

IBM Center for The Business of Government

# Guidance on Regulatory Guidance:

What the Government Needs  
to Know and Do to Engage  
the Public



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2021

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# FOREWORD

**On behalf of the IBM Center for The Business of Government, we are pleased to release this new report, *Guidance on Regulatory Guidance: What the Government Needs to Know and Do to Engage the Public*, by Susan Webb Yackee, professor of public affairs and political science and director of the La Follette School of Public Affairs at the University of Wisconsin-Madison.**

Federal agencies routinely issue guidance documents to clarify the meaning of existing statutes and regulations. Over time, guidance has become a principal tool to help implement regulations. However, agencies have no uniform process for issuing guidance, no common way to engage the public, and no archival record of past policies. As Professor Yackee argues, this creates a mismatch between: (1) the importance of this policy tool, and (2) the ability of the public to influence the policies that govern them.

In this new report, Professor Yackee produces useful insights into current government practices for issuing guidance, how best to bring the public into the development and issuance of guidance through new innovation and process reforms, and timely recommendations for the new Biden administration to foster public engagement. The report presents a roadmap that can help enable agencies to issue guidance in a practical manner that addresses public input. Professor Yackee concludes with several recommendations for improving the guidance process, including standardized definitions that all agencies could adopt, development of a central online repository for guidance, and leveraging technology to enhance public knowledge of and participation in guidance development.

The report builds on the Center's longstanding research on ways to improve public engagement with government across key program, process, and management domains—including the recent essay on “Community-Driven Government—Reimagining Systems in a Pandemic” contained within our report, *COVID-19 and its Impact; The Road to Agile Government: Driving Change to Achieve Success; Transforming How Government Operates: Four Methods of Change; and Applying Design Thinking to Public Service Delivery*.

We hope that Professor Yackee's insights, findings, and recommendations help the new administration design and implement strategies for effective issuance of and public engagement with regulatory guidance.

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# EXECUTIVE SUMMARY

**Federal agencies routinely issue guidance documents to announce policy statements and to clarify the meaning of existing statutes and regulations. Over time, guidance documents have become a principal agency policy instrument.**

However, agencies have had no uniform process to issue guidance, no common strategy for public engagement, and no archival record of past guidance. Taken together, the current system creates a mismatch between the importance of guidance documents as a modern policy tool of government, and the ability of Americans to understand and participate in the public policymaking processes that govern them.

This report provides a roadmap for the government to improve the creation and management of agency guidance documents by fostering a more citizen-driven process. The report reviews guidance document development at the federal level and compares the current process for developing guidance with the more commonly understood process for promulgating notice and comment regulations. The report then highlights findings from an analysis of a past guidance reform effort and a research study of stakeholder involvement during guidance creation at the Food and Drug Administration (FDA).

The report's recommendations could be enacted by executive order or memoranda, or pursued through congressionally passed legislation. The recommendations are designed to retain the flexibility and timeliness present in the current guidance document development process while simultaneously improving that process. In brief, the report recommends that the government:

1. Develop standardized definitions for guidance and major guidance documents.
2. Create a centralized repository for current federal government guidance.
3. Archive guidance at a semiannual interval.
4. Harness technology to alert members of the public to new and rescinded guidance.
5. Enact a public commenting process for major guidance, which would occur immediately *after* a guidance document's issuance.

# INTRODUCTION

## **On February 12, 2021, the director of the Centers for Disease Control and Prevention (CDC) issued long-awaited guidance for reopening K-12 schools during the COVID-19 pandemic.**

This CDC guidance document provided nonbinding policy recommendations for communities to safely deliver in-person instruction. Yet, media reports suggested that select state and local officials, as well as some teachers' unions, planned to treat the guidance as binding standards for reopening in-person education.<sup>1</sup> In fact, some early accounts foretold that these mitigation recommendations might paradoxically make it harder to get students back in the classroom, in situations where schools could not meet the CDC's recommendations.<sup>2</sup>

Guidance documents are defined as an agency's general statements of policy or interpretive rules intended to clarify existing statutes or regulations.<sup>3</sup> Across time, guidance has become a key instrument for policy creation and implementation. For instance, government agencies use guidance documents to signal current thinking about an issue,<sup>4</sup> clarify enforcement priorities,<sup>5</sup> and explain how the agency will exercise authority.<sup>6</sup>

Many guidance documents are technical, and their effects are concentrated on specific business areas or industries. To the regulated entities in these fields, guidance documents are critically important because they establish standards that govern their work.<sup>7</sup> In other cases, however, guidance documents—like the CDC example above—are broader in application and touch the lives of millions of people.

Few Americans realize that this “under the radar” administrative policy tool exists. Even fewer people recognize that guidance documents play a critical role in the federal government's ability to deliver services and enforce existing standards. Still fewer appreciate how guidance is created, know how to access the documents, or participate in their formation. To complicate matters further, basic data—such as how many guidance documents agencies issue each year—are unknown to scholars or government practitioners.

This report focuses on current government practice and makes numerous reform recommendations. The report recommends change to the guidance process with the goals of fostering greater transparency and public engagement and strengthening rule-of-law principles. Moreover, these recommendations are readily actionable via executive order or memoranda, or through congressional legislation.

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1. See <https://www.npr.org/2021/02/12/967033554/cdc-offers-clearer-guidance-yet-for-reopening-schools>, accessed 2/12/2021.

2. See <https://www.npr.org/2021/02/19/969467560/if-schools-follow-cdc-guidance-bidens-reopening-goals-could-be-hard-to-reach>, accessed 2/19/2021.

3. Haeder, Simon and Susan Webb Yackee. 2020. “Policies that Bind? The Use of Guidance Documents by Federal Agencies.” *Journal of Health and Human Services Administration*, 43: 87-100.

4. Lewis, Kevin Michael. 2011. “Informal Guidance and the FDA.” *Food and Drug Law Journal*, 66: 507-50.

5. Potter, Rachel Augustine. 2020. “Providing Political Guidance? Agency Politicization and ‘As If’ Policymaking.” *Journal of Political Institutions and Political Economy*, 1: 1-26.

6. Stack, Kevin M. 2015. “An Administrative Jurisprudence: The Rule of Law in the Administrative State.” *Columbia Law Review*, 2015: 115-150.

7. Mantel, Jessica. 2009. “Procedural Safeguards for Agency Guidance.” *Administrative Law Review*, 61: 343-406.



President Biden issued EO 13992 on January 20, 2021.<sup>8</sup> This executive order set forth the administration's commitment to using agency policy tools to tackle the country's key challenges and priorities. An accompanying Biden administration presidential memorandum, also issued on January 20, announced plans to modernize the Office of Management and Budget's (OMB) regulatory review process, including the identification of reforms that will "determine the appropriate approach with respect to the review of guidance documents."

