Final Report to the Administrative Conference of the United States

PUBLIC AVAILABILITY OF AGENCY GUIDANCE DOCUMENTS

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This report was prepared for the consideration of the Administrative Conference of the United States. The opinions, views and recommendation expressed are those of the author and do not necessarily reflect those of the members of the Conference or its committees, except where formal recommendations of the Conference are cited.

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The word "guidance" connotes helpfulness. When confronting difficult or complex activities in everyday life, and especially when the consequences for making mistakes can be substantial, people usually appreciate guidance—and they even seek it out. When it comes to the activities of the federal government, administrative agencies offer guidance, often in an attempt to be helpful to members of the public who confront difficult or complex questions related to legal obligations or the administration of government programs. Such guidance can be helpful—but when government agencies produce documents offering guidance, these materials can only be useful to the public if they can be readily accessed and understood. When guidance documents are produced but are not disclosed to the public in a readily accessible manner, members of the public not only miss the benefits of helpful guidance, but they may also be limited in how they can understand what their public servants do and how they or their representatives might hold them accountable. A complete absence of public availability of guidance documents would keep the public in the dark about important aspects of how federal agencies understand and apply the laws that they are charged with implementing.

This report addresses concerns that too many guidance documents produced by federal agencies are insufficiently accessible to the public. It reviews the legal requirements imposed on agencies for making their guidance documents publicly available, offers an assessment of existing and persistent challenges with guidance availability, and provides recommendations for improving the accessibility of agency guidance documents. The aim of the report is not to address broader questions about guidance documents, such as whether agencies produce too many or too few guidance documents, or whether agencies should actively solicit public feedback on guidance documents. The role for, and process of developing, guidance documents has already been addressed by other reports commissioned for, and recommendations issued by, the Administrative Conference of the United States (ACUS).[1] Here, the production and existence of guidance documents

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[1] *See* Admin. Conf. of the U.S., Recommendation 76-5, *Interpretive Rules of General Applicability and Statements of General Policy*, 41 Fed. Reg. 56,767, 56,770 (Dec. 30, 1976); Admin. Conf. of the U.S., Recommendation 92-2,

will be taken as given, and the only issue is what agencies might do to make the guidance documents that they do produce more accessible to the public.

Part I of the report introduces the concerns and challenges associated with public availability of guidance documents. This part begins by considering the defining features of guidance documents and highlighting their role in public administration. It then reviews a series of other recent reports and recommendations that demonstrate prevailing concern about public availability of guidance. Part II turns to existing standards that speak to how government agencies are supposed to make their guidance documents available to the public. Those standards include general legal requirements—such as those contained in the Freedom of Information Act—which apply to agencies across the federal government. They also include legal standards applicable to specific agencies as well as a variety of non-binding standards related to guidance—or "guidance on guidance." Part III turns to a consideration of existing practices of guidance availability and "best practices" for making guidance more accessible to the public. This part identifies four main criteria to guide agencies' management of the availability of guidance documents—comprehensiveness, currency, accessibility, and comprehensibility—and discusses practices that, if used more widely and consistently, could help agencies better meet these criteria. Part IV distills the findings from this report into a series of recommendations for agencies to consider.

A main conclusion of this report is that, even in today's digital world, improving public availability of guidance is as much a managerial challenge as a technological one. Agencies obviously should use the Internet to make guidance documents more readily available to the public, but they will only be able to take full advantage of the accessibility that modern technology permits if they make it a management priority to improve guidance availability and take the appropriate management steps to ensure that improvements are implemented. Unlike with binding rules and regulations, which by law must be published if they are to have binding effect, the non-binding and heterogeneous nature of guidance documents means that they are not subject to an effectively self-enforcing legal structure that disciplines publication and promotes public availability in a central repository, such as exists with agency rules which all must appear in the *Federal Register*. To ensure that guidance documents are more readily retrievable, agencies must establish and consistently adhere to internal management practices that track these documents and make them available to the public in a comprehensive, current, accessible, and comprehensible form.

I. The Challenge of Guidance Availability

The first Part of this report focuses on various definitions of guidance because the challenge of making guidance available to the public will depend in part on how guidance is defined and on how different guidance documents are categorized. It may not be essential—or even feasible—for all agency guidance to be made retrievable online; however, determining which guidance should

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Agency Policy Statements, 57 Fed. Reg. 30,101, 30,103 (July 8, 1992); Admin. Conf. of the U.S., Recommendation 2014–3, Guidance in the Rulemaking Process, 79 FR 35,992 (June 25, 2014); Admin. Conf. of the U.S., Recommendation 2017-5, *Agency Guidance Through Policy Statements*, 82 Fed. Reg. 61,734 (Dec. 14, 2017). *See also* Blake Emerson & Ronald M. Levin, Agency Guidance Through Interpretive Rules: Research and Analysis (Mar. 8, 2019) (draft report to the Admin. Conf. of the U.S.), https://www.acus.gov/sites/default/files/documents/ ACUS%20IR%20 draft%20report%203.8.19.2.pdf.

be posted and indexed on agency websites will likely be based on what counts as guidance and how agencies distinguish between different types of guidance. Following a review of definitions and categories of guidance, this Part provides a discussion of the underlying concerns about guidance availability—explaining why it is important to improve the accessibility of agency guidance and identifying sources of concern over insufficient access to guidance today.

A. What is Guidance?

Defining guidance constitutes a necessary precondition for any systematic agency effort to make its guidance publicly available. Such a definitional task might seem relatively straightforward: Any legally non-binding statement by an agency official should presumably be considered guidance. But such a seemingly straightforward notion of legal "non-bindingness" as the *je ne sais quoi* of guidance has not prevented the proliferation of different definitions of guidance—nor ensuing confusion. As one administrative law scholar has recently observed, what distinguishes non-binding guidance from binding regulations "is routinely described as 'fuzzy,' 'tenuous,' 'blurred,' and 'enshrouded in considerable smog.'"[2]

The task of defining guidance has been a particularly challenging only in part because of perceived difficulty in distinguishing guidance from legislative rules, a topic that numerous legal scholars and judges have addressed.[3] The task is also complicated by the basic fact that federal agencies and their employees presumably produce thousands, if not millions, of non-binding statements on a regular basis.[4] Non-binding statements, after all, can be expressed orally, in emails, and in other routine communications with regulated entities and members of the public. As the U.S. Department of Transportation has explained on its guidance website, "[a]gency officials at all levels, such as inspectors in the field, try to be helpful when responding to the need for guidance. The response [by these officials] may be to questions over the telephone, during participation in conferences, [and in] visits to manufacturing facilities."[5] When guidance is conceived in such terms, the federal government can be said to issue guidance every time an Internal Revenue Service representative answers a taxpayer's question over the agency's telephone help line, or whenever a Transportation Security Administration security officer tells passengers in line at an airport to have their boarding passes and identification materials ready for inspection, or whenever any number of other informal statements are made during the course of routine public interactions with government taking place every day.

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[2] Ronald M. Levin, *Rulemaking and the Guidance Exception*, 70 ADMIN. L. REV. 263, 266 (2018).

[3] *See, e.g.*, *id.*; Peter L. Strauss, *Publication Rules in the Rulemaking Spectrum: Assuring Proper Respect for an Essential Element*, 53 ADMIN. L. REV. 803 (2001); Robert A. Anthony, *Interpretive Rules, Policy Statements, Guidances, Manuals, and the Like—Should Federal Agencies Use Them to Bind the Public?*, 41 DUKE L.J. 1311 (1992).

[4] Although a formal count of the total volume of all federal guidance cannot be found, in a federal government with two million executive branch civil service employees—many of whom presumably make some statement related to agency policy each week—the number of non-binding statements made by those employees must be substantial. Professor Peter Strauss has described the volume of guidance in this broadest sense as "countless" and "innumerable." Strauss, *supra* note 3, at 804. *See also* Nicholas R. Parrillo, Federal Agency Guidance: An Institutional Perspective 35 (Final Report to the Administrative Conference of the United States) (Oct. 12, 2017), https://www.acus.gov/sites/default/files/documents/parrillo-agency-guidance-final-report.pdf (noting that although "[t]here is no comprehensive compilation of guidance, but everyone agrees its volume is oceanic").

[5] *Types of DOT Guidance*, U.S. DEP'T OF TRANSP., https://www.transportation.gov/regulations/types-dot-guidance (last visited May 13, 2019).

Not only is the quantity of non-binding communication extraordinarily high, but the varieties of agency statements that can potentially constitute guidance are also vast. One legal scholar has noted that agency statements "come in a myriad of formats and bear a myriad of labels: legislative rules, interpretive rules, opinion letters, policy statements, policies, program policy letters, Dear Colleague letters, regulatory guidance letters, rule interpretations, guidances, guidelines, staff instructions, manuals, questions-and-answers, bulletins, advisory circulars, models, enforcement policies, action levels, press releases, testimony before Congress, and many others."[6] Figuring out which of the many different types of statements produced by agency officials and employees should be treated as guidance is no small task.

The challenge in defining guidance exists regardless of the label officials use to refer to their statements. The label is not dispositive; what matters is the non-binding nature of the statement.[7] A statement that *is* legally binding—that is, a legislative rule—must be issued in accordance with procedures outlined in the Administrative Procedure Act (APA).[8] Non-binding statements do not have to follow the APA's rulemaking procedures. The APA, though, nowhere uses the term "guidance." It does refer to "interpretative rules" and "policy statements," neither of which need to go through the full notice-and-comment process required of legislative rules—and neither of which are binding.[9]

But "interpretative rules" and "policy statements" are not necessarily the only statements that could constitute guidance. A comprehensive and uniform definition of the term "guidance" has so far eluded the field of federal administrative law. Other statutes, beyond the APA, do not provide much clarity. A number of statutes use the term "guidance"—or its equivalent, "guidance document"—but they never offer a formal definition. The Food and Drug Administration Modernization Act of 1997 comes closest, even though it too does not explicitly define the term.[10] But it does reinforce the emphasis on non-bindingness. According to the Modernization Act, guidance documents issued by the Food and Drug Administration "shall not create or confer any rights for or on any person" and "shall not be binding on the Secretary."[11]

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[6] Anthony, *supra* note 3, at 1320. Anthony's article drew on a report he prepared for the Administrative Conference of the United States, which subsequently informed the Conference's Recommendation 92-2. 57 Fed. Reg. 30,103 (1992).

[7] Interestingly, when Congress passed the Small Business Regulatory Enforcement Fairness Act (SBREFA), it did make the label dispositive, for at least one type of guidance. SBREFA requires agencies to produce "small entity compliance guides" with the aim of "assist[ing] small entities in complying with" certain rules. Section 211 of the statute defined a "small entity compliance guide" as "a document designated and entitled as such by an agency." P.L. 104-121.

[8] 5 U.S.C. §§ 553, 556. Of course, if a subsequent or more specific statute authorizes an agency to issue a rule following procedures different than in the Administrative Procedure Act, the agency need not follow the APA's procedures.

[9] *See, e.g.*, Anthony, *supra* note 3, at 1324 (noting that "courts do not treat interpretations as making new law" and policy statements are "not legally binding policy").

[10] 21 U.S.C. § 371(h).

[11] *Id.* § 371(h)(1)(A) & (B). This statute also distinguishes between guidance documents that "set forth initial interpretations of a statute or regulation, changes in interpretation or policy that are of more than a minor nature, complex scientific issues, or highly controversial issues" and those that simply "set forth existing practices or [make] minor changes in policy." *Id.* § 371(h)(1)(C)(i) & (D).

Looking outside of statutes, a commonly-cited definition appears in a bulletin on "good guidance practices" issued by the Office of Management and Budget (OMB) in January 2007:

> 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, section 3(g)), that sets forth a policy on a statutory, regulatory or technical issue or an interpretation of a statutory or regulatory issue.[12]

Of course, this bulletin itself only provides guidance, as it is non-binding in the sense that it is "not intended to, and does not, create any right or benefit … enforceable at law or in equity."[13] Despite this fact, and despite some difficulties created by the definition's parenthetical reference to Executive Order 12,866,[14] the OMB Bulletin's definition of a guidance document as something "other than a regulatory action" makes intuitive sense, because regulations are considered binding while guidance is not. Again, non-bindingness is what matters, not the format or type of statement. A subsequent OMB memorandum has further explained that the bulletin's "definition is not limited to written guidance materials; it encompasses all guidance materials regardless of format, including guidance offered through video, audio tapes, interactive web-based software, or other innovative formats."[15]

Yet the definition in the OMB Bulletin has not been uniformly followed, even by other White House officials. For example, Executive Order 13,791 recently opted for a different definition of guidance for purposes of a directive to the U.S. Department of Education:

> The term ''guidance document'' means any written statement issued by the Department to the public that sets forth a policy on a statutory, regulatory, or technical issue or an interpretation of a statutory or regulatory issue, including Dear Colleague letters, interpretive memoranda, policy statements, manuals, circulars,

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[12] OFFICE OF MGMT. & BUDGET, EXEC. OFFICE OF THE PRESIDENT, OMB BULL. NO. 07-02, FINAL BULLETIN FOR AGENCY GOOD GUIDANCE PRACTICES (2007), https://www.gpo.gov/fdsys/pkg/FR-2007-01-25/pdf/E7-1066.pdf.

[13] *Id*. It also only applies to executive, not independent, agencies. *Id*.

[14] The Bulletin's parenthetical reference to section 3(g) of Executive Order 12,866 for a definition of "regulatory action" leads to three problems. First, Executive Order 12,866 no longer contains a section 3(g)—it only existed from 2007 to 2009. Second, even when section 3(g) did exist, that section defined "guidance document," not "regulatory action." Its definition of a guidance document is virtually identical to the one found in the OMB Bulletin and did nothing to amend the definition of "regulatory action" in section 3(d) of Executive Order 12,866, as the Bulletin suggests. Finally, the definition of "regulatory action" in section 3(d) appears to encompass statements that are widely viewed as guidance—in particular, interpretative rules and policy statements. That is because a "regulatory action" is defined there as a "substantive action" that issues or leads to a final rule. Executive Order 12,866, §3(d). If such a "substantive action" is the same as a "substantive rule," this term would include any non-procedural interpretative rule and policy statement. *See* Anthony, *supra* note 3, at 1321 n. 37 (noting that "the term 'substantive rule'… embraces legislative rules, interpretive rules, and policy statements other than those concerned with procedure, practice, or agency organization.").

[15] Memorandum from Susan E. Dudley, Adm'r, Office of Info. & Regulatory Affairs, on Implementation of Executive Order 13422 (April 25, 2007), https://www.transportation.gov/sites/dot.dev/files/docs/m07_13_EO_13422_implementation_%5B1%5D.pdf.

> memoranda, pamphlets, bulletins, advisories, technical assistance, and grants of applications for waivers.[16]

Strikingly, this definition would actually encompass even legislative rules issued by the Department of Education, since it is not confined to non-binding statements or statements other than regulations. Furthermore, under this order, guidance does not even need to be of "general applicability and future effect." But, unlike the OMB Bulletin, the definition in Executive Order 13,791 is limited only to *written* statements.

In recent years, some proposed legislation has sought to define guidance, but again the precise definitions have varied. The Regulatory Accountability Act of 2017, passed by the House in January 2017 (but not by the Senate), included the following definition that would have limited guidance to non-binding statements but not to written statements or statements of future effect:

> '[G]uidance' means an agency statement of general applicability that— '(A) is not intended to have the force and effect of law; and (B) sets forth a policy on a statutory, regulatory, or technical issue or an interpretation of a statutory or regulatory issue.'[17]

The Guidance Out of Darkness (GOOD) Act, which passed in the House in September 2018 (but never passed in the Senate), similarly would have defined guidance as non-binding and would not have limited the definition to statements with future effect or to written statements.[18] Its definition did, though, include an extended list of examples of materials that its drafters considered to constitute guidance, all of which would presumably would be committed to writing: "memorandum;" "notice;" "bulletin;" "directive;" "news release;" "letter;" "blog post;" "no-action letter;" "speech by an agency official;" "advisory;" "manual;" or "circular."[19]

This list of items in the GOOD Act differs from other lists of guidance documents, such as those used by agencies themselves to help define what is meant by guidance. For example, the U.S. Department of Transportation has stated on its guidance webpage that it considers guidance documents to include: "Preambles to final rules," "Adjudicatory decisions [with] precedential effect on future parties in similar situations," "Generally Applicable Interpretations or Policy Statements," "Letters to Specific Individuals or Entities," "Oral Guidance Statements by Senior Agency Officials," and other "informal guidance statements."[20] But the Department has also stated, in a

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[16] 82 Fed. Reg. 20427, § 3 (April 26, 2017).

[17] Regulatory Accountability Act of 2017, H.R. 5, 115th Cong. (2017).

[18] H.R. 4809, 115th Cong. (2018). Section 5(2) of the bill offered the following definition: "The term 'guidance document'—(A) means an agency statement of general applicability (other than a rule that has the force and effect of law promulgated in accordance with the notice and public procedure under section 553 of title 5, United States Code) that—(i) does not have the force and effect of law; and (ii) sets forth— (I) an agency decision or a policy on a statutory, regulatory, or technical issue; or (II) an interpretation of a statutory or regulatory issue; and (B) may include any of the following [examples as provided in the text accompanying note 16 of this report, or] Any combination of the items described [the examples]." *Id.* § 5(2).

[19] *Id*. The bill also stated that "the term 'guidance document' shall be construed broadly." *Id*. § 4(a).

[20] *Types of DOT Guidance*, U.S. DEP'T OF TRANSP., https://www.transportation.gov/regulations/types-dot-guidance (last visited May 13, 2019). The Department's policy adopted in December 2018 confirms that guidance documents

policy adopted in December, 2018, that it does not consider the following materials to be guidance documents:

> legal advisory opinions for use within the Executive Branch; briefs and other positions taken in litigation or enforcement actions; speeches and individual presentations, editorials, media interviews, press materials, congressional testimony, or congressional correspondence; guidance pertaining to military or foreign affairs functions; grant solicitations and awards; contract solicitations and awards; warning letters; case or investigatory letters responding to complaints or other matters involving fact-specific determinations; purely internal agency policies or guidance directed solely to DOT employees or contractors or to other Federal agencies; or guidance pertaining to the use, operation, or control of a government facility or property.[21]

At least some of the materials the Department has indicated on its website can constitute guidance—such as statements by agency officials, if made in speeches or presentations—would appear now to be excluded from the definition of guidance document for purposes of the Department's recent policy on guidance. The GOOD Act would have treated at least some press releases as guidance, even though the Department's current policy expressly does not.

Other agencies have provided their own lists of what they consider to be guidance—and what they do not. The Food and Drug Administration has adopted a good guidance practice regulation which contains only a general definition of guidance as those documents "that describe the agency's interpretation of or policy on a regulatory issue."[22] The FDA regulation then explains that guidance documents include materials related to "[t]he design, production, labeling, promotion, manufacturing, and testing of regulated products; the processing, content, and evaluation or approval of submissions; and inspection and enforcement policies."[23] But FDA also makes clear that guidance does *not* include "[d]ocuments relating to internal FDA procedures, agency reports, general information documents provided to consumers or health professionals, speeches, journal articles and editorials, media interviews, press materials, warning letters, memoranda of understanding, or other communications directed to individual persons or firms."[24] FDA specifically notes that its "public health alerts are not guidance documents."[25]

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are "not confined to formal written documents." Memorandum of Steven G. Bradbury, Gen. Counsel, U.S. Dep't of Transp. (Dec. 20, 2018), https://cms.dot.gov/sites/dot.gov/files/docs/regulations/328566/gen-counsel-mem-guidance-documents-signed-122018.pdf [hereinafter Bradbury Memorandum]. The Department also provides a helpful spreadsheet listing the types of materials treated as guidance for each major operating unit within the Department. The spreadsheet can be found at https://www.transportation.gov/sites/dot.gov/files/docs/regulations/311111/copy-oa-charts-515.xlsx.

