The Free State Foundation

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Perspectives from FSF Scholars
January 25, 2007
Vol. 2, No. 5

New Executive Order and OMB Bulletin Focus on Agency Guidance

by
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A new Executive Order, E.O, 13422, gives presidential recognition to the importance of federal agency guidances and the problems they can raise. While the specific mandates of the January 18 Order and the accompanying new Office of Management and Budget ("OMB") Bulletin are narrowly drawn, the focus they cast upon the need to confine and regularize agency guidances is of potentially enormous significance. The Bulletin, particularly, strongly affirms that agencies should not misuse guidances -- which lack the procedural foundations to carry the force of law -- by treating them as binding upon the public.

Guidances come in many forms, such as guidelines, policy statements, memorandums, manuals, interpretations, press releases, circulars, bulletins, speeches, Dear Manufacturer letters, Q and As, and the like. The Order amends the well-known Clinton Executive Order concerned with regulations (E.O. 12866), by bringing guidance documents within its coverage. Independent regulatory agencies like the Federal Communications Commission continue to be generally exempt from the Order.

The Order and Bulletin establish good practices for guidances, and subject "significant guidance documents" to OMB review.

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Executive Order 13422

Under the amended Executive Order, OMB's review of a significant guidance document, to be conducted by its Office of Information and Regulatory Affairs ("OIRA"), while substantial, is considerably less intensive than its review of a "significant regulatory action."

A "regulatory action" is an action, such as a notice of inquiry or a notice of proposed rulemaking, that promulgates or is expected to lead to a final regulation. It is "significant" if it is likely (a) to lead to a rule having an annual effect on the economy of $100 million or more or to adversely affect the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state or local or tribal governments or communities, or (b) to have certain budget impacts or to raise inconsistencies or novel issues. A "significant guidance document" is an agency statement – like the guidelines and others cited above -- that is not expected to result in a regulation, and is "significant" because it may be anticipated to lead to the kinds of effects in (a) and (b) just mentioned.

An agency proposing a significant regulatory action must provide OIRA with a text of its draft, with a description of the need for the regulation and how the regulation will meet that need, and with cost and benefit analyses. For significant regulatory actions meeting the criteria in (a) above, more detailed assessments of benefits and costs and of feasible alternatives are required. OIRA publicly discloses certain information, especially concerning its interchange with the agency and any *ex parte* communications. The agency may not publish its action until OIRA has reviewed it in light of the Order's regulatory principles and has resolved any concerns; unresolved disagreements are to be resolved by the President.

The new provisions governing significant guidance documents call for the agency to give OIRA advance notice of the document. Then, if requested by OIRA, the agency must provide to OIRA "the content of the draft guidance document, together with a brief explanation of the need for the guidance document and how it will meet that need." OIRA "shall notify the agency when additional consultation will be required before the issuance of the significant guidance document." The consequences in the event of disagreement are left unstated. A revised provision says that nothing in the Executive Order shall affect the authority vested by law in an agency or its head. So at least in theory the agency head could issue a significant guidance without OIRA's concurrence, but in practice that seems unlikely to happen. No express provision is made for disclosure of materials or other information regarding the guidance that are exchanged between the agency and OIRA.

This new review structure, while not as rigorous as that for proposed regulations, will impose a regime of discipline upon the development and issuance of major guidances. Too often guidances have been concocted and issued without regard for the important general principles of sound regulatory practice that the Executive Order now directs full attention to.

The Order amends several of its regulatory principles to require that they be observed for guidance documents in the same way they are observed for regulations – for example, to use best information before issuance, to avoid inconsistencies, to minimize burdens, and to be consistent with the president's priorities.

An interesting separate amendment encourages agencies to consider using the formal rulemaking procedures of Sections 556 and 557 of the Administrative Procedure Act for the resolution of complex determinations. Although use of those procedures in the Section 556-557 format has been widely disfavored, at least a partial use of their trial-like procedures could be helpful for resolution of specific factual issues where regulations or guidances will be based on those facts. But where those issues can be resolved by other means, trial-type procedures might simply produce delay.

