

# Michigan Journal of Environmental & Administrative Law

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Volume 9 | Issue 2

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2020

## illuminating Regulatory Guidance

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### Recommended Citation

Cary Coglianese, *illuminating Regulatory Guidance*, 9 MICH. J. ENVTL. & ADMIN. L. 243 (2020).

Available at: <https://repository.law.umich.edu/mjeal/vol9/iss2/2>

<https://doi.org/10.36640/mjeal.9.2.illuminating>

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# ILLUMINATING REGULATORY GUIDANCE

Cary Coglianesi\*

*Administrative agencies issue many guidance documents each year in an effort to provide clarity and direction to the public about important programs, policies, and rules. But these guidance documents are only helpful to the public if they can be readily found by those who they will benefit. Unfortunately, too many agency guidance documents are inaccessible, reaching the point where some observers even worry that guidance has become a form of regulatory “dark matter.” This article identifies a series of measures for agencies to take to bring their guidance documents better into the light. It begins by explaining why, unlike the disclosure requirements for binding agency rules, existing legal requirements have failed to make guidance documents more accessible. The basic problem is that the law on guidance disclosure is not self-enforcing. As a result, guidance availability is ultimately a managerial challenge for agencies—dependent on the adoption of internal disclosure practices—as much as it is a problem with a legal or technological fix. To aid agency leaders in meeting their managerial challenge, this article reviews best practices in guidance disclosure across the federal government. It considers these practices in light of four key criteria for assessing guidance management—comprehensiveness, currency, accessibility, and comprehensibility—and provides a series of practical steps that agencies can take to illuminate their guidance. Given the important role that guidance plays in the modern administrative state, meaningful governmental transparency today dictates that agencies take seriously their responsibility to manage the production and release of their guidance documents in a manner that makes them consistently and readily available to the public.*

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## TABLE OF CONTENTS

INTRODUCTION .....	245
I. THE CHALLENGE OF GUIDANCE AVAILABILITY .....	247
A. <i>What is Guidance?</i> .....	247
B. <i>Categorizing Guidance</i> .....	255
1. OMB Bulletin .....	256
2. FDA Good Guidance Regulation .....	257
3. Department of Transportation Memorandum .....	258
C. <i>Concerns About Guidance Availability</i> .....	259
1. Indicators of Concern .....	261
2. Government Accountability Office Audit .....	265
D. <i>House Oversight and Government Reform Committee       Majority Staff Report</i> .....	268
II. STANDARDS FOR GUIDANCE AVAILABILITY .....	269
A. <i>General Legal Requirements</i> .....	269
1. Federal Records Act .....	270
2. Freedom of Information Act .....	270
3. The E-Government Act .....	272
4. The Congressional Review Act .....	273
5. Small Business Regulatory Enforcement Fairness Act ..	274
B. <i>Agency-Specific Legal Requirements</i> .....	274
1. Requirements for Food and Drug Administration Guidance .....	275
2. Other Agency-Specific Requirements .....	276
C. <i>Guidance on Guidance</i> .....	279
1. Generally Applicable Guidance on Guidance .....	279
2. Agency-Specific Guidance on Guidance .....	282
D. <i>Findings and Implications</i> .....	283
III. MANAGING GUIDANCE AVAILABILITY .....	285
A. <i>Guidance Availability Criteria</i> .....	286
1. Comprehensiveness .....	287
2. Currency .....	290
3. Accessibility .....	292
4. Comprehensibility .....	295
B. <i>Best Practices in Guidance Availability</i> .....	298
1. Internal Management .....	298
2. Online Access .....	302
3. Labeling and Explanations .....	307
4. Affirmative Outreach .....	309
5. Review and Feedback .....	311

IV. RECOMMENDATIONS FOR ENHANCING GUIDANCE  
 AVAILABILITY ..... 312  
 CONCLUSION ..... 317

INTRODUCTION

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 too, 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 indeed be quite helpful. But when government agencies produce documents that offer guidance, these materials will 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 public unavailability 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.

In this article, I address concerns that too many guidance documents produced by federal agencies are insufficiently accessible to the public. The article 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. My aim 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 extensively addressed in the broader legal literature.<sup>1</sup> But to date,

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1. See Michael Asimow, *Nonlegislative Rulemaking and Regulatory Reform*, 1985 DUKE L.J. 381, 385-88; 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, 1372 (1992) [hereinafter Anthony, *Interpretive Rules*]; Peter L. Strauss, *The Rulemaking Continuum*, 41 DUKE L.J. 1463, 1468 (1992); Robert A. Anthony, “*Interpretive*” Rules, “*Legislative*” Rules and “*Spurious*” Rules: *Lifting the Smog*, 8 ADMIN. L.J. AM. U. 1, 12-14 (1994); Robert A. Anthony & David A. Codevilla, *Pro-Ossification: A Harder Look at Agency Policy Statements*, 31 WAKE FOREST L. REV. 667, 671, 680 (1996); Randolph J. May, *Ruling Without Real Rules—Or How to Influence Private Conduct Without Really Binding*, 53 ADMIN. L. REV.1303 (2001); Peter L. Strauss, *Publication Rules in the Rulemaking Spectrum: Assuring Proper Respect for an Essential Element*, 53 ADMIN. L. REV. 803, 806-07 (2001) [hereinafter Strauss, *Publication Rules*]; John F. Manning, *Non-legislative Rules*, 72 GEO. WASH. L. REV. 893, 893 (2004); David L.

legal scholarship has given no attention to the question of how agencies can make their guidance documents more accessible to the public. Here, the production and existence of guidance documents will be taken as given, and the only issue will be what agencies might do to make the guidance documents that they do produce more accessible.

In Part I, I introduce the concerns and challenges associated with public availability of guidance documents. I begin by considering the defining features of guidance documents and highlighting their role in public administration. I then review a series of recent reports and recommendations that demonstrate prevailing concern about public availability of guidance. In Part II, I turn 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.” In Part III, I turn 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. Finally, in Part IV, I distill the findings from this article into a series of recommendations for agencies to use in illuminating their guidance.

My main conclusion in this article 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. Guidance documents are different from binding rules and regulations. By law, the latter must be published in the *Federal Register* if they are to have binding effect. The non-binding and heterogeneous nature of guidance documents, however, means that they cannot be

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Franklin, *Legislative Rules, Nonlegislative Rules, and the Perils of the Short Cut*, 120 YALE L.J. 276, 278 (2010); Mark Seidenfeld, *Substituting Substantive for Procedural Review of Guidance Documents*, 90 TEX. L. REV. 331, 378-80 (2011); Ronald M. Levin, *Rulemaking and the Guidance Exemption*, 70 ADMIN. L. REV. 263, 267 (2018); Nicholas R. Parrillo, *Federal Agency Guidance and the Power to Bind: An Empirical Study of Agencies and Industries*, 36 YALE J. REG. 165 (2019); see also generally Recommendation 76-5, Interpretive Rules of General Applicability and Statements of General Policy, 41 Fed. Reg. 56,767, 56,770 (Dec. 30, 1976); Recommendation 92-2, Agency Policy Statements, 57 Fed. Reg. 30,101, 30,103 (July 8, 1992); Recommendation 2014-3, Guidance in the Rulemaking Process, 79 Fed. Reg. 35,988, 35,992 (June 25, 2014); Recommendation 2017-5, Agency Guidance Through Policy Statements, 82 Fed. Reg. 61,728, 61,734 (Dec. 14, 2017); Blake Emerson & Ronald M. Levin, *Agency Guidance Through Interpretive Rules: Research and Analysis* (May 28, 2019) (report to the Admin. Conf. of the U.S.), <https://www.acus.gov/sites/default/files/documents/ACUS%20IR%20final%20report.5.28.2019.pdf>.

subject to the same self-enforcing legal structure that disciplines publication of rules and promotes their public availability in a central repository. 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, up-to-date, accessible, and comprehensible form.

## I. THE CHALLENGE OF GUIDANCE AVAILABILITY

Meeting 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. As a result, determining which types of guidance should be posted and indexed on agency websites will need to be based, first, on what counts as guidance and, second, on how agencies distinguish between different categories of guidance. I thus begin this Part by focusing on various definitions and categories of guidance. Following this initial review, I discuss prevailing 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.<sup>2</sup> But such a seemingly straightforward notion of legal “non-bindingness” as the essence of guidance has prevented neither 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.’”<sup>3</sup>

The task of defining guidance has been particularly challenging only in part because of perceived difficulty in distinguishing guidance from legislative rules.<sup>4</sup> 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

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2. Agency statements that are binding constitute either enforceable orders or legislative rules. See Administrative Procedure Act, 5 U.S.C. §§ 551(4)-(6), 553(b)(3) (2018).

3. Levin, *supra* note 1, at 266 (citing *Comty. Nutrition Inst. v. Young*, 818 F.2d 943, 946 (D.C. Cir. 1987)).

4. See, e.g., *id.*; Strauss, *Publication Rules*, *supra* note 1, at 807, 815; Anthony, *Interpretive Rules*, *supra* note 1, at 1331.

on a regular basis.<sup>5</sup> 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 (DOT) 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.”<sup>6</sup> 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. Such a broad understanding of guidance encompasses a vast number of informal statements made daily by government employees during the course of routine interactions with members of the public.

Not only is the quantity of non-binding communication extraordinarily high, but the types of agency statements that can potentially constitute guidance are also quite varied. 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.<sup>7</sup>

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 of defining guidance exists regardless of the label officials use to refer to their statements. The label is not dispositive. What matters is the non-

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5. 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, *Publication Rules*, *supra* note 1, at 804; *see also* NICHOLAS R. PARRILLO, FEDERAL AGENCY GUIDANCE: AN INSTITUTIONAL PERSPECTIVE 35 (Final Report to the Admin. Conf. of the U.S.) (Oct. 12, 2017), <https://www.acus.gov/sites/default/files/documents/parrillo-agency-guidance-final-report.pdf> (“There is no comprehensive compilation of guidance, but everyone agrees its volume is oceanic.”).

6. *Types of DOT Guidance*, DOT, <https://www.transportation.gov/regulations/types-dot-guidance> (last visited May 13, 2019).

7. Anthony, *Interpretive Rules*, *supra* note 1, 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. Agency Policy Statements, 57 Fed. Reg. 30,103 (1992).

binding nature of the statement.<sup>8</sup> 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).<sup>9</sup> Non-binding statements, by contrast, do not have to follow the APA’s rulemaking procedures. The APA, though, nowhere uses the term “guidance.”<sup>10</sup> It refers instead 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.<sup>11</sup>

Although “interpretative rules” and “policy statements” constitute guidance, they are not necessarily the only non-binding agency statements. Unfortunately, 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 as to what else might be considered guidance. A number of statutes use the term “guidance”—or its equivalent, “guidance document”—but never offer a formal definition.<sup>12</sup> The Food and Drug Administration Modernization Act of 1997 comes closest by articulating the legal effect of such documents—they “shall not create or confer any rights for or on any person” and “shall not be binding on the Secretary”<sup>13</sup>—but even this law never explicitly defines guidance.<sup>14</sup>

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

8. 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.” Contract with America Advancement Act of 1996, Pub. L. No. 104-121 §§ 211(3), 212(a) (codified at statutory notes, Subtitle A, 5 U.S.C. § 601 (2018)).

9. 5 U.S.C. §§ 553, 556 (2018). 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 must follow that other statute’s required procedures and not the Act’s.

10. The entire Administrative Procedure Act can be found at 5 U.S.C. §§ 551-59.

11. See, e.g., Anthony, *Interpretive Rules*, *supra* note 1, at 1324 (noting that “courts do not treat interpretations as making new law” and policy statements are “not legally binding policy”); 5 U.S.C. § 553(a)(3)(A).

12. See, e.g., 42 U.S.C. § 300(j)-24 (2018); 49 U.S.C. § 113 (2018).

13. 21 U.S.C. §§ 371(h)(1)(A), (B) (2018). 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).

14. *Id.* § 371(h).



forth a policy on a statutory, regulatory or technical issue or an interpretation of a statutory or regulatory issue.<sup>15</sup>

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.”<sup>16</sup> Despite this fact, and despite some difficulties created by the definition’s parenthetical reference to Executive Order 12,866,<sup>17</sup> the OMB Bulletin’s definition of a guidance document as something “other than a regulatory action”<sup>18</sup> 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 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.”<sup>19</sup>

15. OFFICE OF MGMT. & BUDGET, EXEC. OFFICE OF THE PRESIDENT, OMB BULL. NO. 07-02, FINAL BULLETIN FOR AGENCY GOOD GUIDANCE PRACTICES, 72 Fed. Reg. 3432, 3439 (Jan. 25, 2007), <https://www.gpo.gov/fdsys/pkg/FR-2007-01-25/pdf/E7-1066.pdf> [hereinafter OMB BULLETIN]. Executive Order 13,891 now also provides a common definition applicable across the executive branch, one that is similar to the definition in the OMB Bulletin but not identical to it. Exec. Order No. 13,891, 84 Fed. Reg. 55,235, 55,235-36 (Oct. 15, 2019). The definition in the executive order is further elaborated and qualified in a memorandum from the Acting Administrator of the Office of Information and Regulatory Affairs, as authorized by the executive order. Office of Info. & Reg. Affairs, OIRA Memorandum M-20-02 on Guidance Implementing Executive Order 13,891 (Oct. 31, 2019), <https://www.whitehouse.gov/wp-content/uploads/2019/10/M-20-02-Guidance-Memo.pdf> [hereinafter OIRA Memorandum]. The OIRA Memorandum indicates that it and the executive order supersede the OMB Bulletin, even though the bulletin “continues to describe best practices that agencies should follow.” *Id.* at 3.