[21] Bradbury Memorandum, *supra* note 20, § 1(b), https://cms.dot.gov/sites/dot.gov/files/docs/regulations/328566/gen-counsel-mem-guidance-documents-signed-122018.pdf. The Department's policy cites to, and in some respects parallels, section 1(4)(b) of the OMB Bulletin in support of these exclusions; however, that provision in the OMB Bulletin only excludes these materials from the category of "*significant* guidance document"—not, as the Department's policy states, from the definition of "guidance document" altogether.

[22] 21 C.F.R. § 10.115(b)(1).

[23] 21 C.F.R. § 10.115(b)(2).

[24] 21 C.F.R. § 10.115(b)(3).

[25] 65 Fed. Reg. 56475 (Sept. 19, 2000).

In a similar fashion, other agencies have indicated that specific types of documents, even though non-binding, do not constitute guidance. For example, the Department of Justice makes clear that, although guidance documents can include materials "designed to advise parties outside the federal Executive Branch about legal rights and obligations falling within the Department's regulatory or enforcement authority," guidance does not include, among other things, "documents informing the public of the Department's enforcement priorities or factors the Department considers in exercising its prosecutorial discretion."[26] The Consumer Financial Protection Bureau (CFPB) has also stated that it "does not regard…as guidance" a variety of "informal documents available on the Bureau's website, such as press releases, blog posts, and speeches."[27]

Three lessons follow from this review of definitions contained in agency policies, White House documents, and legislative materials. First, it should be evident that agencies produce a wide range of different non-binding statements that have been understood under different definitions to constitute guidance. Under varying definitions, guidance can be *written* as well as *unwritten*, *formal* as well as *informal*, *significant* as well as *routine*, and *directed internally* to agency personnel as well as *directed externally* to individuals or entities outside of government. The specific form and substance of guidance documents can be highly varied. The work that agencies do varies, and so too do the types of statements that they produce.

Second, no uniform binding definition of guidance yet applies across the federal government. Under some definitions, statements constituting guidance must have general applicability and future effect; however, other definitions require only general applicability, and still other definitions demand neither of these characteristics. Some definitions are limited to written materials, while others are not. Some include lists of specific types of included or excluded materials. The definition in the OMB Bulletin purports to provide a uniform, government-wide definition—but it is apparent that agencies have sought to treat some classes of materials, such as press releases and speeches, as categorically falling outside the domain of guidance, even though the OMB Bulletin does not do so.[28]

Finally, despite all the various definitions, the common thread running through all of them is the principle that guidance does not have the force of law. The legally non-binding effect of guidance documents does capture best their *je ne sais quoi*.[29] As a result, going forward this report

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[26] Memorandum of Jeff Sessions, Att'y Gen., U.S. Dep't of Justice (Nov. 16, 2017), https://www.justice.gov/opa/press-release/file/1012271/download.

[27] Letter from Mick Mulvaney, Acting Dir., Consumer Fin. Prot. Bureau, to Trey Gowdy, Chairman, U.S. House of Representatives Comm. On Oversight & Gov't Reform (Dec. 21, 2017) (on file with author).

[28] The OMB Bulletin does exclude "speeches," "editorials," "media interviews," "press materials," "Congressional correspondence," and other documents from its definition of a "*significant* guidance document." 72 Fed. Reg. at 3439, § I(4)(b) (emphasis added). But in excepting these materials from the class of significant guidance documents only, the OMB Bulletin necessarily allows that they can still fall within the broader category of guidance document, even if as insignificant ones.

[29] *See* Levin, *supra* note 2, at 266 ("The essence … is that legislative rules have the force of law and guidance does not."). Some courts and commentators have suggested that one type of guidance document—interpretative rules—may have a binding effect. *See* Emerson & Levin, *supra* note 1, at 18 (noting the existence of "language in a variety of doctrinal areas to the effect that interpretive rules may be binding after all"). But the Supreme Court in *Perez v.*

will simply use this feature to characterize what is meant here by "guidance" and "guidance documents," relying for ease of exposition on the most capacious and generic sense of the term unless indicated otherwise. Rather than adopting any one definition of guidance, this report will proceed with a broad understanding that guidance may include a variety of non-binding statements about policies, interpretations of legal requirements, or other matters related to an agency's area of responsibility. It should be evident, though, that one important step for federal administrative agencies to take when seeking to improve the public availability of their guidance materials is to ensure that they explain clearly what *they* mean by guidance.

B. Categorizing Guidance

The foregoing section has focused on what kinds of agency statements and materials fall within different definitions of guidance. It is clear that, in adopting these varied definitions, government officials have made distinctions between different types of agency statements. Executive Order 13,791 only considers written statements to be guidance, for instance, while the Department of Transportation and OMB expressly accept that guidance need not be committed to writing. The Department of Justice, Department of Transportation, and Food and Drug Administration exclude documents related to internal policies and procedures from their definitions of guidance documents, while the OMB Bulletin contains no such exclusion in its definition. These and other efforts to distinguish between what is in, and what is out of, the definition of guidance are understandable responses to the vastness and diversity of the non-binding statements produced regularly as part of administrative government. In order to track, review, and disseminate guidance documents, agencies need to circumscribe the scope of such internal management efforts, if for no reason other than to make oversight of guidance administratively feasible. Deciding what constitutes a "guidance document" in the first place is one way of establishing that scope.

Another way to establish the scope to an agency's guidance management efforts is to differentiate between guidance documents, treating some with more intensive management scrutiny than others. Instead of merely relying on distinctions in determining what constitutes guidance in the first place, agencies can categorize different kinds of guidance. In other words, they can ask: Among those statements that are considered to fall within a definition of guidance, which ones merit specified management efforts, such as additional internal review, public notice and comment, or online availability?

Answering this question will be most critical whenever agencies accept a capacious definition of guidance, as agency employees can routinely generate thousands of statements that could constitute guidance in the broadest sense. Presumably no feasible method could ever exist to track meaningfully or make available online all such statements made in phone calls, meetings, or emails. Even when agencies have adopted narrower definitions of guidance, as discussed in the previous section of this report, they may still have valid reasons for treating different kinds of guidance documents differently. The volume of materials under even a more circumscribed definition may still be too vast for it to be practical to manage all of it in the same way. As a result,

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Mortgage Bankers Association has noted "the longstanding recognition that interpretative rules do not have the force and effect of law." 135 S. Ct. 1199, 1208 (2015).

agencies have categorized different kinds of guidance documents and identified more heightened managerial and disclosure practices for just a subset of guidance documents.

The categories of guidance documents contained in the OMB Bulletin and in guidance policies at the Food and Drug Administration and the Department of Transportation provide useful examples of the variation in how agencies categorize guidance.

OMB Bulletin. The OMB distinguishes between significant guidance documents and other guidance documents, imposing standards that agencies should follow in managing and disclosing the former but not the latter.[30] The Bulletin defines "significant" guidance using the same four criteria that Executive Order 12,866 uses to define significant regulatory actions meriting additional review by the OMB:

> The term ''significant guidance document''— a. Means … a guidance document disseminated to regulated entities or the general public that may reasonably be anticipated to: (i) Lead to an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (ii) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (iii) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (iv) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866, as further amended.[31]

A guidance document that qualifies as significant under the first criterion—that is, an annual effect on the economy of $100 million or more—is considered in the OMB Bulletin to be an "economically significant guidance document."[32]

The OMB Bulletin excludes entirely from its category of "significant guidance document" any of the following documents, regardless of whether they would meet any of the four criteria listed above:

> The term ''significant guidance document''… [d]oes not include legal advisory opinions for internal Executive Branch use and not for release (such as Department of Justice Office of Legal Counsel opinions); briefs and other positions taken by agencies in investigations, pre-litigation, litigation, or other enforcement proceedings (nor does this Bulletin in any other way affect an agency's authority to communicate its views in court or in other enforcement proceedings); speeches; editorials; media interviews; press materials; Congressional correspondence; guidance

[30] It should be noted that the OMB Bulletin only defines "significant" guidance documents and does not use any label or definition to describe guidance documents that are not deemed significant. OFFICE OF MGMT. & BUDGET, *supra* note 12.
[31] *Id.*
[32] *Id.*

> documents that pertain to a military or foreign affairs function of the United States (other than guidance on procurement or the import or export of non-defense articles and services); grant solicitations; warning letters; case or investigatory letters responding to complaints involving fact-specific determinations; purely internal agency policies; guidance documents that pertain to the use, operation or control of a government facility; internal guidance documents directed solely to other Federal agencies; and any other category of significant guidance documents exempted by an agency head in consultation with the OIRA Administrator.[33]

This list of excluded items from the category of *significant guidance*, it should be noted, is almost identical to the list used by the Department of Transportation to exclude materials from its definition of *guidance*, as described in the preceding section of this report.

FDA Good Guidance Regulation. The Food and Drug Administration makes a similar categorization of guidance documents based on their significance, although with different criteria and different labels for its categories. Instead of significant versus non-significant, the FDA distinguishes between "Level 1" and "Level 2" guidance, as follows:

> 1) "Level 1 guidance documents" include guidance documents that:
>
> (i) Set forth initial interpretations of statutory or regulatory requirements;
>
> (ii) Set forth changes in interpretation or policy that are of more than a minor nature;
>
> (iii) Include complex scientific issues; or
>
> (iv) Cover highly controversial issues.
>
> (2) "Level 2 guidance documents" are guidance documents that set forth existing practices or minor changes in interpretation or policy. Level 2 guidance documents include all guidance documents that are not classified as Level 1.[34]

As the OMB Bulletin does for significant guidance documents, the FDA subjects Level 1 guidance to a more intensive set of standards for internal review, commenting, and dissemination, which are described in Part II of this report.

Department of Transportation Memorandum. In its December 2018 memorandum on guidance, the Department of Transportation defined guidance documents in a manner to exclude virtually the same documents the OMB Bulletin allows to count as guidance documents but which OMB nevertheless categorically excludes from the definition of significant guidance.[35] But the Department of Transportation policy nevertheless still creates a category of "significant guidance

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[33] *Id.*
[34] 21 C.F.R. § 10.115 (2018).
[35] Bradbury Memorandum, *supra* note 20.

documents" that are subjected to centralized departmental review and other management standards. A significant guidance document for the Department of Transportation would be one that meets any one of four criteria similar to those in the OMB Bulletin (in language nearly identical to the Bulletin):

> The term "significant guidance document" means a guidance document that will be disseminated to regulated entities or the general public and that may reasonably be anticipated (i) to lead to annual costs in the U.S. of $100 million or more (without regard to estimated benefits) or adversely affect in a material way the U.S. economy or an important sector of the U.S. economy; (ii) to create serious inconsistency or otherwise interfere with the actions of another Federal agency; (iii) to alter materially the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (iv) to raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866, as further amended.[36]

The first criterion of significance here is somewhat narrower than the first criterion contained in the OMB Bulletin, as the department would treat as economically significant any guidance that would lead to $100 million or more in annual "costs," not "effects on the economy" (which presumably encompasses both costs and benefits).[37]

The Department of Transportation memorandum also creates a category of guidance documents that are "otherwise of importance to the Department's interests" and which are effectively supposed to be treated the same as significant guidance.[38] A guidance document falls into this category "if it may reasonably be anticipated" to meet at least one of the following criteria:

- "relate to a major program, policy, or activity of the Department or a high-profile issue pending for decision before the Department;"
- "involve one of the Secretary's top policy priorities;"
- "garner significant press or congressional attention;" or
- "raise significant questions or concerns from constituencies of importance to the Department, such as Committees of Congress, States or Indian tribes, the White House or other departments of the Executive Branch, courts, consumer or public interest groups, or leading representatives of industry"[39]

In addition, the memorandum includes an appendix that lists sixteen specific kinds of documents that are generally treated as exempt from review and approval by the Secretary of Transportation, "[u]nless they present novel issues, significant risk, interagency considerations, unusual circumstances, or other reasons" for such review.[40]

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[36] *Id*. § 7(a).
[37] *Id*.
[38] *Id*. § 7(c).
[39] *Id*.
[40] *Id*.

* * *

As these examples of categories of guidance illustrate, determinations about how to manage and disclose guidance are likely to be assisted by distinguishing between guidance based on their significance and other features. As will be discussed further in Part II of this report, sometimes the standards for disclosure of guidance will depend on the category into which a particular guidance document fits. For now, it is enough simply to recognize that defining guidance is likely to be merely the first step in any system of guidance management. Agencies can and do also establish different categories of guidance documents. As with definitions of guidance, these categorizations can vary based on differences in agency goals and different types of guidance documents they produce—as well as the different definitions they use as a starting point for determining what constitutes guidance.

C. Concerns About Guidance Availability

The accumulation of guidance documents has done more than simply lead agency managers to establish definitions and categories for their management. It has also led to concern about the ease with which guidance is accessible to the public. This section identifies various sources of concern about the transparency of agency guidance. It also reviews two recent reports—one produced by the Government Accountability Office (GAO),[41] the other by majority staff of the House Oversight and Government Reform Committee[42]—that suggest that agencies could do a better job of making guidance more readily available to the public.

Sometimes concerns about guidance availability reflect a still deeper suspicion that agencies issue guidance documents as a way of short-circuiting the rulemaking process but still practically binding private actors.[43] Even if businesses and other private entities are not legally bound to follow agency guidance, as a practical matter they often will—thus, guidance in practice might operate in much the same way that regulations do.[44] Yet, because agencies can issue guidance documents without going through the entire notice-and-comment process, these documents can become what some observers have labeled as "regulatory dark matter."[45]

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[41] U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-18-436T, OPPORTUNITIES TO IMPROVE THE EFFECTIVENESS AND TRANSPARENCY OF REGULATORY AND GUIDANCE PRACTICES (2018).

[42] STAFF OF H. COMM. ON OVERSIGHT & GOV'T REFORM, 115TH CONG., SHINING LIGHT ON REGULATORY DARK MATTER (Comm. Print 2018), https://republicans-oversight.house.gov/wp-content/uploads/2018/03/Guidance-Report-for-Issuance1.pdf.

[43] *See, e.g.*, Clyde Wayne Crews, Jr., A Partial Eclipse of the Administrative State, Competitive Enterprise Institute OnPoint No. 249 (Oct. 3, 2018), https://cei.org/sites/default/files/WayneCrewsAPartialEclipseoftheAdministrativeState.pdf (expressing concern that "administrative agencies can influence policy without going through the established rulemaking process" and urging that "[t]he posting online of individual guidance documents and inventories of significant and secondary guidance for executive and independent agencies should be required on agency websites as well as in central format").

[44] *See, e.g.*, Parrillo, *supra* note 4, at 45-56 (discussing practical reasons for private entities to adhere to guidance as if it were binding).

[45] *See, e.g.*, *id.* at 2 (describing guidance as "encompassing memoranda, notices, circulars, FAQs, administrator's interpretations, bulletins, and other forms of 'regulatory dark matter'—including even press releases and blog posts").

Beyond concerns about the transparency of the process by which agencies create guidance—an issue beyond the scope of this report—related concerns exist about the inability of the public to find guidance documents even after they have been created.[46] To the extent that guidance documents reveal how agencies interpret regulations and how they actually carry out their enforcement of regulations and otherwise administer their programs, regulated entities and the public have an interest in being able to access these documents. Furthermore, even if one does not view guidance suspiciously as a form of "regulatory dark matter," but instead sees guidance as something that can be helpful to the public, concern over guidance availability still remains. After all, if guidance documents are intended to assist members of the public, then the public should be able to find them.

1. *Indicators of Concern*

Although it may be difficult to gauge quantitatively, the perception exists that agency guidance documents have become much too opaque and difficult to find. Sometimes this perception has found its way into legislation. For example, Congress adopted the Food and Drug Administration Modernization Act of 1997 in part to require the Food and Drug Administration to make its guidance documents more accessible to the public.[47] When Congress enacted the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996, it called on agencies to ensure that a specific type of guidance called for by the Act—"small entity compliance guides"—would be posted "in an easily identified location" on their websites and would be distributed to "known industry contacts."[48]

Over the years, a number of additional legislative measures have been introduced that, if enacted, would have required agencies across the federal government to make guidance more transparent. The Congressional Accountability for Regulatory Information Act, introduced in the House in 2000, would have required agencies to place a notice of "nonbinding effect" on the first page of each guidance document.[49] The Regulatory Accountability Act of 2017 would have similarly required agencies to state that their guidance is non-binding—and it also would have required that guidance "be made available by the issuing agency to interested persons and the public" and that, at least for major guidance, it be subjected to a formal determination that it is "understandable."[50] The GOOD Act was specifically introduced "to increase the transparency of agency

[46] *See, e.g.*, H.R. Rep. No. 115-972, at 3 (2018) (noting that lack of easy accessibility "can burden entities seeking guidance, particularly small entities, which may lack the resources to hire legal counsel or compliance staff"). An opinion by the D.C. Circuit Court of Appeals illustrates how a concern about agencies circumventing the rulemaking process also can include a concern about the absence of eventual availability of guidance once it has been created: "One 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. Law is made, without notice and comment, without public participation, and without publication in the *Federal Register* or the Code of Federal Regulations." Appalachian Power Co. v. U.S. Environmental Protection Agency, 208 F.3d 1015, 1019 (D.C. Cir. 2000).
[47] 21 U.S.C. § 301 et seq.
[48] Small Business Regulatory Enforcement Fairness Act of 1996, S. 942, 104th Cong. §212 (1996).
[49] Congressional Accountability for Regulatory Information Act of 2000, H.R. 3521, 106th Cong. §4 (2000), https://www.govinfo.gov/content/pkg/BILLS-106hr3521ih/pdf/BILLS-106hr3521ih.pdf.
[50] Regulatory Accountability Act of 2017, H.R. 5, 115th Cong. (2017).

guidance documents and to make guidance documents more readily available to the public."[51] Passed by the House in September 2018, the GOOD Act would have required agencies to publish guidance documents "in a single location on an online portal designated by the Director of the Office of Management and Budget"—presumably, Regulations.gov.[52] The bill also would have required agencies to provide on the agency's website a link to its guidance and to ensure that guidance documents were "clearly identified," "sorted by subcategories," "searchable," and "published in a machine-readable and open format."[53]

The drafters of the GOOD Act stated that they saw their bill as responding to a recommendation of the Administrative Conference of the United States (ACUS).[54] In December 2017, ACUS recommended that "[a]ll written policy statements affecting the interests of regulated parties, regulatory beneficiaries, or other interested parties should be promptly made available electronically and indexed, in a manner in which they may readily be found."[55]

This ACUS recommendation was consistent with a longstanding concern about transparency reflected in other ACUS recommendations. As early as 1971, for example, ACUS recommended that "[a]gency policies which affect the public should be articulated and made known to the public to the greatest extent feasible."[56] More recently, ACUS has expressed an overarching concern for governmental transparency with respect to a wide range of agency actions and materials.[57] In the preamble to its 2011 recommendation on "Innovations in e-Rulemaking," for example, ACUS noted that agencies "can improve the availability of information" about rulemaking because agency websites "do not always include features to ensure that essential information … is broadly accessible to the public."[58] ACUS formally recommended that agencies "continue to improve the accessibility of their Web sites to members of the public" as well as "take steps to improve access for persons who have faced barriers to effectively participating in rulemaking in the past, including non-English speakers, users of low-bandwidth Internet connections, and individuals with disabilities."[59]

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[51] H.R. 4809, § 2.
[52] *Id*.
[53] *Id*.
[54] H.R. Rep. No. 115-972, at 4.
[55] Admin. Conf. of the U.S., Recommendation 2017-5, *Agency Guidance Through Policy Statements*, 82 Fed. Reg. 61728 (Dec. 29, 2017). In this same recommendation, ACUS urged agencies to "afford members of the public a fair opportunity to argue for lawful approaches other than those put forward by a policy statement or for modification or rescission of the policy statement." *Id*. If members of the public are unable to find a policy statement, it is difficult to see how they can have a "fair opportunity" to argue for alternatives.
[56] Admin. Conf. of the U.S., Recommendation 71–3, *Articulation of Agency Policies*, 38 Fed. Reg. 19,788 (July 23, 1973).
[57] Some of these actions and materials include: agency adjudication materials (Recommendation 2017-1, Recommendation 2018-5), waivers and exemptions (Recommendation 2017-7), meetings of government agencies (Recommendation 2014-2), declaratory orders (Recommendation 2015-3), agency use of science (Recommendation 2013-3), rulemaking dockets and supporting materials (Recommendation 2018-6, Recommendation 2011-1), internal policies related to federalism (Recommendation 2010-1), agency use of federal advisory committees (Recommendation 2011-7).
[58] Admin. Conf. of the U.S., Recommendation 2011-8, *Innovations in e-Rulemaking*, 77 Fed. Reg. 2257 (2011).
[59] *Id*. ACUS noted that its "recommendation also extends to guidance documents on which an agency is seeking or intends to seek public comment." *Id*.

