December 11, 2017

To: ACUS Assembly

From: Ron Levin, Senior Fellow

Re: Proposed amendments to the recommendation on Agency Guidance

At the plenary session, I will ask for a motion to substitute the words "guidance document" (or minor stylistic variations) for "policy statement" comprehensively throughout the proposed recommendation. The substance of the proposed change is that the recommendation should apply to interpretive rules as well as policy statements. Within the Committee on Judicial Review, this was a minority view, but the committee was deeply split.

## I. The anomaly of addressing policy statements but not interpretive rules

1. The predecessor of the proposed recommendation, Conference Recommendation 92-2, applied to policy statements but not interpretive rules (although it contained no explanation for that limitation). This precedent seems to have created a level of inertia that this year's committee could not get past as it considered the present project.

Significantly, however, every subsequent pronouncement on this subject by other governmental or bar groups has applied its principles to both policy guidance and interpretive guidance. These pronouncements include an ABA resolution adopted the year after Recommendation 92-2[1]; the FDA's good guidance practices policy[2]; OMB's Final Bulletin on Good Guidance Practices;[3] and, most recently, the Department of Justice's memorandum issued one month ago.[4] Note that this aspect of the FDA policy was actually ratified by Congress.[5]

2. The premises reflected in these pronouncements do not seem far out of synch, if at all, with current thinking within the agencies. In his consultant's report, Nick Parrillo noted (at p. 26 n.43) that the question of whether, as an administrative matter, statements couched as "interpretive" should have binding status "was not an issue that jumped out in the interviews. While a majority of the 135 interviewees discussed the issue of guidance's binding or nonbinding effect in some way or other, only four brought up the idea that the interpretive status of guidance entailed some special power to bind." Moreover, among interviewees who did speak to the issue,[6] the belief that interpretive rules may be binding did not seem to predominate: "Among my interviewees who spoke on the subject (nearly all current or former officials), some said their agencies took the position that they could bind through interpretive rules, but more were equivocal

[1] ABA Recommendation 120C, 118-2 Ann. Rep. A.B.A. 57 (Aug. 1993).
[2] 21 C.F.R. § 10.115 (2017) (FDA, Sept. 19, 2000).
[3] Final Bulletin for Agency Good Guidance Practices, 72 Fed. Reg. 3432 (OMB, Jan. 25, 2007).
[4] Prohibition on Improper Guidance Documents, (DOJ, Nov. 16, 2017), https://www.justice.gov/opa/press-release/file/1012271/download.
[5] *See* 21 U.S.C. § 371(h)(1)(B) (2012) ("guidance documents shall not be binding on the Secretary").
[6] These consisted, as Nick confirms to me, of the four who raised it unprompted plus about another ten with whom he raised the matter (all cited at pp. 23-25 n.36).

or uncertain or rejected this view outright" (p. 23). This numerical data should not be taken as a representative sample in a statistical sense, because Nick's interviews were unstructured, and this topic was raised by the interviewee or by Nick in only a minority of the interviews. Even so, these responses seem to indicate that the issue was not as salient as one might initially expect. And the finding that most interviewees speaking to the issue did not view interpretive rules as binding is striking.

3. The emerging tendency among administrative lawyers, inside and outside of government, is to speak of "guidance" as a single form of government action. The committee's recognition of this reality was a major reason behind its decision to call its proposed recommendation "Agency Guidance" instead of "Agency Policy Statements." The committee believed that the former term is more recognizable and familiar to agency personnel. I think that's true, which is why the committee's proposed limitation in the scope of the recommendation seems so awkward and artificial. And if readers look to the proposed recommendation itself for an explanation as to why it addresses policy statements but not interpretive rules, they will find none.

There is a good chance that, if agencies were to adopt internal procedural rules to implement the forthcoming recommendation, many or most would apply them to "guidance" generally, because that is the level of generality on which they typically operate (especially since the OMB Bulletin does direct executive branch agencies to maintain analogous procedures regarding "guidance"). Indeed, extant procedural rules cited in Nick's report (see fn. 6 of the draft recommendation) do have that scope. This is all the more reason why the Conference should not leave the status of interpretive rules unaddressed.

## II. The case for including interpretive rules

1. On the merits, the basic reason why the Conference recommendation should apply to interpretive rules is that they are fundamentally similar to policy statements in the respects that matter most for our purposes. Policy statements differ from legislative rules, because they lack the force of law. As the draft recommendation states, policy statements "are sometimes criticized for coercing members of the public, as if they were legislative rules" (lines 37-38). Thus, the agency should not use a policy statement "as a standard with which noncompliance may form an independent basis for action in maters that determine the rights and obligations of any member of the public" (lines 118-20). Per paragraph 2, members of the public should be afforded "a fair opportunity to argue … for modification or rescission of the policy statement" (lines 121-22).