The EO also revoked several existing executive orders focused on regulatory management issued during the former Trump administration, including EO 13891, Promoting the Rule of Law Through Improved Agency Guidance Documents.<sup>9</sup> The revoked order, issued in October 2019, had sought to create public participation opportunities during the development of significant agency guidance, as well as make that process more transparent. However, as described below, EO 13891 did not accomplish these objectives and had several issues that curbed its effectiveness. As a result, a window of opportunity exists to reconsider, modernize, and improve the guidance development process.

## Agency Policymaking

The Administrative Procedure Act of 1946 (APA) establishes the rules governing federal agency policymaking,<sup>10</sup> and notice and comment rulemaking is the best known of these processes.<sup>11</sup> But the APA allows for other forms of agency "rules" as well.<sup>12</sup> In particular, the APA enables agencies to issue public policies via guidance documents.<sup>13</sup> Numerous observers describe the distinction between notice and comment rules and guidance documents to be "fuzzy,"<sup>14</sup> "blurry,"<sup>15</sup> and "tenuous,"<sup>16</sup> and many scholars stress that the policy impact of guidance is

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8. See <https://www.federalregister.gov/documents/2021/01/25/2021-01767/revocation-of-certain-executive-orders-concerning-federal-regulation>, accessed 2/10/2021.

9. See <https://www.federalregister.gov/documents/2019/10/15/2019-22623/promoting-the-rule-of-law-through-improved-agency-guidance-documents>, accessed 2/10/2021.

10. West, William F. 1995. *Controlling the Bureaucracy: Institutional Constraints in Theory and Practice*. M.E. Sharpe, and Yackee, Susan Webb. 2006. "Sweet-Talking the Fourth Branch: Assessing the Influence of Interest Group Comments on Federal Agency Rulemaking." *Journal of Public Administration Research and Theory*, 26: 103-124.

11. Shapiro, Stuart. 2014. "Agency Oversight as Whac-A-Mole: The Challenge of Restricting Agency Use of Nonlegislative Rules." *Harvard Journal of Law and Public Policy*, 37: 523-552.

12. Funk, William F. 2001. "A Primer on Nonlegislative Rules." *Administrative Law Review*, 53: 1321-1352.

13. The APA "contemplates" notice and comment rulemaking as its "default category" (Kristin E. 2009. "IRB Guidance: The No Man's Land of Tax Code Interpretation." *Michigan State Law Review*, 2009: 239-272, see page 253), whereas it frames guidance as an exception to the notice and comment process (Gluck, Abbe R., Rosa Po, and Ann Joseph O'Connell 2015. "Unorthodox Lawmaking, Unorthodox Rulemaking." *Columbia Law Review*, 115: 1789-1865). The guidance exception sits alongside other exceptions, such as rules govern an agency's internal management (Funk 2001).

14. Levin, Ronald M. 2018. "Rulemaking and the Guidance Exemption." *Administrative Law Review*, 70: 263-356, see page 266.

15. Rosenbloom, David. 2003. *Administrative Law for Public Managers*, Westview Press, see page 60.

16. Franklin, David L. 2010. "Legislative Rules, Nonlegislative Rules, and the Perils of the Short Cut." *Yale Law Journal*, 120: 276-326, see page 276.

often just as important as that of notice and comment rules.<sup>17</sup> Nevertheless, differences exist—especially around the public’s ability to access guidance documents and participate in their creation.

Below are key aspects of agency regulatory and guidance tools.



Notice and comment rules help to govern much of American life. Federal agencies issue notice and comment rules across a broad spectrum of topics: from airplane safety to animal testing, from traffic signs to workplace safety, and from financial derivatives to air quality. Such rules are used to make prospective policy decisions, and when issued via the APA-prescribed process, are legally binding on the public.<sup>18</sup> Agencies rely on policymaking authority delegated by Congress to issue notice and comment rules.<sup>19</sup>

Federal agencies at the turn of the 20th century frequently issued rule-like policies to implement congressionally passed laws.<sup>20</sup> However, at that time no common repository for agency rules existed, making it hard for members of the public to identify standards in effect and those rescinded.<sup>21</sup> This changed with the passage of the Federal Register Act of 1935, which created the *Federal Register*—now the official repository for all federal government notice and comment rules.

There was also no common process for how agencies should issue legally binding rules in the early 1900s, but this changed with the passage of the APA in 1946. Section 553 of the APA established the basic requirements for notice and comment rulemaking.<sup>22</sup> Section 553 requires that agencies publicly announce a draft version of their proposed rules. These drafts—published in the *Federal Register*—receive public feedback, typically during a notice and comment period. During that period, any individual, organization, or political group may send a written comment to the agency. After considering the comments, the agency generally issues a final rule in the *Federal Register*. The final rule’s preamble describes the comments and details the agency’s response. The agency may or may not change the content of a final rule in response to the comments but must justify its decision.

17. Mendelson, Nina. 2007. “Regulatory Beneficiaries and Informal Agency Policymaking.” *Cornell Law Review*, 92: 397-452; Mantel 2009.

18. Rossi, Jim. 1997. “Participation Run Amok: The Costs of Mass Participation for Deliberative Agency Decisionmaking.” *Northwestern University Law Review*, 92: 173-249.

19. Kerwin, Cornelius M., and Scott R. Furlong. 2018. *Rulemaking: How Government Agencies Write Law and Make Policy*. 5th ed. Washington, D.C.: CQ Press.

20. Rosenbloom 2003.

21. See [https://www.federalregister.gov/uploads/2011/01/fr\\_101.pdf](https://www.federalregister.gov/uploads/2011/01/fr_101.pdf), accessed 3/10/2021.

22. Davis, Kenneth Culp. 1970. *Administrative Law Treatise*. 1st Edition, Supplement 1970; Funk 2001.

OMB has played a major role in reviewing draft and final notice and comment rules written by executive branch agencies since President Reagan issued EO 12291 in 1981.<sup>23</sup> <sup>24</sup> All subsequent presidents have continued the practice.<sup>25</sup> Under President Clinton, EO 12866 shifted OMB review to focus only on “significant” rules—OMB identifies significant rules as those that have an annual impact on the economy of \$100 million or more; interfere with the work of other agencies; affect entitlements, grants, user fees, or loan programs; or raise legal or policy issues for the president’s priorities.<sup>26</sup> Across time, OMB’s review of notice and comment rules has dramatically increased the policymaking power of the modern presidency.<sup>27</sup>



Guidance documents—much like notice and comment rules—are forwarding-looking policy instruments used by government agencies.<sup>28</sup> Agencies issue guidance across a broad spectrum of topics—from housing to cosmetics, from K-12 school re-openings to outside masking in a pandemic, and from cybersecurity to medical devices. Guidance provides an agency’s current thinking on policy topics, such as enforcement and permitting plans.<sup>29</sup> In doing so, guidance helps to promote consistency across an agency’s activities.<sup>30</sup> Guidance documents also announce agency leadership’s policy priorities.<sup>31</sup>

Many guidance documents focus on specific businesses or regulated industries and can be technical in nature.<sup>32</sup> At times, regulated entities recoil from the additional layer(s) of regulation imposed by guidance; at other times, businesses request agencies to issue guidance to clarify agency practice.<sup>33</sup> The tie between guidance and industry can be strong; in fact, the

23. West 1995; Haeder, Simon and Susan Webb Yackee. 2018. “Presidentially Directed Policy Change: The Office of Information and Regulatory Affairs as Partisan or Moderator.” *Journal of Public Administration Research and Theory*, 28: 475-488; Haeder, Simon and Susan Webb Yackee. 2021. “Out of the Public’s Eye? Lobbying the President’s Office of Information and Regulatory Affairs.” *Interest Groups & Advocacy*, 9: 410-424.

