July 18, 2022

Via ACUS Online Portal

Administrative Conference of the United States
1120 20th Street NW, Suite 706 South
Washington, DC 20036

Re: Notice, Request for Comments; Administrative Conference of the United States; Disclosure of Agency Legal Materials; 87 Fed. Reg. 30445

To Whom It May Concern:

On behalf of the Chamber of Commerce of the United States of America ("Chamber"), I submit this comment in response to the Request for Comments issued by the Administrative Conference of the United States ("ACUS") on May 19, 2022, regarding Disclosure of Agency Legal Materials.

The Chamber strongly supports robust disclosure and accessibility requirements for agency legal materials as a means to promote fairness, transparency, and predictability in the regulatory process. Although the proper role of agency legal materials in the regulatory process continues to evolve, making such materials easily and broadly accessible to the public is a matter of good governance and promotes business growth and job creation.

The Chamber accordingly recommends that ACUS propose legislation to codify, at a minimum, the requirement in Section 3(a) of now-rescinded Executive Order 13891 that “each agency or agency component, as appropriate, shall establish or maintain on its website a single, searchable, indexed database that contains or links to all guidance documents in effect from such agency or component.” The Chamber also recommends codifying the requirements of Section 5 of the also-rescinded Executive Order 13892, which required public disclosure of “[a]ny decision in an agency adjudication, administrative order, or agency document on which an agency relies to assert a new or expanded claim of jurisdiction,” subject to redactions for confidentiality where appropriate. Of course, the Chamber supports even broader disclosure requirements...
for agency legal materials—these two provisions simply represent part of the minimum baseline for disclosure. As explained below, any agency document that potentially imposes a legal or compliance expectation for members of the public, irrespective of its classification, should proactively be made available.

Disclosure requirements should also apply uniformly across all agencies that regulate members of the public. Currently, disclosures vary between agencies, and even within agencies, materials are often not available to the public in a single location in a searchable manner. Access to agency legal materials should not be a matter of luck, and ACUS should encourage agencies to embrace innovation and technology to make one-stop access to agency materials easier.

This is simply a matter of good governance. Guidance documents have been controversial. What should not be controversial is that to provide guidance to regulated entities, they must be available to regulated entities. Moreover, to the extent that guidance documents go beyond mere guidance and effectively impose obligations or liabilities, any sense of fairness or due process requires that they be accessible to regulated entities.

Nor should regulated entities have to incur considerable time and expense hunting for such documents in myriad obscure places. Even for entities that can absorb that expenditure, it is wholly unwarranted. Small businesses, i.e., most businesses, can ill-afford that cost and burden.

**Description of Agency Legal Materials**

materials by all agencies that regulate the public. Current piecemeal approaches create inconsistent and conflicting requirements that undermine and limit the disclosure of agency legal documents. Proposed legislation should create a presumption in favor of proactive disclosure.

The most prominent example of agency legal materials are materials commonly referred to as guidance documents or subregulatory guidance. Although technically not binding on the regulated public or agencies, these materials have practically binding effects but are often not available to the public in a clear and comprehensive way. As described below, the burdens and legal obligations that such materials place on regulated entities necessitate making such materials available to the public and to regulated entities in a clear, accessible, and comprehensive manner.