OMB's *Final Bulletin for Agency Good Guidance Practices*

The accompanying OMB Bulletin's mandates upon the agencies are narrow: (1) to observe standards of good practice, including public access and feedback, in issuing and publicizing significant guidance documents, and (2) to observe a form of "notice and public comment" procedure for *economically* significant guidance documents, as described below.

But the Bulletin is most noteworthy for its emphasis on "the non-binding nature of guidance documents," a precept found in varied formulations throughout the 18-page preamble.

Non-Binding Nature of Guidances

A blight on government practice has been agency use – misuse -- of guidances to bind members of the public. Guidances cannot have the force of law because, in almost all cases, they are documents that have not been promulgated through the notice-and-comment procedures mandated by the Administrative Procedure Act for valid regulations. They nevertheless can be and often are put forth in such a way as to have practical binding effect on members of the public. If an applicant wants a permit or a benefit or an approval, he or she may have to conform to a guidance, even though it was not promulgated as a regulation through proper notice-and-comment procedures. Or an officer may threaten enforcement for nonconformity to a guidance, even where no statute or regulation was violated.

The Bulletin declares that one of the purposes of its Good Guidance Practices is "to ensure that guidance documents of Executive Branch departments and agencies are : * * * not improperly treated as binding requirements." It states that "Nothing in this Bulletin is intended to indicate that a guidance document can impose a binding requirement."

These precepts are reflected in the requirement that "significant guidance documents" "[n]ot include mandatory language such as 'shall,' 'must,' 'required,' or 'requirement,' unless the agency is using these words to describe a statutory or regulatory requirement, or the language is addressed to agency staff and will not foreclose agency consideration of positions advanced by affected private parties."

Although the mandatory provisions of the Bulletin deal only with "significant" guidance documents, the language and thrust of the preamble speak generically to guidances in general, and its declarations about the non-binding nature of guidances and the impropriety of treating them as binding apply to all guidances great and small.

The Bulletin notes the misuse of guidances: "Because it is procedurally easier to issue guidance documents, there also may be an incentive for regulators to issue guidance documents in lieu of regulations," quoting a famous passage from the *Appalachian Power* case, 208 F.3d 1015, 1019 (D.C. Cir. 2000). It adds: "The courts, Congress, and other authorities have emphasized that rules which do not merely interpret existing law or announce tentative policy positions but which establish new policy positions that the agency treats as binding must comply with the APA's notice-and-comment requirements, regardless of how they initially are labeled."

The insistence on the nonbinding effect of guidances is of signal importance. The Executive Office of the President has joined in condemning the misuse of guidance documents for binding the public.

It is not too much to say that a distinction between democracy and autocracy depends on whether government observes democratically-legislated authority and procedures when it places rights and obligations upon its citizens. Our federal system, with some exceptions, requires APA notice-and-comment for rules of general applicability if they are to have the force of law – that is, if they are to be binding on members of the public. Guidances that are not so promulgated cannot legitimately bind. Neither the Executive Order nor the Bulletin in any way diminishes the APA's requirements.

While only the subset of "significant" guidances is regulated by the Executive Order and Bulletin, both instruments contain this useful general definition: "The term 'guidance document' means an agency statement of general applicability and future effect, other than a regulatory action (as defined in Executive Order 12866, as further amended, § 3(g)), that sets forth a policy on a statutory, regulatory or technical issue or an interpretation of a statutory or regulatory issue." Much of the Bulletin's preamble states practices and legal circumstances applicable to all guidances, the great majority of which will not be "significant."

The Bulletin's definition of "significant guidance documents," which are subjected to procedures more extensive than those required by the APA, expressly excludes certain categories, which consequently need not endure the additional procedures. But exemption from the extra procedures imposed by the Bulletin does not create an exemption from APA requirements.

For example, speeches and press releases are not "significant," but in particular cases they may be vehicles through which new agency regulatory policy is promulgated. Although outside of the Bulletin definition, these formats do not supply avenues of escape from APA notice-and-comment requirements.