16. OMB BULLETIN, *supra* note 15, at 3440. It also only applies to executive, not independent, agencies. *Id.* at 3439.

17. 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. Exec. Order No. 13,422, Further Amendment to Executive Order 12,866 on Regulatory Planning and Review, 72 Fed. Reg. 2763, 2763 (Jan. 23, 2007). Second, even when section 3(g) did exist, that section defined “guidance document,” not “regulatory action.” *Id.* 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, *Interpretive Rules*, *supra* note 1, 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.”).

18. OMB BULLETIN, *supra* note 15, at 3434.

19. Memorandum from Susan E. Dudley, Adm’r, Office of Info. & Reg. Affairs, on Implementation of Executive Order 13,422 at 2 (Apr. 25, 2007), [https://www.transportation.gov/sites/dot.dev/files/docs/m07\\_13\\_EO\\_13422\\_implementation\\_%5B1%5D.pdf](https://www.transportation.gov/sites/dot.dev/files/docs/m07_13_EO_13422_implementation_%5B1%5D.pdf).

Yet the definition in the OMB Bulletin has not been uniformly followed, even by other White House officials. For example, Executive Order 13,791 has subsequently opted for a different definition of guidance in issuing direction 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, memoranda, pamphlets, bulletins, advisories, technical assistance, and grants of applications for waivers.<sup>20</sup>

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.”<sup>21</sup> But, unlike the OMB Bulletin, the definition in Executive Order 13,791 is limited only to *written* statements.<sup>22</sup>

In recent years, some proposed legislation has sought to define guidance, but again the precise definitions have varied. The Senate version of the Regulatory Accountability Act of 2017, a set of regulatory reforms that passed in the House but never did in the Senate, included the following definition that would have limited guidance to non-binding statements, without being restricted 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.’<sup>23</sup>

The Guidance Out of Darkness (GOOD) Act, which passed in the House in September 2018 (but not in the Senate), similarly would have defined guidance as non-binding and would not have limited the definition to written statements or statements with future effect.<sup>24</sup> Its definition did, though, include an extended list

20. 82 Fed. Reg. 20,427, § 3 (Apr. 26, 2017).

21. See OMB BULLETIN, *supra* note 15, at 3439.

22. 82 Fed. Reg. 20,427, § 3 (Apr. 26, 2017).

23. Regulatory Accountability Act of 2017, S. 951, 115th Cong. § 2(5) (2017).

24. H.R. 4809, 115th Cong. § 5(2) (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 follow-

of examples of materials that its drafters considered to constitute guidance, all of which 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.”<sup>25</sup>

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. DOT 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.”<sup>26</sup> But the Department has also stated, in a policy adopted in December 2018, that it does not consider the following materials to be guidance documents:

[L]egal 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.<sup>27</sup>

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ing [examples as provided in the text accompanying note 21 of this article, or] Any combination of the items described [the examples].” *Id.* § 5(2).

25. *Id.* The bill also stated that “the term ‘guidance document’ shall be construed broadly.” *Id.* § 4(a).

26. *Types of DOT Guidance*, DOT, <https://www.transportation.gov/regulations/types-dot-guidance> (last updated June 1, 2018). The Department’s policy adopted in December 2018 confirms that guidance documents are “not confined to formal written documents.” Memorandum from Steven G. Bradbury, Gen. Counsel, U.S. Dep’t of Transp. on Review and Clearance of Guidance Documents (Dec. 20, 2018), <https://www.transportation.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>.

27. Bradbury Memorandum, *supra* note 26, § 1(b), <https://www.transportation.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.

At least some of the materials the Department has indicated on its website can constitute guidance—such as statements by senior 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.<sup>28</sup>

Other agencies have provided their own lists of what they consider to be guidance—and what they do not. The Food and Drug Administration (FDA) has adopted a “good guidance practices” regulation which contains, in only the most general terms, a definition of guidance as those documents “that describe the agency’s interpretation of or policy on a regulatory issue.”<sup>29</sup> 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.”<sup>30</sup> 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.”<sup>31</sup> FDA specifically notes that its “public health alerts are not guidance documents.”<sup>32</sup>

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 (DOJ) 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.”<sup>33</sup> The Consumer Financial Protection Bureau (CFPB) has also stated that it “does not regard . . . as

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28. Compare H.R. 4809, 115th Cong. § 5(2) (including “news release”), with text accompanying *supra* note 27 (excluding “press materials”).

29. 21 C.F.R. § 10.115(b)(1) (2012).

30. *Id.* § 10.115(b)(2).

31. *Id.* § 10.115(b)(3).

32. Administrative Practices and Procedures; Good Guidance Practices, 65 Fed. Reg. 56,468, 56,475 (Sept. 19, 2000).

33. Memorandum from Jeff Sessions, Att’y Gen., U.S. Dep’t of Justice, on Prohibition of Improper Guidance Documents (Nov. 16, 2017), <https://www.justice.gov/opa/press-release/file/1012271/download>.

guidance” a variety of “informal documents available on the Bureau’s website, such as press releases, blog posts, and speeches.”<sup>34</sup>

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. The specific form that guidance documents take, as well as their substance, can be highly varied. After all, the work that agencies do varies, and so too do the types of statements that they produce. 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.

Second, no uniform binding definition of guidance yet applies across the federal government.<sup>35</sup> Under some definitions, statements constituting guidance must have general applicability and future effect; other definitions, however, 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.<sup>36</sup>

Finally, despite all the various definitions, the common thread running through all of them is the principle that guidance lacks the force of law. Its essence is its legally non-binding effect.<sup>37</sup> As a result, going forward I will simply use this feature to characterize the terms “guidance” and “guidance documents,” relying for ease of exposition on the most capacious and generic sense of the terms, unless indicated otherwise. Recognizing the variation that exists in definitions of guidance

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34. 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).

35. Although Executive Order 13,891 now contains an authoritative definition that supersedes the one in the OMB Bulletin, the executive order still does not apply to independent agencies nor is it enforceable at law. *See generally* Exec. Order No. 13,891, *supra* note 15.

36. The OMB Bulletin does exclude “speeches,” “editorials,” “media interviews,” “press materials,” “Congressional correspondence,” and other documents from its definition of a “significant guidance document.” OMB BULLETIN, *supra* note 15, at 3439, § I(4)(b) (emphasis added). But in excepting these materials from the class of significant guidance documents only, the OMB Bulletin implies that they can still fall within the broader category of guidance document, even if as insignificant ones.

37. *See* Levin, *supra* note 1, 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 19 (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. Mortgage Bankers Ass’n* noted “the longstanding recognition that interpretive rules do not have the force and effect of law.” 575 U.S. 92, 103 (2015).

documents, as well as in agencies' needs, purposes, and uses of these documents, I will not adopt any single definition of guidance for my purposes here. Instead, I 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. The only way for an agency to begin to manage effectively the accessibility of its guidance documents is by first defining what exactly they are.

### B. *Categorizing Guidance*

The preceding 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.<sup>38</sup> 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, agencies need to circumscribe the scope of such internal management efforts, if for no other reason than to make oversight of guidance administratively feasible. Deciding what constitutes "guidance" in the first place is one way of establishing that scope.

Another way to establish the scope of an agency's guidance management efforts is to differentiate between types of guidance, treating some non-binding statements with more intensive management scrutiny than others. Instead of merely relying on distinctions between statements to determine 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 merit specified management efforts, such as additional internal review, public notice and comment, or online availability?

Answering this question will be especially 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 exists to track meaningfully or make available online all such statements made in phone calls, meetings, or emails. Even when agencies

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38. For instance, Executive Order 13,791 only considers written statements to be guidance, while the Department of Transportation and OMB expressly accept that guidance need not be committed to writing. *See supra* Part I.A; *see supra* notes 22 & 26 and accompanying text. 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. *See supra* Part I.A.

have adopted narrower definitions of guidance, as discussed in the previous section of this article, they may still have valid reasons for treating different kinds of guidance 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.<sup>39</sup> As a result, agencies have categorized different kinds of guidance documents and identified 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 FDA and DOT, provide useful examples of the variation in how agencies categorize guidance.

### 1. OMB Bulletin

The OMB distinguishes significant guidance documents from other guidance documents, imposing standards that agencies should follow in managing and disclosing the former but not the latter.<sup>40</sup> 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.<sup>41</sup>

A guidance document that qualifies as significant under the first criterion—that is, has an annual effect on the economy of \$100 million or more—is considered in the OMB Bulletin to be an “economically significant guidance document.”<sup>42</sup>

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39. See *supra* note 5 and accompanying text.

40. 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. OMB BULLETIN, *supra* note 15.

41. *Id.*

42. *Id.*

The OMB Bulletin excludes entirely from its category of “significant guidance document” any of the following documents, regardless of whether they 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 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.<sup>43</sup>

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

## 2. FDA Good Guidance Regulation

The Food and Drug Administration makes a similar categorization of guidance documents based on their significance, although it uses different criteria and different labels for its categories. Instead of significant versus non-significant, 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

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43. *Id.*



guidance documents include all guidance documents that are not classified as Level 1.<sup>44</sup>

As the OMB Bulletin does for significant guidance documents, 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 article.<sup>45</sup>

### 3. Department of Transportation Memorandum

In its December 2018 memorandum on guidance, the DOT defined guidance documents in a manner to exclude virtually the same documents the OMB Bulletin counts as guidance but categorically excludes from its definition of significant guidance.<sup>46</sup> But the DOT policy nevertheless still creates a category of “significant guidance documents” that are subjected to centralized departmental review and other management standards.<sup>47</sup> A significant guidance document for the DOT 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.<sup>48</sup>

The first criterion of significance here is somewhat narrower than the first criterion contained in the OMB Bulletin, as the DOT 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).<sup>49</sup>

The DOT memorandum also creates a category of guidance documents that are “otherwise of importance to the Department’s interests” and which are effec-

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44. 21 C.F.R. § 10.115 (2019).

45. See *infra* Part II.

46. Bradbury Memorandum, *supra* note 26, § 1.

47. *Id.* §§ 7-8.

48. *Id.* § 7(a).

49. *Id.*

tively supposed to be treated the same as significant guidance.<sup>50</sup> A guidance document falls into this category “if it may reasonably be anticipated” to meet at least one of the following criteria:

- “[R]elate to a major program, policy, or activity of the Department or a high-profile issue pending for decision before the Department;”
- “[I]nvolve one of the Secretary’s top policy priorities;”
- “[G]arner significant press or congressional attention;” or
- “[R]aise 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.”<sup>51</sup>

In addition, the DOT memorandum includes an appendix that lists fifteen 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.<sup>52</sup>

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As suggested by these examples of different categorizations of guidance, determining how to manage and disclose guidance is likely to be assisted by distinguishing between guidance based on their significance and on other features. As I discuss further in Part II of this article, 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 merely the first step in any system of guidance management. Agencies must also establish different categories of guidance documents. As with definitions of guidance, these categorizations can vary based on differences in agency goals and the types of guidance documents agencies 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

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50. *Id.* § 7(c).

51. *Id.*

52. *Id.* App. A.

agency guidance. It also reviews two recent reports—one produced by the Government Accountability Office (GAO),<sup>53</sup> the other by the majority staff of the House Oversight and Government Reform Committee<sup>54</sup>—that suggest that agencies could do a better job of making guidance more readily available to the public.

At the outset, it is important to acknowledge that sometimes concerns about guidance availability have grown out of substantive objections to guidance in general. These concerns may at times even reflect a suspicion that agencies issue guidance documents as a way of short-circuiting the rulemaking process but still practically binding private actors.<sup>55</sup> After all, even though businesses and other private entities are not legally bound to follow agency guidance, as a practical matter they often will—and, thus, guidance in practice can operate in much the same way that regulations do.<sup>56</sup> Because agencies can issue guidance documents without going through the entire notice-and-comment process, these documents can become what some observers have labeled regulatory “dark matter.”<sup>57</sup> As a result, anyone con-

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

54. 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>.

55. See, e.g., CLYDE WAYNE CREWS, JR., COMPETITIVE ENTERPRISE INST. NO. 249, A PARTIAL ECLIPSE OF THE ADMINISTRATIVE STATE 1, 15 (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”). This suspicion is reflected in Executive Order 13,891, which states that “agencies have sometimes used [their guidance-issuing] authority inappropriately in attempts to regulate the public without following the rulemaking procedures of the APA.” Exec. Order No. 13,891, 84 Fed. Reg. 55,235, 55,235 (Oct. 15, 2019).

56. See, e.g., PARRILLO, *supra* note 5, at 45-56 (discussing practical reasons for private entities to adhere to guidance as if it were binding).

57. See, e.g., CREWS, *supra* note 55, 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”). Astrophysicists have used the term “dark matter” for more than a century to refer to the vast bulk of matter in the universe that is not visible through normal means of detection but the existence of which can be inferred from its effect on gravitational pull. See, e.g., Corey S. Powell, *Dark Matter is Real*, DISCOVER (Apr. 1, 2019) (discussing the history of dark matter as “something invisible that generates an anomalous gravitational pull”). In 2015, Clyde Wayne Crews, Jr. apparently coined the term “regulatory dark matter” to refer to a range of “agency and presidential memoranda, guidance documents (‘non-legislative’ or interpretive rules), notices, bulletins, directives, news releases, letters, and even blog posts” that announce policies without going through the notice-and-comment rulemaking process. CLYDE WAYNE CREWS, JR., MAPPING WASHINGTON’S LAWLESSNESS 2016: A PRELIMINARY INVENTORY OF “REGULATORY DARK MATTER,” at 3 (Dec. 2015), <https://cei.org/sites/default/files/Wayne%20Crews%20%20Mapping%20Washington%27s%20Lawlessness.pdf>. An earlier example linking concern about agencies circumventing the rulemaking process with concern about access to guidance can be found reflected in an opinion by the D.C. Circuit Court of Appeals: “One guidance document may yield another and then another and so on. Several words in a regu-

cerned about government regulators effectively bypassing normal notice-and-comment procedures will want to ensure that guidance documents are, at a minimum, readily accessible after they are created.