In 2014, ACUS issued a recommendation on "Guidance in the Rulemaking Process" which mostly addressed other issues related to guidance but noted that, notwithstanding the requirement in SBREFA that agencies post their small entity compliance guides in an "easily identifiable location" online, "these guides are often difficult to find on agency Web pages."[60] ACUS recommended that "[a]gencies should reassess how they are displaying the small entity compliance guides on their websites" and that "[t]he Small Business Administration should work with agencies to develop guidelines for posting small entity compliance guides on agency websites in ways that make them easily identifiable."[61]

Last year, ACUS expressed concern about the online accessibility of information related to the rules governing agency adjudications, including guidance documents:

> A review of existing agency websites reveals that agency practices vary widely. Some provide access on their websites to all relevant statutes, rules of practice, precedents, standing orders, forms, and guidance documents and explanatory materials, whereas others publish few or none of these things. Of those that do publish such documents and materials, some identify the sources of law from which the rules derive and clearly delineate between agency-promulgated rules of procedure with legal effect and (non-binding) guidance documents, whereas others do not. Finally, some websites are much more effective than others in organizing these materials and placing them in a logical location on the agency website such that they are easily accessible.[62]

In its recommendation on public availability of adjudication rules, ACUS urged agencies to consider providing "updated access on their website to all … guidance documents and explanatory materials" related to adjudicatory procedures.[63]

In addition to expressions of concern about accessibility reflected in legislation and previous ACUS recommendations, the American Bar Association's Section of Administrative Law and Regulatory Practice has recommended that agencies "make it a priority to ensure that all agency guidance documents are made available online in a timely and easily accessible manner."[64] The Section has noted that "[m]embers of the public need to be able to find relevant guidance documents, but they are not always accessible on agency websites—and even when the documents are accessible, they can be very difficult for members of the public to locate."[65]

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[60] Admin. Conf. of the U.S., Recommendation 2014–3, *Guidance in the Rulemaking Process*, 79 Fed. Reg. 35988 (2014).
[61] *Id*.
[62] Admin. Conf. of the U.S., Recommendation 2018-5, *Public Availability of Adjudication Rules*, 84 Fed. Reg. 2139, 2142 (Feb. 6, 2019).
[63] *Id*.
[64] ABA Section of Administrative Law and Regulatory Practice, Improving the Administrative Process: A Report to the President-Elect of the United States 11 (2016), https://www.americanbar.org/content/dam/aba/administrative/administrative_law/ Final%20POTUS%20Report%2010-26-16.authcheckdam.pdf. The author of the present report was a member of an ad hoc committee that prepared the ABA section report.
[65] *Id*.

2. *Government Accountability Office Audit*

In 2015, the U.S. Government Accountability Office (GAO) released the findings from an audit of guidance practices at four departments: Agriculture, Education, Health and Human Services, and Labor.[66] The audit focused on how and when the departments, and their component units (25 in all), used guidance and how they make guidance documents available to the public. The GAO found that these agencies used guidance for a variety reasons, including to interpret new regulations, address questions from regulated entities and others affected by government programs, distribute information on best practices, and explain how grants or benefits programs are administered.[67]

The GAO team looked to see if the agencies, in accordance with the OMB Bulletin, had established written procedures for approving significant guidance: The Departments of Agriculture and Education had done so, but not the Department of Health and Human Services. Officials at the Department of Labor were reportedly not aware during the course of the GAO audit that they had any written procedures for significant guidance either. Only when reviewing the final draft of the GAO report did someone at the Labor Department apparently discover that the Department had in fact prepared some procedures for significant guidance in response to the OMB Bulletin.[68] With respect to procedures for non-significant guidance at the four departments, "[m]ost components did not have written procedures for guidance initiation, development, and review."[69]

Only about half of the 25 components within the four departments reported regularly reviewing existing guidance documents to ensure they remained current.[70] The GAO singled out the Department of Labor's Office of Federal Contract Compliance Programs for its particularly dedicated efforts to review its guidance. Through a dedicated initiative, officials at that Office had:

> identified necessary updates to guidance, clarified superseded guidance, and rescinded guidance where appropriate. Officials told us that these actions reduced the original number of directives by 85 percent. Officials also told us that they did this to ensure that their guidance was more accurate and correct, and the actions resulted in officials posting only relevant and current guidance information on the component's website. Officials told us they now routinely monitor their directives about once a year and review other guidance documents each time they issue new regulations or change a policy to decide if they need to revise them.[71]

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[66] Government Accountability Office, "Regulatory Guidance Processes: Selected Departments Could Strengthen Internal Control and Dissemination Practices," No. 15-368 (2015), https://www.gao.gov/assets/670/669688.pdf.
[67] *Id*. at 11-12.
[68] *Id*. at 20 n. 33.
[69] *Id*. at 24.
[70] *Id*. at 29.
[71] *Id*. at 30.

The GAO suggested that other agencies would "benefit from procedures to continually reassess and improve guidance processes and documents to respond to the concerns of regulated entities."[72] Reviewing guidance regularly allows officials to "assess whether guidance meets intended goals or whether they need to provide additional guidance to supplement and improve upon prior guidance."[73]

With respect to making guidance available to the public, GAO reported that all 25 components used their websites, while most also used email (22) or meetings (22) to disseminate guidance.[74] Some of these agencies also reported using email listservs (19), external partners such as other federal agencies, state governments, or nongovernmental organizations (17), social media (13), mass media such as through press releases (11), and newsletters (7).[75] The agencies "used different strategies to reach certain groups," with perhaps the obvious challenge that "it was more resource intensive to distribute guidance to a wider audience."[76] But some agencies succeeded in readily reaching wide audiences because they had developed lists of interested members of the public and the regulated community. The Employee Benefits Security Administration within the Labor Department, for example, reportedly maintains a listserv with more than 335,000 subscribers.[77] The Department of Education's Office for Civil Rights keeps "readily available e-mail lists for the purpose of sending guidance to all public school superintendents or college presidents."[78]

Officials sometimes tried other dissemination strategies too. At the Occupational Safety and Health Administration (OSHA), officials reported that they "use social media to communicate with hard-to-reach populations, such as non-English speakers and temporary/contract workers who were more likely to be working in dangerous jobs."[79] To reach members of the public "during disaster recovery efforts or to reach those who did not have access to the Internet," agency officials still sometimes use printed pamphlets or other hard-copy documents.[80] GAO reported that "[c]omponents also reached wider audiences by engaging with the public directly through conferences, webinars, media outreach, or public awareness campaigns."[81] In addition, GAO noted that "[a] few components told us that they posted guidance in the *Federal Register*."[82]

Focusing on accessibility of guidance on agency websites, GAO made a point to note that "[w]ithout providing the public an easy way to access significant guidance, agencies cannot ensure that the public can know about or provide feedback on these documents."[83] It found that the Departments of Agriculture, Education, and Labor followed the OMB Bulletin in making a list of

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[72] *Id*. at 29.
[73] *Id*.
[74] *Id*. at 31.
[75] *Id*.
[76] *Id*.
[77] *Id*. at 32.
[78] *Id*. at 33.
[79] *Id*.
[80] *Id*.
[81] *Id*.
[82] *Id*. at 32.
[83] *Id*. at 34.

significant guidance documents available on the their websites; however, the GAO could not locate any similar page on the Department of Health and Human Services's website.[84] Still, all departments and their components did make at least some guidance available online, and the GAO noted a number of steps agencies undertook to make that guidance easy to find, including highlighting new major guidance documents on their homepages. Still, the GAO found a variety of limitations to the departments' and their components' online access to guidance documents, including:

- Links were broken to two of the four department's webpages dedicated to significant guidance;[85]
- "Components posted long lists of guidance, which could make it difficult for users to find particular guidance documents."[86]
- "[F]ew components effectively distinguished whether their online guidance was current or outdated to ensure the relevance of their online information."[87]
- "[I]t was not always clear where to find guidance on a component website. We found guidance was sometimes dispersed across multiple pages within a website, which could make guidance hard to find and could contribute to user confusion."[88]
- "[M]any component officials told us that they did not have a systematic way to evaluate whether the public could access their guidance online."[89]

Overall, the GAO recommended that all four departments take steps to "[i]mprove the usability of selected component websites to ensure that the public can easily find, access, and comment on online guidance," such as by "improving website usability by clarifying which links contain guidance," "highlighting new or important guidance," and "ensuring that posted guidance is current."[90]

3. *House Oversight and Government Reform Committee Majority Staff Report*

The House Oversight and Government Reform Committee's majority staff released a report in 2018 addressing guidance practices across the federal government. The Committee staff submitted requests to 46 agencies, asking them to submit lists of all their guidance documents issued since 2008—both significant and non-significant guidance.[91] The Committee reported that, of the 46 agencies contacted by its staff, 27 responded by providing what they said were complete inventories of all their guidance documents (with two agencies, though, reporting that they actually issued no guidance during the period). An additional 11 agencies responded with what they acknowledged was a partial list, while eight agencies apparently failed to provide any substantive

[84] *Id*. at 33-34.
[85] *Id*. at 33 n. 38 & 39.
[86] *Id*. at 38.
[87] *Id*.
[88] *Id*.
[89] *Id*. at 39.
[90] *Id*. at
[91] STAFF OF H. COMM. ON OVERSIGHT & GOV'T REFORM, 115TH CONG., SHINING LIGHT ON REGULATORY DARK MATTER (Comm. Print 2018), https://republicans-oversight.house.gov/wp-content/uploads/2018/03/Guidance-Report-for-Issuance1.pdf..

response at all.[92] In total, the responding agencies provided information on over 13,000 guidance documents. Of these, however, the agencies identified only 536 as significant guidance documents, leading the Committee staff to suggest that "[a]gencies may not be effectively identifying significant guidance documents."[93]

The Committee staff reported that "most agencies" provided links to guidance documents on their webpages. Indeed, when two agencies responded to the Committee request with lists of only a very small number of guidance documents, the Committee staff reportedly went online and found many more guidance documents on these agencies' own websites.[94]

The Committee staff noted that "[s]ome agencies maintain easily identifiable and navigable online repositories for their guidance documents on their websites."[95] It identified guidance repositories on the websites of the Consumer Financial Protection Bureau and the Mine Safety and Health Administration as models for other agencies to emulate. The staff recommended that all agencies create such repositories, noting that "[s]uch publishing would alleviate the burden on regulated entities of seeking out new guidance documents issued by their regulators by placing the onus on the regulators to assemble and organize these documents."[96]

II. Standards for Guidance Availability

Notwithstanding the concerns that have emerged over the availability of agency guidance, federal agencies are actually subject to certain legal standards and non-binding standards that call for making guidance accessible to the public. The research presented in this Part helps to provide some context for understanding the concerns over the inaccessibility of guidance by revealing inherent limitations in efforts to promote guidance availability through the imposition of requirements for their publication. Publication requirements work well for promoting public availability of legislative rules because these rules cannot take effect—or at least will not be enforced by courts—if they are not published as required in the *Federal Register*. But no similar self-enforcing structure exists for guidance documents because they are non-binding statements and for that reason they never need to "take effect" in the way that binding legal rules do. When it comes to guidance, publication requirements simply lack a structural mechanism that helps to ensure compliance.[97]

This Part reviews existing legal requirements related to the publicly availability of guidance, starting with the most general legal requirements addressed to all agencies and then turning to a consideration of agency-specific statutory or regulatory obligations to make at least certain guidance documents readily available. Overall, the research discussed in this Part indicates that, outside of a few general legal standards that call for making guidance available, there appear to

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[92] *Id*.
[93] *Id*.
[94] *Id*. at 4.
[95] *Id.* at 13.
[96] *Id*. at 21.
[97] For a general discussion of how legal structures can promote self-enforcing results, see Edward K. Cheng, *Structural Laws and the Puzzle of Regulating Behavior*, 100 Nw. U. L. Rev. 655 (2006).

exist relatively few overall agency-specific legal requirements for guidance availability. This Part also reviews non-binding standards for guidance availability, such as those contained in the OMB Bulletin discussed in Part I of this report.

A. General Legal Requirements

Federal agencies are subject to several overarching publication or open government requirements that apply to guidance documents. This section reviews these general requirements from the Federal Records Act, the Freedom of Information Act, E-Government Act, Congressional Review Act, and Small Business Regulatory Enforcement Fairness Act.

1. Federal Records Act

Each agency has an overall responsibility under the Federal Records Act for managing records it produces and processes. In 2016, the Act was amended to impose the following general responsibility on each agency:

> The head of each Federal agency shall establish and maintain an active, continuing program for the economical and efficient management of the records of the agency. The program, among other things, shall provide for … procedures for identifying *records of general interest or use to the public that are appropriate for public disclosure, and for posting such records in a publicly accessible electronic format.*[98]

For the reasons discussed in Part I of this report, many guidance documents would likely qualify as "records of general interest or use to the public." To comply with the Federal Records Act, it would appear that agencies should include such guidance documents in their records management program and ensure that they are posted online.

2. Freedom of Information Act

The Freedom of Information Act (FOIA) requires some guidance documents to be published in the *Federal Register* and others to be made available to the public in an electronic format.[99] FOIA imposes two standards relevant to guidance availability.

First, under Section 552(a)(1), each agency must publish in the *Federal Register* a variety of materials, including legislative rules. But it must also publish "rules of procedure, descriptions of forms available or the places at which forms may be obtained, and instructions as to the scope and contents of all papers, reports, or examinations" as well as "statements of general policy or interpretations of general applicability formulated and adopted by the agency."[100] These latter documents—general policy statements and interpretative rules—fall within any conventional definition of guidance, as discussed in Part I. In addition, FOIA makes clear that "each amendment,

[98] 44 U.S.C. § 3102 (emphasis added).
[99] Freedom of Information Act, 5 U.S.C. § 552 (2018).
[100] *Id.* § 552(a)(1).

revision, or repeal" of guidance or any other document covered by Section 552(a)(1) must also be published in the *Federal Register*.

Second, Section 552(a)(2) of the Freedom of Information Act states that agencies "shall make available for public inspection in an electronic format" a variety of documents, including (a) "administrative staff manuals and instructions to staff that affect a member of the public," and (b) "statements of policy and interpretations which have been adopted by the agency and are not published in the *Federal Register*," that is, those that are not "general" in nature.[101]

FOIA contains several categories of exemptions to its requirements, such as for documents containing trade secrets, personnel records, or law enforcement information. Information need not be published, for example, if it "would disclose guidelines for law enforcement investigations or prosecutions."[102] Furthermore, neither of the publication requirements in Sections 552(a)(1) and (2) apply to the extent that an affected person has "actual and timely notice" of the guidance.[103] For this reason, it would appear that most informal forms of guidance—such as answers to questions provided by an agency inspector or an agency representative staffing a help line—would not be required under FOIA to be published in either the *Federal Register* or the agency website.

Both Sections 552(a)(1) and (2) illustrate the kind of self-enforcing legal structure that helps ensure the publication of legislative rules, but which fits less well in the context of documents that are avowedly non-binding. Section 552(a)(1)(E) provides that "a person may not in any manner be required to resort to, or be adversely affected by, a matter required to be published in the *Federal Register*." Similarly, Section 552(a)(2)(E) provides that a "statement of policy, interpretation, or staff manual or instruction that affects a member of the public may be relied on, used, or cited as precedent by an agency against a party other than an agency only if (i) it has been indexed and either made available or published as provided by this paragraph; or (ii) the party has actual and timely notice of the terms thereof."[104] These provisions make clear the stakes for an agency for failing to publish guidance documents; however, because guidance is non-binding, these stakes will necessarily be limited. Presumably, by definition, agencies do not intend to rely on guidance documents as binding precedent or a legal basis for enforcement penalties.

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[101] *Id.* § 552(a)(2). In addition, agencies are instructed to make available copies of certain records that have been released to any person and meet certain other requirements, along with a general index of those records. All of these requirements are further elaborated in guidance issued by the Department of Justice. *See* DEP'T OF JUSTICE, UNITED STATES DEPARTMENT OF JUSTICE GUIDE TO THE FREEDOM OF INFORMATION ACT (last updated July 11, 2016), https://www.justice.gov/oip/doj-guide-freedom-information-act-0.

[102] *Id.* § 552(b)(7)(E).

[103] *Id.* § 552(a)(1)(E) and § 552(a)(2)(E); *see also, e.g.*, United States v. Mowat, 582 F.2d 1194 (9th Cir. 1978) (the non-publication of a Department of Navy instruction prohibiting admission to a military reservation did not bar appellants' prosecution where appellants had actual and timely notice of it); Royer v. Fed. Bureau of Prisons, 934 F. Supp. 2d 92, 97 (D.D.C. 2013) ("Although the APA requires that agencies publish interpretive rules and statements of policy in the *Federal Register*, 5 U.S.C. § 552(a)(1)(D), if a person has 'actual and timely notice of the terms thereof,' there is no associated penalty on the agency.").

[104] 5 U.S.C. § 552(a)(2)(E).

3. *The E-Government Act*

The E-Government Act of 2002 was enacted to promote the use of the Internet and other technologies to improve citizen access to government information and services, improve government decision making, and enhance accountability and transparency.[105] The Act requires agencies, to the extent practicable, to "ensure that a publicly accessible Federal Government website includes all information about that agency required to be published in the *Federal Register*."[106] Since Section 552(a) of title 5 of the United States Code requires at least some guidance documents to be published in the *Federal Register*, the E-Government Act applies to those guidance documents.

The E-Government Act also directs each agency to "establish a process for determining which Government information the agency intends to make available and accessible" and then to develop a strategy for in fact making it available and accessible.[107] OMB has also issued memoranda on the implementation of the E-Government Act. For example, OMB Memorandum M-06-02 specifically calls for agencies to organize and categorize information that it intends to make available to the public and then to make that information searchable across agencies to improve public access and dissemination of government information.[108] That memorandum also provides that when disseminating information to the public-at-large, agencies must publish information on the Internet.[109] These provisions apply to agencies' public dissemination of guidance documents.