24. Across time, all three branches of the government—the legislative, executive, and judicial—have placed additional procedural requirements, such as OMB review, on select notice and comment rulemakings (Yackee, Jason Webb and Susan Webb Yackee. 2010. “Is Agency Rulemaking ‘Ossified’? Testing Congressional, Presidential, and Judicial Procedural Constraints.” *Journal of Public Administration Research and Theory*, 20: 261-282).

25. Yackee, Jason Webb and Susan Webb Yackee. 2009. “Is the Bush Bureaucracy Any Different? A Macro-Empirical Examination of Notice and Comment Rulemaking under ‘43’” in *President George W. Bush’s Influence Over Bureaucracy and Policy: Extraordinary Times, Extraordinary Powers*. Editors: Colin Provost and Paul Teske. New York, NY: Palgrave Macmillan, 41-59.

26. Haeder, Simon and Susan Webb Yackee. 2015. “Influence and the Administrative Process: Lobbying the U.S. President’s Office of Management and Budget.” *American Political Science Review*, 109: 507-522.

27. Nathan, Richard P. 1983. *The Administrative Presidency*. Wiley Press; Moe, Terry M. 1985. “The Politicized Presidency.” In *The New Directions in American Politics*, ed. John Chubb and Paul Peterson. Brookings Institution Press; Kagan, Elena. 2001. “Presidential Administration.” *Harvard Law Review*, 114: 2245-2385.

28. Mendelson 2007; Lewis 2011; Yackee, Susan Webb. 2020. “Hidden Politics? Assessing Lobbying Success during U.S. Agency Guidance Development.” *Journal of Public Administration Research and Theory*, 30: 548-562.

29. Potter 2020.

30. Funk 2001.

31. U.S. Government Accountability Office. 2015. *Regulatory Guidance Processes: Selected Departments Could Strengthen Internal Control and Dissemination Practices*. GAO-15-368.

32. Mantel 2009.

33. Parrillo, Nicholas R. 2017. “Federal Agency Guidance: An Institutional Perspective.” *Administrative Conference of the United*

FDA begins many of its guidance documents with the phrase “Guidance for Industry.”<sup>34</sup> Agencies also use guidance “to make major policy changes” that broadly apply to the public.<sup>35</sup> The public policy impact of guidance is demonstrated by the Obama administration’s change on transgender students’ bathroom use in 2016, which was issued as a guidance document.<sup>36</sup>

Guidance provides agencies with a flexible and easy-to-use agency policy instrument.<sup>37</sup> Guidance can be issued quickly and thereby allow for a timely policy response from government.<sup>38</sup> As described below—and unlike notice and comment rulemaking—this arises because most agencies face no standardized requirements for how to issue or track guidance.<sup>39</sup> This has raised concerns that agencies may employ guidance as an “administrative workaround” to notice and comment rulemaking,<sup>40</sup> and that the speed and flexibility of the current guidance process is associated with weak public scrutiny and political oversight.<sup>41</sup>

Agencies use guidance with great frequency.<sup>42</sup> Parrillo quotes a former Environmental Protection Agency official stating that guidance documents are the “bread and butter” of the agency’s practice, while a former senior FDA official states, “I cannot imagine a world without guidance.”<sup>43</sup> Another former official states that operating Medicare would be “impossible” without guidance, while a previous Occupational Safety and Health Administration official finds guidance to be an “essential responsibility” of the agency.<sup>44</sup> Romano reports that many financial agencies, including the Consumer Financial Protection Bureau, use guidance extensively,<sup>45</sup> while Strauss suggests that the Internal Revenue Service’s guidance documents consume 20 times the space of its notice and comment rules.<sup>46</sup>

Importantly, guidance documents are not legally binding.<sup>47</sup> Guidance may recommend actions to the public but not require them. Yet, as Gluck, O’Connell, and Po conclude, while guidance may be “technically” nonbinding, in practice guidance has “real bite in many contexts.”<sup>48</sup> Observers report that external stakeholders generally treat guidance as legally binding<sup>49</sup> and may “comply out of fear” of the agency.<sup>50</sup> Some scholars worry that guidance documents “coerce compliance.”<sup>51</sup>

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*States Report*, October 12, 2017.

34. See <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, accessed 3/11/2021.

35. Potter 2020, see page 2.

36. Walters, Daniel E. 2019. “The Self-Delegation False Alarm: Analyzing Auer Deference’s Effect on Agency Rules.” *Columbia Law Review*, 119: 85-169.

37. Funk 2001.

38. Stack 2015.

39. One exception is the FDA, which has a statutorily prescribed process for guidance issuance and which I discuss later in the report..

40. Gluck, O’Connell and Po 2015, see page 1814.

41. Anthony, Robert A. 1992. “Interpretive Rules, Policy Statements, Guidances, Manuals, and the Like—Should Federal Agencies Use them to Bind the Public.” *Duke Law Journal*, 41: 1311–84; McGarity, Thomas O. 1992. “Some Thoughts on ‘Deossifying’ the Rulemaking Process.” *Duke Law Journal*, 41: 1385-1462; Greve, Michael, and Ashley Parrish. 2014. “Administrative Law Without Congress.” *George Mason Law Review*, 22: 501-547.

42. GAO 2015.

43. Parrillo 2017, see pages 34-35.

44. Parrillo 2017, see pages 34-35.

45. Romano, Roberta. 2019. “Does Agency Structure Affect Agency Decisionmaking? Implications of the CFPB’s Design for Administrative Governance.” *Yale Journal on Regulation*, 36: 273-358.

46. Strauss, Peter L. 1992. “The Rulemaking Continuum.” *Duke Law Journal*, 41: 1463-1489.

47. Many guidance documents come with a written disclaimer stating that they are nonbinding. However, Mendelson concludes that, even with a disclaimer, guidance documents are likely to prompt behavioral change in regulated entities (Mendelson 2007).