But it is not necessary to accept any broader critique of guidance documents to recognize that, once such documents are created, they should be made more accessible to the public. Guidance availability, in other words, should matter even to those individuals who are not skeptical of guidance in general. It is possible to reject the suspicious characterization of guidance as “regulatory dark matter”—and to decry as overwrought and alarmist claims about a regulatory state overrun with guidance documents<sup>58</sup>—but still agree that members of the public should be able to find guidance documents. After all, the mere fact that guidance documents can provide helpful information about how agencies interpret their regulations, carry out enforcement activities, and otherwise administer programs makes it important for the public to be able to access these documents that affect them.<sup>59</sup> If guidance documents are valuable tools designed to inform and assist members of the public, then the public must at least be able to find them.

The upshot is that the concerns with guidance availability expressed in this section do not depend on any particular view about the substantive merits of guidance as a regulatory tool. No matter whether one thinks that agencies currently issue too much guidance, or not enough guidance, it is possible still to agree that agencies could do a better job in making the guidance documents they create more accessible to the public.

## 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 FDA to make its guidance documents more accessible to the public.<sup>60</sup> When Congress enacted the Small Business Regulatory Enforcement Fair-

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lation 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. EPA*, 208 F.3d 1015, 1020 (D.C. Cir. 2000).

58. For a thoughtful response to critics of guidance, see Rena Steinzor, *The Guidance Racket*, REG. REV. (Mar. 26, 2018), <https://www.theregreview.org/2018/03/26/steinzor-guidance-racket/> (explaining why it is wrong to “condemn all guidance as the tool of the overly zealous who comprise the imaginary deep state” and explaining how guidance can be helpful for those seeking earnestly to comply with the law).

59. Cf. 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”).

60. Pub. L. No. 105-115, 111 Stat. 2368, (codified as amended at 21 U.S.C. § 405).

ness 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.”<sup>61</sup>

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.<sup>62</sup> The Regulatory Accountability Act of 2017 would have similarly required agencies to state that their guidance is non-binding.<sup>63</sup> 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.”<sup>64</sup> The GOOD Act was specifically introduced “to increase the transparency of agency guidance documents and to make guidance documents more readily available to the public.”<sup>65</sup> 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.<sup>66</sup> 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.”<sup>67</sup>

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).<sup>68</sup> 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.”<sup>69</sup>

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61. Small Business Regulatory Enforcement Fairness Act of 1996 § 212, 5 U.S.C. § 601 (2018).

62. 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>.

63. Regulatory Accountability Act of 2017, H.R. 5, 115th Cong. § 104 (2017).

64. *Id.*

65. Guidance Out of Darkness Act, H.R. 4809, 115th Cong. § 2 (2018).

66. *Id.* § 3(c)(1).

67. *Id.* § 3(c)(3).

68. H.R. Rep. No. 115-972, at 4 (2018).

69. ACUS, Recommendation 2017-5, *supra* note 1. 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.

That ACUS recommendation was consistent with a longstanding concern reflected in other ACUS recommendations about governmental transparency in general and about guidance availability specifically.<sup>70</sup> In issuing a recommendation on the online transparency of rulemaking information in 2011, for example, ACUS noted that agency websites “do not always include features to ensure that essential information . . . is broadly accessible to the public.”<sup>71</sup> The Conference formally recommended that agencies “continue to improve the accessibility of their Web sites to members of the public,” noting that its “recommendation also extends to guidance documents on which an agency is seeking or intends to seek public comment.”<sup>72</sup>

In a 2014 recommendation mainly addressing other issues related to guidance, ACUS 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.”<sup>73</sup> 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.”<sup>74</sup>

More recently, 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

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70. 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.” ACUS, Recommendation 71–3, *Articulation of Agency Policies*, 38 Fed. Reg. 19,788 (July 23, 1973). More recently, ACUS has expressed an overarching concern for governmental transparency with respect to a wide range of agency actions and materials, including: 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 related materials (Recommendation 2018-6, Recommendation 2011-8, Recommendation 2011-1), internal policies related to federalism (Recommendation 2010-1), and federal advisory committees (Recommendation 2011-7). See *Recommendations*, ACUS, <https://www.acus.gov/recommendations> (last visited Mar. 21, 2020) (collecting sources).

71. ACUS, Recommendation 2011-8, *Innovations in e-Rulemaking*, 77 Fed. Reg. 2257, 2265 (2011).

72. *Id.* at 2265 & n.5.

73. ACUS, Recommendation 2014–3, *Guidance in the Rulemaking Process*, 79 Fed. Reg. 35,988, 35,993 (2014).

74. *Id.* at 35,993, 35,995.

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.<sup>75</sup>

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.<sup>76</sup>

In addition to expressed concern about guidance accessibility reflected in ACUS recommendations and legislative proposals,<sup>77</sup> 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.”<sup>78</sup> 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.”<sup>79</sup>

75. ACUS, Recommendation 2018-5, *Public Availability of Adjudication Rules*, 84 Fed. Reg. 2139, 2142 (Feb. 6, 2019).

76. *Id.* Furthermore, most recently of all, in June 2019, ACUS formally adopted a comprehensive recommendation on the public availability of guidance documents based on findings from the study on which this present article is based. ACUS, Recommendation 2019-3, *Public Availability of Agency Guidance Documents*, 84 Fed. Reg. 38,931 (Aug. 8, 2019). That recommendation started with the premise that “[m]embers of the public should have ready access to . . . guidance documents so that they can understand how their government works and how their government relates to them.” *Id.* at 38,931. It then called on agencies to improve their internal management of agency guidance, make their guidance documents available on agency websites, and engage in affirmative steps to notify interested persons of the availability of new guidance materials. *Id.* at 38,932-33.

77. In addition to the legislative proposals and ACUS recommendations discussed in the text, President Trump issued two executive orders on guidance in October 2019. Exec. Order No. 13,891, *supra* note 15; Exec. Order No. 13,892, 84 Fed. Reg. 55,239 (Oct. 15, 2019). The first of these calls for agencies to “establish or maintain on its website a single, searchable, indexed database that contains or links to all guidance documents.” Exec. Order No. 13,891, *supra* note 15, § 3(a). The second states that, in enforcement actions or other adjudicatory proceedings, agencies may only cite a guidance document to “articulate the agency’s understanding of how a statute or regulation applies to particular circumstances” if the document was previously published in the *Federal Register* or on the agency’s dedicated webpage for guidance documents. Exec. Order No. 13,892, § 3.

78. AM. BAR ASS’N, SECTION OF ADMIN. LAW & 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](https://www.americanbar.org/content/dam/aba/administrative/administrative_law/Final%20POTUS%20Report%2010-26-16.authcheckdam.pdf). The author of the present article was a member of an ad hoc committee that prepared the ABA section report.

79. *Id.*

## 2. Government Accountability Office Audit

In 2015, the U.S. Government Accountability Office (GAO) released findings from an audit of guidance practices at four departments: Agriculture, Education, Health and Human Services, and Labor.<sup>80</sup> The audit focused on how and when the departments, and their component units (25 in all), used guidance and how they made guidance documents available to the public. The GAO found that these agencies used guidance for a variety of 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.<sup>81</sup>

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 written procedures, but the Department of Health and Human Services did not.<sup>82</sup> Officials at the Department of Labor were reportedly not aware during the course of the GAO audit that they had written procedures for significant guidance. However, when reviewing the final draft of the GAO report, someone at the Labor Department apparently did discover that the Department had in fact prepared some procedures for significant guidance in response to the OMB Bulletin.<sup>83</sup> With respect to procedures for non-significant guidance at the four departments, the GAO reported that “[m]ost components did not have written procedures for guidance initiation, development, and review.”<sup>84</sup>

Only about half of the 25 components within the four departments reported regularly reviewing existing guidance documents to ensure they remained current.<sup>85</sup> 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 special 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. Offi-

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80. GOV’T ACCOUNTABILITY OFFICE, GAO-15-368, REGULATORY GUIDANCE PROCESSES: SELECTED DEPARTMENTS COULD STRENGTHEN INTERNAL CONTROL AND DISSEMINATION PRACTICES (2015), <https://www.gao.gov/assets/670/669688.pdf>.

81. *Id.* at 11-12.

82. *Id.* at 20.

83. *Id.* at 20 n.33.

84. *Id.* at 24.

85. *Id.* at 29.



cials 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.<sup>86</sup>

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.”<sup>87</sup> 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.”<sup>88</sup>

With respect to making guidance available to the public, GAO reported that all 25 components posted guidance on their websites, while most also used email (22) or meetings (22) to disseminate guidance.<sup>89</sup> Some of these agencies also reported disseminating guidance materials through email listservs (19), external partners (e.g., federal agencies, state governments, or nongovernmental organizations) (17), social media (13), mass media such as through press releases (11), and newsletters (7).<sup>90</sup> The agencies “used different strategies to reach certain groups,” with the obvious challenge that “it was more resource intensive to distribute guidance to a wider audience.”<sup>91</sup> But some agencies succeeded in readily reaching wider audiences because they had developed lists of interested members of the public and the regulated community.<sup>92</sup>

Officials sometimes tried other dissemination strategies. At the Occupational Safety and Health Administration (OSHA), for example, 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.”<sup>93</sup> To reach members of the public “during disaster recovery efforts or to reach those who did not have access to the Internet,” officials at various agencies still sometimes used printed pamphlets or other hard-copy documents.<sup>94</sup> GAO reported that “[c]omponents also reached wider audiences by engaging with the public directly through conferences, webinars, media outreach, or

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86. *Id.* at 30.

87. *Id.* at 29.

88. *Id.*

89. *Id.* at 31.

90. *Id.*

91. *Id.*

92. The Employee Benefits Security Administration within the Labor Department, for example, reportedly maintains a listserv with more than 335,000 subscribers. *Id.* at 32. 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.” *Id.* at 33.

93. *Id.* at 33.

94. *Id.*

public awareness campaigns.”<sup>95</sup> In addition, GAO noted that “[a] few components told us that they posted guidance in the *Federal Register*.”<sup>96</sup>

Focusing on the 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.”<sup>97</sup> It found that the Departments of Agriculture, Education, and Labor followed the OMB Bulletin in making a list of significant guidance documents available on their websites; however, the GAO could not locate any similar page on the Department of Health and Human Services’ website.<sup>98</sup> 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.<sup>99</sup> Still, the GAO found a variety of obstacles to online access of the departments’ and their components’ guidance documents, including:

- Links were broken to two of the four department’s webpages dedicated to significant guidance;<sup>100</sup>
- “Components posted long lists of guidance, which could make it difficult for users to find particular guidance documents.”<sup>101</sup>
- “[F]ew components effectively distinguished whether their online guidance was current or outdated to ensure the relevance of their online information.”<sup>102</sup>
- “[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.”<sup>103</sup>
- “[M]any component officials told us that they did not have a systematic way to evaluate whether the public could access their guidance online.”<sup>104</sup>

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

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95. *Id.*

96. *Id.* at 32.

97. *Id.* at 34.

98. *Id.* at 33-34.

99. *Id.* at 36.

100. *Id.* at 33 nn.38-39.

101. *Id.* at 38.

102. *Id.*

103. *Id.*

104. *Id.* at 39.

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.”<sup>105</sup>

#### D. *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 provide lists of all their guidance documents issued since 2008—both significant and non-significant guidance.<sup>106</sup> The Committee reported that, of the 46 agencies contacted by its staff, 27 agencies responded by providing what they said were complete inventories of all their guidance documents.<sup>107</sup> An additional 11 agencies responded with what they acknowledged was a partial list, while eight agencies apparently failed to provide any substantive response at all.<sup>108</sup> In total, the responding agencies provided information on over 13,000 guidance documents.<sup>109</sup> 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.”<sup>110</sup>

The Committee staff reported that “most agencies” provided links to guidance documents on their webpages.<sup>111</sup> 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.<sup>112</sup>

The Committee staff noted that “[s]ome agencies maintain easily identifiable and navigable online repositories for their guidance documents on their websites.”<sup>113</sup> 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 regula-

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105. *Id.* at 47.

106. STAFF OF H. COMM. ON OVERSIGHT & GOV’T REFORM, 115TH CONG., *supra* note 54.

107. *Id.* at 9. Two of these agencies, though, reported that they actually issued no guidance during the period.

108. *Id.*

109. *Id.*

110. *Id.* at 4.

111. *Id.* at 13.

112. *Id.* at 4.

113. *Id.* at 13.

tors by placing the onus on the regulators to assemble and organize these documents.”<sup>114</sup>

## II. STANDARDS FOR GUIDANCE AVAILABILITY

Perhaps surprisingly, given the concerns that have emerged over guidance availability, federal agencies are actually subject to certain legal requirements and non-binding standards that call for making guidance accessible to the public. But, as I discuss in this Part, requirements that agencies publish guidance documents are inherently feeble. 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*.<sup>115</sup> But no similar self-enforcing structure exists for guidance documents because they are non-binding statements that never “take effect” in the way that binding legal rules do. When it comes to guidance, publication requirements simply lack any clear structural mechanism that can ensure compliance.<sup>116</sup>

In this Part, I review existing requirements related to the public availability of guidance, starting with the most general 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 findings discussed in this Part indicate that, outside of a few general legal standards that call for making guidance available, there appear to exist relatively few agency-specific overarching legal requirements for guidance availability. In this Part, I also review non-binding standards for guidance availability, such as those contained in the OMB Bulletin discussed in Part I of this article.

### A. General Legal Requirements

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

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114. *Id.* at 21.