Agencies generate subregulatory guidance to fill in regulatory gaps and, in some cases, to take a “shortcut by issuing ‘guidance’ in lieu of regulations.” Deputy Associate Attorney General Stephen Cox, Remarks at the 2019 Advanced Forum on False Claims and Qui Tam Enforcement (Jan. 28, 2019). Agencies may believe that they can use such guidance to avoid “the notice-and-comment process of rulemaking, which can be cumbersome and slow.” Id. They may also seek to augment regulations that “contain[ ] broad language, open-ended phrases, ambiguous standards, and the like.” Appalachian Power Co. v. EPA, 208 F.3d 1015, 1020 (D.C. Cir. 2000); see also, e.g., Azar v. Allina Health Servs., 139 S. Ct. 1804, 1816 (2019) (acknowledging but rejecting Government’s policy argument that “providing the public with notice and a chance to comment on all Medicare interpretive rules . . . would take ‘many years’ to complete”). Guidance documents that merely interpret “genuinely ambiguous’ regulations” may be entitled to deference under Kisor v. Wilkie, at least to the extent that they represent an agency’s “authoritative” or “official position.” See Kate R. Bowers, Congressional Research Service, Agency Use of Guidance Documents at 3 (April 19, 2021) (citing Kisor v. Wilkie, 139 S. Ct. 2400 (2019); Auer v. Robbins, 519 U.S. 452 (1997); and Bowles v. Seminole Rock & Sand Co., 325 U.S. 410 (1945)). Such guidance can guide the public only if it is made available to the public. In the case of guidance that is improperly used to evade the notice-and-comment process, it can be challenged by a member of the public only if the public is made aware of it. Accordingly, whether used (properly) to inform the public or (improperly) to evade public comment, it is important that all guidance documents, irrespective of their form, be deemed agency legal materials and subject to disclosure.

Another significant characteristic of guidance documents is their volume. Ultimately, “[o]ne guidance document may yield another and then another and so on.

Several words in a regulation may spawn hundreds of pages of text as the agency offers more and more detail regarding what its regulations demand of regulated entities.” Appalachian Power, 208 F.3d at 1020. The result is that “[f]or individuals and firms regulated by federal agencies, actual regulations are just the beginning of the story.” Nichola R. Parrillo, Federal Agency Guidance and the Power to Bind: An Empirical Study of Agencies and Industries, 36 Yale J. on Reg. 165, 167 (2019). Indeed, as one “veteran EPA lawyer” declared, “[g]uidance is ‘the bread and butter of agency practice,’” so having full access to the evolution of guidance documents is essential to effectively representing entities before agencies. See id. at 168; see also Kristin E. Hickman, IRB Guidance: The No Man’s Land of Tax Code Interpretation, 2009 Mich. St. L. Rev. 239, 239 (2009) (“Legal scholars have long recognized that many or even most agency legal interpretations are made informally rather than by regulations promulgated through notice-and-comment rulemaking and published in the Code of Federal Regulations.”). These reasons also weigh in favor of disclosure of guidance documents in an accessible and comprehensive manner.

Although guidance documents are the most voluminous and often most impactful form of agency legal materials, ACUS’s recommendations, and any statutory mandate, should not be limited to “guidance documents” or “subregulatory guidance” but should be broad enough to also extend to any materials that an agency uses, whether directly or indirectly, to “assert a new or expanded claim of jurisdiction—such as a claim to regulate a new subject matter or an explanation of a new basis for liability.” See Executive Order 13892 § 5. That includes, for example, documents arising out of litigation, such as briefs, consent decrees, or settlement agreements. Id. In other words, an agency’s obligation of transparency should attach to legal materials based on their effect, not on how they are labeled.

Making Guidance Documents Accessible Promotes Transparency and Fairness

Subregulatory guidance is ubiquitous because it is convenient for agencies. Through use of guidance documents, an agency “can issue or amend its real rules, i.e., its interpretive rules and policy statements, quickly and inexpensively without following any statutorily prescribed procedures.” Appalachian Power, 208 F.3d at 1020. Such guidance “can be produced and altered much faster, in higher volume, and with less accountability than legislative rules can.” Parrillo, supra, at 168.

Some posit that the absence of checks and balances on subregulatory guidance is justified on the basis that, “in the familiar telling . . . guidance, unlike a legislative rule, is not binding on the agency or the public.” Id. Accordingly, the appropriate use of subregulatory guidance is to “educate[] the public about statutes, regulations, and legal developments,” not to “bind the public by imposing legal obligations beyond those already enshrined in existing statutes or properly promulgated regulatory provisions.”
Cox, *supra*. To accomplish its legitimate purpose of “educat[ing]” the public, agency guidance must be readily accessible to regulated entities and the public. See Cary Coglianese, *Illuminating Regulatory Guidance*, 9 Mich. J. Envt'l & Admin. L. 243, 261 (2020) (“If guidance documents are valuable tools designed to inform and assist members of the public, then the public must at least be able to find them.”).