48. Gluck, O’Connell, and Po 2015, see page 1815.

49. Anthony 1992; Greve and Parrish 2015.

50. Shapiro 2014, see page 531.

51. Funk 2001, see page 1323.

Compliance with nonbinding guidance may occur because regulated entities feel compelled to conform to stay in good standing with an agency that they will interact with repeatedly in the future,<sup>52</sup> or because they wish to avoid confronting that agency.<sup>53</sup> Compliance may also occur because current agency enforcement or permitting actions draw on guidance<sup>54</sup> or because guidance reflects the best available science on a topic. Additionally, as Levin reports, the distinction between guidance and notice and comment rules is quite blurred at times, making it hard for members of the public and regulated entities to tell the difference.<sup>55</sup> Finally, compliance with nonbinding guidance may occur because affected parties have often been unsuccessful in challenging guidance in the courts.<sup>56</sup>

OMB reviews significant guidance documents promulgated by executive branch agencies on behalf of the president in a similar fashion to its review of notice and comment rules.<sup>57</sup> President Bush formalized this practice in EO 13422 in 2007. While President Obama revoked that order, his OMB director made clear through an official memorandum that OMB would continue to review significant guidance documents, and this practice has continued across subsequent administrations.<sup>58</sup> President Biden's EO 13992 announced the administration's intention to modernize and reform OMB's rule review process in the future, including its approach to guidance documents.

### Five Management Challenges in Current Guidance Practice

This report identifies five challenges raised by current guidance document practice. These challenges reflect the public values of transparency and engagement. Weaknesses in the current system create a mismatch between the importance of guidance documents as a modern policy instrument of government, and the ability of Americans to appreciate and participate in public policymaking processes.



The first three challenges focus on transparency, which embodies the idea that society benefits from open government decision-making processes and outputs, and from access to policy information that facilitates public review, understanding, and oversight.

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52. See <https://www.mercatus.org/publications/regulation/confronting-problem-stealth-regulation>, accessed 3/20/2021.

53. Hickman 2009.

54. Potter 2020.

55. Levin, Ronald M. 2018. "Rulemaking and the Guidance Exemption." *Administrative Law Review*, 70: 263–356.

56. Romano 2019; Funk 2001; Mendelson 2007; Raso, Connor N. 2010. "Strategic or Sincere? Analyzing Agency Use of Guidance Documents." *Yale Law Journal*, 119: 648–847.

57. Stack, Kevin M. 2016. "Preambles as Guidance." *George Washington Law Review*, 84: 1252-1292.

58. See <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2009/m09-13.pdf>, accessed 3/11/2021. The memorandum cites EO 12866 as OMB's authority to review significant notice and comment rules and significant guidance documents. See <https://www.archives.gov/files/federal-register/executive-orders/pdf/12866.pdf>, accessed 3/11/2021.

- **Lack-of a Common Definition.** One inadequacy in current guidance practice is the lack of a common, governmentwide definition for guidance. This makes it difficult to determine which agency decisions are guidance and which are not, which is exacerbated by the fact that agencies are generally not required to label—or otherwise call attention to—guidance. This hampers public disclosure. Such shortcomings significantly raise the public’s monitoring costs by making it difficult for citizens to separate agency guidance from other agency actions.

Scholars define *guidance* as any document that an agency puts forward as a statement of policy or that provides the agency’s interpretation of existing statutes or notice and comment rules.<sup>59</sup> Yet in practice, agencies do not adhere to a standard definition; this definitional ambiguity is complicated by the fact that agencies often release guidance in different formats—such as press releases, “Dear Colleague” letters, formal policy statements, interpretative rules, circulars, memoranda, and bulletins.

The array of vehicles for guidance promulgation complicates the public’s ability to identify, track, and scrutinize agency policy activity. In short, this increases the “opacity” surrounding guidance.<sup>60</sup> The numerous forms of guidance documents also create an uneven playing field. Those individuals, regulated entities, or interest groups with time, staff, and other resources devoted to actively and aggressively monitoring agency guidance activities have insight into the agency’s thinking; others, who cannot pay those costs, lack such insight. And it is not just members of the public who find these definitional and monitoring issues to be challenging. Shapiro reports that elected officials also view guidance as “difficult-to-monitor,” making it harder for elected officials to provide oversight.<sup>61</sup>

- **Lack of a Governmentwide Repository.** Another shortcoming is the lack of a central, governmentwide repository to house all agency guidance. This creates significant public access issues, and it hampers the public’s ability to appreciate which guidance documents are currently in effect across the federal government. Given that guidance documents hold substantive public policy effects for regulated entities and citizens,<sup>62</sup> this presents a major problem.

Guidance disclosure systems across the federal government vary considerably.<sup>63</sup> As a result, there is neither a centralized, governmentwide repository to house guidance nor consistent information at the agency level in almost all cases. These facts add to the complexity and intractability of the current system.

A dearth of even the simplest of metrics about federal government guidance has resulted. It is unknown how many guidance documents are currently in effect across government. Some scholars believe that federal guidance use is “massive.”<sup>64</sup> Others conjecture that the number of guidance documents likely dwarfs the number of notice and comment rules issued each year,<sup>65</sup> while Whisner infers that the use of guidance is “growing, both in volume and in importance.”<sup>66</sup> However, statistics capturing the actual number are impossible to calculate, as are statistics focused on how guidance usage varies by agency or by topic.

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59. Haeder and Yackee 2020.

60. Manning, John F. 1996. “Constitutional Structure and Judicial Deference to Agency Interpretations of Agency Rules.” *Columbia Law Review*, 96: 612–696, see page 680.

61. Shapiro 2014, see page 526.

62. Gluck, Po, and O’Connell 2015.

63. This variation across disclosure systems is detailed later in the report.

64. Mendelson 2007, see page 398.

65. Shapiro 2014.

66. Whisner, Mary. 2013. “Some Guidance About Federal Agencies and Guidance.” *Law Library Journal*, 105: 385-394, see page 394.

This lack of systematized, consistent, and transparent information on guidance disclosure stands in sharp contrast to the notice and comment rulemaking process. As detailed above, similar issues plagued notice and comment rulemaking a century ago; as a result, the *Federal Register* was created to serve as the official government repository for all new draft and final notice and comment rules.<sup>67</sup> This includes rules promulgated by executive branch and independent agencies.

- **No Archival Record.** The public lacks an archival record of guidance document issuance across time. Accordingly, no governmentwide historical record of guidance promulgation exists. This type of information would generate a proper understanding and appreciation of the size and scope of the modern regulatory state and would serve as a critical legal resource capturing agency guidance policies in place at specific times.

This shortcoming makes it impossible to characterize over time trends in guidance usage by government agencies. Agency reliance on guidance has likely increased across time.<sup>68</sup> Close observers, for instance, believe that guidance usage has outpaced the production of notice and comment rules in more recent years.<sup>69</sup> However, inferences regarding these types of dynamic relationships are speculative without an archival record of all guidance.