Also excluded from the Bulletin definition of "significant" are "purely internal agency policies" and "internal guidance documents directed solely to other Federal agencies." Most such documents operate on a general policy plane, and are subject to further implementation before their substances are applied to persons outside the agency. But if a purportedly "internal" document definitively affects the established rights and obligations of private persons – for example, by changing the criteria by which entitlements are granted or specific regulatory requirements are satisfied – it should get APA notice-and-comment even if it is kept within the agency and thereby exempted from the Bulletin's definition. Similarly, the definition of "significant guidance document" (though not the general definition of "guidance document") is limited to those "disseminated to regulated entities or to the general public," and "[d]isseminaton does not include distribution limited to government employees." If it affects specific rights and obligations of the public, a document held close to the agency's vest can amount to the sort of "secret law" that was so widely resented in the years leading up to the APA, and should go through notice-and-comment.

Good Guidance Practices

As mentioned above, the Bulletin's mandatory strictures have a narrow scope, falling as they do only upon those guidances that qualify as "significant." But its "Good Guidance Practices," as the preamble language of the Bulletin states, "set[] forth general policies and procedures for developing, issuing and using guidance documents. * * * All offices in an agency should follow these policies and procedures."

The "Basic Agency Standards for Significant Guidance Documents" are set forth in the operative text of the Bulletin. Each agency shall have written procedures for approval of the documents by appropriate senior officials. The document shall contain, among other details, identification of the activity to which and persons to whom it applies, notation of the date and docket number of the document, citation of the statute or regulation it relates to, and identification of previous documents that it may replace. The document may not include mandatory language such as "shall" or "require" except under limited conditions. The agency shall maintain on its website a list of significant guidance documents, with links to each document, and a means for the public to comment electronically and to request issuance or modification of such documents.

Also, "[a]gency employees should not depart from significant guidance documents without appropriate justification and supervisory concurrence." If the document affects private rights and obligations, unvarying routine application by agency employees can amount to binding effect. But the agency can avoid notice-and-comment requirements if it treats the document as tentative and allows proposal of alternative policies to be considered at an appropriately high agency level. The Bulletin very helpfully permits the use of mandatory language if "the language is addressed to agency staff and will not foreclose agency consideration

of positions advanced by affected private parties." One might wish that this language had been included in the preamble and directed to all guidances, not just significant ones. The preamble does offer a suggested form of disclaimer, which also might valuably be considered for use with any guidance. It declares that the guidance represents the agency's current thinking, that it does not confer or create rights or bind the public, and that "you can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations" and may discuss an alternative approach with appropriate agency staff. Observance of the terms of such a disclaimer ought to avert concern about the improper use of guidances to bind the public.

"Economically Significant Guidance Documents"

Guidance documents "that may reasonably be anticipated to lead to an annual effect on the economy of $100-million or more or adversely affect in a material way the economy or a sector of the economy" must undergo further procedures. (This definition excludes "guidance documents on Federal expenditures and receipts," although those guidances may still qualify as "significant guidance documents" and be subject to the procedures therefor.) The draft of any such guidance must be announced in the Federal Register, posted on the Internet, and made publicly available in hard copy. The agency must invite public comment, and then prepare and post on its website what the preamble calls a "robust response-to-comments document."

Obviously, these requirements come close to those of the APA Section 553 notice-and-comment structure, but "this Bulletin in no way alters (nor is it intended to interpret) the APA requirements for legislative rules under 5 U.S.C. § 553." Presumably, the Bulletin would catch pronouncements – that a substance is unhealthy, perhaps, or one like the HHS/USDA Dietary Guidelines cited in the preamble – which the agency regards as unsuitable for issuance as regulations under Section 553. The preamble also references a guidance offering "fast track treatment for a particular narrow form of behavior but subject[ing] other behavior to a burdensome application process with uncertain likelihood of success." In some situations, though, such a guidance could conceivably be regarded by the courts as having practical binding effect and therefore needing notice-and-comment.

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