115. 5 U.S.C. § 552(a)(1) (2018) (stating 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 and not so published”); *see also id.* § 553(d) (requiring publication of “a substantive rule” prior to its “effective date”); *id.* § 706(d)(2) (stating that a “reviewing court shall . . . hold unlawful and set aside agency action . . . found to be . . . without observance of procedure required by law”).

116. 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).

## 1. Federal Records Act

Each agency has an overall responsibility under the Federal Records Act for managing records it produces and processes.<sup>117</sup> 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.*<sup>118</sup>

For the reasons discussed in Part I of this article, many guidance documents would likely qualify as “records of general interest or use to the public.”<sup>119</sup> 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.<sup>120</sup> FOIA imposes two standards directly relevant to guidance availability.

First, Section 552(a)(1) calls for each agency to publish in the *Federal Register* a variety of materials, including its legislative rules. The agency must in particular 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.”<sup>121</sup> 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, revision, or repeal” of guidance or any other document covered by Section 552(a)(1) must also be published in the *Federal Register*.<sup>122</sup>

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117. See 44 U.S.C. §§ 3101-07 (2018).

118. 44 U.S.C. § 3102 *amended by* FOIA Improvement Act of 2016, Pub. L. No. 114-185, 130 Stat. 538 (emphasis added to indicate amendment).

119. See *supra* Part I.

120. See Freedom of Information Act, 5 U.S.C. § 552(a) (2018).

121. *Id.* § 552(a)(1)(C)-(D).

122. *Id.*

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.<sup>123</sup> These categories of documents can also include guidance.

FOIA contains several 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.”<sup>124</sup> Furthermore, neither of the publication requirements in Sections 552(a)(1) and (2) apply to the extent that an affected person has received “actual and timely notice” of the guidance.<sup>125</sup> 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 never be required under FOIA to be made available to the public.

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 does not fit as well in the context of documents that are avowedly non-binding. Section 552(a)(1) 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* and not so published.”<sup>126</sup> Similarly, Section 552(a)(2) 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

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123. *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. U.S. DEPT OF JUSTICE, GUIDE TO THE FREEDOM OF INFORMATION ACT, (2016), available at <https://www.justice.gov/oip/doj-guide-freedom-information-act-0> (stating that agencies are instructed to make available copies of certain records that have been released to any person and provide a general index of those records).

124. 5 U.S.C. § 552(b)(7)(E).

125. *Id.* § 552(a)(1)-(2); *see also, e.g.*, *United States v. Mowat*, 582 F.2d 1194, 1199-1201 (9th Cir. 1978) (holding that the non-publication of a Department of the 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) (stating that “[a]lthough 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.”).

126. Freedom of Information Act, 42 U.S.C. § 552(a)(1) (2018).

of the terms thereof.”<sup>127</sup> 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.<sup>128</sup> Agency officials presumably already know that they cannot rely on guidance documents as binding precedent or a legal basis for enforcement penalties.

### 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 public access to government information and services as well as improve government decision-making.<sup>129</sup> 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*.”<sup>130</sup> Since Section 552(a) of title 5 of the *U.S. Code* requires at least some guidance documents to be published in the *Federal Register*, the E-Government Act applies to those guidance documents.<sup>131</sup>

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.<sup>132</sup> 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 they intend to make available to the public, and then to make that information searchable across agencies to improve public access and dissemination of government information.<sup>133</sup> That memorandum also provides that, when disseminating information to the public-at-large, agencies must publish information on the Internet.<sup>134</sup> These provisions apply as well to agencies’ dissemination of guidance documents.

127. *Id.* § 552(a)(2).

128. Executive Orders 13,891 and 13,892 arguably preclude an agency from relying on a guidance that has not been published in the *Federal Register* or posted on the agency’s website, but neither order is enforceable by a court. Exec. Order No. 13,891, *supra* note 15; Exec. Order No. 13,892, *supra* note 77. Moreover, since guidance is, by definition, non-binding, it is difficult to imagine a circumstance where an agency would find it adverse to be precluded from relying on a guidance document.

129. E-Government Act, 1 Pub. L. No. 107-347 (Dec. 17, 2002) (codified in scattered sections of 44 U.S.C.).

130. *Id.* § 206(b).

131. 44 U.S.C. § 3501 (2018).

132. E-Government Act, 1 Pub. L. No. 107-347, § 207(f)(2)(A)(ii).

133. 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>.

134. *Id.*

#### 4. The Congressional Review Act

Although the Congressional Review Act (CRA) does not address issues of general public accessibility of guidance documents, it requires agencies to notify Congress of the creation of guidance documents.<sup>135</sup> More generally, the CRA establishes a process for congressional review of agency rules and their possible disapproval by joint resolution.<sup>136</sup> 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).<sup>137</sup>

GAO has determined that certain guidance documents are “rules” under the CRA, meaning that such guidance will be subject to any publication requirements set forth in the statute. The CRA states that the word “rule” in the statute has the meaning given the term in section 551 of the Administrative Procedure Act, with certain exceptions.<sup>138</sup> The APA’s definition of 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, procedure, or practice requirements of an agency.”<sup>139</sup> 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.<sup>140</sup>

According to GAO, the CRA’s requirements apply to guidance documents that are general statements of policy, even though, by definition, they are not legally binding. In 2017, GAO’s general counsel issued a guidance letter indicating that, although a Consumer Financial Protection Bureau bulletin advising certain auto loan providers of steps to take to avoid liability under the Equal Credit Opportunity Act was non-binding, it nevertheless constituted a “rule” under the CRA.<sup>141</sup> 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.<sup>142</sup>

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135. 5 U.S.C. §§ 801-08 (2018).

136. *Id.* § 802.

137. *Id.* § 801(a)(1)(A)-(B).

138. *Id.* § 804(3).

139. 5 U.S.C. § 551(4) (2018).

140. 5 U.S.C. § 804(3) (2018).

141. Letter from Thomas H. Armstrong, General Counsel, U.S. Gov’t Accountability Off., to Senator Pat Toomey, U.S. Senate (Dec. 5, 2017), <https://www.gao.gov/assets/690/688763.pdf>. An earlier general counsel letter offered similar guidance on an interagency guidance related to the exercise of enforcement discretion with respect to the supervision of financial institutions. Letter from Susan A. Poling, General Counsel, U.S. Gov’t Accountability Office, to Senator Pat Toomey, U.S. Senate (Oct. 19, 2017), <https://www.gao.gov/assets/690/687879.pdf>.

142. Under broader definitions of guidance, many guidance documents will not be considered rules under the APA and thus will not be covered by the CRA. *See supra* Part I. For those guidance



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.”<sup>143</sup> Given that a guidance document is non-binding, it does not ever really “take effect” in any legally binding way, and for that reason is arguably not subject to the CRA’s reporting requirements—even though the general counsel at the GAO has concluded otherwise.<sup>144</sup> At the very least, any agency that fails to report a guidance document faces little, if any, meaningful consequence for such failure.<sup>145</sup>

## 5. Small Business Regulatory Enforcement Fairness Act

As noted in Part I, the Small Business Regulatory Enforcement Fairness Act of 1996<sup>146</sup> 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.”<sup>147</sup> 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.”<sup>148</sup>

### 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 by agencies themselves through regulations. This section does not purport to catalog all such agency-specific requirements. Instead, I begin by reviewing those that apply to guidance documents produced by the Food and Drug Administration (FDA), as FDA appears rather distinctive in being subject to a specific statutory requirement that it make its guidance documents public-

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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).

143. 5 U.S.C. § 801(a)(1)(A) (2018).

144. See Letter from Thomas H. Armstrong, *supra* note 141.

145. Keith Bradley & Larisa Vaysman, *CRA Resolutions Against Agency Guidance*, 4 U. PA. J.L. PUB. AFF. 459, 465 (2019).

146. Business Regulatory Enforcement Fairness Act of 1996, § 212, 5 U.S.C. § 601 (2011)

147. *Id.* § 212(a)(1), 5 U.S.C. § 605(b).

148. *Id.* § 212(a)(2)(A), 5 U.S.C. § 601.

ly available. I then report the findings from a systematic study of the *U.S. Code* and *Code of Federal Regulations* conducted in 2019, which looked for provisions related to public availability of guidance for fourteen agencies. In this section, I distinguish between provisions that apply generally to all or most guidance documents issued by an agency and those that apply to more specific types of guidance documents. Overall, more provisions were found related to specific guidance documents; few agencies appear to be subjected by statute or regulation to general agency-specific guidance policies, as FDA is.<sup>149</sup>

## 1. Requirements for Food and Drug Administration Guidance

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.<sup>150</sup> Without regard to the significance of guidance, the statute 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."<sup>151</sup>

Under 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.<sup>152</sup> 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."<sup>153</sup> 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."<sup>154</sup> The regulations state that, should comments come in

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149. This statement was valid as of the spring of 2019, when the report that forms the basis for this article was written. Since that time, ACUS has recommended that agencies develop their own internal plans for managing their guidance documents. ACUS, Recommendation 2019-3, *supra* note 76. Moreover, in October 2019, President Trump issued Executive Order 13,891 under which executive agencies will be expected to have in place "regulations . . . to set forth processes and procedures for issuing guidance documents" by no later than the end of August 2020. Exec. Order No. 13,891, *supra* note 15 at 55,237. Thus, in time, more agencies can be expected to subject themselves by regulation to various guidance policies. Perhaps unfortunately for the cause of guidance availability, though, Executive Order 13,891's requirement for agencies to develop regulations on guidance documents does not demand that such regulations include any internal records management plans or disclosure procedures of the kind that are recommended later in this article and in the ACUS recommendation.

150. 21 U.S.C. § 371(h)(3) (1997).

151. *Id.*

152. 21 C.F.R. § 10.115 (2018).

153. *Id.* § 10.115(g)(1)(iv)(B)-(C).

154. *Id.* § 10.115(g)(4)(i)(A).

later and lead FDA to revise a Level 2 guidance document, “the new version will be placed on the Internet.”<sup>155</sup> No equivalent assurance is provided in the regulation about posting any revisions to final Level 1 guidance documents.

Regardless of whether guidance is categorized as Level 1 or Level 2, the regulation states that any guidance document is required to:

- (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 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.<sup>156</sup>

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.”<sup>157</sup>

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.”<sup>158</sup> 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.”<sup>159</sup> 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.”<sup>160</sup>

## 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 FDA. In an effort to gauge more systematically how common such statutory or regulatory requirements might be, an intensive search was made of the *U.S. Code* and the *Code of Federal Regulations* for guidance disclosure provisions for fourteen agencies. Many of the requirements found relate to specific guidance documents, on specific issues or topics, rather than imposing any

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155. *Id.* § 10.115(g)(4)(i)(C).

156. *Id.* § 10.115(i)(1).

157. *Id.* § 10.115(i)(2).

158. *Id.* § 10.115(n)(1).

159. *Id.* § 10.115(n)(2).

160. *Id.* § 10.115(n)(3).

general agency-wide legal regimen for managing and disclosing all guidance documents (as with FDA).

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 guidance disclosure requirements imposed on a diverse group of federal agencies. To build on prior work on guidance availability discussed in Part I of this article, I included the four agencies that GAO audited in 2015 and the seven agencies discussed most extensively in the House Committee majority staff report.<sup>161</sup> The overall sample comprised the following fourteen agencies: Agriculture (USDA); Consumer Financial Protection Bureau (CFPB); Defense (DOD); Education (DOE); Department of Transportation (DOT); Environmental Protection Agency (EPA); Food and Drug Administration (FDA); Health and Human Services (HHS); Housing and Urban Development (HUD); Internal Revenue Service (IRS); Labor (DOL); National Highway Traffic Safety Administration (NHTSA); Securities and Exchange Commission (SEC); and 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).<sup>162</sup> Each provision was coded for whether it was: (1) “descriptive” versus “prescriptive,” that is, respectively, just documenting an agency’s practice of publishing guidance documents versus establishing a requirement or obligation; and (2) “general” versus “specific,” that is, respectively, 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

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161. STAFF OF H. COMM. ON OVERSIGHT & GOV’T REFORM, 115TH CONG., *supra* note 54. 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.

162. 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
<b>Total</b>	<b>3</b>	<b>10</b>	<b>18</b>	<b>32</b>	<b>0</b>	<b>69</b>	<b>132</b>

*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, and all of these were 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, with respect to the Federal Transit Administration (FTA), a descriptive provision at 49 C.F.R. § 601.10 stated 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 appeared at 12 C.F.R. § 1070.1, which stated 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.”

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 gen-

eral legal obligations with respect to guidance. Beyond FDA, only one other agency—DOT—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. Overall, 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.

#### 1. Generally Applicable Guidance on Guidance

OMB's Bulletin on good guidance practices—already mentioned in Part I of this article—provides standards that call for making guidance documents publicly available.<sup>163</sup> 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.”<sup>164</sup>

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 sub-agency's Web site—a current list of its significant guidance documents in effect.”<sup>165</sup> 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

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163. OMB BULLETIN, *supra* note 15, at 3432. Notably, the OMB Bulletin on good guidance practices does not require independent agencies to comply. *Id.* (noting that “[t]his 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).

164. *Id.* at 3433 (emphasis added).

165. *Id.* at 3440.

and their Web site links shall be added promptly to this list, no later than 30 days from the date of issuance.<sup>166</sup>

The list is also supposed to “identify significant guidance documents that have been added, revised or withdrawn in the past year.”<sup>167</sup> It is also supposed to be situated on the agency’s 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).”<sup>168</sup>

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.”<sup>169</sup> The Bulletin also calls on agencies to “[p]repare and post on the agency’s Web site a response-to-comments document.”<sup>170</sup>

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 documents that make up the day-to-day business of an agency could be of interest to the public.<sup>171</sup> The Bulletin states that it is important to avoid “inhibit[ing] the beneficial practice of agencies providing informal guidance to help specific parties.”<sup>172</sup>

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<sup>173</sup> in 2009 in response to a presidential memorandum on transparency and open government.<sup>174</sup> The Directive calls for executive agencies and departments to take steps to

166. *Id.*

167. *Id.*

168. *Id.* at 3437.