On this point, notice and comment rulemaking again provides a historical precedent, specifically through the creation of the Code of Federal Regulations as part of previous reform efforts. In the CFR, the Office of the *Federal Register* publishes an annual compilation of all notice and comment rules presently in effect.<sup>70</sup> This yearly snapshot allows for historical analyses and a legal record of notice and comment regulation across time.



The next two management challenges concern the value of public engagement in policymaking, which embodies the idea that society benefits when the public can participate in government decisions that affect them.

- **No Public Notification.** No requirement exists to alert concerned members of the public to the issuance of new guidance—another deficiency in current guidance practice. As Funk notes, guidance documents frequently convey how an agency plans to use power in the future,<sup>71</sup> which includes information on future investigative, permitting, and enforcement actions. Yet despite the importance of such information, no governmentwide public notification system is in place to call attention to a policy change made through guidance.

67. See [https://www.federalregister.gov/uploads/2011/01/fr\\_101.pdf](https://www.federalregister.gov/uploads/2011/01/fr_101.pdf), accessed 3/10/2021.

68. Anthony 1992; McGarity 1992; Greve and Parrish 2015.

69. Gluck, Po, and O'Connell 2015.

70. See [https://www.federalregister.gov/uploads/2011/01/fr\\_101.pdf](https://www.federalregister.gov/uploads/2011/01/fr_101.pdf), accessed 3/10/2021.

71. Funk 2001.

From a rule-of-law perspective, this raises significant problems. As Stack writes, public notice of government decision making reflects a core rule-of-law principle.<sup>72</sup> In fact, Mantel implies this lack of public notice as a reason that guidance can raise legitimacy concerns for administrative policy decision making.<sup>73</sup>

Select government agencies have experimented with ways to alert the public to guidance. This experimentation has resulted in a mishmash of approaches across government agencies. Some agencies use websites and email lists to share information on guidance,<sup>74</sup> while others share information on new guidance via small group meetings or conferences. Others rely on external partners to disseminate information, and some use social media, such as Facebook and Twitter.<sup>75</sup>

Moreover, an agency may rescind guidance without any formal alert to the public and thus without calling attention to the policy change. This creates a system where members of the public may believe that they comply with an agency's guidelines on an issue, when in fact they do not. Given that guidance brings the key benefit of reflecting an agency's current thinking on an issue,<sup>76</sup> the public should be able to identify when that current thinking is out of date.

- **Limited Public Commenting.** Most guidance documents—including those important to citizens—do not provide for open public engagement opportunities. Consequently, agencies miss out on the ability to garner information regarding the likely impact of their guidance decisions, or to incorporate public feedback and views that would improve the on-the-ground implementation of policy decision making.

Past efforts to engage the public in agency policymaking within the notice and comment rulemaking process have been celebrated as opening government policymaking to public scrutiny.<sup>77</sup> Others have stressed that this type of public engagement may mitigate the “democratic deficit” attached to policymaking by unelected agency officials.<sup>78</sup> In part, the ability of the public to participate via the submission of comments during the formation of agency policies lessens this concern.<sup>79</sup> Additionally, public engagement during notice and comment rulemaking has proven efficacious, with an increasing body of research yielding suggestive evidence of agency policy change in response to the content of public comments.<sup>80 81</sup>

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72. Stack 2015.

73. Mantel 2009.

74. GAO 2015.

75. GAO 2015.

76. Potter 2020.

77. Davis 1970.

78. Bignami, Francesca E. 1999. “The Democratic Deficit in the European Community Rulemaking: A Call for Notice and Comment in Comitology.” *Harvard International Law Journal*, 40: 451–516, see page 451.

79. Kerwin and Furlong 2018; Yackee, Susan Webb. 2019. “The Politics of Rulemaking in the U.S.” *Annual Review of Political Science*, 22: 37-55.

80. Yackee 2006; Yackee, Susan Webb. 2013. “Assessing Regulatory Participation by Health Professionals: A Study of State Health Rulemaking.” *Public Administration Review*, 73: 105-114; Yackee, Susan Webb. 2014. “Reconsidering Agency Capture During Regulatory Policymaking,” in *Preventing Capture: Special Interest Influence in Regulation, and How to Prevent It*. Editors: Daniel Carpenter and David Moss. Cambridge, UK: Cambridge University Press, 292-325; Yackee, Susan Webb. 2015a. “Invisible (and Visible) Lobbying: The Case of State Regulatory Policymaking.” *State Politics and Policy Quarterly*, 15: 322-344; Yackee, Susan Webb. 2015b. “Participant Voice in the Bureaucratic Policymaking Process.” *Journal of Public Administration Research and Theory*, 25: 427-449.

81. Research cautions, however, against seeing the public commenting opportunity as fully democratizing (Yackee 2019). The participants to most notice and comment rules are not usually ordinary citizens but instead tend to be interest groups and regulated entities (Yackee 2006; Kerwin and Furlong 2018), and of all participants, business interests appear to submit the most influential comments (Yackee, Jason Webb and Susan Webb Yackee. 2006. “A Bias toward Business? Assessing Interest Group Influence on the Bureaucracy.” *Journal of Politics*, 68: 128-139).

Agencies do engage external entities during select guidance creation. Parrillo writes that some agencies may use “handpicked stakeholders” in developing guidance, while others sometimes use stakeholder meetings, advisory committees, or occasionally public comments.<sup>82</sup> However, in 2015 the Government Accountability Office raised concerns about whether, how, and from whom federal agencies take external feedback during an often-opaque guidance creation process.<sup>83</sup>

The lack of an open participation process also presents problems because experience with the notice and comment process shows that participants frequently share novel technical or political data and insights regarding a proposed rule’s likely impacts through their public comments.<sup>84</sup> In addition, participants can signal consensus views on policy concerns in need of modification to agency officials.<sup>85</sup>

## Past Guidance Reform Efforts

The lack of procedural protections within current guidance practice has “troubled” scholars and government officials for years,<sup>86</sup> and proposals to restrict agency guidance usage “have been discussed for decades.”<sup>87</sup>

Three past proposals resulted in major government reforms to guidance practice.

- **The Food and Drug Administration Modernization Act (1997).** The FDA has a more established and extensive process for issuing guidance than other government agencies.<sup>88</sup> This process was initiated by the agency but concretized through congressional statute in the bipartisan FDA Modernization Act of 1997. These reforms remain in effect today.

Lewis writes that “to achieve its regulatory objectives” the FDA has settled on “guidance as its policymaking weapon of choice.”<sup>89</sup> Hwang et al. write that the complexity, time delays, and often adversarial nature of notice and comment rulemaking contributed to the FDA’s increased reliance on other policy tools, including guidance.<sup>90</sup> Today, a “widespread view” holds that the FDA relies heavily on guidance to make policy decisions.<sup>91</sup> For instance, a congressional aide and close observer of the FDA has said that the agency makes policy decisions via guidance unless forced by statute to use a different approach.