Despite their purportedly benign role, guidance documents often “can, as a practical matter, have a binding effect.” *Appalachian Power*, 208 F.3d at 1021. Even though not technically binding, regulated entities have strong incentives to adhere to subregulatory guidance. “If an agency acts as if a document issued at headquarters is controlling in the field, if it treats the document in the same manner as it treats a legislative rule, if it bases enforcement actions on the policies or interpretations formulated in the document, if it leads private parties or State permitting authorities to believe that it will declare permits invalid unless they comply with the terms of the document, then the agency's document is for all practical purposes ‘binding.’” *ld*. Even where the guidance contains language disclaiming binding effect, it is often generally understood that such language is “boilerplate” – even a “charade, intended to keep the proceduralizing courts at bay.” *ld*. at 1023; *see also*, *e.g.*, Hickman, *supra*, at 246 (noting that even though the IRS “occasionally disclaims” that its revenue rulings “provid[e] substantive interpretive guidance,” “both the IRS and the tax community at large tend to regard revenue rulings as a format for providing” such guidance).

Empirical evidence demonstrates that “[r]egulated parties often face overwhelming practical pressure to follow what a guidance document ‘suggests,’ at least absent an individual dispensation from the agency saying that it is okay, in the present instance, for a regulated party to act differently from the guidance.” Parrillo, *supra*, at 174. That pressure is “hard-wired into the structure of the regulatory scheme.” *ld*. Regulated entities feel particular pressure when they are required to “obtain pre-approval . . . in order to get some legal advantage”; when they are subject to “continuous monitoring and frequent evaluations”; where an entity’s compliance staff have a “strong incentive to maintain good relations with the agency”; and where a party is “subject to ex post enforcement.” *ld*. at 177.

In addition, agencies themselves may feel constrained by the effect of subregulatory guidance, even though such guidance in theory should not limit their discretion to act within the bounds of relevant statutes and regulations. “The great fear is that agency officials, in real life, are not tentative or flexible when it comes to guidance but instead follow guidance as if it were a binding legislative rule, and regulated parties are under coercive pressure to do the same.” *ld*. at 169. For instance, “agencies are sometimes inflexible about guidance, that is, they are not practically open to entertaining regulated parties’ arguments for . . . individual dispensations” from guidance requirements. *ld*. at 174.
Thus, the practical effect of subregulatory guidance is to impose obligations, often significant, on the public and regulated entities. Indeed, agencies engage in subregulatory guidance “knowing that it will achieve [the] effect of changing behavior.” Cox, supra.

The practical effects of subregulatory guidance arise in numerous contexts. For example:

- In *Azar v. Allina Health Services*, 139 S. Ct. 1804, 1808 (2019), the Supreme Court held invalid a government policy that the Centers for Medicare & Medicaid Services had “revealed . . . on its website that dramatically – and retroactively – reduced payments to hospitals serving low-income patients.” There was no advance notice or opportunity to comment, and no excuse for not offering an opportunity for notice and comment. *Id.*

- The DC Circuit struck down an EPA guidance document in *Appalachian Power* that imposed requirements on states in connection with their operating permit programs under the Clean Air Act. The guidance document was issued over the signature of two EPA officials, consisted of 19 pages available on the EPA’s website, and concerned requirements for periodic monitoring. 208 F.3d at 1019-20.

- Subregulatory guidance has been influential in causing regulated entities to separate Chief Compliance Officer and Chief Legal Officer roles “because HHS’s Office of Inspector General . . . has expressed this expectation on numerous occasions.” Eden Marcu, Note, *One Person, Two Hats: Combining the Roles of Chief Compliance Officer and Chief Legal Officer*, 47 Fla. St. U. L. Rev. 705, 706 (2020). “Those within the health care community typically conform to the stance of the OIG, even when it is non-binding.” *Id.* at 717.