169. *Id.* at 3438.

170. *Id.* at 3440.

171. *See id.* at 3435 (stating that documents that are not “significant” do not fall within the definition of guidance document and are therefore not governed by the publication requirements imposed by the Bulletin).

172. *Id.*

173. 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].

174. Presidential Memorandum on Transparency and Open Government, 74 Fed. Reg. 4685 (Jan. 26, 2009).

expand access to information by making it available online in open formats.<sup>175</sup> OMB subsequently issued another memorandum which outlined supplemental best practices to assist agencies in their open government efforts.<sup>176</sup>

With respect to information made available on agency websites, Executive Order 13,642<sup>177</sup> and OMB Memorandum M-13-13<sup>178</sup> call for each executive agency to create an open data policy to support information processing and dissemination activities.<sup>179</sup> Under these policies, agencies are always encouraged to use machine-readable and open formats as well as make available certain core metadata for all new information. Following technical data-sharing standards like these in the context of agency guidance could make it easier for third parties—such as the Cornell Legal Information Institute<sup>180</sup>—to aggregate information and make linkages between statutes, agency rules, and agency guidance in ways that might productively advance public access and understanding. Further standards with broader implications relevant to the online dissemination of agency guidance documents come from the federal Digital Government Strategy<sup>181</sup> and the U.S. Digital Service Playbook.<sup>182</sup> 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 usable.<sup>183</sup> Information is supposed to be searchable and discoverable, which means that agencies' public websites must contain a search function and that agencies must ensure that all con-

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175. OMB MEMORANDUM M-10-06, *supra* note 173.

176. 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>.

177. Exec. Order No. 13,642, 78 Fed. Reg. 28,111 (May 14, 2013).

178. 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>.

179. *Id.*

180. *Welcome to LII*, CORNELL LEGAL INFORMATION INSTITUTE, <https://www.law.cornell.edu/> (last visited Mar. 24, 2020).

181. U.S. CHIEF INFO. OFFICER, 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> [hereinafter DIGITAL GOVERNMENT]. 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/>.

182. DIGITAL SERVICES PLAYBOOK, <https://playbook.cio.gov/> (last visited July 6, 2018).

183. 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>.



tent intended for public use on their websites can be indexed or searched by commonly used commercial search engines.<sup>184</sup>

## 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.”<sup>185</sup> 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.

DOT, for example, adopted a department-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.<sup>186</sup> 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<sup>187</sup> and to submit requests electronically

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184. In addition to the White House documents discussed in the text, Executive Order 13,891 also now imposes general standards for guidance availability. Exec. Order No. 13,891, *supra* note 15.

185. OMB BULLETIN, *supra* note 15, at 3440. Similarly, Executive Order 13891 imposes a requirement for agencies to develop regulations to this effect. Exec. Order No. 13,891, *supra* note 15, at 55,237.

186. Bradbury Memorandum, *supra* note 26, § 4.

187. Section 8(a) provides:

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

for issuance, reconsideration, modification, or rescission of guidance documents; and

(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.<sup>188</sup>

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.”<sup>189</sup> 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.”<sup>190</sup> Of course, as noted in Part I, DOT’s starting definition of a guidance document excludes many of the same categories of documents that the OMB Bulletin categorically excludes from its definition of significant guidance documents.<sup>191</sup>

#### 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, including guidance documents.<sup>192</sup> And FOIA specifically requires agencies either to publish certain guidance in the *Federal Register* or to make it available online.<sup>193</sup> But unlike with legislative rules, which 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. Guidance is inherently non-binding, which makes legal mechanisms that prevent unpublished or undisclosed guidance material from “taking effect” have little meaning. Furthermore, the OMB Bulletin on guidance, while applicable to executive agencies across the government, is itself non-binding

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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.

188. *Id.* § 4.

189. *Id.* § 4 n.6.

190. *Id.* § 7(a).

191. *See supra* Part I.

192. *See supra* Part II.A.

193. *See supra* notes 121-28 and accompanying text.

and thus provides no additional self-reinforcing mechanism to ensure agencies consistently and meaningfully make guidance materials accessible.<sup>194</sup>

Second, few agencies appear to be subject to meaningful agency-specific legal requirements. Based on a review of requirements for fourteen agencies, few statutory or regulatory provisions compel individual agencies to make all their guidance materials transparent.<sup>195</sup> A notable exception is FDA, which is subject both to statutory and regulatory provisions that address guidance availability across the board.<sup>196</sup> 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.<sup>197</sup> 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. Neither Congress nor many agencies, it appears, have adopted general rules addressing guidance availability in any holistic manner. Some agencies have, of course, adopted their own internal guidance procedures. But as these agency-made “guidance on guidance” policies are also non-binding, the extent of public accessibility to guidance documents at these agencies will depend, in the end, on how well such 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 exists by which agencies make their guidance documents known to the public.<sup>198</sup> 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. 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

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194. OMB BULLETIN, *supra* note 15. Much the same can be said of Executive Orders 13,891 and 13,892. *See supra* note 128. Moreover, given guidance documents’ non-binding status, it is hard to see how it would ever be essential for an agency to rely on guidance in any dispositive manner.

195. *See supra* Part II.B.2. As indicated *supra* in note 149, this can be expected to change as agencies implement Executive Order 13,891.

196. *See supra* Part II.B.1.

197. *See supra* Part II.B.2. 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.” 20 U.S.C. § 7904 (2002).

198. *See supra* Part II.B.2.

the readers of regulations can be expected to want to know about the existence of relevant agency guidance.<sup>199</sup>

Finally, the discovery of many descriptive statements and other provisions about individual guidance documents within agency-specific regulations reinforces that agencies do themselves recognize that it can be valuable to work to meet the management challenges related to making guidance documents accessible to the public.<sup>200</sup> The high volume and variety of guidance materials produced by agencies creates several management challenges: tracking the 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 date. In this regard, the fact that more than three-quarters (101 out of 132) of the guidance-specific requirements and descriptive statements were contained not in legislation but in the *Code of Federal Regulations*—that is, in rules created by agencies themselves—indicates that agencies are aware of and responding to the challenges of guidance management and availability.<sup>201</sup>

Even without a self-enforcing structure to create firm incentives for public accessibility, agencies do have intrinsic reasons to disseminate their guidance documents. These documents are produced, after all, to communicate helpful information to relevant segments of the public, including regulated entities. Guidance documents can only be helpful if those who would benefit from their information and assistance can find them. The volume and variety of guidance documents can make agencies' guidance management challenges seem daunting, and no matter how well an agency is currently managing guidance accessibility there will always exist opportunities to do better in meeting those challenges. The next Part of this article identifies some of these opportunities and offers suggestions about "best practices" that agencies can 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

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199. Such cross-references within the regulatory corpus will, of course, only be helpful to the extent that these references are accurate and kept up to date.

200. A full ninety 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. See *supra* Table 1.

201. 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 requirement. 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.

Bulletin, all point in the same direction: toward greater governmental transparency.<sup>202</sup> 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. Many agencies also have established dedicated webpages that provide lists of and links to their own significant guidance documents.

Yet especially in light of the concerns discussed in Part I.C of this article, agencies have opportunities to improve as well. Digital communication technology has given agencies exceptional tools for making guidance easier than ever to find. But technology by itself cannot offer a quick or easy fix to 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 management challenges as much as technological ones. In this Part of the article, I articulate these management challenges confronting agencies by reference to four core criteria of meaningful guidance availability that every agency should pursue. I first explicate these criteria and provide examples that illustrate opportunities for improvement with respect to each criterion. Then I turn to five types of “best practices” that agencies should consider adopting or refining in their effort to make the guidance documents they produce more readily available—and therefore more effective and helpful.

### 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 a 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.<sup>203</sup> Agencies need to make sure that relevant guidance documents that any of their employees, located anywhere, might produce are identified, and then that those documents which 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 agencies must provide a way of managing their collection of relevant non-binding materials that ensures the set of documents disclosed is *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.

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202. See *supra* Part II.

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

## 1. Comprehensiveness

Availability begins with completeness. If agency managers are to make guidance documents available to the public, they first 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 done much to illuminate its regulatory guidance, no matter how easy it might be to find that one available document. Focusing on the comprehensiveness of any agency's disclosure of guidance documents is a way of asking how well an agency is living up to its intentions about making its guidance documents available.<sup>204</sup>

At its best, a comprehensive system of guidance availability calls for an agency to identify the overall "population" of material that meets the relevant definition of guidance—and then to make all of that material available. This is a tall order, at least under the most capacious understanding of guidance.<sup>205</sup> Guidance, after all, 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.<sup>206</sup> 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 these agencies to determine what fraction of all guidance that should be made available online is actually available in this way. Because documents that are not disclosed are effectively invisible, at present it is simply not possible for an outside observer to say how comprehensively any agency is making its guidance available.

The extensiveness and elusiveness of guidance makes it difficult, if not impossible, to estimate a denominator to compute the fraction of all guidance that has been made available. In remarks made at an oral argument before the U.S. Supreme Court, Justice Stephen Breyer surmised that "[t]here are hundreds of thousands, possibly millions, of interpretive regulations"—just one type of agency guidance.<sup>207</sup> That estimate makes the number of documents reported to House Committee staff members last year pale in comparison. When the staff asked 46 agencies to provide lists of all guidance documents produced since 2008, the agen-

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

205. See *supra* Part I.

206. See *supra* notes 40-43 and accompanying text.

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

cies responded with lists containing a total of more than 13,000 entries.<sup>208</sup> That number clearly understated the real volume of guidance. We know that because the Committee staff reported that some agencies' lists contained fewer guidance documents than could be quickly found on their own websites.<sup>209</sup> Some agencies also openly acknowledged that their lists were incomplete, and eight agencies failed to provide any list at all.<sup>210</sup> 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 provides little confidence that most agencies have a comprehensive internal accounting of their own documents.<sup>211</sup>

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*. Such guidance appears to be rarely if ever issued, though, and no such published notices for economically significant guidance could be found in the course of this study.<sup>212</sup> 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, I conducted two searches 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*, they may use terms such as "guidance," "policy," or "interpretation," which I used as search terms. 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 five-year period of 2014-2018.<sup>213</sup>

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208. STAFF OF H. COMM. ON OVERSIGHT & GOV'T REFORM, 115TH CONG., *supra* note 54, at 2.

209. *Id.* at 14.

210. *Id.* at 9.

211. *Id.* at 4.

212. 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*.

213. These search results may include some documents announcing proposed guidance as well as final guidance, but the publication of proposed guidance is less common than that of rules. Still, it is 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 between 2008 and 2017. The "ac-

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
<b>Total</b>	<b>599</b>	<b>8691</b>

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

Getting similar aggregate estimates of guidance documents listed on agencies' websites is possible for some agencies.<sup>214</sup> For example, FDA has a well-organized and easily accessible list of guidance documents that can be readily used to com-

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tion" 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.

214. Approximately ten years ago, Connor Raso collected such data in an important study of guidance documents that he based on what agencies had posted online at that time. Connor N. Raso, Note, *Strategic or Sincere? Analyzing Agency Use of Guidance Documents*, 119 YALE L.J. 782, 811 n.140 (2010). Ironically, at that time, Raso found data to be unavailable for the Food and Drug Administration (FDA). *Id.* at 811. Yet today, FDA has one of the more sophisticated online repositories of guidance. Another difference between FDA and other agencies' online repositories: FDA 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. *Search for FDA Guidance Documents*, FDA, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents> (last visited Apr. 6, 2020).



pute an aggregate number of its guidance documents by year. FDA's website shows 823 documents issued from 2014-2018, with 544 labeled as final guidance (as opposed to those labeled as "draft").<sup>215</sup> 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.

Of course, even when reasonable estimates of numerators such as these 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.<sup>216</sup> As already noted, that denominator will be unknown to the public. The public cannot 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 are so crucial.<sup>217</sup> Only with internal controls can agency managers ever hope to provide comprehensive guidance disclosure. Presumably the public can have greater confidence in the comprehensiveness 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. The overarching aspiration should be for all agencies to make available online all of the documents that fall within their relevant definitions 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

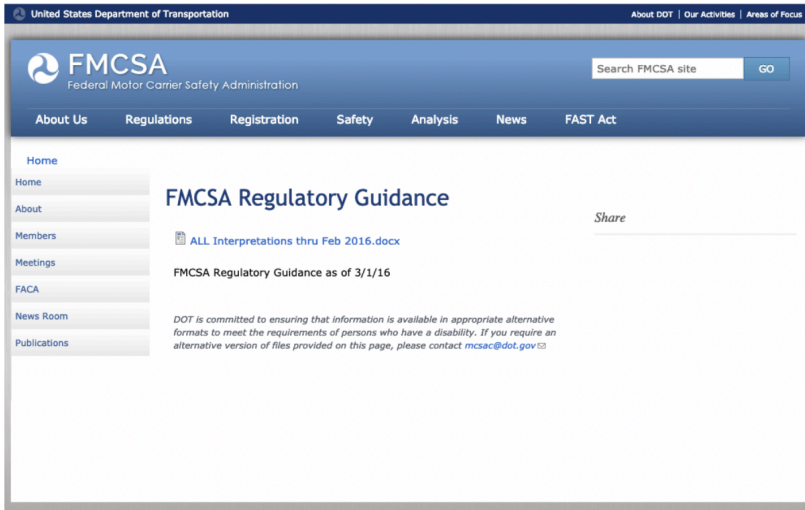
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215. *Search for FDA Guidance Documents*, FDA, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents> (last visited Apr. 6, 2020).

216. 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 perhaps 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.

