of applicability for a guidance document. Clear identification of the specific regulation(s) modified or interpreted by the guidance document is essential,⁷

2. Agency procedures for departing from guidance

We commend OMB for including a specific provision concerning the procedures that agencies should follow for departing from a guidance document. OMB is less clear concerning what constitutes an “appropriate

⁵ “The purpose of GGP is to ensure that agency guidance documents are: developed with appropriate review and public participation, accessible and transparent to the public, of high quality, and not improperly treated as binding requirements. Moreover, GGP clarify what does and does not constitute a guidance document to provide greater clarity to the public.” Preamble at 3.

⁶ Basic agency standards proposed by OMB include such items as using the word “guidance,” disclosing the date of issuance, and providing the title. See § II(C)(2).

⁷ Overly broad descriptions of statutory (e.g., the Clean Air Act; the Federal Food, Drug and Cosmetic Act) are generally unhelpful. A clear statement of regulation(s) affected by a guidance document must identify *precisely* the relevant portion of the *Code of Federal Regulations* to which the guidance document applies.

justification” or which senior agency officials’ approval is sufficient. More clarity concerning the circumstances under which agencies might (or perhaps should not) depart from guidance is necessary. For example, agencies *should not depart* from guidance if a regulated entity has complied with a regulation based on good-faith reliance on a guidance document. Agencies *should depart* from a guidance document if its application in a specific circumstance is nonsensical, counterproductive, or it conflicts with other regulatory standards—or guidance.

Other aspects of this proposed provision are problematic. For example, by suggesting that agencies better manage (and presumably reduce) these departures from guidance, OMB may be unwittingly reducing future regulatory flexibility. If the hurdle to depart from guidance is set too high, agency staff may be deterred from applying common sense if that also requires obtaining the approval of a series of busy senior officials, each of whom has reasons to object on bureaucratic grounds. What’s important is to restrict the discretion of low-level staff to depart from guidance in ways that adversely affect regulated entities. Unfortunately, the current text makes no distinction between these very different circumstances.

PUBLIC ACCESS AND FEEDBACK

We support the timely public disclosure of accurate information about agency guidance, and it is instructive that in this case OMB proposes language that is highly directive with respect to both Internet posting and public feedback. The section on public feedback unfortunately contains only the weakest of requirements; section III(2)(a) requires agencies to provide a means for the public to comment on guidance documents, but section III(2)(b) invites agencies to ignore whatever comments it receives.⁸ Similarly, the section on public disclosure requires agencies to disclose very little information, and it provides no mechanism for the public to assist agencies in identifying guidance documents that need to be listed.

We believe that Section III ought to be the centerpiece of the Bulletin, and that this section is so important that the Bulletin would be valuable if only this section were issued, as long as appropriate modifications were made to ensure it was effective.

The text below represents our best effort to craft such language:

⁸ Section III(2) does not even require agencies to make public comments accessible to the public.

III. Public Access and Feedback.

1. Internet Access: Each agency shall maintain within a single page on its Web site a Table of Guidance Documents including all guidance documents issued by the agency. For each document the agency shall include:

a. The name or title of the document, including a working link to a full and complete version of its text, including all appendices and attachments. Each new guidance document and working link shall be added promptly to this list, and in no case later than 15 calendar days from issuance or 90 days prior to its effective date, whichever is later;

b. The date of issuance;

c. The effective date;

d. The date of revocation or rescission, if the guidance is no longer in force;

e. The regulatory provision to which the guidance applies, in CFR format; and

f. A working link to public comments submitted in accordance with 2(a) and 2(b) of this Section, and a search utility that enables users to identify all guidance documents that match relevant criteria such as date range and CFR section.

Guidance documents may be grouped by program or other form of categorization so long as it enhances public access and understanding. Each agency shall complete all responsibilities under this subsection within 90 calendar days of [insert issuance date].

2. Public Feedback: Each agency shall establish and clearly advertise on its web page containing the Table of Guidance Documents:

a. A means for the public to electronically submit comments on guidance documents, and to electronically request that guidance documents be created, reconsidered, modified, or rescinded.

b. A means for the public to electronically submit requests for correction of any guidance document believed to be incomplete or inaccurate;

c. A means for the public to electronically identify (or submit copies of) guidance documents issued by the agency that are not included in the Table of Guidance Documents.

3. Agency response: Each agency shall respond to public feedback by:

a. Posting a link adjacent to the applicable guidance document to any action proposed or taken in response to a request under 2(a);

b. Posting a corrected or complete version in response to a valid request under 2(b); and

c. Adding to the Table of Guidance Documents the missing guidance document identified pursuant to a request under 2(c).

Each agency shall perform its responsibilities under this subsection within 30 calendar days of receiving public feedback.

A focused effort to achieve full disclosure of all agency guidance is the first logical step toward promoting good management practices in this area. OMB has clearly struggled to write a single set of guidelines for the federal government. One reason this has been difficult may be that a reasonably complete inventory of federal agency guidance documents does not yet exist. Without such an inventory, and a significant analytic effort by qualified members of the public to understand and interpret it, any comprehensive improvement of governmental practice may be doomed to frustration.

NOTICE AND COMMENT ON ECONOMICALLY SIGNIFICANT GUIDANCE DOCUMENTS

This section might make sense if the distinction between “economically significant” and other guidance were sustainable. As we have commented earlier, we do not believe this distinction is justifiable. “Guidance documents” that, for example, are reasonably expected to have costs exceeding \$100 million should be managed as regulations. OMB has authority under Executive order 12866 to review any regulatory action the Administrator deems to be “significant.” Moreover, the definition of “regulatory action” is sufficiently broad to encompass guidance documents. In short, there are few obstacles currently impeding more effective centralized oversight, and a better exercise of OMB’s management authority would be to ensure that agency procedures for actions of similar magnitude are essentially identical irrespective of whether the product of the action is memorialized in the *Code of Federal Regulations*.

The language OMB proposes to address the special problem of “economically significant” guidance documents is brief and limited. It is instructive that OMB has devoted 1-1/2 pages in the preamble to elaborate on just 11 lines of text in the guidelines themselves.

A superior approach would be to simply direct agencies to utilize applicable APA procedures except where it is infeasible to do so. If OMB believes APA procedures are inadequate, then it should propose that Congress amend the law to incorporate specific statutory changes necessary to make the APA more effective.

CONCLUSIONS

We agree that it is important to regain management control over the burgeoning inventory of federal guidance documents. We believe, however, that it is at least premature to try to craft government-wide best management practices when the scope and scale of this inventory are both unknown. An abbreviated version of the *Proposed Bulletin*, modeled after our substitute Section III, would be a better way to start. Our rewrite would require agencies to promptly set up infrastructure for their guidance

document inventories, but beyond that it would impose relatively little burden. Our version also provides powerful incentives for regulated entities and the general public to assist federal agencies in building this inventory.

Thank you for providing the opportunity to comment on this latest effort to improve federal regulatory practice. We are especially grateful that OMB extended the deadline for public comments beyond December 23, 2005.

Sincerely,

A handwritten signature in black ink, appearing to read "R. Belzer". The signature is fluid and cursive, with a long horizontal stroke at the end.

President
Regulatory Checkbook

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