4. *The Congressional Review Act*

Although the Congressional Review Act (CRA) does not address issues of general public accessibility of guidance documents, it requires that agencies notify Congress of guidance documents. More generally, the CRA establishes a process for congressional review of agency rules and their possible disapproval by joint resolution. To support this process, the CRA provides that "[b]efore a rule can take effect," the federal agency promulgating it must submit a copy of it (along with other information concerning the rule) to Congress and the Government Accountability Office (GAO).[110]

GAO has determined that certain guidance documents are "rules" under the CRA, meaning that such guidance is subject to any publication requirements set forth in the statute. The CRA states that "rule" under the statute has the meaning given that term in section 551 of the Administrative Procedure Act, with certain exceptions.[111] The APA's definition of a rule provides that a rule is "the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization,

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[105] E-Government Act, 1 Pub. L. No. 107-347 (Dec. 17, 2002) (codified in scattered sections of 44 U.S.C.).
[106] *Id*. § 206(b).
[107] *Id*. § 207(f)(2)(A)(ii).
[108] Office of Mgmt. & Budget, Exec. Office of The President, OMB Memorandum M-06-02, Improving Public Access to and Dissemination of Government Information and Using the Federal Enterprise Architecture Data Reference Model § 1 (2005), https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2006/m06-02.pdf.
[109] *Id.*
[110] 5 U.S.C. § 801(a)(1)(A)-(B) (2018).
[111] 5 USC § 804(3).

procedure, or practice requirements of an agency."[112] The CRA further narrows its coverage by exempting rules of particular applicability; rules relating to agency management or personnel; and rules of agency organization, procedure, or practice that do not substantially affect the rights or obligations of non-agency parties.[113]

According to GAO, CRA requirements apply to guidance documents that are general statements of policy, even though, by definition, they are not legally binding. In 2017, GAO opined that a Consumer Financial Protection Bureau bulletin advising the public prospectively of the manner in which the Bureau proposed to exercise its discretionary enforcement power under the Equal Credit Opportunity Act constituted a "rule" under the CRA.[114] The upshot is that all guidance documents that are non-legislative rules and are not otherwise exempted will be treated as falling within the confines of the CRA.[115]

The stakes for an agency that fails to report to Congress the release of a guidance document, however, will be different than the stakes for failure to report a legislative rule. In fact, when guidance documents constitute rules under the definition used in the CRA, the law only requires agencies to report such rules to Congress "before [they] take effect."[116] Given that a guidance document is non-binding, it does not ever really "take effect" in any legally binding way and for that reason arguably is not subject to the CRA's reporting requirements, or at least any agency that fails to report a guidance document faces little, if any, meaningful consequence for such failure.

5. Small Business Regulatory Enforcement Fairness Act

As noted in Part I, the Small Business Regulatory Enforcement Fairness Act of 1996[117] requires agencies to produce a "small entity compliance guide"—a guidance document intended especially to help small businesses—for any rule that is deemed to have a "significant economic impact on a substantial number of small entities."[118] It requires "the posting of the guide in an easily identified location on the website of the agency" and the "distribution of the guide to known industry contacts, such as small entities, associations, or industry leaders affected by the rule."[119]

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[112] 5 USC § 551(4).
[113] 5 USC § 804(3).
[114] U.S. Gov't Accountability Office, GAO/B-329129, Bureau of Consumer Financial Protection: Applicability of the Congressional Review Act to Bulletin on Indirect Auto Lending and Compliance with the Equal Credit Opportunity Act (2017).
[115] Under broader definitions of guidance, many guidance documents will not be considered to be rules under the APA and thus will not be covered by the CRA. *See supra* Part I. For those guidance documents that do meet the APA's definition of a rule, OMB directs all agencies subject to the CRA to send their guidance documents to the Office of Information and Regulatory Affairs for review to determine whether they constitute a "major" rule under the CRA. Office of Mgmt.& Budget, Exec. Office of The President, OMB Memorandum M-19-14, Guidance on Compliance with the Congressional Review Act (Apr. 11, 2019).
[116] 5 U.S.C. § 801(a)(1)(A).
[117] Pub. L. No. 104–121, 110 Stat. 873, codified at 5 U.S.C. § 601 nt., § 212 (2019).
[118] 5 U.S.C. § 605(b).
[119] *Id.*

B. **Agency-Specific Legal Requirements**

Federal agencies may also be subject to agency-specific legal requirements related to the availability of guidance documents. These requirements may originate in statutes or may be imposed on agencies themselves through regulations. This section does not purport to catalog all such agency-specific requirements. Instead, it begins by illustrating the agency-specific requirements generally governing guidance documents produced by the Food and Drug Administration. Then it reports the findings from a review of the U.S. Code and Code of Federal Regulations for provisions related to public availability of guidance for fourteen agencies. We distinguish between provisions that apply generally to all or most guidance documents issued by an agency and those that apply to specific guidance documents, such as those addressing specified issues. Overall, we find more provisions related to specific guidance documents; few agencies appear to be subjected by statute or regulation to agency-specific guidance policies.

1. Requirements for Food and Drug Administration Guidance

The Food and Drug Administration (FDA) is an example of an agency subject to separate general requirements for guidance availability. The Food and Drug Administration Modernization Act of 1997 imposes statutory requirements for public participation in the process of developing FDA's more significant guidance documents.[120] Without regard to the significance of guidance, it also requires that FDA "maintain electronically and update and publish periodically in the *Federal Register* a list of guidance documents," stating that "[a]ll such documents shall be made available to the public."[121]

Under the FDA's Good Guidance Practice regulation, the agency generally makes publicly available the draft versions of its Level 1 guidance documents and invites public comment on them.[122] The regulations state that, after these more significant guidance documents are final, "FDA will…[p]ublish a notice in the Federal Register announcing that the guidance document is available" and will "[p]ost the guidance document on the Internet and make it available in hard copy."[123] For a Level 2 guidance document, FDA does not commit to soliciting comments on a draft but will simply "[p]ost the guidance document on the Internet and make it available in hard copy."[124] The regulations state that, should comments come in later and lead FDA to revise a Level 2 guidance document, "the new version will be placed on the Internet."[125] No equivalent assurance is provided in the regulation about posting any revisions to final Level 1 guidance documents.

Regardless of whether a guidance is categorized as Level 1 or Level 2, the regulation states that it "must ... (i) Include the term "guidance," (ii) Identify the center(s) or office(s) issuing the document, (iii) Identify the activity to which and the people to whom the document applies, (iv) Prominently display a statement of the document's nonbinding effect, (v) Include the date of

[120] 21 U.S.C. § 371(h)(3).
[121] *Id.*
[122] 21 C.F.R. § 10.115.
[123] *Id.* § 10.115(g)(1)(iv)(B) & (C).
[124] *Id.* § 10.115(g)(4)(i)(A).
[125] *Id.*

issuance, (vi) Note if it is a revision to a previously issued guidance and identify the document that it replaces, and (vii) Contain the word "draft" if the document is a draft guidance."[126] In addition the FDA regulation states that "[g]uidance documents must not include mandatory language such as "shall," "must," "required," or "requirement," unless FDA is using these words to describe a statutory or regulatory requirement.[127]

Under its Good Guidance Practice regulation, "FDA will maintain on the Internet a current list of all guidance documents" and "[n]ew documents will be added to this list within 30 days of issuance."[128] In addition, "[o]nce a year, FDA will publish in the Federal Register its comprehensive list of guidance documents," which "will identify documents that have been added to the list or withdrawn from the list since the previous comprehensive list."[129] Finally, the regulation states that "FDA's guidance document lists will include the name of the guidance document, issuance and revision dates, and information on how to obtain copies of the document."[130]

2. Other Agency-Specific Requirements

Initial interviews with knowledgeable government staff as well as a general search of the literature did not reveal other agencies that had agency-specific requirements along the lines of the FDA. In an effort to gauge more systematically how common such statutory or regulatory requirements might be, an intensive search was made of the United States Code and the Code of Federal Regulations for guidance disclosure provisions for fourteen agencies. Many of these requirements relate to specific guidance documents, on specific issues or topics, rather than, as with FDA, imposing any general, agency-wide legal regimen for managing and disclosing all guidance documents.

The review of agency-specific guidance disclosure requirements began by selecting a sample of agencies to examine. The aim was to find a sample that would reflect the diversity of federal agencies, so the sample included both independent and executive agencies as well as some full departments and some sub-agencies within a larger department. No claims can be made that the sample of agencies was random nor, in that sense, fully representative; however, the sample did identify a broad range of agency-specific legal requirements that a diverse group of federal agencies confront related to guidance disclosure. To build on prior work on guidance availability discussed in Part I of this report, we included the four agencies that GAO audited in 2015 and the seven agencies discussed most extensively in the House Committee majority staff report.[131] The overall sample comprised the following fourteen agencies:

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[126] *Id.*
[127] *Id.*
[128] *Id.*
[129] *Id.*
[130] *Id.*
[131] STAFF OF H. COMM. ON OVERSIGHT & GOV'T REFORM, 115TH CONG., SHINING LIGHT ON REGULATORY DARK MATTER (Comm. Print 2018), https://republicans-oversight.house.gov/wp-content/uploads/2018/03/Guidance-Report-for-Issuance1.pdf. The report discussed the performance of the Department of Defense, Department of Education, Department of Labor, Department of Health and Human Services (including separately the Centers for Medicare & Medicaid Services (CMS) and Food and Drug Administration), and Securities and Exchange Commission. We included all of these agencies in our review except for CMS.

(1) Agriculture (USDA);
(2) Consumer Financial Protection Bureau (CFPB);
(3) Defense (DOD);
(4) Education (DOE);
(5) Transportation (DOT);
(6) Environmental Protection Agency (EPA);
(7) Food and Drug Administration (FDA);
(8) Health and Human Services (HHS);
(9) Housing and Urban Development (HUD);
(10) Internal Revenue Service (IRS);
(11) Labor (DOL);
(12) National Highway Traffic Safety Administration (NHTSA);
(13) Securities and Exchange Commission (SEC); and
(14) Federal Trade Commission (FTC).

The U.S. Code and the Code of Federal Regulations were intensively searched using an electronic database to find provisions related to the publication of guidance documents for these fourteen agencies, looking in particular for any provisions that spoke to making guidance documents available in a particular location (e.g., the *Federal Register*, an agency website, or a specific agency publication).[132] Each provision was coded for whether it was: (1) "descriptive" versus "prescriptive," that is, merely documenting an agency's practice of publishing guidance documents versus establishing a requirement or obligation; and (2) "general" versus "specific," that is, requiring the publication of all of an agency's guidance (or a significant subset) versus requiring the publication of a specific, individual guidance document issued by the agency. The latter two codings—*general* and *specific*—are both subcategories within the larger *prescriptive* category. Furthermore, within all of these categories, each provision was classified according to whether it was statutory or regulatory, based on the primary legal source in which it appeared.

For each agency and each type of legal source, Table 1 shows the number of provisions that fell into each of the categories. Overall, a total of 132 provisions were identified across the fourteen agencies that spoke in some way to the publication or availability of guidance documents. Of these, slightly more than half (69) were descriptive in nature, all of these contained in the Code of Federal Regulations. Such descriptive provisions merely pointed the reader to a location where a guidance document or documents could be located. For example, a descriptive provision at 49 C.F.R. Section 601.10 states in part that "[c]irculars and other guidance/policy information are available on FTA's Web site: http://www.fta.dot.gov." By contrast, an example of a prescriptive provision can be found at 12 C.F.R. Section 1070.1, which states that "[t]he CFPB shall separately state, publish and maintain current in the Federal Register for the guidance of the public … statements of general policy or interpretations of general applicability formulated and adopted by the CFPB."

[132] The electronic searches were structured to seek statutory and regulatory provisions where terms such as "guidance" or "policy statements" were located with proximity to terms such as "publish," "disclose," or "publication." As such, the review reported here may understate to some degree the number of legal provisions related to guidance availability, at least to the extent that some statutes or regulations might conceivably use different language to address guidance access considerations.

Table 1: Agency-Specific Requirements Found for Fourteen Agencies

Agency	Statutory-General	CFR-General	Statutory-Specific	CFR-Specific	Statutory-Descriptive	CFR-Descriptive	Total
CFPB	0	1	0	1	0	3	5
HHS	0	0	8	1	0	9	18
FDA	1	3	4	0	0	9	17
Labor	0	1	0	0	0	1	2
Education	0	0	2	0	0	0	2
USDA	0	1	3	9	0	11	24
EPA	0	0	0	0	0	7	7
DOD	0	2	1	4	0	6	13
SEC	0	0	0	0	0	0	0
FTC	0	0	0	0	0	0	0
DOT	2	0	0	0	0	13	15
NHTSA	0	0	0	0	0	0	0
HUD	0	0	0	5	0	1	6
IRS	0	2	0	12	0	9	23
Total	3	10	18	32	0	69	132

Based on the search results, four of the fourteen agencies appear to have no applicable statutory or regulatory provision that imposes an agency-specific requirement to make guidance documents publicly available (EPA, FTC, NHTSA, SEC). The remaining ten agencies were found to have either a statutory or regulatory provision that spoke to guidance availability by their agency either generally or with respect to specific guidance documents. Few agencies were subject to general legal obligations with respect to guidance. Beyond FDA, only one other agency—the U.S. Department of Transportation—was found to be subject to a *statutory* provision addressing publication of guidance generally across the agency. Outside of FDA, only five other agencies were found subject to such *regulatory* provisions that were general in scope. A total of five agencies were identified to have a statutory provision that required publication of a specific guidance; for six agencies, a regulatory provision on a specific guidance was found. By far, most of the provisions addressed specific guidance documents (50 out of 63), and regulatory provisions (42) outnumbered statutory provisions (21) by a two-to-one margin.

C. Guidance on Guidance

In addition to requirements contained in statutes and regulations, agencies confront other sources of standards related to guidance availability. Non-binding standards can be found in what might be thought of as guidance on guidance. Some such guidance emanates from the OMB and

applies to all executive agencies, while other guidance on guidance derives from within agencies themselves when they have created their own agency-specific guidance on guidance.

1. Generally Applicable Guidance on Guidance

OMB's Bulletin on good guidance practices—already mentioned in Part I of this report—provides standards that call for making guidance documents publicly available.[133] The Bulletin's purpose is "to ensure that guidance documents of Executive Branch departments and agencies are: developed with appropriate review and public participation, *accessible and transparent to the public*, of high quality, and not improperly treated as legally binding requirements."[134]

The Bulletin calls for each agency to maintain "on its Web site—or as a link on an agency's Web site to the electronic list posted on a component or subagency's Web site—a current list of its significant guidance documents in effect."[135] According to the Bulletin,

> The list shall include the name of each significant guidance document, any document identification number, and issuance and revision dates. The agency shall provide a link from the current list to each significant guidance document that is in effect. New significant guidance documents and their Web site links shall be added promptly to this list, no later than 30 days from the date of issuance.

The list is also supposed to "identify significant guidance documents that have been added, revised or withdrawn in the past year."[136] It is also supposed to be situated on the agency website in a "quickly and easily identifiable manner (e.g., as part of or in close visual proximity to the agency's list of regulations and proposed regulations)."[137]

When developing economically significant guidance, agencies are supposed to publish in the *Federal Register* a notice when a draft of the guidance document has been released and solicit public comments on it. The agency should then "[p]ost the draft document on the Internet and make it publicly available in hard copy."[138] The Bulletin also calls on agencies to "[p]repare and post on the agency's Web site a response-to-comments document."[139]

The Bulletin does not impose any standards for guidance documents that are not significant. This means that guidance documents concerning "routine matters" are not covered by any disclosure standard, even though some of the documents that might make up the day-to-day

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[133] OFFICE OF MGMT. & BUDGET, *supra* note 12. Notably, the OMB Good Guidance Practices Bulletin does not require independent agencies to comply. *Id.* ("This Bulletin establishes policies and procedures for the development, issuance, and use of significant guidance documents by *Executive Branch departments and agencies* and is intended to increase the quality and transparency of agency guidance practices and the significant guidance documents produced through them.") (emphasis added).
[134] *Id*. at 3433 (emphasis added).
[135] *Id.* at 3440.
[136] *Id.*
[137] *Id*. at 3437.
[138] *Id.* at 3438.
[139] *Id*. at 3440.

business of an agency could be of possible interest to the public.[140] The Bulletin states that it is important to avoid "inhibit[ing] the beneficial practice of agencies providing informal guidance to help specific parties."[141]

In addition to the OMB Bulletin on good guidance practices, several other standards merit brief mention—not because they speak directly to guidance availability but because they pertain to issues of open access to government information more generally and thus reinforce the notion that agency guidance documents, as well as agency websites which link to guidance documents, should be accessible to the public. For example, OMB issued an Open Government Directive[142] in 2009 in response to a presidential memorandum on transparency and open government.[143] The Open Government Directive calls for executive agencies and departments to take steps to expand access to information by making it available online in open formats.[144] OMB subsequently issued another memorandum which outlined supplemental best practices to assist agencies in their open government efforts.[145]

With respect to information made available on agency websites, Executive Order 13,642[146] and OMB Memorandum M-13-13[147] call for each executive agency to create an open data policy to support information processing and dissemination activities.[148] Agencies are encouraged to use machine-readable and open formats, establish data standards, and provide common core and extensible metadata for all new information creation and collection. Further standards with broader implications relevant to the online dissemination of agency guidance documents come from the federal Digital Government Strategy[149] and the U.S. Digital Service Playbook.[150] OMB's Memorandum M-17-06 supports the goals outlined in those documents by calling for executive agencies to disseminate information to the public in a way that enables the data to be fully discoverable and

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[140] *Id.* at 3435.
[141] *Id.*
[142] Office of Mgmt. & Budget, Exec. Office of the President, OMB Memorandum M-10-06, Open Government Directive (2009), https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2010/m10-06.pdf [hereinafter OMB Memorandum M-10-06].
[143] PRESIDENTIAL MEMORANDUM ON TRANSPARENCY AND OPEN GOVERNMENT, 74 Fed. Reg. 4685 (Jan. 26, 2009), https://www.gpo.gov/fdsys/pkg/FR-2009-01-26/pdf/E9-1777.pdf.
[144] OMB Memorandum M-10-06, *supra* note 142.
[145] Office of Mgmt. & Budget, Exec. Office of the President, OMB Memorandum M-16-16, 2016 Agency Open Government Plans (2016), https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2016/m-16-16.pdf.
[146] Exec. Order No. 13,642, 78 FR 28,111 (May 14, 2013), https://www.gpo.gov/fdsys/pkg/FR-2013-05-14/pdf/2013-11533.pdf.
[147] Office of Mgmt. & Budget, Exec. Office of the President, OMB Memorandum M-13-13, Open Data Policy—Managing Information as an Asset (2013), https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2013/m-13-13.pdf.
[148] *Id.*
[149] DIGITAL GOVERNMENT: BUILDING A 21ST CENTURY PLATFORM TO BETTER SERVE THE AMERICAN PEOPLE (2012), https://obamawhitehouse.archives.gov/sites/default/files/omb/egov/digital-government/digital-government-strategy.pdf. The Digital Government Strategy and other materials to help agencies learn about the methods, practices, policies and tools that are needed to create effective digital services may be found at https://digital.gov/.
[150] DIGITAL SERVICES PLAYBOOK, https://playbook.cio.gov/ (last visited July 6, 2018).

usable.[151] Information is supposed to be searchable and discoverable, which means, importantly, that agencies' public websites must contain a search function and that agencies must ensure that all content intended for public use on their websites can be indexed or searched by commonly used commercial search engines.

2. *Agency-Specific Guidance on Guidance*

The OMB Bulletin on good guidance practices calls on executive agencies to "develop or have written procedures for the approval of significant guidance documents" in order to "ensure that the issuance of significant guidance documents is approved by appropriate senior agency officials."[152] Some agencies' internal procedures speak not only to the approval of significant guidance but also provide an overall framework for the management and dissemination of guidance.

The U.S. Department of Transportation, for example, adopted a departmental-wide memorandum in December 2018 on the "review and clearance of guidance documents" that speaks directly to how guidance should be made available to the public.[153] The memorandum's section on public access to guidance states:

> Each [operating administration] and component of [the Office of the Secretary] responsible for issuing guidance documents shall-
>
> (a) Maintain on its DOT Web site an electronic list identifying each of its guidance documents by a unique identifier, including, at a minimum, the document's title and date of issuance or date of revision and its Z-RIN, if applicable;
>
> (b) Ensure that all its guidance documents are readily accessible to the public in electronic form, including by hyperlinks from the current list maintained on the DOT Web site;
>
> (c) Maintain and advertise on its Web site a means for the public to comment electronically on any guidance documents that are subject to the notice-and-comment procedures described in paragraph 8 of this memorandum[154] and to submit requests electronically for issuance, reconsideration, modification, or rescission of guidance documents; and

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[151] Office of Mgmt. & Budget, Exec. Office of the President, OMB Memorandum M-17-06, Policies for Federal Agency Public Websites and Digital Services (2016), https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2017/m-17-06.pdf.

[152] OFFICE OF MGMT. & BUDGET, *supra* note 12.

[153] Bradbury Memorandum, *supra* note 20, § 4.