The FDA’s reliance on guidance has had detractors. In part to address public critiques, the FDA issued a “Good Guidance Practices” document in the 1990s, which yielded much stronger written procedures for guidance document development. Many of these guidelines were then codified in the FDA Modernization Act.<sup>92</sup> The reforms required that the FDA state that their guidance was advisory and thus not legally-binding and required a public participation process during important guidance creation.<sup>93</sup> The statute also directed the FDA to issue regulations further specifying its guidance practice.

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82. Parrillo 2017, see page 137.

83. GAO 2015.

84. Yackee 2015a.

85. McKay, Amy and Susan Webb Yackee. 2007. “Interest Group Competition on Federal Agency Rules.” *American Politics Research*, 35: 336-357.

86. Mantel 2009, see page 345; Raso 2010; Stack 2016.

87. Shapiro 2014, see page 525.

88. Yackee 2020.

89. Lewis 2011, see page 508.

90. Hwang, Thomas J., Jerry Avorn, Daniel Carpenter, and Aaron S. Kesselheim. 2014. “Quantifying the Food and Drug Administration’s Rulemaking Delays Highlights the Need for Transparency.” *Health Affairs*, 33: 309-315.

91. Parrillo 2017, see page 181.

92. Lewis 2011.

93. Mendelson 2007.

The FDA places guidance into two tiers because of these reforms. Level 1 guidance documents include those that relate to “complex or highly controversial issues” or where the “agency believes there is a major change.”<sup>94</sup> For Level 1 guidance, the FDA takes public feedback in a similar fashion to the notice and comment rulemaking process. The agency first issues a draft guidance document, and then opens this draft for public comment. After taking public feedback, the FDA then generally issues a final guidance document, which may or may not have changed because of the public feedback.

While like notice and comment rulemaking, differences do exist for the guidance process. In particular, the agency does not have to provide a written summary of the comments received on draft guidance and does not detail the policy changes made in response to those public comments in an open and accessible fashion.<sup>95</sup> In fact, the FDA has expressly rejected the proposition to provide this type of response to commenters during guidance creation.<sup>96</sup>

The FDA uses Level 2 guidance for more minor changes in policy or implementation practice.<sup>97</sup> These guidance documents go immediately into effect upon issuance and without a prior draft for comment. Concerned individuals or groups may submit comments after the issuance of the Level 2 guidance. FDA policies call for a review of those comments, and the agency will publish a new version online if there are any revisions.<sup>98</sup> No written response to comments is required.

The reform efforts also increased the transparency of FDA guidance development. All FDA guidance—Level 1 and Level 2—must appear on an agency-maintained website, which allows users to search for guidance by keywords, as well as by date issued, topic, and FDA sub-unit. The website provides copies of guidance, an FDA docket number, document status (draft or final), and whether the guidance is open for comment. For Level 1 guidance, the agency places a notice in the *Federal Register* regarding the availability of the draft and final documents on the FDA’s website. The FDA does not publish notice of Level 2 guidance in the *Federal Register*.<sup>99</sup> The FDA makes the public comments received on guidance available at Regulations.gov, the multiagency government website for regulatory documents including public comments.

Observers generally point to the FDA reforms as a success, and the FDA’s guidance process has become a model for subsequent reform efforts that span the executive branch—especially OMB’s good guidance bulletin.<sup>100</sup>

- **OMB’s Good Guidance Practices Bulletin (2007).** Twenty years after the FDA’s statutory reforms, President Bush’s OMB issued reforms to encourage guidance transparency and public engagement. OMB’s “Final Bulletin for Agency Good Guidance Practices” (GGP) came out in January 2007.<sup>101</sup> OMB’s GGP serves as a guidance document for executive branch agencies and remains on the White House’s website today.<sup>102</sup> OMB’s GGP focuses

94. Hwang, Thomas J., Jerry Avorn, and Aaron S. Kesselheim. 2014. “Life Cycle of Medical Product Rules Issued by the US Food and Drug Administration.” *Journal of Health Politics, Policy and Law*, 39: 751-780, see page 772.

95. Lewis 2011.

96. Yackee 2020.

97. Yackee, Susan Webb. 2021. “The Science of Policy Development during Administrative Rulemaking.” *Policy Studies Journal*, 49: 146-163; Yackee 2020.

98. See 65 *Federal Register* 56477, Sept. 19, 2000.

99. Lewis 2011.

100. Noah, Lars. 2014. “Governance by the Backdoor: Administrative Law(lessness?) at the FDA.” *Nebraska Law Review*, 93:89-138.

101. At approximately the same time, President Bush also expanded OMB’s regulatory review process to include significant and economically significant guidance via EO 13422. See <https://www.govinfo.gov/content/pkg/WCPD-2007-01-22/pdf/WCPD-2007-01-22-Pg48.pdf>, accessed 3/10/2021. President Obama later revoked that order, but his OMB director instructed federal agencies to continue to send significant guidance to OMB as part of its rule review process (Stack 2016).

102. See <https://www.whitehouse.gov/omb/information-for-agencies/bulletins/>, accessed 3/11/2021.

exclusively on significant and economically significant guidance,<sup>103</sup> defining these terms in a similar fashion to that of significant and economically significant notice and comment regulations for OMB review.

In the bulletin, OMB guides executive branch agencies to develop written procedures for internal clearance of significant guidance. OMB also recommends that agencies establish and maintain a website that makes all significant guidance available to the public and post new documents within 30 days. Like the FDA's statutory requirement, OMB guides agencies to label guidance as nonbinding. OMB also encourages agencies to create a list-serv or other mechanism to notify members of the public who may be interested in an annual update on the agency's significant guidance activity.

OMB recommends public engagement opportunities—through a comment process—for all significant guidance. However, OMB does not specify when that process should occur. The comment period may occur pre-adoption of the final guidance or post-adoption. OMB also does not require an agency to provide a response-to-comments document for significant guidance.

For those guidance documents deemed economically significant, OMB recommends heightened disclosure and engagement procedures. For instance, OMB guides agencies to publish draft versions of guidance on their websites, as well as provide notice in the *Federal Register* to announce that the guidance is available for public comment. After reviewing any comments and making any substantive changes, the agency would publish final guidance on its website and place a notice in the *Federal Register*. Additionally, for economically significant guidance, OMB recommends that agencies prepare a response-to-comments document and make it available to the public.

OMB's GGP represented a major reform to guidance practice; yet important access, coverage, and compliance concerns remain even after its implementation. In particular, the bulletin does not apply to independent agencies,<sup>104</sup> making a broad swath of guidance out of its reach. Furthermore, as Stack reports, “only a sliver of agency guidance qualifies as significant guidance.”<sup>105</sup> As a result, few guidance documents follow these disclosure and public engagement opportunities.

Little data exists regarding agency compliance with OMB's GGP.<sup>106</sup> This poses challenges because of incentives to avoid labeling regulatory activities as significant or economically significant and thus escape OMB and public attention.<sup>107</sup> In 2015, GAO studied the guidance practices in the Departments of Agriculture, Education, Health and Human Services, and Labor, and GAO found considerable variation with regards to the departments' compliance with OMB's GGP.<sup>108</sup> The report concluded that concerns continued around transparency and public engagement opportunities for significant guidance.