- In 2013, CMS released a final rule revising reimbursement criteria for hospital claims and creating a requirement that, generally, for inpatient hospital admissions to be deemed medically necessary, an admitting physician must anticipate that hospital care will require a stay crossing two midnights. Jessica L. Gustafson, *2-Midnight Rule Update: Hospitals Must Continue Implementation of the 2-Midnight Rule*, 26 No. 4 Health Law 34, 34 (2014). Following that change, there were at least six subregulatory guidance documents issued in 2013 and 2014. *Id.* at 35. That “evolving sub-regulatory guidance . . . created confusion among hospitals” and for the “[Medicare Administrative Contractors] enforcing the” revised rules because of their inconsistencies. *Id.*

- The Internal Revenue Service “publishes a series of official and authoritative, if informal, guidance documents in the Internal Revenue Bulletin (IRB) each week and the Cumulative Bulletin (CB) annually.” Hickman, supra, at 240. In addition,
“reams” of informal guidance, in the form of “letter rulings, internal memoranda, and other documents containing IRS legal interpretations and analysis” are available “through Westlaw, Lexis, and other sources.” Id. at 241.


- The Interagency Working Group (IWG) on the Social Cost of Greenhouse Gases is charged with reviewing and revising the estimates of the social cost of carbon, methane, and nitrous oxide to “allow agencies to understand the social benefits of reducing emissions of each of these greenhouse gases, or the social costs of increasing such emissions, in the policy making process.” Interagency Working Group on Social Cost of Greenhouse Gases, Technical Support Document: Social Cost of Carbon, Methane, and Nitrous Oxide: Interim Estimates Under Executive Order 13990 at 2 (Feb. 2021). The IWG’s estimates have been applied in the cost-benefit analysis for regulations, environmental permitting documents, agency procurement, and other areas. Yet the IWG has updated the estimates without providing any opportunity for substantive public comment, nor put the most recent estimates through peer review.

Guidance documents may also be used to assert a basis for liability in private lawsuits. As former Associate Attorney General Rachel Brand stated in 2018, guidance documents are often front and center in qui tam lawsuits, where relators (and government attorneys) try to “use noncompliance with guidance documents as a basis for proving violations of applicable law in [False Claims Act] cases.” See Memo, Limiting Use of Agency Guidance Documents in Affirmative Civil Enforcement Cases at 2 (Jan. 25, 2018).3

For all of these reasons, and the myriad circumstances in which guidance documents constrain or influence the discretion of agency staff or otherwise have real world legal consequences, regulated entities are entitled as a matter of basic fairness and good governance to understand the substance of that guidance.

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2 Available at https://www.forbes.com/sites/waynecrews/2021/04/26/laws-have-mercy-here-is-how-biden-is-restricting-access-to-regulatory-guidance-documents/.

3 Available at https://www.justice.gov/file/1028756/download.
Importance of transparency

Unlike notice and comment rulemaking, subregulatory guidance does not have built-in transparency. “Notice and comment gives affected parties fair warning of potential changes in the law and an opportunity to be heard on those changes – and it affords the agency a chance to avoid errors and make a more informed decision.” Azar, 139 S. Ct. at 1816. However, as described above, subregulatory guidance can be used to try to impose (and, at the very least, explain) potentially significant obligations or liabilities on regulated entities and the public with no corresponding transparency requirement. Despite the fact that regulated entities may be subjected to efforts to bind them using subregulatory guidance, some courts have been reluctant to consider guidance documents that are not publicly available when regulated entities rely on them in court. See, e.g., Casey v. Odwalla, Inc., 338 F. Supp. 3d 284, 293–95 (S.D.N.Y. 2018) (refusing to take judicial notice of guidance document that was available through FOIA request but was not publicly available).