217. U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note 80, at 35; *see also supra* Part I.C.2.

FIGURE 1: FMCSA REGULATORY GUIDANCE PAGE  
(NOT UPDATED IN OVER THREE YEARS)



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

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

The GAO reported that it had found the Labor Department’s Office of Labor Management Standards failed to “update its website in a timely manner to reflect guidance that would be affected by finalized regulation.”<sup>218</sup> At the time of my research (2019), the Federal Motor Carrier Safety Administration (FMCSA) had a webpage devoted to regulatory guidance that declared that it was last updated on March 1, 2016 (Figure 1), even though the agency had clearly announced additional guidance in the *Federal Register* after that time.<sup>219</sup>

218. U.S. GOV’T ACCOUNTABILITY OFFICE, *supra* note 80, at 38.

219. For some subsequent FMCSA guidance, see Commercial Driver’s License Standards, Requirements and Penalties, 84 Fed. Reg. 8464 (Mar. 8, 2019) (to be codified at 49 C.F.R. pts. 383-84), <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) (to be codified at 49 C.F.R. pt. 395), <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) (to be codified at 49 C.F.R. pt. 383), <https://www.federalregister.gov/documents/2017/08/03/2017-16338/commercial-drivers-license->

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.<sup>220</sup> Unfortunately, this does not always occur. For example, in September 2018, the Nuclear Regulatory Commission (NRC) announced in the *Federal Register* that it was withdrawing a 1994 guidance on “protection against malevolent use of vehicles at nuclear power plants.”<sup>221</sup> 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.”<sup>222</sup> 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.<sup>223</sup>

### 3. Accessibility

If members of the public cannot access guidance documents, they are not really available. For this reason, accessibility is an intuitive ingredient in securing the public availability of guidance. But access has multiple facets. In particular, 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

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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. Figure 1, as with all similar figures in this article capturing screenshots of agency webpages, was current as of the time of the initial preparation of the report on which this article is based—that is, the spring of 2019. As the Internet is dynamic, no image capture of a website can ever claim to be permanent or necessarily current, and thus no attempt was made to ensure that each figure in this article was still current throughout the time it took to publish this article. These figures are merely intended to illustrate general concerns that, even if they should no longer be applicable to the specific webpages identified in this report, will remain perennial concerns for agencies in making their guidance documents available to the public.

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

221. Nuclear Regulatory Comm’n, Protection Against Malevolent Use of Vehicles at Nuclear Power Plants, 83 Fed. Reg. 47,648 (Sept. 20, 2018).

222. *Id.*

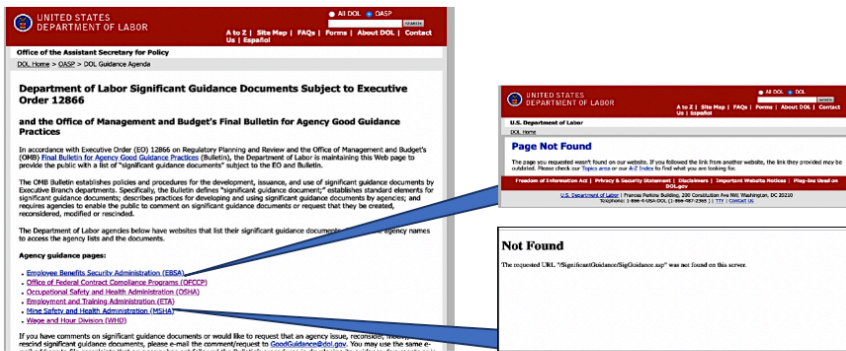
223. See U.S. NUCLEAR REGULATORY COMM’N, REGULATORY GUIDE 5.68, PROTECTION AGAINST MALEVOLENT USE OF VEHICLES AT NUCLEAR POWER PLANTS (1994), <https://www.nrc.gov/docs/ML0037/ML003739379.pdf>.

to specific rules, issues, or programs can be found in corresponding portions of agency websites.

One seemingly banal but still significant barrier to access must 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.<sup>224</sup> That webpage helpfully includes links to dedicated guidance pages for six sub-agencies within the Labor Department, and yet, as shown in Figure 2, the links pointing to two of these sub-agencies were broken at the time I conducted the research for this article.<sup>225</sup>

A similar malady afflicted the DOT's central guidance webpage: the links for five of the ten listed operating administrations were broken.<sup>226</sup> The Federal

FIGURE 2: BROKEN LINKS AS BARRIERS TO ACCESS



Source: <https://www.dol.gov/agencies/oasp/rulemaking/guidance>

Railroad Administration and Saint Lawrence Seaway Development Corporation were listed but not hyperlinked at all.<sup>227</sup> Still another two, the Federal Highway

224. OMB BULLETIN, *supra* note 15.

225. *Significant Guidance Documents Subject to Executive Order 12,866*, U.S. DEP'T OF LABOR, <https://www.dol.gov/agencies/oasp/rulemaking/guidance> (last visited Mar. 14, 2020).

226. At the time the research for this article was conducted in March 2019, the links were broken to the significant guidance pages for the Federal Aviation Administration, Federal Transit Administration, Maritime Administration, National Highway Traffic Safety Administration, and Pipeline and Hazardous Materials Safety Administration (PHMSA). *Lists of Significant DOT Guidance Documents*, U.S. DEP'T OF TRANSP., <https://www.transportation.gov/regulations/lists-significant-dot-guidance-documents> (last updated Aug. 28, 2019). When this webpage was later accessed during editing of this article in October 2019, the links for four of the five sub-agencies within DOT were still broken. Only the link to PHMSA had been fixed.

227. *Id.* The entry for the Federal Railroad Administration indicated that this sub-agency had no significant guidance.

Administration and Federal Motor Carrier Safety Administration, pointed to pages that contained no lists of or links to guidance documents.<sup>228</sup> In other words, other than the Office of the Secretary, none of the listed entries on the Department's main guidance page took the user to any guidance documents.<sup>229</sup>

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."<sup>230</sup>

As a simple test of accessibility for the present study, two research assistants were asked to find a dedicated guidance webpage for each of the 14 agencies listed in Part II.B.2.<sup>231</sup> The research assistants were given the objective of finding, for each of the 14 agencies, either (1) a single webpage listing all significant guidance documents or (2) a single webpage describing the guidance issued by the agency and where to find guidance. Overall, the research assistants successfully met their assigned objective, finding dedicated guidance pages for 12 of the 14 agencies.<sup>232</sup> 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, for each researcher, the two agencies that the researcher was unable to find differed, suggesting that the difficulties encountered may have been largely idiosyncratic rather than associated with deficiencies in any one agency's website design or execution.

An example of an agency's website that presented difficulty was that of the Securities and Exchange Commission (SEC). Rather than containing a single page labeled simply "guidance," the SEC site divided guidance material across two separate webpages: one legally labeled "interpretive releases," the other labeled

228. By October 2019, the link for the Federal Motor Carrier Administration did point the user to a page with regulations, which contained a link pointing to a further page where the user could click further links to find agency interpretations of some of its regulations. 49 *CFR Parts 300-399*, FED. MOTOR CARRIER SAFETY ADMIN., [https://www.fmcsa.dot.gov/regulations/title49/b/5/3?section\\_type=G](https://www.fmcsa.dot.gov/regulations/title49/b/5/3?section_type=G) (last accessed June 22, 2020).

229. The GAO also reported encountering broken links at various agencies' websites. U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note 80, at 33.

230. *Id.* at 33 n.39.

231. One researcher was a lawyer; the other was a nonlawyer but a college graduate.

232. 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 nonlawyer researcher reported being unable to locate a dedicated guidance page for the SEC. That same nonlawyer research assistant also found she needed to leave the agency website and use Google to find the dedicated webpage for another agency (FTC).

“policy statements.”<sup>233</sup> Even though the links to these pages were fully operational, 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 report having any difficulty with the SEC’s website, 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 website reinforces a more general finding from the GAO’s audit: “[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.”<sup>234</sup>

To make guidance access meaningful and real, agency officials should strive to avoid user confusion. At a minimum, they can maintain a central webpage devoted to guidance that, if necessary, links to additional pages where guidance may be found.<sup>235</sup> 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. Finally, agencies can 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 for guidance in related entries for regulations published in the *Federal Register* or *Code of Federal Regulations*.

#### 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 these documents are non-binding. Yet some agency websites that contain lists of guidance documents do not even explain what “guidance” means. And 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—both at the level of webpages and individual documents.

Consider first the SEC’s website noted above. At the time of this study, the SEC did not have a central, dedicated webpage for all of its guidance documents;

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233. *SEC Interpretive Releases*, SEC, <https://www.sec.gov/rules/interp.shtml> (last modified Feb. 25, 2020); *SEC Policy Statements*, SEC, <https://www.sec.gov/rules/policy.shtml> (last modified Oct. 24, 2019). If the SEC’s division of guidance across these two different pages were not challenging enough for some members of the public, the Commission’s website also included yet a third, separate page for agency staff-created guidance: <https://www.sec.gov/interps.shtml>. The staff guidance page contained no visible references or links to the two pages for Commission-issued interpretive releases and policy statements, nor vice versa.

234. U.S. GOV’T ACCOUNTABILITY OFFICE, *supra* note 80, at 38.

235. Executive Order 13,891 now requires that all executive branch agencies establish just such a central webpage dedicated to guidance. Exec. Order No. 13,891, *supra* note 15.

instead, as already noted, it had a webpage that listed “interpretive releases” as well as a separate webpage for “policy statements” (Figure 3). But nowhere on either of these two webpages did the Commission provide any meaningful explanation of what constitutes an “interpretive release” or a “policy statement,” nor did it explain how these documents might differ from each other or differ from what appears on a still separate webpage for “final rules.”<sup>236</sup> The lack of comprehensibility created by the separation of lists of guidance documents onto two pages, and the use of legalistic labels rather than the plainer word “guidance,” undoubtedly helped to explain why, as noted in the preceding section, one of the researchers involved in this study was unable to locate a central webpage for guidance documents at the SEC, notwithstanding considerable search.<sup>237</sup>

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. In October 2013, 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. The agencies first published joint “proposed standards” in the

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236. The SEC webpage for policy statements merely stated that the Commission sometimes “issues a ‘policy statement’ to clarify its position on a particular matter,” while the agency’s webpage for interpretive releases merely said that sometimes the SEC issues “‘interpretive’ releases, in which we publish our views and interpret the federal securities laws and SEC regulations.” *Policy Statements*, SEC, <https://www.sec.gov/rules/policy.shtml> (last modified Oct. 24, 2019); *Interpretive Releases*, SEC, <https://www.sec.gov/rules/interp.shtml> (last modified Feb. 25, 2020). Nowhere on these pages did the Commission describe these documents in any less tautological terms. It also did not explain its view of the legal status of either of these documents nor did it explain what differentiates a policy statement from an interpretive release. The SEC webpage for its staff-created guidance, discussed *supra* at note 233, offers only a marginally more illuminating description: “This page provides links to written and oral statements made by members of the SEC’s staff on various accounting and legal matters. These staff interpretations provide guidance to those who must comply with the federal securities laws. However, because they represent the views of the staff, they are not legally binding.” *Staff Interpretations*, SEC, <https://www.sec.gov/interps.shtml> (last modified Nov. 25, 2019). Arguably, this description of staff-issued guidance sows confusion for the public about the binding nature of Commission-issued guidance, as it suggests that the former is not binding solely because it is staff-issued. Members of the public could reasonably, but erroneously, infer from this description that Commission-issued interpretive releases and policy statements are binding.

237. 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 nor the central page for staff interpretations.

FIGURE 3: SEPARATE WEBPAGES FOR SEC GUIDANCE

The screenshot shows the SEC's website for Policy Statements. At the top left is the SEC logo. To its right is the text 'U.S. SECURITIES AND EXCHANGE COMMISSION'. A search bar is located at the top right. Below the header is a dark navigation bar with links: ABOUT, DIVISIONS & OFFICES, ENFORCEMENT, REGULATION, EDUCATION, FILINGS, NEWS. On the left is a 'REGULATORY ACTIONS' sidebar with links like 'Rulemaking Index', 'Proposed Rules', etc. The main content area is titled 'SEC Policy Statements' and contains a paragraph explaining the Commission's use of policy statements. Below this is a table with columns 'Release No.', 'Date', and 'Details'. The table lists three recent statements. To the right of the table is a 'Quick Links' box with a link to 'How to Submit Comments'.

Release No.	Date	Details
34-84511	Oct. 31, 2018	<b>Commission Statement on Certain Provisions of Business Conduct Standards for Security- Based Swap Dealers and Major Security-Based Swap Participants</b> (Conformed to Federal Register version) <i>File No.:</i> 57-24-18 <i>Effective Date:</i> November 6, 2018 <i>See also:</i> Comments from Church Alliance and IIB/SIFMA
34-80870	Jun. 7, 2017	<b>Commission Statement Concerning a Request Made Pursuant to Exchange Act Rule 3a68-2</b> <i>See also:</i> Exhibits
34-75050	May 27, 2015	<b>Final Interagency Policy Statement Establishing Joint Standards for Assessing the Diversity Policies and Practices of Entities Regulated by the Agencies</b>

Source: <https://www.sec.gov/rules/policy.shtml>

*Federal Register* and solicited public comment.<sup>238</sup> 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.<sup>239</sup>

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.<sup>240</sup> Other comments urged the agencies to “clarify that the final Policy Statement is a guidance document”<sup>241</sup> and to “frame the final Policy Statement as a ‘best practices’ guide with which regulated entities were not required to comply.”<sup>242</sup> In response to these comments, the agencies did eventually

238. 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).