- **Promoting the Rule of Law Through Improved Agency Guidance Documents (2019).** President Trump signed EO 13891 on October 9, 2019, and OMB issued a memo providing further implementation details for agencies on October 31, 2019. The order sought to make the guidance process more transparent for executive branch agencies and to create public participation opportunities during the development of significant agency guidance documents. Independent agencies were not included.

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103. Mendelson 2009.

104. GAO 2015.

105. Stack 2016, see page 1274.

106. Shapiro 2014.

107. Nou, Jennifer. 2013. “Agency Self-Insulation Under Presidential Review.” *Harvard Law Review*, 126: 1755-1837.

108. It may also be argued that President Trump would not have needed to enact EO 13891—especially that order's public engagement provisions—had OMB's GGP been widely followed by executive branch departments.

The order required that each executive branch agency create a single, searchable, and indexed database for all guidance currently in effect and which would be housed on the agency's website. Given its focus on all guidance—and not the subset of significant guidance—EO 13891 had a much larger disclosure reach than OMB's GGP and provided stronger direction to the agencies. For instance, the accompanying OMB memo stated that agency portals must be found at [www.\[agencyname\].gov/guidance](http://www.[agencyname].gov/guidance) on each agency's website. Portals had to include information such as: the guidance's title, date issued, date posted, unique agency identifier, hyperlink to guidance, topic of guidance, and one or two sentences summarizing the guidance. Agencies had until February 28, 2020, to set up their portals. All guidance documents were to state that they were nonbinding and must be labeled as "guidance." EO 13891 introduced a new petitioning process as well, where concerned parties could petition the agency to withdraw a guidance document.

For significant guidance, EO 13891 and OMB's implementation memo required that draft and final notices appear in the *Federal Register* with a pre-adoption public comment period of at least 30 days before the issuance of final guidance. The EO required agencies to consider comments and to prepare a response-to-comments document for all significant guidance, akin to a preamble for a final notice and comment rule. The OMB memo stated that the response may appear within the final guidance text or in a companion document. Draft and final significant guidance documents required sign off from agency leadership, as well as review by OMB before publication.

As described below, EO 13891 did not fully accomplish its objectives and several implementation issues curbed its effectiveness.

In January 2021, President Biden signed EO 13992, Revocation of Certain Executive Orders Concerning Federal Regulation. This order revoked EO 13891, along with several other Trump administration regulatory orders, and required OMB and other agency leaders to rescind any actions taken to implement EO 13891. Consequently, executive branch agencies are no longer bound by EO 13891.

## Guidance: New Research and Analysis

Having identified five management challenges in current guidance document practice that—despite the reforms just detailed—still exist across the federal government today, this report provides additional insights derived from recent research on guidance practice that puts these issues into sharper focus.



## Transparency: What Happened to the Guidance Portals?

The author of this report completed an analysis of the guidance repository portals for all cabinet departments and subagencies, completed in early February of 2021, provides information on the changes to agency guidance disclosure practice that may have resulted from EO 13891, as well as the early indications of President Biden's revocation of this EO.<sup>109</sup>

Overall, the research revealed that all cabinet departments established a website at [www.\[agencyname\].gov/guidance](http://www.[agencyname].gov/guidance) (or similar). Additionally, most of the websites provided information on how to petition an agency for a guidance document's rescission, which was a requirement of EO 13891. For instance, the Department of Defense listed an agency email address to send petition requests. After these commonalities, the analysis uncovered uneven evidence of the implementation of EO 13891—with some departments seemingly embracing the new guidance standardization and others less so.

On the one end of the agency spectrum, EO 13891 appeared to affect some department's guidance practice considerably. The Department of Justice (DOJ), for instance, had a searchable online portal with columns for program, title, date issued, identification number, topic, and overview. DOJ also issued an Interim Final Rule in the *Federal Register* on October 7, 2020, which detailed principles and compliance procedures based on EO 13891. The Interim Final Rule also referenced previous limitations on guidance usage at DOJ put in place by former Attorney General Jeff Sessions.

Similarly, the Department of Health and Human Services (HHS) appeared to have high compliance with EO 13891. HHS listed a single, searchable database for its subagencies, even while subagencies like FDA retained their own searchable portals. The HHS website highlighted a Final Rule issued on December 3, 2020, to implement EO 13891. An earlier draft of the HHS rule had received 88 public comments. In response to comments, two HHS replies stood out. First, one commenter recommended that HHS create a means for the public to identify guidance rescinded by the department. This was not a specific requirement of EO 13891, and HHS made no change. Second, a separate commenter asked HHS to create a notification system for the posting of new guidance. Again, the order did not require this; HHS declined to do so, stating that it lacked the resources to create this functionality.

The Department of Agriculture (USDA) represented a middle ground case in the implementation analysis. USDA had a website, but it did not create a searchable database for all department guidance. Instead, USDA linked to its subagencies and their portals. Additionally, the information contained was inconsistent, and some subagencies' portals appeared to only list significant guidance—calling into question the overall coverage of the data. Similarly, the

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109. The report's author undertook the analysis between February 1 and 9, 2021. It is possible that some agencies had already removed information from their portals regarding the implementation of EO 13891 by early February 2021. However, it appeared that the majority of the agency-specific guidance portals were yet unaltered by EO 13992's revocation.

Department of Veterans Affairs did not have a searchable guidance portal, but instead had a downloadable Excel sheet listing guidance that did not include information on when it was last updated.

On the other end of the spectrum, EO 13891 met with weaker implementation in select departments. The Department of Homeland Security's portal stated that it was last updated on February 28, 2020, and suggested that it would include guidance documents conforming to the EO's definition as well as other types of "guidance." This implied a lack of uniformity in the definition of "guidance." The Department of Housing and Urban Development's portal was not searchable and included a number of documents—such as legal opinions—that did not appear to conform with EO 13891's guidance definition. The Treasury Department created a website, but it stated that "Links to Treasury and bureau guidance documents and portals will be made available here when portals are established."<sup>110</sup>

The analysis suggested that EO 13891 received uneven implementation across the executive branch agencies. Numerous factors may have led to this result. One possible explanation revolves around the timing of the order, issued approximately 15 months before the end of the presidential term. There may have been insufficient time for OMB to oversee these practice changes across all units, and there may have been other competing priorities. Another explanation may be tied to agency experience. Select agencies—such as DOJ and HHS—appeared to embrace EO 13891 more fully, and these same agencies also had more experience with past guidance reforms. In the case of HHS, the FDA had over 20 years of experience implementing congressionally passed reforms to its guidance processes. At DOJ, a task force to study guidance in the department in 2017 had initiated its own reevaluation of DOJ practice and process reforms.<sup>111</sup>

Only limited evidence of President Biden's revocation was uncovered as of early February 2021 (more actions may have taken place since then). A key exception emerged from the Department of Labor (DOL), which referenced the Biden administration's executive order on its guidance portal website and issued a regulation on January 27, 2021, immediately removing any requirements associated with the prior order. Notably, DOL's internal regulation stated that its revocation was needed because EO 13891 took away agency flexibility and restricted the timeliness of agency guidance issuance.