[154] "Except as provided in subparagraph (b) of this paragraph, all proposed DOT guidance documents determined to be a 'significant guidance document' within the meaning of paragraph 7 of this memorandum shall be subject to the following informal notice-and-comment procedures. The issuing OA or component of OST shall publish a notice in the *Federal Register* announcing that a draft of the proposed guidance document is publicly available, shall post the draft guidance document on its Web site, shall invite public comment on the draft document, and, if substantive or otherwise notable and relevant comments are received, shall prepare and post responses to such public comments, as appropriate, on its Web site, either before or when the guidance document is finalized and issued." *Id.*, at para. 8.

> (d) Designate an office to receive and address complaints from the public that [an operating administration or component] is not following the requirements of OMB's Good Guidance Bulletin or is improperly treating a guidance document as a binding requirement.[155]

In a footnote, the memorandum states that "[i]t is DOT's policy to make all guidance documents readily accessible to the public, not just 'significant' guidance documents."[156] The footnote makes clear that, other than documents that fall into excluded categories, all guidance is to be "readily accessible" even if it does not meet the other criteria for significance, such as leading to annual costs of $100 million or raising "novel legal or policy issues."[157] Of course, as noted in Part I, the Department's starting definition of guidance document excludes many of the same categories of documents that the OMB Bulletin categorically excludes from its definition of significant guidance documents.[158]

D. Findings and Implications

This review of legal standards and guidance on guidance leads to four main findings and implications. First, although several legal standards address guidance availability at agencies across the federal government, these requirements lack the same structural features that tend to promote consistent publication of legislative rules. Admittedly, agencies are subject to statutes like the Federal Records Act and the E-Government Act that generally promote the accessibility of all types of government information.[159] And FOIA specifically requires agencies either to publish certain guidance in the *Federal Register* or to make it available online.[160] But unlike with legislative rules, which FOIA states cannot be enforced unless they are published, agencies do not face the same built-in incentives to ensure that guidance documents are routinely and consistently published and made available to the public. In the context of non-binding documents, statutory provisions provide little built-in incentive to agencies. Non-binding materials are inherently non-binding, which makes legal mechanisms that prevent unpublished or undisclosed guidance material to "take effect" have little meaning. Furthermore, the OMB Bulletin on guidance, while applicable to executive agencies across the government, is itself non-binding and thus provides no additional self-reinforcing mechanism for ensuring agencies will consistently and meaningfully make guidance materials accessible to the public.

Second, few agencies appear to be subject to meaningful agency-specific legal requirements. Based on a review of agency-specific requirements for fourteen agencies, few statutory or regulatory provisions compel individual agencies to make all their guidance materials transparent.[161] A notable exception is the FDA, which is subject both to a statutory and regulatory

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[155] *Id*., at para. 4.
[156] *Id*., at para. 8 n. 6.
[157] *Id*.
[158] *See supra* Part I.
[159] *See supra* Part II.A.
[160] *See supra* notes 99-104 and accompanying text.
[161] *See supra* Part II.B.2.

provisions that address guidance availability across the board at the agency.[162] These kinds of agency-specific legal requirements, of course, contain no greater structural incentives for compliance than do the government-wide legal requirements. Moreover, when legal requirements are imposed on or by specific agencies, they tend to focus on the availability of specific guidance documents in connection with particular program needs or policy issues. For instance, a federal statute requires the Secretary of Education to provide guidance on constitutionally protected prayer in public schools and to "pos[t] the guidance on the Department's website in a clear and easily accessible manner."[163] Such requirements to disclose guidance on specific topics may help in promoting public accessibility for those individual guidance documents, but they ultimately take an ad hoc approach to guidance availability. It would appear that neither Congress nor many agencies have adopted rules addressing guidance availability in a holistic manner. Some agencies have, of course, implemented their own internal guidance procedures—creating their own agency-made guidances on guidance. But as these are also non-binding, the extent of public accessibility to guidance documents at these agencies will depend, in the end, on how well internal procedures are followed and whether agency managers make it a priority to track guidance documents closely and make them readily available.

Third, the large number of descriptive provisions (69 out of 132) that surfaced in the review of agency-specific regulations reveals some positive news: a meaningful but previously unacknowledged method by which agencies make the public aware of their guidance documents.[164] The placement of references about guidance within the regulatory corpus itself, pointing readers to the existence of related guidance material, is an appropriate and helpful means of increasing public access to guidance, assuming these references are accurate and kept up-to-date. After all, any reader who reaches a regulatory provision published in the *Federal Register* or Code of Federal Regulations for which an agency has created applicable guidance ought to be presumed to have an interest in that guidance. Inserting statements about how to find such guidance is a bit like taking advantage of what educators call a "teachable moment"—or what is, in this context, a moment when the readers of regulations can be expected to want to know about the existence of relevant agency guidance.

Finally, the discovery of many descriptive statements and other provisions about individual guidance documents within agency-specific regulations reinforces the nature of the management challenge facing agencies—but also suggests that agencies recognize that it can be valuable to work to meet those management challenges. A full 90 percent of the agency-specific provisions located (119 out of 132) either related to specific individual guidance documents or comprised descriptive statements about where to find guidance.[165] Agencies do produce a large volume and variety of guidance documents, as discussed in Part I of this report, and the legal requirements encountered in this study seem to reflect that variety and individuality, too. That is the management challenge agencies face: tracking that full variety and proliferation of guidance material, ensuring it is published or posted in an accessible location, reaching out to interested segments of the public about new or revised guidance, and following up to make sure online repositories are kept up to

[162] *See supra* Part II.B.1.
[163] 20 U.S.C. § 7904.
[164] *See supra* Part II.B.2.
[165] *See supra* Table 1.

date. In this regard, it seems noteworthy that more than three-quarters (101 out of 132) of the guidance-specific requirements and descriptive statements were contained in the Code of Federal Regulations—that is, created by agencies themselves.[166]

Even though the lack of a self-enforcing structure may mean that legal standards related to guidance disclosure do not provide agencies with built-in incentives for making guidance accessible to the public, agencies do have intrinsic reasons for disseminating their guidance documents. These documents are produced, after all, to communicate helpful information to relevant segments of the public, including regulated entities. Guidance documents will only be able to be helpful if those who would benefit from their information and assistance can find them when they need to know or are interested. The volume and variety of guidance documents can make agencies' management challenge daunting, but opportunities will always exist for agencies to do better in meeting that challenge. The next Part of this report identifies some of those opportunities and offers suggestions about "best practices" for agencies to implement.

III. Managing Guidance Availability

The legal standards outlined in statutes such as the E-Government Act, FOIA, and the Federal Records Act, along with the norms contained in the OMB Bulletin, all point in the same direction: toward greater governmental transparency. Agencies clearly have a responsibility for making their guidance documents readily available to the public. Toward that end, they already publish a considerable amount of guidance material in the *Federal Register* or on their websites. Most agencies have established a dedicated webpage that provides lists of and links to at least their agencies' significant guidance documents. Some agencies have also adopted their own internal policies, and even regulations, to reinforce the importance of systematic review, management, and dissemination of guidance materials.

Yet, especially in light of the concerns discussed in Part I.C of this report, agencies have opportunities to improve as well. Digital communication technology has given agencies exceptional tools for making guidance easier to find than ever before. But technology by itself cannot offer a quick or easy fix to recent concerns about guidance availability. Because federal agencies regularly generate a profusion of guidance, making sure these documents, or at least an appropriate subset of them, are readily available to the public requires meeting a management challenge as much as a technological one. This Part of the report illuminates that management challenge by reference to four core criteria of meaningful guidance availability that every agency should pursue. This Part explicates these criteria and provides examples that illustrate opportunities for improvement with respect to each criterion. This Part then turns to five types of "best practices" that agencies should consider adopting or refining in their effort to make the guidance documents they produce more available—and therefore more effective and helpful.

[166] It is possible, of course, that some of these provisions in the Code of Federal Regulations were prompted by legislative requirements. No research was undertaken to determine whether any particular agency provision related to guidance had been prompted by a statutory direction. But for two reasons it seems unlikely that many agency provisions would have been inserted at the behest of Congress. First, the wording of these provisions suggested that most were inserted merely to be helpful. Second, the overall sample of provisions derived from both the U.S. Code and the Code of Federal Regulations, and the former contained far fewer provisions related to guidance publication.

A. Guidance Availability Criteria

What does it mean for guidance to be made "available" to the public? Due to digital technology, the availability of a government document today often means that anyone with a computer or smart phone and an Internet connection can read or download it. Unlike with availability "upon request," as in response to a FOIA letter, the prevailing on-demand understanding of open government places an affirmative management responsibility on agencies to take steps to place materials online.[167] They need to make sure that relevant documents that employees anywhere in their agency could produce are identified and then those that meet specified criteria for disclosure are uploaded in a manner that interested members of the public can easily find them. For guidance documents, this means that they must provide a way of managing their collection of relevant non-binding materials that ensures they are *comprehensive*, *current*, *accessible*, and *comprehensible*. From what can be gleaned about current guidance practices, agencies still have room to improve with respect to each of these criteria of availability.

1. Comprehensiveness

Availability begins with completeness. If agency managers are to make their agencies' guidance documents available to the public, they have to know that these documents have been created and then they need a system to ensure that the appropriate documents are made available. If an agency were to publish on its website only one of, say, thousands of guidance documents that it was supposed to disclose, the agency could not credibly claim to have provided much public availability overall, no matter how easy it might be for members of the public to find that one available document. Asking about the comprehensiveness of any agency's disclosure of guidance documents is a way of asking, at a minimum, how well an agency is living up to its intentions about making its guidance documents available.[168]

At its best, a comprehensive system of guidance availability calls for an agency to identify the overall "population" of material that meets the agency's or another relevant definition of guidance—and then to make all of that material available. Of course, this makes for potentially a tall order, at least under the most capacious understanding of guidance, for the reasons discussed in Part I. Guidance can be generated daily. This is exactly why OMB and some agencies have worked to try to define guidance with some precision and to create categories within such definitions.[169] Managers need definitions and categories to undergird internal control systems that can help track the generation of guidance and ensure that it gets made available to the public.

Yet as difficult as it may be for agency managers themselves to identify the underlying population of relevant guidance at their own agencies, it is still more difficult for those outside of

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[167] *Cf.* Coglianese et al., *Transparency and Public Participation in the Rulemaking Process*, 77 GEO. WASH L. REV. 924 (2009).

[168] *Cf.* E-Government Act of 2002, Pub. L. No. 107-347, § 207(f)(2), 116 Stat. 2899, 2919 (2002) (calling on agencies to make a determination of "which Government information the agency intends to make available and accessible to the public on the Internet").

[169] *See supra* notes 30-33 and accompanying text.

these agencies to determine what fraction of all guidance that should be made available online is actually available in this way. Indeed, it is simply not possible at present for an outside observer to say how comprehensively any agency is making its guidance documents available—even under agencies' own definitions of guidance. This is because the materials that are not disclosed are effectively invisible.

The extensiveness and elusiveness of guidance (especially under the broadest understanding of the term) makes it difficult, if not impossible, to estimate a denominator to compute the fraction of all guidance that has been made available. In a recent oral argument at the Supreme Court, Justice Stephen Breyer surmised that "[t]here are hundreds of thousands, possibly millions, of interpretive regulations"—just one type of agency guidance.[170] That estimate makes the number of documents reported to House Committee staff members last year pale in comparison. When they asked 46 agencies to provide lists of all guidance documents produced since 2008, the agencies responded with lists containing, in total, more than 13,000 entries.[171] Of course, that number clearly understated the real volume of guidance because some agencies' lists contained fewer documents than could be found listed as guidance on their own websites, some agencies openly acknowledged that their lists were incomplete, and eight agencies failed to provide any list at all.[172] Furthermore, the fact that "only a few [agencies] were able to produce a comprehensive list of guidance documents within two weeks" would seem to indicate an absence of internal control systems cataloging and tracking guidance documents, which lessens the confidence that many agencies have a comprehensive internal accounting of their own documents.[173]

If an underlying denominator for the population of all guidance documents cannot be feasibly determined, estimating the numerator is more achievable, at least by looking at central locations where many agencies disclose their guidance: websites and the *Federal Register*. The OMB Bulletin calls for agencies to publish notices of *economically* significant guidance documents in the *Federal Register*; however, no such published notices for economically significant guidance could be found in the course of this study.[174] Nevertheless, even when not required to do so, many agencies do make a point to announce or publish other guidance documents in the *Federal Register*.

To illustrate how the volume of guidance appearing in the *Federal Register* can be estimated, even if only roughly, two searches were conducted in an electronic legal database. The first search was restricted to each *Federal Register* document's "action" field, which contains a brief label of the type of action being announced. For regulations, the typical action labels are "proposed rule" and "final rule;" however, when agencies publish guidance materials in the *Federal Register*,

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[170] Richard Wolf, *Supreme Court Appears Wary of Taking on Federal Agencies Over Regulations*, USA TODAY (Mar. 27, 2019) (quoting Justice Breyer).

[171] STAFF OF H. COMM. ON OVERSIGHT & GOV'T REFORM, 115TH CONG., SHINING LIGHT ON REGULATORY DARK MATTER (Comm. Print 2018), https://republicans-oversight.house.gov/wp-content/uploads/2018/03/Guidance-Report-for-Issuance1.pdf.

[172] *Id.*

[173] *Id.*

[174] A government official interviewed for this study suggested that at most one or two economically significant guidance documents have ever been issued; however, despite comprehensive searches, no indication of any guidance of such significance could be located in the *Federal Register*.

Table 2: *Federal Register* Entries on Guidance by Year, 2014-2018 (all agencies)

Year	*Action Field*	*Summary Field*
2014	150	1932
2015	136	1889
2016	148	2061
2017	84	1304
2018	81	1505
Total	599	8691

Table 3: *Federal Register* Entries on Guidance for Selected Agencies, 2014-2018

Agency	*Action Field*	*Summary Field*
HHS	37	1795
FDA	10	1271
DOT	93	582
EPA	8	516
DOD	8	454
USDA	8	321
IRS	3	225
Labor	13	150
HUD	8	112
CFPB	60	88
Education	4	81
SEC	37	66
NHTSA	4	34
FTC	8	18

they may use terms such as "guidance," "policy," "interpretation," or other variants. The second search applied these same guidance-related terms to the "summary" field, a paragraph or two that appears at the top of each *Federal Register* document and briefly describes the document. The results from these two searches, shown in Tables 2 and 3, probably provide a reasonable upper bound on the range of guidance documents published or announced in the *Federal Register* over the last five years.[175]

Getting similar aggregate estimates of guidance documents listed on agencies' websites is possible for many agencies.[176] For example, the Food and Drug Administration (FDA) has a well-

[175] These searches may include references, of course, to proposed guidance as well as final guidance. Still, it may be interesting to compare the estimates from the *Federal Register* with the more than 13,000 guidance documents reported to the House Committee as having been generated since 2008. The "action" field estimate from the *Federal Register* from 2008 through 2017 is 1,404, whereas the "summary" field estimate for the same period is 19,523.

[176] Approximately ten years ago, Connor Raso collected such data in an important study of guidance documents which he based on what agencies had posted online at that time. Connor N. Raso, *Strategic or Sincere? Analyzing Agency Use of Guidance Documents,* 119 YALE L. J. 782 (2010). Ironically, at that time, Raso found data to be unavailable for the Food and Drug Administration (FDA). *Id*. at 811 n. 140. Yet today, FDA has one of the more sophisticated online repositories of guidance. Another difference between FDA and other agencies' online repositories: FDA

organized and easily accessible list of guidance documents that can be readily used to compute an aggregate number of guidance documents by year. FDA's website shows 823 documents issued from 2014-2018, with 544 labeled as final guidance (as opposed to "draft"). By comparison, from Tables 2 and 3, FDA had published only ten *Federal Register* notices with guidance-related terms in the action field but 1,271 notices with such terms in the summary field. For FDA, the average of the estimates derived from *Federal Register* searches (641) is at least close to the average of the total and final guidance numbers from the FDA's website (684).

Of course, even when reasonable estimates of numerators can be obtained, comprehensiveness—that fraction of all guidance documents subject to disclosure that are actually disclosed—will be impossible to gauge without any reasonable estimate of a denominator.[177] As already noted, that denominator will be unknown to the public. The public does not know how many FDA documents that meet the agency's definition of guidance were created between 2014-2018 but never made it into either the *Federal Register* or the agency's online list. That is why internal controls of the kind recommended by the GAO in its audit are so crucial.[178] Presumably the public will be able to have greater confidence in the comprehensive-ness of FDA's online list precisely because of the kind of management structure that is needed to maintain such a list in the first place. Only with internal controls can agency managers ever hope to provide comprehensive guidance disclosure. The overarching aspiration should be for agencies to make available online all of the documents that fall within the relevant definition of guidance, and then to maintain an internal management system designed to achieve that high level of comprehensiveness in disclosure.

2. *Currency*

Currency—that is, keeping guidance websites and other dissemination efforts up to date—is closely related to comprehensiveness. If agencies fail to keep their websites updated, or if they fail to publish new or revised guidance in the *Federal Register*, the public misses the most up-to-date advice and interpretations from the agency. To be sure, keeping websites updated is an ongoing challenge for all organizations. Yet if agency guidance is to serve its purpose of helping to inform the public, agencies will need to make ongoing maintenance a priority and follow records

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purports to include all agency guidance documents on its webpage, while most other agencies only list significant guidance documents, in accord with the OMB Bulletin.

[177] Caution should be exercised whenever a numerator consists only of a subset of all guidance documents, such as "significant" ones. In such cases, the question will arise: Should the denominator comprise *all* guidance documents or just *significant* ones? Presumably the numerator and denominator should be kept in the same units: significant and significant, nonsignificant and nonsignificant. If a policy determination is made only to make significant guidance available online, then common units will be useful to determine how well the agency is doing in making available those materials that it intends to or should be posting online. Without care, though, such a measure could become tautological if significance is determined only by which documents are posted online. The meaningful question is whether the agency is being sufficiently comprehensive about identifying all the truly significant guidance documents for designation and online publication. Agencies might plausibly assess comprehensiveness in this sense by using relatively objective if imperfect proxies for significance (such as page counts) and asking what fraction of documents with the identified proxy (page length) have been designated as significant and posted online. In addition, surveys and comments from the public could also help agencies assess whether they are missing significant documents that should be uploaded. Given the difficulty with estimating denominators, agencies will best promote comprehensiveness by erring on the side of disclosure and, whenever in doubt, publishing documents online.

[178] U.S. Gov't Accountability Office, *supra* note 41. *See also infra* Part I.C.2.

Figure 1: FMSCA Regulatory Guidance Page Last Updated March 1, 2016

Source: https://www.fmcsa.dot.gov/advisory-committees/mcsac/fmcsa-regulatory-guidance

management procedures that will make it more automatic for guidance to be disseminated in a timely fashion.

The GAO reported that, in the course of its audit, it "found that DOL's Office of Labor Management Standards did not update its website in a timely manner to reflect guidance that would be affected by finalized regulation."[179] At the time of the present study (2019), the Federal Motor Carrier Safety Administration had a webpage devoted to regulatory guidance that declared that it was last updated on March 1, 2016 (Figure 1), even though the agency has clearly announced additional guidance in the *Federal Register* after this date.[180]

In addition to keeping websites and lists of guidance documents up-to-date, agencies also need to be mindful that individual documents that are outdated should be labeled as withdrawn or amended—or be removed altogether from the agency website and replaced with a more current version, if any.[181] Unfortunately, this does not always occur. For example, in September 2018, the Nuclear Regulatory Commission announced in the *Federal Register* that it was withdrawing a

[179] U.S. Gov't Accountability Office, *supra* note 41, at 38.