239. For example, comments could be emailed to [rule-comments@sec.gov](mailto:rule-comments@sec.gov), “[regcomments@nca.gov](mailto:regcomments@nca.gov),” “[regs.comments@federalreserve.gov](mailto:regs.comments@federalreserve.gov),” and “[regs.comments@occ.treas.gov](mailto:regs.comments@occ.treas.gov).” *Id.* at 64,053. They could be submitted online at “[www.regulations.gov](http://www.regulations.gov),” “[www.nca.gov/Legal/Regs/Pages/PropRegs.aspx](http://www.nca.gov/Legal/Regs/Pages/PropRegs.aspx),” and “<http://www.federalreserve.gov/apps/foia/proposedregs.aspx>.” *Id.*

240. 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).

241. *Id.*

242. *Id.*



realize that they needed to clarify the non-binding nature of what they had proposed. In their final policy statement, the agencies inserted the following text as the document's second paragraph:

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.<sup>243</sup>

The agencies admitted that "it [was] clear that [they] need[ed] to provide additional guidance about the intended legal effect of the final Policy Statement."<sup>244</sup>

Many agencies can do more to make clear 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. They can also better attend to comprehensibility in individual guidance documents, by making sure to include notations that indicate that such documents are non-binding and are intended merely to provide assistance and clarity.<sup>245</sup>

### B. *Best Practices in Guidance Availability*

As the examples in the preceding section indicate, agencies can make their guidance documents more meaningfully available to the public in terms of four key criteria. 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*. In this section, I turn to the following five general "best practices" to show how some agencies are already taking steps to increase the availability of their guidance. Along with common sense and a commitment to continuous improvement, these best practices will point the way toward the more concrete recommendations offered in the final Part of this article for agencies to develop an operational framework that will enhance the availability and helpfulness of their guidance documents.

#### 1. Internal Management

Throughout this article, I have emphasized that improving the public availability of guidance documents is ultimately a management challenge. Fortunately, modern technology offers tools that make it easier than ever before to manage records and make them downloadable over the Internet to interested individuals

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243. *Id.* at 33,022.

244. *Id.* at 33,017.

245. Executive Order 13,891 now directs executive agencies to do just this. Exec. Order No. 13,891, *supra* note 15, at 55,237.

wherever they may be. But these technological tools are not self-executing. They depend on agency managers and employees regularly tending to the steady flow of documents that make up the guidance production process, flagging those documents for initial review, and then tracking them to make 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 DOT and FDA have adopted as described in Part II of this article.<sup>246</sup> 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, such as 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 all 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.<sup>247</sup>

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246. As indicated *supra* at note 149, agencies are now expected to have in place their own internal regulations on the development of guidance documents. Exec. Order No. 13,891, *supra* note 15, at 55,237.

247. *How to Use the Unified Agenda*, OFFICE OF INFO. & REGULATORY AFFAIRS, [https://www.reginfo.gov/public/jsp/eAgenda/StaticContent/UA\\_HowTo.myjsp](https://www.reginfo.gov/public/jsp/eAgenda/StaticContent/UA_HowTo.myjsp) (last visited May 13, 2019) (italics added). The Unified Agenda further states that “[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.” *Id.*

The value ascribed to RINs would apply as well to a similar numbering system applied to guidance documents.

Agency systems for tracking and managing guidance documents could be fruitfully based around GINs—Guidance Identification Numbers.<sup>248</sup> Each guidance document, or at least each significant guidance document, could receive such a number as soon as it begins the internal review process. That number could then remain with the document when it is released as a draft for public comment, and then later appear on the final version that is posted online or published in the *Federal Register* (or both). That number could also be used still later if the guidance 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 a rule could be linked with that rule (perhaps via a corresponding RIN). Such a guidance identification numbering system 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 Regulations*, much as some agencies currently do with descriptive statements discussed in Part II of this article.<sup>249</sup>

Additional analysis should be undertaken before establishing a guidance identification numbering system. One question to ask would be whether to pursue a government-wide system, such as might be implied by the analogy I have drawn to 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 in rulemaking preambles or in relevant sections of CFR about the availability (or likely availability) of guidance. Such notations could then facilitate user searches on an agency's guidance webpage.

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248. The OIRA Memorandum implementing Executive Order 13,891 requires agencies to list an “identifier” in connection with each guidance document posted on the agency website. OIRA Memorandum, *supra* note 15, at 6. Unfortunately, nothing in this memorandum clearly demands that agencies should develop uniform standards for their identifiers. When agencies list such identifiers, they sometimes appear to have been assigned in an ad hoc manner rather than necessarily implemented in the consistent manner envisioned in the following discussion of a proposed system of GINs. For example, a quick perusal of the EPA air office's webpage on guidance documents includes identifiers with multiple prefixes (e.g., OTAG, CD, EPA, OAQPS). See *Guidance Documents Managed by the Office of Air and Radiation*, EPA, <https://www.epa.gov/guidance/guidance-documents-managed-office-air-and-radiation> (last updated Mar. 27, 2020). Perhaps these differences have some underlying rhyme and reason, but no explanation for what these different prefixes mean is provided on the EPA's website. One can only surmise that the very short time period agencies were given to implement an identifier system under the executive order—namely, just four months—precluded more thoughtful and careful implementation of this requirement.

249. See *supra* notes 198-99 and accompanying text.

All agency employees involved in the development or use of guidance—or anyone who might possibly become involved—should receive training in their 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 exist for continuous improvement.

At least some of these internal management practices have been adopted already by some agencies. At FDA, for example, “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.”<sup>250</sup> 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.”<sup>251</sup> 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.”<sup>252</sup> According to 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 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.<sup>253</sup>

Although FDA has noted that it has been in “the process of updating and enhancing this tracking system,”<sup>254</sup> the general structure described above provides a model of the type of managerial system needed to pursue the four criteria of guidance availability discussed earlier in this Part.

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250. FDA, REPORT ON GOOD GUIDANCE PRACTICES 8-9 (2011), <https://www.fda.gov/downloads/AboutFDA/Transparency/TransparencyInitiative/UCM285124.pdf>.

251. U.S. GOV’T ACCOUNTABILITY OFFICE, *supra* note 80, at 11.

252. *Id.*

253. FDA, REPORT ON GOOD GUIDANCE PRACTICES 9 (2011), <https://www.fda.gov/downloads/AboutFDA/Transparency/TransparencyInitiative/UCM285124.pdf>.

254. *Id.*

The GAO has reported that other agencies have found value in giving priority to the management of guidance documents. For example, GAO noted that the Department of Labor's Office of Federal Contract Compliance Programs' "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.<sup>255</sup> Other agencies can expect to find similar advantages from establishing internal controls 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 article, during my research for this article, I identified two rather simple website design features already being used by some agencies to facilitate online access to guidance documents. First, some agencies use simple words, such as "guidance," to title or label their relevant webpages, rather than relying on legalistic terms such as "interpretative rules" or "policy statements," which are less comprehensible to many users (including lawyers).<sup>256</sup> Second, a number of agencies include a designated tab or an option for "guidance" on a pull-down menu from their website's home page to lead the user to a centralized guidance webpage.<sup>257</sup> More agencies should follow both of these simple best practices.

Beyond these two small recommendations, three much larger design choices confront agencies when creating 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).<sup>258</sup> 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

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255. U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note 80, at 38.

256. See *supra* Part III.A.3. Under the OIRA Memorandum implementing Executive Order 13,871, each agency is supposed to create a dedicated guidance webpage designated with the URL "www.[agencyname].gov/guidance." OIRA Memorandum, *supra* note 15, at 5.

257. For a similar emphasis on access to links to rulemaking materials on an agency's homepage, see Cary Coglianese, *Enhancing Public Access to Online Rulemaking Information*, 2 MICH. J. ENVTL. & ADMIN. L. 1, 27-28, 31-33, 47-52 (2012).

258. *Significant Guidance Documents*, EPA (last updated Nov. 5, 2019), <https://www.epa.gov/laws-regulations/significant-guidance-documents> (pointing users to "view or comment on" documents falling into the categories of "air," "chemical safety and pollution prevention," "land and emergency management," "science," and "water").

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 agencies that go the route of different pages for different topics, or for different sub-agencies or offices within the agency, would still do well to follow EPA's lead and create a single top-level page that includes an index and links to each of the separate pages.<sup>259</sup> The SEC, for example, could easily reduce any confusion created by 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."

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 on 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. This is a workable option for most agencies without many guidance documents to make available online. FDA, however, has opted for the latter (Figure 5). Under FDA's approach, 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 to the user 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. Such a strategy can also facilitate better, more fine-grained searches by the user; a site such as EPA's is largely searchable only by the search bar on the user's browser.<sup>260</sup>

Finally, agencies face a third choice about what metadata (or data fields) to associate with each guidance document, and then whether to include these in either tabular form on a website or within the searchable fields in 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 the physical or screen space available with a webpage. Agencies will need to choose the fields, but some obvious options

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259. Doing so also accords with the OMB Bulletin's call for a centralized online location for an agency's significant guidance. OMB BULLETIN, *supra* note 15.

260. A back-end database offers another plus in that it can be integrated into the agency's internal guidance tracking system, discussed *supra*, 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)	<a href="#">Comment</a>	<a href="#">Learn More</a>	11/19/2001	08/23/2007	n/a
2003 Water Quality Trading Policy	<a href="#">Comment</a>	<a href="#">Learn More</a>	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)	<a href="#">Comment</a>	<a href="#">Learn More</a>	08/05/2005	08/23/2007	n/a

Source: <https://www.epa.gov/laws-regulations/significant-guidance-documents-water>

FIGURE 5: FDA SEARCH INTERFACE

**Search All Guidance Documents:**

Showing 1 to 10 of 2,700 entries

**Filter Results** ^

<b>Product</b>	<b>Subject</b>
<input type="text"/>	<input type="text"/>
<b>Date Issued</b>	<b>Draft or Final</b>
<input type="text"/>	<input type="text"/>
<b>FDA Organization</b>	<b>Open for Comment*</b>
<input type="text"/>	<input type="text"/>
<b>Document Type</b>	<b>Comment Closing Date on Draft*</b>
<input type="text"/>	<input type="text"/>

Source: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>

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
<a href="#">CVM GFI #120 Veterinary Feed Directive Regulation Questions and Answers</a>	03/28/2019	CVM	Feed	Draft	Yes	05/28/2019	<a href="#">FDA-2010-N-0155</a>
<a href="#">Pediatric Information Incorporated into Human Prescription Drug and Biological Products Labeling Good Review Practice</a>	03/27/2019	CDER	Labeling	Final	No		
<a href="#">Standards Development and the Use of Standards in Regulatory Submissions Reviewed in the Center for Biologics Evaluation and Research; Guidance for Industry</a>	03/25/2019	CDER	Administrative / Procedural	Final	No		<a href="#">FDA-2017-D-6535</a>
<a href="#">Rare Diseases: Natural History Studies for Drug Development</a>	03/22/2019	CDER		Draft	No		

Source: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>

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

Second, notwithstanding the merits 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



FIGURE 7: SEC SMALL BUSINESS COMPLIANCE GUIDE WEBPAGE

The screenshot shows the top portion of the SEC website. On the left is the SEC logo. In the center, the text reads "U.S. SECURITIES AND EXCHANGE COMMISSION". On the right is a search bar with the text "Search SEC.gov" and a magnifying glass icon, with links for "COMPANY FILINGS" and "MORE SEARCH OPTIONS". Below this is a dark blue navigation bar with white text for "ABOUT", "DIVISIONS & OFFICES", "ENFORCEMENT", "REGULATION", "EDUCATION", "FILINGS", and "NEWS".

Below the navigation bar is a sidebar menu with the following items: Corporation Finance, About, Accounting and Financial Reporting Guidance, Compliance and Disclosure Interpretations, Filing Review Process, Financial Reporting Manual, No-Action, Interpretive and Exemptive Letters, Statutes, Rules and Forms, Small Business, and Contact Us. The "Small Business" item is highlighted.

The main content area is titled "Small Business Compliance Guides". Below the title is a paragraph: "The following small business compliance guides provide information on SEC rules related to offering and selling securities as well as on financial and other reporting by publicly traded companies." This is followed by a bulleted list of links:

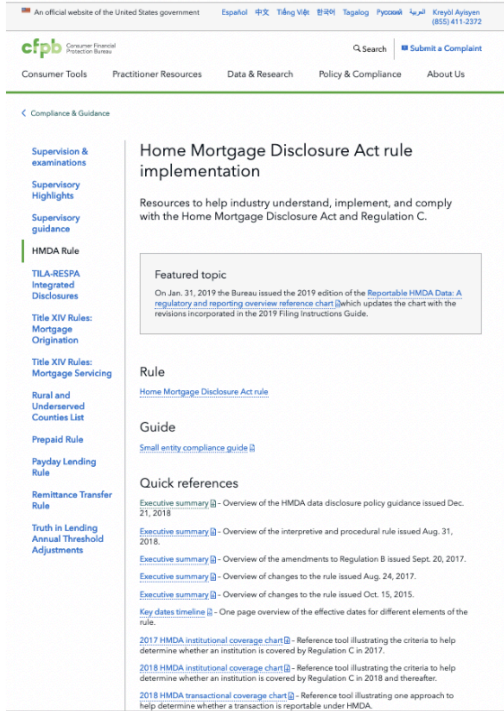
- Covered Investment Fund Research Reports
- Disclosure of Hedging by Employees, Officers and Directors
- Disclosure Update and Simplification
- Operating Company Inline XBRL Filing of Tagged Data
- Open-End Management Investment Company Inline XBRL Filing of Tagged Data
- Amendments to the Smaller Reporting Company Definition
- Optional Internet Availability of Investment Company Shareholder Reports Rules
- Exhibit Hyperlinks and HTML Format
- Amendment to Securities Transaction Settlement Cycle
- Intrastate Offering Exemptions (Rules 147 and 147A)
- Rule 504 of Regulation D
- Investment Company Liquidity Risk Management Program Rules
- Investment Company Reporting Modernization Rules
- Investment Company Swing Pricing
- Form ADV and Investment Advisers Act Rules

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

who will look for their guidance documents in different ways.<sup>261</sup> Many users will undoubtedly use search engines. Others will benefit from information on webpages devoted to related regulations or topics, perhaps because they already know the landscape sufficiently well to look directly to specific webpages for relevant guidance documents. But other users will be seeking a general understanding of the landscape of the agency's overall rules, programs, and practices. These users will seek the information and reassurance that can best 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 can be found on the agency's website. In terms of best practices, 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, including the creation of easily accessible centralized guidance webpages.