Historically, guidance documents have often been difficult to access and poorly organized. See, e.g., Coglianese, supra, at 264 (discussing findings and recommendations of ACUS and ABA); Jill E. Family, Easing the Guidance Document Dilemma Agency by Agency: Immigration Law and Not Really Binding Rules, 47 U. Mich. J. L. Reform 1, 5–6, 11–12 (2013); Caring Hearts Personal Home Servs., Inc. v. Burwell, 824 F.3d 968, 970 (10th Cir. 2016) (Gorsuch, J.) (noting that the “about 37,000 separate guidance documents . . . found on CMS’s website” did not even “purport to be a complete inventory”). For instance, a 2015 GAO audit of agency guidance availability found problems including broken links; “long lists of guidance, which could make it difficult for users to find particular guidance documents”; failure to distinguish current from outdated guidance; confusion created by guidance “dispersed across multiple pages within a website”; and the lack of any “systematic way to evaluate whether the public could access . . . guidance online.” Coglianese, supra at 267.

Recent efforts at transparency regarding guidance have been walked back by the current Administration. In Executive Orders 13891 and 13892, President Trump ordered that agencies take steps to promote transparency with respect to subregulatory guidance. Among other things, Executive Order 13892 required the publication of “[a]ny decision in an agency adjudication, administrative order, or agency document on which an agency relies to assert a new or expanded claim of jurisdiction – such as a claim to regulate a new subject matter or an explanation of a new basis for liability.” Id. § 5. Executive Order 13891 similarly required that “guidance documents” upon which an agency relies to create a new basis of liability must be published in a “single, searchable, indexed database” on the agency’s website. Id. § 3(a). By September 2020, “a number of agencies did establish online portals as required by E.O. 13891” and more than 70,000 documents had been posted. Crews, supra. Following President Biden’s revocation of these Executive Orders, agencies have deleted their portals. See id.
Pause to consider that—these agencies took *affirmative steps* to conceal their legal pronouncements.

To avoid such actions, as well as policy swings from Administration to Administration, the Chamber strongly supports durable requirements, mandated by statute and not revocable at the discretion of the Executive, for the permanent disclosure of these materials.

**Recommendations**

**Scope of Guidance (Question 1)**

One of the challenges of subregulatory guidance is that it “comes in an endless variety of labels and formats, depending on the agency: advisories, circulars, bulletins, memos, interpretive letters, enforcement manuals, fact sheets, FAQs, highlights, you name it.” Parrillo, *supra*, at 167. The scope of ACUS’s recommendations should be broad enough to cover all such materials that may be interpreted to impose legal obligations on the regulated public or that clarify the scope of such obligations. Accordingly, “agency legal materials” should be defined broadly to encompass guidance documents, adjudication rules, adjudication materials, and litigation materials. As described above, each of these documents can impact legal obligations and inform the public of enforcement intentions. Moreover, relators or the government may attempt to invoke such guidance as a basis for False Claims Act liability.

Specifically, “agency legal materials” should be defined at least as broadly as the definition of “Guidance Document” in Executive Order 13891 – that is, with some exceptions, “an agency statement of general applicability, intended to have future effect on the behavior of regulated parties, that sets forth a policy on a statutory, regulatory, or technical issue, or an interpretation of a statute or regulation.”4 *Id.* § 2(b). It should

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4 It is important to state explicitly that technical and scientific materials (or documents denominated as such) that fit within this definition are within the scope of agency legal materials. Agencies sometimes rely (and often are required by statute to rely) on the exercise of technical expertise in making factual assumptions or other determinations that, in practical terms, have the same effect as regulations or guidance. An agency may not shield regulations or guidance materials from public disclosure or scrutiny by characterizing the relevant materials as technical or scientific in nature. And as noted above, the form of the materials does not matter to whether the materials must be disclosed. If modeling software, for example, is used as part of the regulatory process or otherwise fits within the scope of guidance as described herein, then the software warrants disclosure just as much as would be the case for a white paper or memorandum.
also encompass “jurisdictional determinations” as defined in Executive Order 13892, which include “[a]ny decision in an agency adjudication, administrative order, or agency document on which an agency relies to assert a new or expanded claim of jurisdiction—such as a claim to regulate a new subject matter or an explanation of a new basis for liability.” *Id.* § 5.