[180] For some subsequent FMSCA guidance, see: Commercial Driver's License Standards, Requirements and Penalties, 84 Fed. Reg. 8464 (Mar. 8, 2019), https://www.federalregister.gov/documents/2019/03/08/2019-04180/commercial-drivers-license-standards-requirements-and-penalties-regulatory-guidance; Hours of Service of Drivers of Commercial Motor Vehicles, 83 Fed. Reg. 26,377 (June 7,2018), https://www.federalregister.gov/documents/2018/06/07/2018-12256/hours-of-service-of-drivers-of-commercial-motor-vehicles-regulatory-guidance-concerning-the-use-of-a; Commercial Driver's License Standards, 82 Fed. Reg. 36,101 (Aug. 3, 2017), https://www.federalregister.gov/documents/2017/08/03/2017-16338/commercial-drivers-license-standards-regulatory-guidance-concerning-the-issuance-of-commercial. Interestingly, as of March 2019, the main Department of Transportation webpage on guidance contained a link that purported to point to the FMSCA's webpage on guidance—but it pointed to a different FMSCA webpage that contained no guidance whatsoever.

[181] Ideally, agencies would retain the older guidance too, for historical reference, but in any such instance they should label guidance documents clearly as either repealed or superseded.

1994 guidance on "protection against malevolent use of vehicles at nuclear power plants.''[182] According to the NRC, the old guidance document was "being withdrawn because it is outdated and has been superseded by other NRC guidance" and "[t]herefore, it no longer provides methods that the NRC staff finds acceptable."[183] Nevertheless, as of March 2019, the withdrawn security guidance remained posted on the NRC's website without any notation on the site indicating that it had been superseded nor any indication provided on the document that NRC no longer considered it acceptable.[184]

3. Accessibility

If members of the public cannot access guidance documents, they are not really available. For this reason, accessibility may be the most intuitive ingredient for the public availability of guidance. But access has multiple facets. Access *in principle*—that is, the mere existence of a guidance document somewhere on an agency website—is distinct from meaningful access *in reality*. Meaningful access becomes a reality when users can easily find their way to agencies' guidance pages; when search engines work effectively at finding relevant information; when lists of documents are indexed, tagged, and sortable; and when guidance material related to specific rules, issues, or programs can be found in the corresponding portions of agency websites where users are likely to need that information most.

One seemingly banal but still significant barrier to access must also be studiously combatted: the broken link. Just as the content on websites must remain current, so too must these sites' structures and links. Yet at present, users encounter too many broken links when searching for agency guidance. For example, the Department of Labor has established a central webpage for significant guidance, as called for by the OMB Bulletin on good guidance practices and which helpfully includes links to six sub-agencies' dedicated guidance pages. And yet, as shown in Figure 2, the links pointing to two of these sub-agencies are broken.

A similar malady currently afflicts the Department of Transportation's central guidance webpage: the links for five of the 10 listed operating administrations are broken (Federal Aviation Administration, Federal Transit Administration, Maritime Administration, National Highway Traffic Safety Administration, and Pipeline and Hazardous Materials Safety Administration). Another two operating administrations are listed but not hyperlinked (Federal Railroad Administration and Saint Lawrence Seaway Development Corporation). Still another two point to pages that contain no lists of or links to guidance documents (Federal Highway Administration and Federal Motor Carrier Safety Administration). In other words, other than the Office of the Secretary, none of the listed entries on the Department's main guidance page take the user to any guidance documents.[185]

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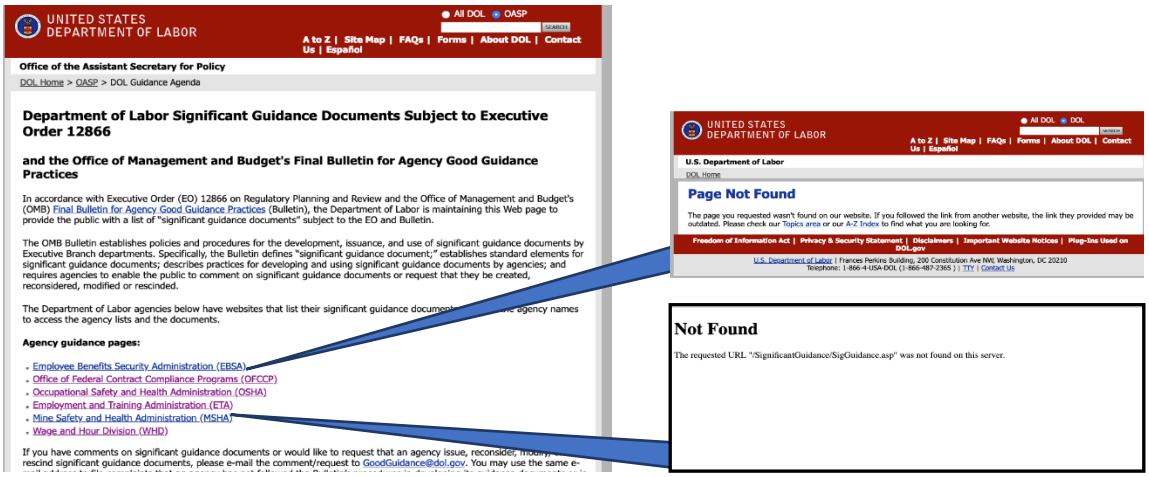
[182] Nuclear Regulatory Commission, Protection Against Malevolent Use of Vehicles at Nuclear Power Plants, 83 Fed. Reg. 47,648 (Sept. 20, 2018).
[183] *Id*.
[184] U.S. NUCLEAR REGULATORY COMM., REGULATORY GUIDE 5.68, PROTECTION AGAINST MALEVOLENT USE OF VEHICLES AT NUCLEAR POWER PLANTS (1994), https://www.nrc.gov/docs/ML0037/ML003739379.pdf.
[185] The GAO also reported encountering broken links at various agencies' websites. U.S. Gov't Accountability Office, *supra* note 41, at 33.

Figure 2: Broken Links as Barriers to Access



Even when links are not broken, websites may still prove hard to navigate and users may be unable to locate the dedicated guidance webpages called for in the OMB Bulletin. For example, GAO auditors reported, somewhat mysteriously, that, while they initially were able to find "HHS's page for significant guidance through a search of the agency's website," later they were "unable to locate HHS's significant guidance page."[186]

As a simple test of accessibility for the present study, two research assistants were asked to find a dedicated webpage for each of the 14 agencies listed in Part II.B.2.[187] The research assistants were given the objective of finding, for each of the 14 agencies, a single webpage listing all significant documents or a single webpage describing the guidance issued by the agency and where to find guidance (or some combination of the two). The results suggest that accessibility is not a major concern in terms of a user's ability to locate dedicated agency guidance webpages. Overall, the research assistants successfully met their assigned objective, finding dedicated guidance pages for 12 of the 14 agencies.[188] Most agencies were found to have a central repository for guidance that was accessible on agency websites within a click or two of their homepages and that could be found fairly quickly. Moreover, the two agencies for which each researcher was unable to find a dedicated webpage differed across the researchers, suggesting that the difficulties encountered may have been largely idiosyncratic rather than associated with deficiencies in any one agency's website design or execution.

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[186] *Id*. at 33 n. 39.

[187] One researcher was a lawyer; the other was a nonlawyer but college graduate.

[188] Although both research assistants found dedicated guidance webpages for 12 agencies, one of the webpages found by one of the research assistants only pertained to a subdivision within the agency. The other researcher (the lawyer) treated the SEC's two separate guidance pages—one for policy statements, the other for interpretive releases—as a dedicated guidance webpage, while the other researcher reported being unable to locate a dedicated guidance page for the SEC. That same research assistant also found she needed to leave the agency website and use Google to find the dedicated webpage for one agency (FTC).

One exception might be the Securities and Exchange Commission (SEC) website and how it labels and organizes guidance. Rather than a single page labeled simply "guidance," the SEC site divides guidance material across two separate webpages: one legalistically labeled "interpretive releases," the other labeled "policy statements." The nonlawyer research assistant involved in this study reported being unable to find a dedicated guidance website for the SEC. (It is telling that the other research assistant who did not experience difficulty had legal practice experience in administrative law.) Despite both assistants' overall success in finding guidance pages across almost all of the 14 agencies, the experience with the SEC's site reinforces a finding from the GAO: "[I]t was not always clear where to find guidance on a component website" because "guidance was sometimes dispersed across multiple pages within a website, which could make guidance hard to find and could contribute to user confusion."[189]

To make guidance access meaningful and real, agency officials should, at a minimum, strive to avoid user confusion. They can do so easily by one or more simple steps. At a minimum, they can maintain a central webpage devoted to guidance that, if necessary, simply links to additional pages where guidance may be found. Agencies can also take further steps on any pages devoted to guidance documents to tag each document or entry in a list of documents to allow users to search and sort by topics, dates, and other user-oriented categories—instead of forcing users simply to scroll down lengthy lists of documents arrayed in a fixed fashion. Agencies can also enhance access by linking to guidance on other parts of their websites, such as those pages devoted to specific rules or topics, as well as listing URLs in related entries in the *Federal Register* or Code of Federal Regulations. They can take affirmative steps to reach out to potentially interested members of the public too—using listservs and social media to promote access by bringing new or revised guidance documents to the attention of busy individuals who have many other demands on their attention.

4. Comprehensibility

Still, it is not sufficient for guidance documents merely to be accessible. Members of the public also should be able to understand what they find—and, with guidance documents, that means also knowing that they are non-binding. Yet some agency websites that contain lists of guidance documents do not even explain what "guidance" means. In addition, it is not always clear from individual guidance documents themselves that these documents are non-binding. Two examples illustrate both of these aspects of comprehensibility—at the level of webpages and individual documents.

Consider first the SEC's website. It does not have a central, dedicated webpage for all of its guidance documents; instead, as already noted it has a webpage that lists "interpretive releases" as well as a separate webpage for "policy statements" (Figure 3). But nowhere on either of these two webpages does the Commission explain what constitutes an "interpretive release" or a "policy statement," nor does it explain how these documents might differ from each other or differ from what appears on a still separate webpage for "final rules." The lack of comprehensibility created by the separation of lists of guidance documents onto two pages, and the use of legalistic labels

[189] U.S. Gov't Accountability Office, *supra* note 41.

Figure 3: Separate Webpages for SEC Guidance

rather than the plainer word "guidance," undoubtedly helps explain why, as noted in the preceding section, one of the researchers involved in this study reported being unable to locate a central webpage for guidance documents at the SEC, notwithstanding considerable search.[190]

At the level of the individual document, an effort the SEC undertook with five other financial regulatory agencies illustrates the importance of making clear the non-binding status of guidance documents. The six financial regulatory agencies sought to issue joint standards for diversity and the inclusion of minorities and women in hiring, procurement, and management practices at various financial firms. In October 2013, the six agencies published joint "proposed standards" in the *Federal Register* and solicited public comment.[191] Although the *Federal Register* document was titled a "proposed interagency policy statement," it otherwise did not say anything about the intended legal effect of the proposed standards. In addition, the instructions for submitting public comments looked identical to what a reader would expect for a legislative rule, as, perhaps not unreasonably, the agencies used the same email addresses and websites for comment submission on these proposed standards as they would use for comments on proposed binding regulations.[192]

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[190] Separately, another researcher assisting with this study in another way found himself looking for a central guidance repository at the SEC and reported finding only the overall Commission webpage for "interpretive releases" and another webpage for "guidance updates" from the Division of Investment Management. Although he had legal training and years of experience, he did not come across the SEC's general "policy statements" page.

[191] Proposed Interagency Policy Statement Establishing Standards for Assessing Joint Diversity Policies and Practices of Entities Regulated by the Agencies and Request for Comment, 78 Fed. Reg. 64,052 (Oct. 25, 2013).

[192] For example, comments could be emailed to rule-comments@sec.gov, "regcomments@ncua.gov," "regs.comments@federalreserve.gov," and "regs.comments@occ.treas.gov." *Id*. at 64,053. They could be submitted online at "www.regulations.gov," "www.ncua.gov/Legal/Regs/Pages/PropRegs.aspx," and "http://www.federalreserve.gov/apps/foia/proposedregs.aspx." *Id*.

It should come as no surprise that the agencies received public comments objecting to the imposition of "new legal requirements on regulated entities" related to diversity and inclusion.[193] Other comments urged the agencies to "clarify that the final Policy statement is a guidance document"[194] and to "frame the final Policy Statement as a 'best practices' guide with which regulated entities were not required to comply."[195] In response to these comments, the agencies inserted the following text as the second paragraph of their final policy statement:

> This document is a general statement of policy under the Administrative Procedure Act, 5 U.S.C. 553. It does not create new legal obligations. Use of the Standards by a regulated entity is voluntary. The Agencies will not use their examination or supervisory processes in connection with these Standards.[196]

The agencies concluded that "it [was] clear that [they] need[ed] to provide additional guidance about the intended legal effect of the final Policy Statement."[197]

Experience makes it clear that agencies can do more to make known the legal status of all of their guidance documents. Efforts to make the non-binding status comprehensible to the public can start by how agencies organize their website and the explanatory text they provide on these pages. They can also include attention to comprehensibility in individual guidance documents, by making sure to include notations to indicate that such documents are non-binding and are intended to provide assistance and clarity.

B. Best Practices in Guidance Availability

With common sense and a commitment to continuous improvement, agencies' guidance documents can be made more meaningfully available to the public. Agency officials need to make sure the materials they post online are comprehensive and current, and they need to use website design elements and clear terminology to make guidance documents accessible and comprehensible. The following five general "best practices" will help ensure that agencies can enhance the availability and helpfulness of their guidance documents.

1. Internal Management

This report has emphasized that improving the public availability of guidance documents is ultimately a management challenge. Modern technology offers tools that make it easier than ever before to manage records and make them downloadable over the Internet to interested individuals wherever they may be. But these technological tools are not self-executing. They depend on agency managers and employees tending to the steady flow of documents that make up the guidance production process, flagging documents for initial review and then tracking them and

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[193] Final Interagency Policy Statement Establishing Joint Standards for Assessing the Diversity Policies and Practices of Entities Regulated by the Agencies, 80 Fed. Reg. 33,016, 33,017 (June 10, 2015).
[194] *Id.*
[195] *Id.*
[196] *Id*. at 33,022.
[197] *Id.*

making sure they are posted online and included in appropriate social media or other communications campaigns.

To ensure sufficient attention to the maintenance of good guidance management, agencies should develop written procedures, such as those that the Department of Transportation and the FDA have adopted as described in Part II of this report. Given the extensive and elusive forms that agency guidance can take, the written procedures should include clear definitions of what the agency deems guidance to constitute as well as how management procedures and dissemination efforts vary, if at all, depending on different categories of guidance documents, as discussed in Part I.

The large number of potential guidance documents produced by major administrative agencies will necessitate a means of tracking these documents, both through the process of development as well as over time as they are revised or withdrawn. Some agencies (e.g., the Employment Training Administration in the Department of Labor) already use numbering systems to identify and keep track of guidance documents, but these efforts are far from uniform across agencies let alone even used at most agencies. Agencies should consider borrowing, or at least learning from, the model of the "Regulation Identifier Numbers" (RIN) that forms the backbone of the records management system for federal rulemaking. The Unified Agenda explains the valuable records management and public access functions performed by the RIN in the context of rulemaking:

> Every entry appearing in the Unified Agenda or Regulatory Plan is assigned a Regulation Identifier Number (RIN), in accordance with the requirements for the Unified Agenda set forth in section 4 of Executive Order 12866. RINs help the public to identify and follow the progress of each regulatory action or rulemaking proceeding in the Unified Agenda, the Federal Register, and on the Reginfo.gov website. Each regulatory action retains the same RIN throughout the entire rulemaking process.
>
> A RIN consists of a 4-digit agency code plus a 4-character alphanumeric code, assigned sequentially when a rulemaking is first entered into the database, which identifies the individual regulation under development. For example, all RINs for the Occupational Safety and Health Administration have agency code 1218. The RIN for OSHA's rulemaking on hazard communication is 1218-AC20.[198]

The purpose and value ascribed to RINs could apply as well to a similar identification system for guidance documents. Perhaps it could be based around GINs—guidance identification numbers. Each guidance document, or at least each significant guidance document, could receive such a number as soon as it begins the internal review process but it would remain with the document as a draft of it is released for public comment, then later as the final version is posted online or published in the *Federal Register* (or both), and still later if it is revised or withdrawn. Agencies might even assign GINs in advance, at the time a new rule is finalized, so that any future guidance related to that rule (or RIN) could be linked with that rule (or RIN). Such a guidance identification system

[198] *How to Use the Unified* Agenda, OFFICE OF INFO. & REGULATORY AFFAIRS, https://www.reginfo.gov/public/jsp/eAgenda/StaticContent/UA_HowTo.myjsp (last visited May 13, 2019).

would not only assist agencies in their own internal records management but also would provide a useful feature to assist members of the public in their search for documents. Agencies could use the GIN to link to other relevant documents or to include cross-references more regularly in parts of the Code of Federal Regulation, much as some agencies currently do with descriptive statements discussed in Part II of this report.[199]

Further analysis of any guidance identification numbering system would be needed. One question to ask would be whether to pursue a government-wide system, such as might be implied by the parallel with the RIN system and the Unified Agenda. But even absent any government-wide system, individual agencies would do well to consider creating their own similar internal systems for tracking and managing the flow of guidance materials. They should consider ways that they can more systematically connect guidance with the rules they interpret or explain—such as by expanding notations about the availability (or likely availability) of guidance in preambles in the *Federal Register* or in relevant sections of CFR so as to notify interested individuals of the availability of guidance, which could then be searched for using the assigned identification number.

All agency employees involved in the development of or use of guidance—or who might possibly do so—should receive training in the agency's internal guidance procedures and control systems. Especially since the non-binding nature of guidance inherently limits the self-enforcing incentives that surround publication requirements for legislative rules, agency employees need to know how to create guidance documents and what procedures to follow. Leadership priority and management vigilance will be important. Agencies will need to monitor their internal controls to assess how well their procedures are being implemented and what opportunities would exist for continuous improvement.

At least some of these internal management practices have been adopted already by at least some agencies. At FDA, "most of the Centers/Offices … begin tracking guidance immediately after the decision is made to develop it. The Centers/Offices employ a number of different tracking methods, such as cover sheets and internal databases that use e-rooms, commercial software, and/or web-platforms."[200] In addition, "FDA officials [have] established internal policies and practices to ensure appropriate adherence to their good guidance practices, including a written process to document decisions about the appropriate level of review for each guidance document."[201] FDA officials "use tools, such as 'guidance initiation forms' or 'concept papers' to, among other things, ensure they avoid duplicative or overlapping guidance and to prioritize proposed guidance."[202] According a 2011 report prepared by FDA, the agency at that time used a

> tracking system for all documents that are published in the *Federal Register*, including [Notices of Availability, or NOA], which accompany all Level 1 guidances and may accompany certain Level 2 guidances, such as Small Entity Compliance Guides. The tracking

[199] *See supra* notes 131-32 and accompanying text.
[200] U.S. FOOD & DRUG ADMIN, FOOD AND DRUG ADMINISTRATION REPORT ON GOOD GUIDANCE PRACTICES (2011), https://www.fda.gov/downloads/AboutFDA/Transparency/TransparencyInitiative/UCM285124.pdf, at 8-9.
[201] U.S. Gov't Accountability Office, *supra* note 41, at 11.
[202] *Id.*

> system is web-based, and FDA staff in all affected Centers/Offices can sign into the system to check on a document's progress. Centers are asked to create a record in the system as soon as they determine that a Level 1 guidance and accompanying NOA will be developed. In practice, however, records often are not created until later in the process.[203]

Although FDA has noted that it has been in "the process of updating and enhancing this tracking system,"[204] the general structure provides a model of the managerial system needed to pursue the four criteria of guidance availability discussed earlier in this Part of the present report.

The GAO has reported that other agencies have found value from giving priority to the management of guidance documents. For example, GAO noted the Department of Labor's Office of Federal Contract Compliance Programs' deliberate "efforts to ensure the relevancy and currency of its directives system resulted in the removal of 85 percent of their documents" because they were determined to be out of date or no longer needed.[205] Other agencies will find advantages to deliberate efforts to establish internal control to monitor the development and dissemination of guidance documents.