261. Cf. Coglianesi, *supra* note 257, at 39 (noting that "agencies confront the particular challenge that their websites serve multiple audiences").

FIGURE 8: CFPB TOPICAL WEBPAGE



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

### 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.<sup>262</sup>

Best practices would call for agencies to heed this ACUS recommendation for all of their guidance documents. The OMB Bulletin on guidance states that signifi-

262. ACUS, Recommendation 2017-5, *supra* note 1.

cant 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.’”<sup>263</sup>

The Department of Justice has adopted a similar policy: “[g]uidance 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.”<sup>264</sup> 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.”<sup>265</sup>

In addition, ACUS Recommendation 2017-3<sup>266</sup> accentuates requirements in the Plain Writing Act of 2010<sup>267</sup> and in Executive Order 13,563<sup>268</sup> by urging agencies to use plain language when drafting guidance documents:

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 . . . [A]gencies should [also] 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.<sup>269</sup>

Agency officials should strive to apply these recommended drafting practices not merely when developing guidance documents, but also when designing their dedicated webpages as called for by the OMB Bulletin.<sup>270</sup> 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

263. OMB BULLETIN, *supra* note 15, at 3437.

264. Memorandum from Jeff Sessions, Att’y Gen., U.S. Dep’t of Justice 2 (Nov. 16, 2017), <https://www.justice.gov/opa/press-release/file/1012271/download>.

265. *Id.*

266. ACUS, Recommendation 2017-3, Plain Language in Regulatory Drafting, 82 Fed. Reg. 61,728, 61,728 (Dec. 29, 2017).

267. Plain Writing Act, Pub. L. No. 111-274, 124 Stat. 2861 (2010).

268. Exec. Order No. 13,563, 76 Fed. Reg. 3821 (Jan. 21, 2011).

269. ACUS, Recommendation 2017-3, Plain Language in Regulatory Drafting, 82 Fed. Reg. 61,728, 61,730 (Dec. 29, 2017).

270. OMB BULLETIN, *supra* note 15, at 3437-38.

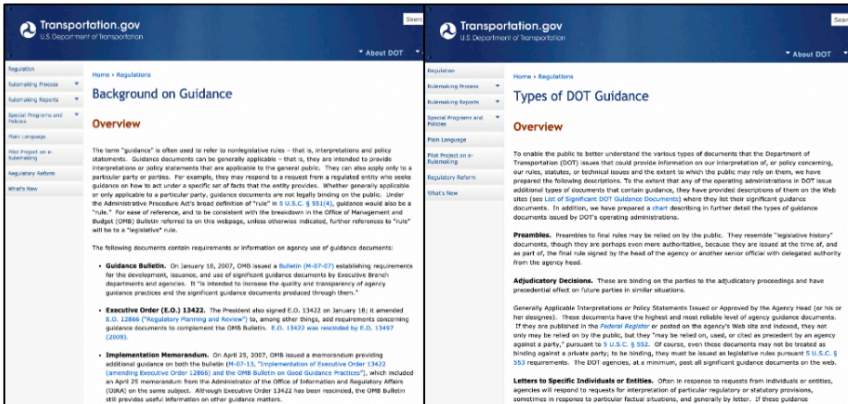
Department of Transportation’s guidance page links to a page that provides a “Background on Guidance,” shown in Figure 9, that offers an excellent model for other agencies to follow in this regard. As with the Department of Transportation, the Internal Revenue Service provides a “primer” on common kinds of guidance documents issued by the agency.<sup>271</sup>

#### 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 to find it, not everyone 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 will not know that such a document 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

FIGURE 9: DEPARTMENT OF TRANSPORTATION GUIDANCE EXPLAINER PAGES



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

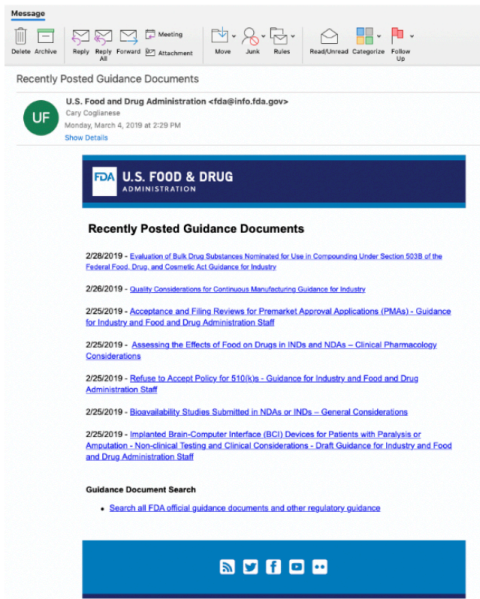
271. *Understanding IRS Guidance*, IRS, <https://www.irs.gov/newsroom/understanding-irs-guidance-a-brief-primer> (last updated Nov. 6, 2019).

disseminate alerts about new guidance.<sup>272</sup> 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.”<sup>273</sup>

Officials sometimes try 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.<sup>274</sup> GAO reports that some agencies reach out to “the public directly through conferences, webinars, media outreach, or public awareness campaigns.”<sup>275</sup>

At OSHA, officials report 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.”<sup>276</sup> At FDA,

FIGURE 10: FDA EMAIL LISTING “RECENTLY POSTED GUIDANCE DOCUMENTS”



Source: FDA guidance document email update, with subscriptions available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>

272. U.S. GOV’T ACCOUNTABILITY OFFICE, *supra* note 80, at 32.

273. *Id.* at 33.

274. *Id.*

275. *Id.*

276. *Id.*

“all the Centers/Offices conduct outreach on significant guidance, which may include, among other things, press releases, workshops, and social media.”<sup>277</sup> 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 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.”<sup>278</sup> Agencies should consider including in their guidance management strategies a range of possible affirmative efforts to inform relevant portions of the public, including the regulated community, of new or revised agency guidance.

## 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.<sup>279</sup> Listening to feedback from interested members of the public can help inform agency officials about the big picture of how well their guidance management and dissemination strategies are working. It can also 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.<sup>280</sup> 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.<sup>281</sup> 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

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277. FDA, REPORT ON GOOD GUIDANCE PRACTICES 16 (2011), <https://www.fda.gov/downloads/AboutFDA/Transparency/TransparencyInitiative/UCM285124.pdf>.

278. ACUS, Recommendation 2013-5, Social Media in Rulemaking, 78 Fed. Reg. 76,269, 76,270 (Dec. 17, 2013).

279. 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>.

280. OMB BULLETIN, *supra* note 15, at 3437.

281. *Id.* at 3440.

FIGURE 11: EPA SIGNIFICANT GUIDANCE COMMENT FORM

The image shows two parts of the EPA website. On the left is a screenshot of the 'Significant Guidance Documents by Environmental Topic' page, which lists various topics like Air, Chemical Safety and Pollution Prevention, and Land and Emergency Response. On the right is a callout box containing the 'Significant Guidance Comment Form'. This form includes instructions for submitting comments, contact information for the Office of Policy (1303A), and a note about overnight deliveries.

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

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.”<sup>282</sup> As noted earlier, inviting feedback in this way can help agencies ensure that they are maintaining a comprehensive and current list of guidance.

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.”<sup>283</sup> 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 improvement.<sup>284</sup>

#### IV. RECOMMENDATIONS FOR ENHANCING GUIDANCE AVAILABILITY

The best practices described in the preceding section aim to improve guidance availability judged against one or more of the four key “open guidance” criteria

282. *Significant Guidance Documents*, EPA, <https://www.epa.gov/laws-regulations/significant-guidance-documents> (last visited Mar. 27, 2020). 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.

283. DIGITAL SERVICES PLAYBOOK, *supra* note 182; *see also* DIGITAL GOVERNMENT, *supra* note 181, at 22.

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

discussed in Part III.A: *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 criteria will always be important for agency lawyers and managers to keep in mind as they consider concrete ways to enhance the availability of their organizations' guidance documents.

At the same time, the precise steps that any agency should take to implement any of the best practices presented here—and even which ones to adopt or to adopt first—will necessarily depend on a variety of other 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 public's need to find guidance and the current gaps in filling that need, and a variety of other relevant institutional considerations, such as the agency's organizational capacity and resources. Nevertheless, all of the best practices identified in this article 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.

To summarize and distill the best practices into an overarching plan to guide agency action, I offer in this Part a series of concrete recommendations for any agency seeking to improve its management of guidance documents and their public availability. These recommendations are organized into the same basic five categories as the best practices elaborated in the preceding section. This final Part of the article can thus be viewed as offering a checklist of steps for each agency to take, recognizing of course that each agency will need to adapt these steps to their own circumstances. Agencies do, after all, vary considerably, as do their guidance documents and the audiences for these documents. Any checklist of recommendations should obviously be approached flexibly and adapted as appropriate by different agencies. Still, it is possible to generalize by recommending a series of concrete "next steps" that any agency would do well to pursue to improve the availability of their guidance, if they have not already done so.<sup>285</sup>

1. *Develop and implement a system for internal management.* The first step for an agency to take 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 article, an

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285. On the basis of the study on which this article is based, ACUS has adopted a series of recommendations that, in many key ways, track those presented in this final Part. ACUS, Recommendation 2019-3, *supra* note 76. Some of these recommendations are also reflected in Executive Order 13,891 and the OIRA Memorandum implementing the order. *See supra* note 15.



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.<sup>286</sup> It will prove helpful for the agency also to make clear exactly what types of documents it considers 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. An agency's procedures can also include specific examples of documents either considered or not considered to fall within different categories.

An agency's written procedures should also include standards for the development of guidance documents. The procedures should address the steps for internal review, public comment (if any), periodic review of existing documents, and, most relevant here, the publication and dissemination of draft or final guidance documents. The agency should indicate the extent to which any of its procedural steps will vary depending on whether a guidance document falls into a specific category, such as might be appropriate for 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. If doubts arise when implementing the agency's open guidance procedures 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 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 website, in public announcements, or in the *Federal Register* or the *Code of Federal Regulations*. 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 guidance will generate a comprehensive list or database of an agency's guidance documents. At a minimum, this list or database should include all guidance documents required to

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286. OMB BULLETIN, *supra* note 15.

be published in the *Federal Register*, as outlined in Part II of this article, and all other guidance documents required to be made publicly available by the agency's written procedures and any other applicable standards. 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. No matter how a guidance document list or database might be structured, agencies should strive to keep such lists or databases fully 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 changes in terms of withdrawal or revision.

2. *Provide easy online access to guidance documents.* Each agency should maintain a central webpage dedicated to guidance documents, even if that central page merely contains links directing users to separate guidance-related pages organized by topic, type of guidance document, or agency office or sub-division. Even if the agency does create (and link to) multiple guidance pages, each agency should still 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 of 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.

This central guidance webpage is also an excellent place for the agency to provide explanatory content in simple language about what constitutes guidance and what legal status it holds.

An agency's overall 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 should 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 where to look for

agency guidance documents or may look for them in different ways, agencies should include notations and links to guidance documents at appropriate places within 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. *Deploy clear labeling and explanations for guidance.* Merely making guidance materials available online is not sufficient. Not only must any agency guidance webpages be easy to find, but they should be designed to ensure that they are as helpful to the 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. Agencies should also make available plain language explanations—sometimes called explainers—that define guidance, state its legal effect, and give examples of different types of guidance.

When displayed on webpages, guidance documents should be appropriately indexed and tagged, or made available in sortable tables. Search results from 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, but only if withdrawn or superseded documents are clearly labeled as out of date.

4. *Undertake affirmative outreach to the public.* Agencies should do more than merely upload new or revised guidance documents to their websites. They should also take affirmative steps to reach out to potentially interested members of the public by using listservs and social media to bring new or revised guidance documents to the attention of busy individuals who have many other demands on their attention. In addition to using social media and allowing members of the public to sign up for listservs, agencies should have agency staff speak about guidance documents at relevant conferences, as well as disseminate 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. At a minimum, agencies should periodically, at least once per year, 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. Such a notice need not itself provide the full list of guidance documents, but it can merely inform the public of its existence. An internal procedure that calls for providing such a notice on an annual basis can also help leverage

the ongoing maintenance of an agency's guidance corpus and serve to reinforce the implementation of its written procedures.

5. *Seek public feedback and engage in continuous review.* 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. Provisions for such periodic review should be included in the agency's written guidance procedures.

## CONCLUSION

Although I have focused in this article on what agencies can do to improve the public availability of guidance documents, many agencies do already provide considerable online access to such documents. The research conducted for this article suggests, for example, that most agencies have already devoted some space on their websites where members of the public can find information about guidance documents. Some agencies, such as 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 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 to be 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 article. But these broader criticisms need not be accepted to see the need for further action to promote 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 administra-

tion counsel in favor of governmental transparency and hence support efforts to enhance the public availability of agency guidance documents.<sup>287</sup>

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 any meaningful 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 on diligent agency management. Agencies need to make sure they have in place effective internal procedures and systems for tracking guidance documents, and then 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. In the end, to illuminate regulatory guidance, agencies must act deliberately to ensure that all such material reaches those members of the public who can benefit from the assistance that guidance documents provide.

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287. Cf. Coglianesi et al., *supra* note 203; *see also supra* notes 70-76 and accompanying text.