As I see the matter, all of these points apply, or should apply, to interpretive rules as well. When private persons come forward with reasons as to why an interpretive rule, or part of it, should be rethought or not applied in a particular situation, the agency should not respond that the interpretive rule is determinative. Rather, it should find an appropriate way to allow these person to get their views considered by the agency, inasmuch as the rule presumably would not have been subjected to the notice and comment process earlier. During the committee meetings, members from a few agencies said that they do, in fact, entertain submissions that ask them to consider changing a given interpretive rule, granting a waiver, or otherwise acting favorably on the

submitter's interpretation. The goal of allowing some sort of opportunity to be heard regarding the rule must, of course, be balanced against the public interest in preserving unimpeded access to agency advice. Again, however, this tradeoff is basically the same regardless of whether the focus is on policy statements or on interpretive rules.

2. Coverage of both policy statements and interpretive rules is all the more desirable because there is no clear line of distinction between them. As one EPA source told Nick (p. 24 n.35): "[I]n most instances, a guidance document consist[s] of a mixture of interpretive-rule material and policy-statement material that [is] hard to disentangle." This should not be surprising, because it is well recognized that many administrative judgments that we commonly characterize as "interpretation" (particularly interpretations that could survive scrutiny under *Chevron* step one and then be reviewed under step two) are analytically equivalent to policy judgments that are typically reviewed for abuse of discretion. It would be unwise to make the applicability of the recommendation turn on which label an agency chooses to affix to a particular guidance document.

A good illustration of the close interrelationship between interpretive guidance and policy guidance is paragraph 5 of the draft recommendation, which provides that a guidance document "should not include mandatory language unless the agency is using that language to describe an existing statutory or regulatory requirement . . . ." As a matter of logic, this principle should have been omitted from the draft if interpretive guidance were to be categorically omitted from the recommendation. I supported its inclusion because, as a matter of good sense, the principle – which actually comes almost verbatim straight out of the OMB Good Guidance Practices Bulletin – ought to be brought to the attention of agency personnel who draft guidance documents. But the fact that it is included demonstrates that the committee itself was not willing to live with the implications of its artificial distinction.

3. If the Conference decides that an agency need not be open to giving consideration at the administrative level to arguments that call its interpretive guidance into question, what is the alternative? Presumably, it is to say that private persons who disagree with the interpretation should raise their objections for the first time in court instead. This would be quite a turnaround from the position that many government members of the Conference took two years ago during the Assembly's debate on the issue exhaustion project.[7] Their view at that time was that objections to an agency's views generally *should* be raised at the agency level before being presented to a court. The Conference's able consultant had suggested that this expectation would impose an undue workload on the agencies, but the government lawyers maintained that any such burden was worthwhile, in terms of enabling the agency to respond at a time when it was in the best position to do so (as opposed to having to formulate a post hoc rationalization at the judicial review level). I agreed with that general view at the time; it should be taken seriously now as an expression of how an orderly administrative process ought to work.

4. If anything, the burdens of entertaining challenges to interpretive rules should generally be *less* than the corresponding burden applicable to policy statements. The issues will typically

[7] This project culminated in ACUS Statement #19, *Issue Exhaustion in Preenforcement Judicial Review of Administrative Rulemaking* (Oct. 7, 2015), https://www.acus.gov/research-projects/issue-exhaustion-preenforcement-judicial-review-administrative-rulemaking.

be legal in nature, calling primarily for library research (or the electronic equivalent thereof). Compilation of witness statements, empirical research, scientific studies, and the assembly of a factual record would usually not be involved. Moreover, once the agency has articulated its legal conclusions in the interpretive rule or elsewhere, it would thereafter be able to refer back to that articulation in any subsequent challenge. In this regard, the recommendation's advice regarding agencies' handling of policy statements would seem to be at least as manageable as applied to interpretive rules, if not more so, and the exclusion of the latter from the scope of the recommendation seems all the more unwarranted.

III. Considerations that supposedly justify the exclusion of interpretive rules

1. In conducting his research, Nick focused his questions on policy statements. This fact led some members of the committee to question whether his research was sufficient to support any recommendations about interpretive rules. However, the deficiency seems more theoretical than real. As noted above, the findings that he did make cast doubt on the idea that agency lawyers generally draw sharp distinctions between interpretive rules and policy statements. Indeed, during committee deliberations we did not hear about a single agency that actually maintains different procedures for these two types of guidance. To the extent that Nick's interview subjects (a minority of those offering an opinion) made arguments favoring the proposition that interpretive rules may be binding, my responses to those arguments appear below.