2. *Online Access*

The main vehicle for guidance availability is the agency website. Although a full consideration of website design is beyond the scope of this report, during the research conducted for this report two rather simple design features used by some agencies were identified as being helpful for facilitating online access to guidance documents. First, in describing webpages that list guidance documents, some agencies use simple words, such as "guidance," rather than legalistic terms such as "interpretative rules" or "policy statements," which are less comprehensible to many users (including lawyers). Second, a number of agencies include a designated tab or an option for "guidance" on a pull-down menu from the home page to lead the user to a centralized guidance webpage. More agencies should follow these two best practices.

Beyond these two smaller recommendations, three larger choices confront agencies when designing online access to guidance documents. First, agencies have a choice about placement of guidance materials: on a single page or on more than one. Some agencies have opted to divide their guidance documents across more than one page. For example, EPA has created five separate pages for its lists of guidance documents, one for each topic area (air, water, chemical safety and pollution prevention, land and emergency management, and science). The SEC, as noted in the preceding section, has divided its guidance documents across two pages, one for "interpretative releases" and the other for "policy statements." In principle, there is nothing problematic with multiple pages, especially when the distinctions fall clearly into topics or other categories that will align with users' expectations and needs. For example, it makes sense for agencies such as large departments—say, the Department of Health and Human Services—to have separate dedicated pages for and associated with its sub-agencies—such as the Food and Drug Administration. But

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[203] U.S. FOOD & DRUG ADMIN, FOOD AND DRUG ADMINISTRATION REPORT ON GOOD GUIDANCE PRACTICES (2011), https://www.fda.gov/downloads/AboutFDA/Transparency/TransparencyInitiative/UCM285124.pdf.
[204] *Id*.
[205] U.S. Gov't Accountability Office, *supra* note 41, at 38.

agencies that go the route of different pages for different topics or sub-agencies or offices within the agency would still be well advised to follow EPA's lead and create a single top-level page that includes an index and links to each of the separate pages.[206] The SEC could easily reduce any confusion encountered with its splitting of different documents across two pages simply by creating a single page for "guidance" that includes on it links to the separate pages for "interpretative releases" and "policy statements." This is what EPA does now; it provides a single page that serves as a bridge to the five topical pages.

Second, the choice between a single page versus multiple pages may for some agencies be affected by another choice, namely, between (a) displaying guidance document lists as HTML tables within a webpage or (b) relying on a back-end data or content management software that interfaces with the front-end of the webpage that the user experiences. The EPA has opted for the former, as illustrated in Figure 4, and it is a workable option for most agencies without many guidance documents that they seek to make available online. The FDA, however, has opted for the latter (Figure 5). Under the approach adopted by the FDA, the user selects search criteria on a dedicated guidance webpage via a user interface and then the data management software uses those criteria to pull documents from a back-end database (not visible or otherwise normally accessible to the user) and displays the search results on the webpage (Figure 6). The use of a back-end data management software is an excellent choice for an agency that wants to make a larger number of guidance documents available to the public. It also can facilitate better, more fine-grained searches by the user; a site such as EPA is largely searchable only by the search bar on the user's browser. (A back-end database offers another plus in that it can be able to be integrated into the agency's internal guidance tracking system, discussed above in Part III.B.1.)

Figure 4: EPA Webpage Design

Water

Name (ID Number)	Comment	Learn More	Issuance Date	Date Added to This List	Most Recent Revision
2002 Integrated Water Quality Monitoring and Assessment Report Guidance - Robert H. Wayland III (EPA-HQ-OW-2007-0787-0001)	Comment	Learn More	11/19/2001	08/23/2007	n/a
2003 Water Quality Trading Policy	Comment	Learn More	2003	08/23/2007	n/a
Agency Interpretation of Applicability of Section 402 of the Clean Water Act to Water Transfers (EPA-HQ-OW-2007-0805-0001)	Comment	Learn More	08/05/2005	08/23/2007	n/a

[206] Doing so also accords with the OMB Bulletin's call for a centralized online location for an agency's significant guidance. OFFICE OF MGMT. & BUDGET, *supra* note 12.

Figure 5: FDA Search Interface

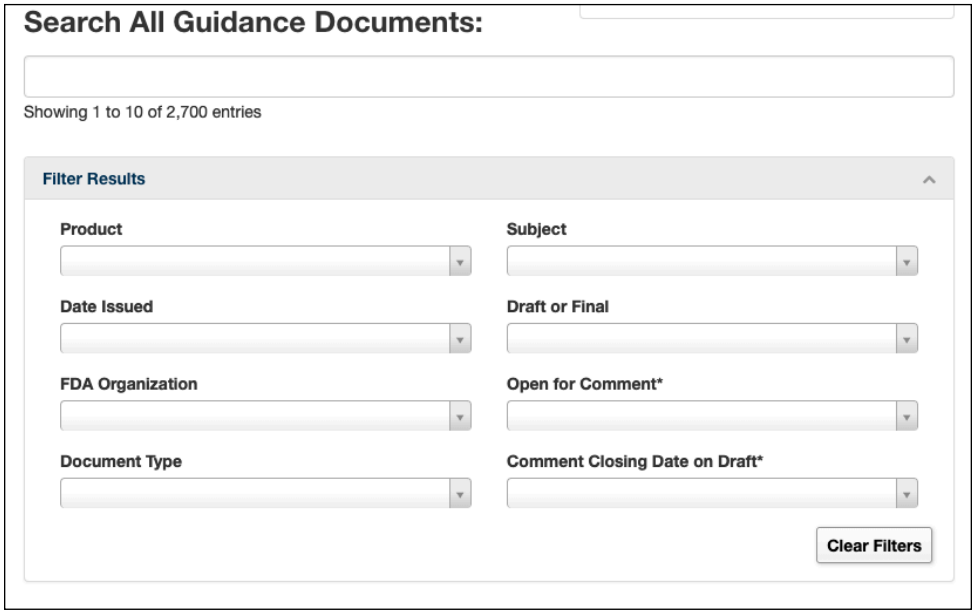
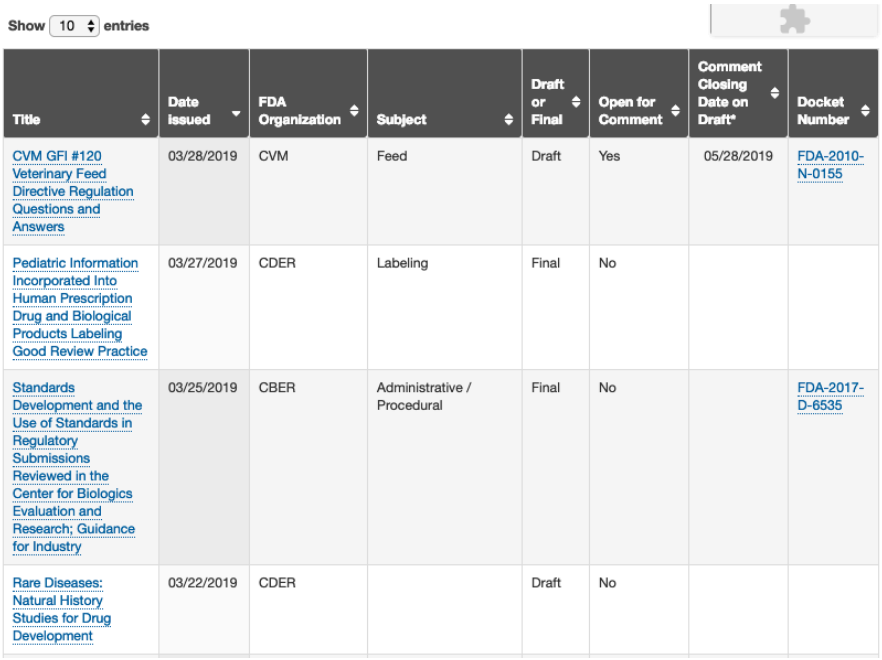


Figure 6: FDA Display of Search Results



Show 10 entries

Title	Date issued	FDA Organization	Subject	Draft or Final	Open for Comment	Comment Closing Date on Draft*	Docket Number
CVM GFI #120 Veterinary Feed Directive Regulation Questions and Answers	03/28/2019	CVM	Feed	Draft	Yes	05/28/2019	FDA-2010-N-0155
Pediatric Information Incorporated Into Human Prescription Drug and Biological Products Labeling Good Review Practice	03/27/2019	CDER	Labeling	Final	No		
Standards Development and the Use of Standards in Regulatory Submissions Reviewed in the Center for Biologics Evaluation and Research; Guidance for Industry	03/25/2019	CBER	Administrative / Procedural	Final	No		FDA-2017-D-6535
Rare Diseases: Natural History Studies for Drug Development	03/22/2019	CDER		Draft	No		

Finally, agencies face a third choice about what metadata (or data fields) to associate with each guidance document and to include in either tabular form on a website or a back-end database. The EPA webpage table includes six fields, one for each column, while the FDA system has at least eight, one for each of the search filtering options. A back-end database can accommodate any number of fields that would be helpful to associate with a document, while a table is limited by

Figure 7: SEC Small Business Compliance Guide Webpage

Source: https://www.sec.gov/info/smallbus/secg.shtml

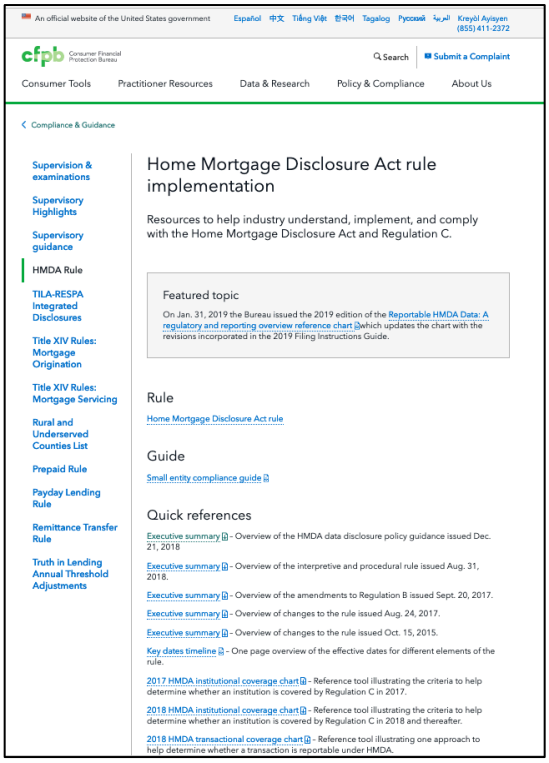
the space available on a webpage. Agencies will need to choose the fields, but some obvious options are displayed in the two figures above (Figures 4 and 5), such as date, description, identifying or tracking number, current status, and any revisions.

Outside of those three main design choices, two other best-practice points bear noting when it comes to online access. First, in light of the repeated expressions of concerns about access to small entity compliance guides, as discussed in Part I, agencies should consider either incorporating these into their general guidance webpages or creating special dedicated webpages that contain all of these guides for each agency's rules, as the SEC has done (Figure 7). Of course, if an agency has a separate page dedicated to these small entity guides, it would be helpful for the agency to a link to this page on its main, centralized guidance webpage.

Second, notwithstanding the virtues of a centralized repository or dedicated guidance webpage, agencies should keep in mind the virtues of including links elsewhere on their websites to guidance documents that relate to the topics or rules addressed at those other pages. For example, Figure 8 shows a dedicated CFPB webpage for its Home Mortgage Disclosure Act Rule, which contains both the rule as well as the relevant small business compliance guide (as well as additional materials not displayed). Agencies should bear in mind that they have multiple users who will look for their guidance documents in different ways.[207] Many will undoubtedly use search engines. But some users will be seeking a general understanding of the landscape of the agency's overall rules, programs, and practices and will seek the information and reassurance that can only be provided by a centralized page that either itself contains a comprehensive list or searchable database of agency guidance or, at a minimum, provides links pointing to the locations where distributed lists

[207] *Cf.* Cary Coglianese, *Enhancing Public Access to Online Rulemaking Information*, 2 MICH. J. ENVTL. & ADMIN. L. 1, 39 (2012) (noting that "agencies confront the particular challenge that their websites serve multiple audiences").

Figure 8: CFPB Topical Webpage



https://www.consumerfinance.gov/policy-compliance/guidance/hmda-implementation/

can be found on the agency's website. Still other users will already know the landscape sufficiently well to know what particular program or webpage to go to for information, which means that these specific topical or institutional webpages will benefit from information about any relevant guidance documents. In terms of best practices, then, no one size is likely to fit all agencies—or all users—which counsels in favor of multiple points of access to an agency's guidance documents which can be facilitated by appropriate use of links.

3. *Labeling and Explanations*

The Administrative Conference of the United States (ACUS) has previously identified several best practices for promoting the comprehensibility of agency guidance documents. For example, ACUS Recommendation 2017-5 makes clear that:

> A policy statement should prominently state that it is not binding on members of the public and explain that a member of the public may take a lawful approach different from the one set forth in the policy statement or request that the agency take such a lawful approach. The policy statement should also include the identity and contact information of officials to whom such a request should be made.[208]

[208] Admin. Conf. of the U.S., Recommendation 2017-5, *supra* note 1.

Best practices would call for agencies to heed this ACUS recommendation for all of their guidance documents. The OMB Bulletin on guidance states that significant guidance documents "should aim to communicate effectively to the public about the legal effect of the guidance" and "should not include mandatory language such as 'shall,' 'must,' 'required,' or 'requirement.'"[209]

The Department of Justice has adopted a similar policy: "Guidance documents should identify themselves as guidance, disclaim any force or effect of law, and avoid language suggesting that the public has obligations that go beyond those set forth in the applicable statutes or legislative rules."[210] The Justice Department policy further states that, "[t]o the extent guidance documents set out voluntary standards (e.g., recommended practices), they should clearly state that compliance with those standards is voluntary and that noncompliance will not, in itself, result in any enforcement action."[211]

In addition, ACUS Recommendation 2017-3[212] accentuates requirements in the Plain Writing Act of 2010[213] and in Executive Order 13563[214] by urging agencies to use plain language when drafting guidance documents. Specifically, ACUS recommends:

- "When drafting guidance documents, agencies should tailor the guidance to the informational needs and level of expertise of the intended audiences. Audiences that are particularly likely to benefit from tailored guidance include: regulated small business; regulatory beneficiaries, e.g., benefit recipients, consumers, and protected classes; and private compliance offices, e.g., human resources departments. For audiences that may find complex technical and legal details inaccessible, plain language summaries, Q&As, or related formats may be especially helpful."[215]

- "When drafting guidance documents, agencies should strive to balance brevity, usefulness, and completeness. One way to help strike this balance is for guidance documents to include citations, hyperlinks, or other references or points of contact enabling readers to easily locate underlying regulatory or statutory requirements."[216]

Agency officials should strive to apply these recommended drafting practices not merely when developing guidance documents themselves, but also when designing their dedicated webpages as called for by the OMB Bulletin. All such webpages should include informative descriptions, sometimes known as explainers, that define guidance, explain its legal effect, and give examples of different types of guidance. The Department of Transportation's guidance page links to a page that

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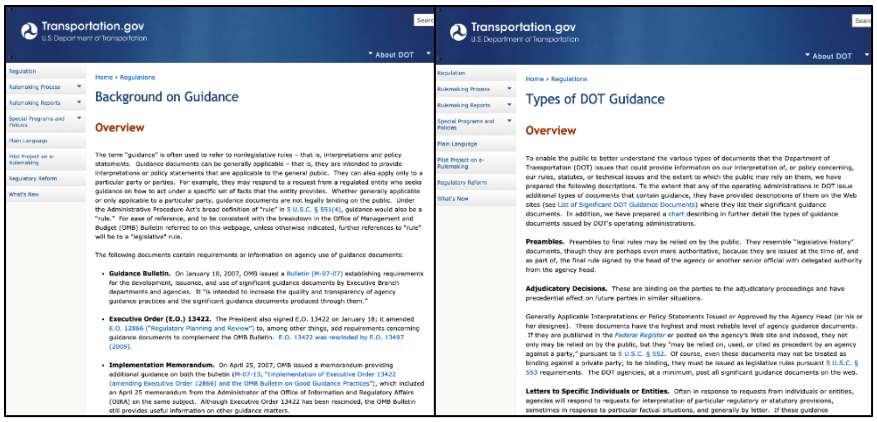
[209] OFFICE OF MGMT. & BUDGET, *supra* note 12.
[210] Memorandum of Jeff Sessions, Att'y Gen., U.S. Dep't of Justice, Nov. 16, 2017, https://www.justice.gov/opa/press-release/file/1012271/download, p. 2.
[211] *Id*.
[212] Admin. Conf. of the U.S., Recommendation 2017-3, *Plain Language in Regulatory Drafting*, 82 Fed. Reg. 61728, 61728 (Dec. 29, 2017).
[213] Pub. L. No. 111-274, 124 Stat. 2861.
[214] Exec. Order No. 13,563 (2011).
[215] Admin. Conf. of the U.S., Recommendation 2017-3, *supra* note 212, at 61730.
[216] *Id*.

Figure 9: Department of Transportation Guidance Explainer Pages



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Background on Guidance

Overview

The term "guidance" is often used to refer to nonlegislative rules – that is, interpretations and policy statements. Guidance documents can be generally applicable – that is, they are intended to provide interpretations or policy statements that are applicable to the general public. They can also apply only to a particular party or parties. For example, they may respond to a request from a regulated entity who seeks guidance on how to act under a specific set of facts that the entity provides. Whether generally applicable or only applicable to a particular party, guidance documents are not legally binding on the public. Under the Administrative Procedure Act's broad definition of "rule" in 5 U.S.C. § 551(4), guidance would also be a "rule." For ease of reference, and to be consistent with the breakdown in the Office of Management and Budget (OMB) Bulletin referred to on this webpage, unless otherwise indicated, further references to "rule" will be to a "legislative" rule.

The following documents contain requirements or information on agency use of guidance documents:

- **Guidance Bulletin.** On January 18, 2007, OMB issued a Bulletin (M-07-07) establishing requirements for the development, issuance, and use of significant guidance documents by Executive Branch departments and agencies. It "is intended to increase the quality and transparency of agency guidance practices and the significant guidance documents produced through them."
- **Executive Order (E.O.) 13422.** The President also signed E.O. 13422 on January 18; it amended E.O. 12866 ("Regulatory Planning and Review") to, among other things, add requirements concerning guidance documents to complement the OMB Bulletin. E.O. 13422 was rescinded by E.O. 13497 (2009).
- **Implementation Memorandum.** On April 25, 2007, OMB issued a memorandum providing additional guidance on both the bulletin (M-07-13, "Implementation of Executive Order 13422 (amending Executive Order 12866) and the OMB Bulletin on Good Guidance Practices"), which included an April 25 memorandum from the Administrator of the Office of Information and Regulatory Affairs (OIRA) on the same subject. Although Executive Order 13422 has been rescinded, the OMB Bulletin still provides useful information on other guidance matters.

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Types of DOT Guidance

Overview

To enable the public to better understand the various types of documents that the Department of Transportation (DOT) issues that could provide information on our interpretation of, or policy concerning, our rules, statutes, or technical issues and the extent to which the public may rely on them, we have prepared the following descriptions. To the extent that any of the operating administrations in DOT issue additional types of documents that contain guidance, they have provided descriptions of them on the Web sites (see List of Significant DOT Guidance Documents) where they list their significant guidance documents. In addition, we have prepared a chart describing in further detail the types of guidance documents issued by DOT's operating administrations.

Preambles. Preambles to final rules may be relied on by the public. They resemble "legislative history" documents, though they are perhaps even more authoritative, because they are issued at the time of, and as part of, the final rule signed by the head of the agency or another senior official with delegated authority from the agency head.

Adjudicatory Decisions. These are binding on the parties to the adjudicatory proceedings and have precedential effect on future parties in similar situations.