Existing Obstacles to Access (Questions 2 and 3)

Agencies are inconsistent with respect to the subregulatory guidance materials that they make available, and how those materials are provided and organized. As described above, guidance documents are often not presented in a comprehensive, transparent, and accessible manner, and that issue was exacerbated by the rescission of Executive Orders 13891 and 13892.

Guidance documents should be made available regardless of how an agency labels them. In addition, agencies should not be allowed to avoid disclosure by labeling subregulatory guidance as “non-significant.” For example, Executive Order 13422, an earlier attempt at addressing some of the lack of accountability for guidance documents, subjected certain “significant” guidance documents to review by the Office of Information and Regulatory Affairs. In this context, such an exception risks being applied inconsistently or incorrectly by agencies. Any statutory requirement for the disclosure of subregulatory guidance should avoid incorporating a similar exception that would allow agencies to avoid disclosure by designating certain documents as non-significant. If they are truly so unimportant, the agency should have no need for them.

Means for Access (Questions 4-5)

All subregulatory guidance should be affirmatively disclosed by agencies, except for certain proprietary financial, technical, or privileged information, as described below.

At a minimum, agencies should make subregulatory guidance available through the type of database required by Executive Orders 13891 and 13892 – that is, a “portion of the agency’s website that contains a single, searchable, indexed database of all guidance documents in effect.” Before the rescission of Executive Orders 13891 and 13892, many agencies had already developed such databases, demonstrating that it is feasible and practicable to do so. See Crews, *supra*. Any argument that guidance documents have become so unwieldy as to make the construction of such a database burdensome to the agency just underscores the importance of it to the public.

Exemptions (Question 6)

The Chamber recognizes that certain limited sets of information or documents should not be disclosed. Those include, for instance, documents that contain
confidential proprietary and technical information that is submitted to agencies subject to an expectation of confidentiality. Maintaining confidentiality is an important part of protecting the free market. Where such information may be contained in documents that fall within the broad definition of agency legal materials described above, it may be possible to redact the confidential information or aggregate it to a higher level to balance the needs for confidentiality with those for disclosure.

Carveouts for law enforcement and national security are appropriate and should be addressed as they already are in the Freedom of Information Act (FOIA), 5 U.S.C. § 552, Exemptions 1 (applying to classified national defense and foreign relations information) and 7 (certain types of information compiled for law enforcement purposes).

Indeed, documents (or portions of documents) that should be exempt from disclosure will generally, if not always, fall within exemptions to disclosure already established in FOIA. For instance, FOIA Exemption 4 applies to trade secrets and confidential or privileged commercial or financial information, and FOIA Exemption 5 applies to privileged communications within or between agencies. Incorporation of exemptions already established by FOIA would serve interests of predictability and efficiency and would ensure that there is no conflict between agency obligations under FOIA and any new statute implementing ACUS’s recommendations.

Proposed Statutory Reforms (Questions 7-10)

In general, the Chamber does not favor a piecemeal approach to disclosure. Our members span a range of industries and have interests in appropriate transparency and accountability across the spectrum.

The statutory requirement for disclosure should address broad concepts such as the requirement that databases of subregulatory guidance be indexed and searchable. Other specifics concerning the format and mechanisms of disclosure should be left to the discretion of the Executive Branch to allow for developments in technology, subject to the overarching mandate to make materials easily accessible to the members of the public. The scope of any such discretion should be carefully delimited to prevent the Executive Branch from claiming the discretion to prevent or materially delay the timely disclosure of agency legal materials.
Sincerely,

Daryl Joseffer

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U.S. Chamber of Commerce Litigation Center