2. In confining the draft recommendation to policy statements, committee members may have been influenced by the fact that, in the case law discussing the § 553(b)(A) exemption in the APA, one can find statements (generally dicta) to the effect that an agency may apply interpretive rule in a more binding fashion than it could do in the case of policy statements. The reported comments of some of Nick's interview subjects also seem to rest on their view of what the law permits (as distinguished from what they actually do). In a forthcoming article, however, I explore this confused and "smoggy" body of case law and argue that the APA should be construed to reject this view of interpretive rules.[8]

For purposes of the present recommendation, we can agree to disagree on this point. The Conference does not need to enter into this debate. Consistently with usual ACUS practice, the proposed recommendation is basically designed to speak in terms of sound principles of administration, not of legal interpretation. As part of my package of amendments, I will propose a few language adjustments to revise a few phrases that could be read to suggest otherwise. It should be clear, therefore, that the recommendation would deal only with what agencies should and should not do, not with what they legally may do.

[8] *Rulemaking and the Guidance Exemption*, forthcoming in 70 Admin. L. Rev. # 2 (Spring 2018), currently posted on SSRN at http://ssrn.com/abstract=295b8267. A short summary of the article may be found in the appendix to my comments of October 13, 2017 on the Conference's Agency Guidance webpage, https://www.acus.gov/sites/default/files/documents/Levin%20memo%20for%20COJR%2010.13.2017_0.pdf.

3. On a more specific level, some government members had reservations about being asked to declare their interpretive rules to be binding, because such an expectation could (they thought) detract from their ability to explain to the public what they regard as the binding force of the statutes and regulations that they administer. As a theoretical matter, I do not believe that these two goals are contradictory. An agency should be free to express its *position* that a given interpretation declares statutory principles that citizens are required to obey. This is not incompatible with an expectation that the agency should provide some opportunity for affected persons to be heard on the question of *what its position should be*.

Admittedly, however, the draft recommendation as currently written leaves room for uncertainty on this issue. As one element of my proposal to include interpretive rules in the recommendation, I am supporting an additional amendment designed to assuage the concerns just mentioned. The amendment would add the following language at the end of paragraph 4 of the recommendations: "In the case of interpretive guidance, the document should indicate that it is open to contestation to the extent and in the manner envisioned by the foregoing recommendations, but it may also make clear, where relevant, that in the agency's view the statute or other interpreted text, as construed in the guidance document, imposes mandatory requirements or prohibitions on members of the public."

4. An additional reason for some committee members' hesitation to include interpretive rules in the recommendation was that such rules often will receive deference on judicial review. Such deference adds to the pressure to obey them and can be characterized as a "binding" effect, or so it was argued.

Although that theory of deference is itself contested, I do not think the Conference needs to confront it, because it refers to a different kind of binding effect from the one with which this recommendation is concerned. The two kinds do not have to go hand-in-hand. The recommendation basically sets forth a set of behavioral expectations, which could apply or not apply regardless of the level of deference a guidance document would receive if judicially reviewed. One might say, in a directly analogous fashion, that a policy statement may well have a "binding effect" in the sense that people know that if it reaches the courts, it is likely to be upheld unless it is arbitrary and capricious, ultra vires, etc. That kind of binding effect is entirely compatible with the nonbinding status that everyone recognizes should be accorded to policy statements in the sense relevant to the recommendation.

5. One other argument that appeared to underlie some of the committee's disinclination to address interpretive rules was the idea that the recommendation should focus on the kind of individualized adjustments that can often be arranged with policy statements, such as by saying "this document explains one way in which you can comply with the statute or regulation, but we are open to discussing alternative ways with you." The premise of the argument was that interpretive rules do not lend themselves as well to such individualized adjustments, because controversies about such rules instead tend to turn into broad challenges aimed at forcing rescission or modification of those rules.

I have no doubt that the use of policy statements to open up a dialogue about alternative modes of compliance is a useful tool of administrative governance. The committee did write the recommendation to include language encouraging agencies to make use of that tool. However, the committee's recommendation also calls on agencies to accommodate stakeholders that simply disagree with the guidance document and wish to ask the agency to modify or rescind it. If anything, the latter type of relief may be especially appealing to persons who feel coerced into complying with agency guidance – the main problem discussed in the preamble and the research underlying it. In the context of requests for modification or rescission, the status of policy statements and interpretive rules seems quite similar.

## IV. Conclusion

The draft recommendation draws a line between two forms of guidance that are actually quite similar in material respects. Adherence to that distinction could be expected to give rise to perplexity and criticism. In my view, the Conference should get into line with other groups that have examined the same issues since Recommendation 92-2 and should amend the draft recommendation to avoid that anomaly.