Generally Applicable Interpretations or Policy Statements Issued or Approved by the Agency Head (or his or her designee). These documents have the highest and most reliable level of agency guidance documents. If they are published in the *Federal Register* or posted on the agency's Web site and indexed, they not only may be relied on by the public, but they "may be relied on, used, or cited as precedent by an agency against a party," pursuant to 5 U.S.C. § 552. Of course, even these documents may not be treated as binding against a private party; to be binding, they must be issued as legislative rules pursuant 5 U.S.C. § 553 requirements. The DOT agencies, at a minimum, post all significant guidance documents on the web.

Letters to Specific Individuals or Entities. Often in response to requests from individuals or entities, agencies will respond to requests for interpretation of particular regulatory or statutory provisions, sometimes in response to particular factual situations, and generally by letter. If these guidance

Sources: https://www.transportation.gov/regulations/background-guidance
https://www.transportation.gov/regulations/types-dot-guidance

provides a "Background on Guidance," shown in Figure 9, that offers an excellent model for other agencies to follow in this regard. As with the Department of Transportation, the Internal Revenue Service provides a "primer" on common kinds of guidance documents issued by the agency.[217]

4. *Affirmative Outreach*

Although an easy-to-navigate website, especially one with a centralized searchable online repository, will make it more likely that members of the public who go in search of an agency guidance document will be able find it, not everyone one will go searching for guidance documents, even ones that would be relevant to them. In fact, many members of the public who could benefit and learn from an agency guidance document will not go looking for it because they simply do not know that it exists. For this reason, agencies should undertake affirmative steps to alert interested members of the public to new and revised guidance.

A number of agencies already engage in guidance outreach. According to the GAO, the Employee Benefits Security Administration within the Labor Department maintains a listserv with more than 335,000 subscribers and uses it to disseminate alerts about new guidance.[218] Similarly, the Department of Education's Office for Civil Rights keeps "readily available e-mail lists for the purpose of sending guidance to all public school superintendents or college presidents."[219]

Officials sometimes tried other strategies too. To reach members of the public "during disaster recovery efforts or to reach those who did not have access to the Internet," agency officials still sometimes use printed pamphlets or other hard-copy documents.[220] GAO reported that

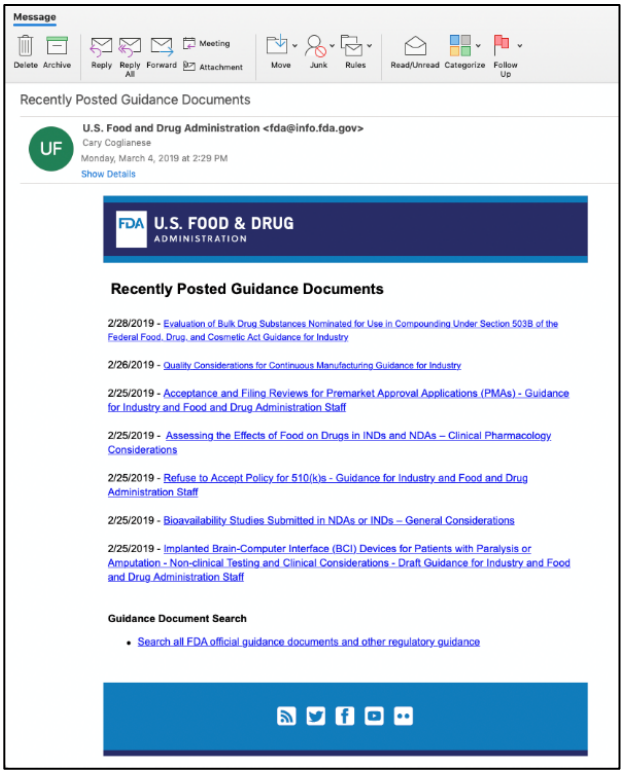
[217] *Understanding IRS Guidance*, U.S. INTERNAL REVENUE SERV., https://www.irs.gov/newsroom/understanding-irs-guidance-a-brief-primer (last visited May 13, 2019).
[218] U.S. Gov't Accountability Office, *supra* note 41, at 32.
[219] *Id*. at 33.
[220] *Id*.

"[c]omponents also reached wider audiences by engaging with the public directly through conferences, webinars, media outreach, or public awareness campaigns."[221]

At OSHA, officials reported that they "use social media to communicate with hard-to-reach populations, such as non-English speakers and temporary/contract workers who were more likely to be working in dangerous jobs."[222] At the FDA, "all the Centers/Offices conduct outreach on significant guidance, which may include, among other things, press releases, workshops, and social media."[223] As Figure 10 shows, members of the public can sign up for an FDA listserv to receive regular email announcements about newly posted guidance documents.

ACUS Recommendation 2013-5 already encourages agencies to consider using "social media to inform and educate the public about paperwork requirements associated with a rule or the availability of regulatory guidance."[224] Agencies should consider including in their guidance management strategies the use of a range of possible affirmative efforts to inform relevant portions of the public, including the regulated community, of new or revised agency guidance.

Figure 10: FDA Email Listing "Recently Posted Guidance Documents"



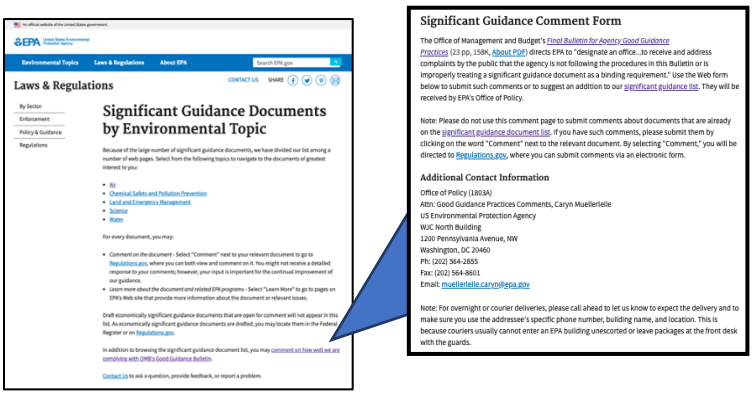
[221] *Id.*
[222] *Id.*
[223] U.S. FOOD & DRUG ADMIN, FOOD AND DRUG ADMINISTRATION REPORT ON GOOD GUIDANCE PRACTICES (2011), https://www.fda.gov/downloads/AboutFDA/Transparency/TransparencyInitiative/UCM285124.pdf.
[224] Admin. Conf. of the U.S., Recommendation 2013-5, Social Media in Rulemaking, 78 Fed. Reg. 76269, 76269 (Dec. 17, 2013).

5. *Review and Feedback*

At the same time that agencies use listservs, social media, and other strategies to reach out affirmatively to the public, they should also find ways to encourage the public to provide feedback to agency officials about their guidance-availability efforts and tools.[225] Listening to feedback from interested members of the public can help inform agency officials on the big picture of how well their guidance management and dissemination strategies are working, as well as provide information about smaller but still critical details concerning website design, broken links, missing documents, and other operational issues.

It is already considered best practice for agencies to include a clear means for users to submit substantive questions and comments about the agencies' significant guidance documents themselves.[226] But agencies should also invite feedback on their *management* and *availability* of guidance documents. The OMB Bulletin instructs agencies to include contact information to receive complaints about the handling of guidance documents and adherence to the OMB Bulletin.[227] Some agencies have acted accordingly. EPA's significant guidance webpages, for example, include links to a comment form page that gives users an easy means of submitting a comment to the agency about their guidance management (Figure 11). EPA specifically invites users to avail themselves of this opportunity to provide feedback: "You may use our significant guidance comment page to tell us how well we're complying with OMB's Good Guidance Bulletin. You may also use this form to tell us if you think a document is missing from the significant guidance list."[228] As noted earlier, inviting feedback in this way can help agencies ensure that they are maintaining a comprehensive and current list of guidance.

Figure 11: EPA Significant Guidance Comment Form



Sources: https://www.epa.gov/laws-regulations/significant-guidance-documents-environmental-topic; https://www.epa.gov/laws-regulations/forms/significant-guidance-comment-form

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[225] On the value of listening and "constantly learning" from public feedback, see Cary Coglianese, Listening, Learning, and Leading: A Framework for Regulatory Excellence 79 (2015), https://www.law.upenn.edu/live/files/4946-pprfinalconvenersreport.pdf.

[226] OFFICE OF MGMT. & BUDGET, *supra* note 12.

[227] *Id.*

[228] *Significant Guidance Documents*, U.S. ENVTL. PROT. AGENCY, https://www.epa.gov/laws-regulations/significant-guidance-documents. EPA—and other agencies—could expand their invitations of feedback still more broadly, such as by affirmatively soliciting users to report withdrawn or revised guidance documents that remain on the agency website without any appropriate designation.

In addition to soliciting feedback via online comment forms, agencies should develop and monitor more systematic metrics for evaluating guidance availability. Federal digital policy advises that each agency "should measure how well [its website] service is working for [its] users."[229] Metrics should help agency officials assess the performance of their guidance document management system, using criteria such as comprehensiveness, currency, accessibility, and comprehensibility. In the end, the key is to develop a measurement strategy that enables agency officials to learn what is working well and what opportunities exist for continuous improvement.[230]

IV. Recommendations for Enhancing Guidance Availability

This report has aimed to provide agencies with recommendations for best practices in guidance availability. The best practices described here are ultimately motivated by four key "open guidance" principles: *comprehensiveness*, or the degree to which all guidance documents that are supposed to be disclosed are in fact made available online; *currency*, or the timely online posting of new or updated guidance materials (and the timely updating of any labels or notations when documents have been withdrawn or superseded); *accessibility*, or the ease with which users can actually find guidance documents on agency websites; and *comprehensibility*, or the extent to which users can understand what they find on agency websites, including the legal status of guidance documents. These four principles will be important for lawyers and managers to keep in mind as they seek to enhance the availability of their agencies' guidance documents.

In addition to the four principles of open guidance, this report has offered agencies a series of best practices that can be implemented to put these principles into action. All of the best practices identified in this report have been implemented by at least one other agency already, so they are all practical and feasible actions that presumably any agency with the necessary vision, commitment, and resources could adopt. Of course, the precise steps that any agency should take to implement the best practices along the lines presented here—and even which ones to adopt or to adopt first—will necessarily depend on a variety of factors related to that agency. These factors will include what that agency is already doing to make its guidance documents available, the volume and kinds of documents it produces, the needs of the public for open guidance and current gaps in filling those needs, and a variety of other relevant institutional considerations, such as the agency's organizational capacity and resources.

The recommendations for future action that follow here are offered in full recognition that agencies, their guidance documents, and the audiences for these documents vary considerably across the federal government. Still, it is possible to generalize and conclude this report by recommending the following concrete next steps that every agency would do well to take to improve the availability of their guidance, if they have not already done so. These next steps, which can obviously be approached flexibly and adapted as appropriate by different agencies, fall into the five best-practice areas discussed in Part V of this report.

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[229] DIGITAL SERVICES PLAYBOOK, *supra* note 150, https://playbook.cio.gov/#play12. *See also* DIGITAL GOVERNMENT, *supra* note 149, at 22.

[230] Cary Coglianese, *Measuring Regulatory Excellence*, in ACHIEVING REGULATORY EXCELLENCE 291, 303 (Cary Coglianese, ed. 2017).

1. *Internal Management*. The first step for any agency should be to develop its own written procedures for how it will track, develop, and manage its guidance documents. Given the range of possible understandings and definitions of guidance, as discussed in Part I of this report, an agency's written procedures should begin by defining guidance in some fashion. This could take the form of adopting or modifying the definition contained in the OMB Bulletin, or establishing another definition.[231] It will likely prove helpful for the agency also to make clear what types of documents it does consider to constitute guidance—e.g., oral statements or press releases—and to describe any categories of different types of guidance—e.g., significant or Level 1 guidance. It will also prove helpful if the agency's procedures can include specific examples of documents either considered or not considered to fall within different categories.

In addition to defining guidance, the agency's written procedures should address the agency's standards and procedures for the development of guidance documents. The procedures should address the steps for internal review, opportunity for public comment (if any), periodic review of existing documents, and, most relevant, the publication and dissemination of draft or final guidance documents. The agency should indicate the extent to which any of the steps created or identified in its procedures should vary depending on whether a guidance document falls into a specific category, such as the different handling and publication practices for significant versus non-significant guidance.

An agency's written procedures will only prove helpful, of course, if they are actually followed. Toward this end, all relevant agency staff should receive training in the agency's guidance procedures. In addition, the agency should develop and apply appropriate internal controls to ensure that guidance procedures are adhered to in practice. When implementing the agency's open guidance procedures, and doubts arise as to whether a particular document is required to be disclosed under the procedures, the agency should consider erring on the side of disclosure.

An agency's internal management of its guidance documents will necessarily include a process for internal review and tracking of guidance documents. After all, it will be impossible for an agency's managers to ensure that all the guidance documents that are supposed to be disclosed under the agency's procedures are in fact disclosed properly if they do not know that such documents exist. To facilitate internal tracking of guidance documents, an agency should consider establishing a process for assigning unique identification numbers to guidance documents covered by their written guidance procedures. Once a guidance identification number has been assigned to a guidance document, it should then appear on that document and be used to refer to the document whenever it is listed or referenced on the agency's Web site, in public announcements, or in the *Federal Register* or the Code of Federal Regulation. Not only will identifying numbers help agency staff and managers keep track of guidance documents but, once such documents are disclosed, they can help members of the public more easily identify the guidance documents they need.

Any serious internal system for tracking and managing agency will generate in some form a comprehensive list or database of an agency's guidance documents. At a minimum, the list or database should include all guidance documents required to be published in the *Federal Register*,

[231] OFFICE OF MGMT. & BUDGET, *supra* note 12.

as outlined in Part II of this report, and all other guidance documents required by the agency's written procedures and any other applicable standards to be made publicly available. For some agencies, such a list or database might well comprise an amalgamation of several separate lists or databases that are best maintained by specific offices or sub-agencies within the larger agency. However or wherever guidance document lists or databases are maintained, agencies should strive to keep these lists or databases up to date. Entries in such a list or database should include relevant information for each guidance document, such as a brief description (including, if applicable, any corresponding regulatory or statutory provision that the guidance relates to or interprets), the date of issue, any assigned identifying number, and any status in terms of withdrawal or revision.

2. *Online access*. Each agency should maintain a central webpage dedicated to guidance documents, even if that central page merely contains links that direct users to separate guidance-related pages, such as those organized by topic, type of guidance document, or agency office or sub-division. The agency should make available to the public on its central guidance webpage the following materials:

- The current version of the agency's written guidance procedures.
- The agency's latest list or database of guidance documents, or links to the locations where such lists might be found on other pages on the agency's website.
- Either links to downloadable copies of all of the guidance documents contained on the agency's latest guidance list or database, or links to other agency webpages containing downloadable copies of such documents.
- Links to downloadable copies of any Small Entity Compliance guides or to other agency webpages containing downloadable copies of such guides.

An agency's website should be designed to ensure that access to guidance documents is as easy and helpful to the end user as possible. In particular, agencies should ensure that a linked tab, word, or entry in a pull-down menu from the home page of the agency's overall website leads users to the agency's central guidance webpage. The search engine on the agency's website should work effectively to allow users to find relevant guidance information. Websites need to be kept up to date, with any broken links fixed and any withdrawn or revised documents clearly labeled as such.

In recognition of the fact that members of the public, including representatives from regulated businesses, either may not always know to look for agency guidance documents or may look for them in different ways, agencies should consider including notations and links to guidance documents at appropriate places their websites other than on pages dedicated to guidance documents. In particular, each agency should strive to ensure that clearly labeled links to all guidance documents related to specific rules, issues, or programs are easily found in the corresponding sections of the agency's website where users are likely to find that information especially helpful.

3. *Labeling and Explanations*. Merely making guidance materials available online is not sufficient. Not only must guidance webpages be easy to find but they should be designed to ensure that they are as helpful to the end user as possible. In particular, agencies should be sure to use plain language and simple words, such as "guidance," when describing webpages that discuss or list guidance documents. Plain language explanations—explainers—that define guidance, explain

its legal effect, and give examples of different types of guidance should be included on agencies' guidance webpages.

When displayed on webpages, guidance documents should be appropriately indexed and tagged, or made available in sortable tables. Search results of any guidance databases should display clearly and include relevant fields of information. To help members of the public know the status of any guidance document they may come across, agencies should include notations indicating whether guidance documents have been revised or withdrawn. Maintaining a historical archive of earlier versions of guidance documents can be helpful to the public as long as they are clearly labeled as out of date.

4. *Affirmative Outreach*. Agencies should do more than merely upload new or revised guidance documents to their websites. They should undertake affirmative steps to alert interested members of the public to new and revised guidance documents. Such steps could include, among other things: allowing members of the public to sign up for listservs used to disseminate alerts about new or revised guidance; using social media to disseminate guidance documents information; having agency staff speak about guidance documents at relevant conferences or meetings; or even preparing printed pamphlets or other hard-copy documents when appropriate.

Even when agencies are not already required to do so, they should consider publishing information about new or revised guidance documents in the Federal Register. They should also consider providing descriptive references to relevant guidance documents in appropriate sections of the Code of Federal Regulations and indicating where members of the public can access such documents. Periodically, such as once per year, they should publish a brief notice in the *Federal Register* to indicate where the public can find the latest list or lists of the agency's guidance.

5. *Review and Feedback.* Each agency should provide opportunities for public feedback on its guidance procedures and their implementation. An agency's central guidance webpage should contain contact information or a comment form to facilitate public feedback related to potentially broken links, missing documents, or other errors or issues related to the agency's procedures for the development, publication, or disclosure of its guidance documents. In addition, an agency should periodically review its guidance procedures and their implementation to assess the agency's performance in making guidance documents available as well as to identify opportunities for improvement.

Conclusion

Although this report has offered a series of recommendations for improving the public availability of guidance documents, many agencies do already provide considerable online access to such documents. The research conducted for this report suggests, for example, that most agencies have already devoted spaces on their websites where members of the public can find information about guidance documents. Some agencies, such as the FDA, have even taken comprehensive steps to implement internal management systems to track and review their guidance documents and to make them available in a central, easily searchable online repository. Despite the many laudable efforts already taking place to make many agency guidance documents publicly

available, too many agencies' practices still appear ad hoc or incomplete. Judging from the concerns that have been expressed in recent years, most agencies could benefit from taking additional steps to manage and disclose their guidance materials more systematically.

Admittedly, some concerns about guidance availability appear associated with broader criticisms of the volume of agency guidance overall or of the processes by which agencies develop such documents. Evaluating these larger substantive and procedural criticisms has been outside the scope of this report. In any event, these broader criticisms hardly need to be accepted to see the value in promoting the public availability of guidance documents. Even those who fully embrace the value of agency guidance and recognize its important role in administrative government must surely agree that its availability to the public is essential for advancing the positive purposes it serves. Guidance documents can only help inform the public, including regulated industry, if members of the public know about them and can find them when needed. Moreover, general principles of good administration—evidenced by a longstanding series of ACUS recommendations[232]—counsel in favor of governmental transparency and hence support efforts to enhance the public availability of agency guidance documents.

To motivate agencies to enhance the availability of their guidance documents, legal requirements for disclosure are unlikely to prove sufficient because they lack the self-enforcing incentives that exist for legislative rules. It is of little consequence, after all, that non-binding guidance documents should fail to "take effect" if they are not disclosed properly. Because these documents are non-binding in the first place, they never really take effect in a legal sense anyway. Furthermore, although digital technology will obviously prove essential in making guidance documents available, technology alone cannot ensure that agency websites are designed for easy access nor that all relevant and current guidance documents are routinely uploaded to those websites. Improving the availability of guidance depends ultimately on diligent agency management. Agencies need to make sure they have in place effective internal procedures and systems for tracking guidance documents and take steps to ensure that these documents are consistently posted online in a timely manner and in an easy-to-access location on the agency's website. Agencies must take deliberate and systematic management steps to improve guidance transparency.

[232] *See supra* notes 55-59 and accompanying text.