Overall, two conclusions from this transparency-related research are:

- Over a year after the issuance of EO 13891, select executive branch agencies had not yet created their own searchable, online databases to house all guidance documents in effect. This suggests that agency-specific systems may be unlikely to generate the type of consistent and standardized information needed for a governmentwide guidance repository.
- The recent revocation of EO 13891 demands that agencies rethink their online guidance portals. Without new government standards, members of the public may have more difficulty identifying relevant agency guidance.

110. See <https://home.treasury.gov/guidance>, accessed 2/9/2021.

111. See <https://www.justice.gov/opa/pr/attorney-general-jeff-sessions-rescinds-25-guidance-documents>, accessed 3/11/2021.

## Engagement: Does Participation During Guidance Development Matter?

The report includes findings from a major research project focused on how the FDA provides evidence regarding the efficacy of public engagement during guidance creation.<sup>112</sup> The project aimed to better understand whether public engagement opportunities during guidance development mattered to the content of agency regulation. As highlighted above, the FDA is—at present—the only federal agency required by statute to take public comments during guidance creation. As a result, the FDA case provides a venue to learn lessons that may later extend across government.

The FDA research compared commenter success in affecting the content of FDA decision making across different policy instruments. The analysis focused on the development of 41 FDA policies—20 of which began as a draft notice of proposed rulemaking, and 21 of which began as a Level 1 draft agency guidance. Each was finalized between January 1, 2009 and December 31, 2014.<sup>113</sup> The research collected information from three sources:

- First, data were collected on each FDA policy from government sources, including the Unified Agenda of Regulatory and Deregulatory Actions and Regulations.gov.
- Second, a professional firm was hired to implement a telephone survey of the organizational commenters to these rules. Through this survey, 227 responses from commenters were gathered (38 percent response rate) on questions about the underlying policy. For instance, information was gleaned on the perceived public salience and technical complexity of each policy, as well as the level of scientific consensus or conflict underlying it.<sup>114</sup> The survey also queried commenters for their perceived success in influencing the specific policy. Finally, respondents were asked three general questions about influencing FDA policymaking, as well as demographic items.
- Third, two graduate students performed a hand-coded content analysis of the FDA's regulatory texts and comments to generate measure of commenter success during policy development.

The analysis used multivariate techniques to compare commenter success in affecting FDA policy decision making. This analysis found that organizational commenters to guidance documents often succeeded in achieving policy change on the top issues brought up in their comments.<sup>115</sup>

112. The report's author was the principal investigator for this research project. See Yackee 2020; Yackee 2021; Yackee, Susan Webb. "Regulatory Capture's Self-Serving Application." *Public Administration Review*, Forthcoming; Haeder and Yackee 2020.

113. For more information on the study design, see Yackee 2020.

114. Yackee 2021.

115. Yackee 2020.

The substantive effect suggested that the probability that an organization received some movement toward one of its top lobbying requests increased by almost 30 percent when engaging with an FDA guidance document, rather than a notice and comment rule. These results were then replicated using a wholly separate dependent variable that focused on perceived commenter success.<sup>116</sup>

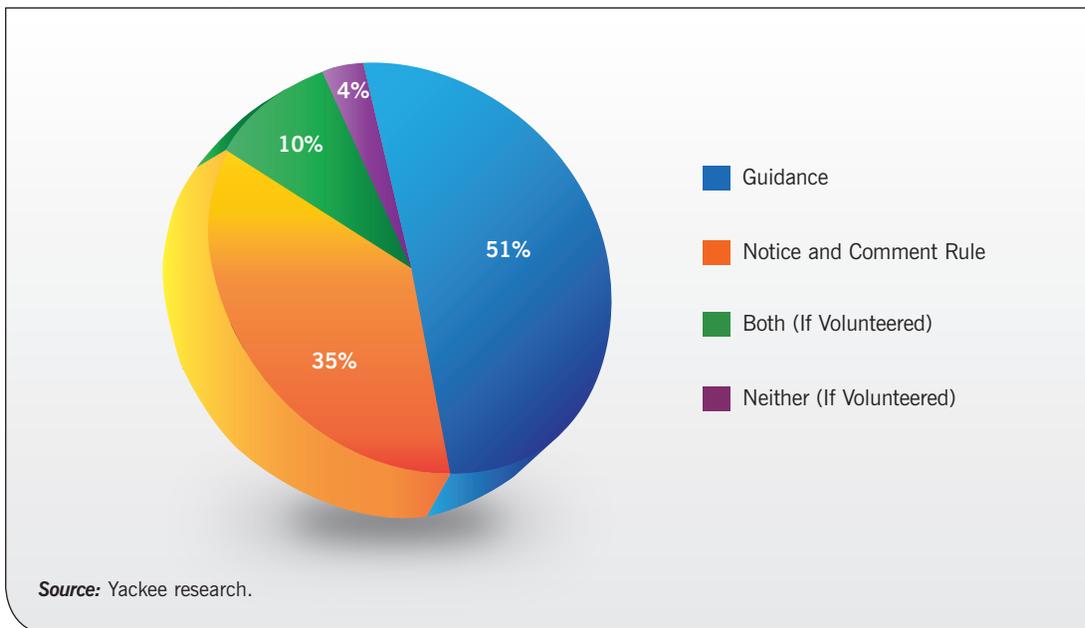
Similar findings emerged in the survey questions tapping general patterns in commenter influence in FDA policy decision making.<sup>117</sup> The first question queried:



*Next we want to ask you about the FDA's use of different policymaking tools. In general do organizations, like yours, have a better chance of influencing the content of an FDA guidance statement or an FDA notice and comment regulation?*

Figure 1 displays the responses. Over half of the organizational respondents (51 percent) answered that they have a better chance of influencing FDA guidance, while 35 percent replied yes to notice and comment rules and 14 percent offered both or neither. In a series of difference-of-means assessments, the organizational respondents who answered “guidance statement” (which is another name for a guidance document) were neither statistically more likely to come from large organizations nor more likely to come from the Washington, D.C. area. Significant differences did emerge, however, when considering organizational type, with pharmaceutical respondents statistically more likely to believe that they had a better chance at influencing guidance.

**Figure 1: FDA Policy Tools: Perception of Influence**



116. The quantitative modeling controlled for such factors as the rule's salience and complexity, overall number of public comments, other potential influence tactics, and organizational characteristics.

117. For more details, see Haeder and Yackee 2020.

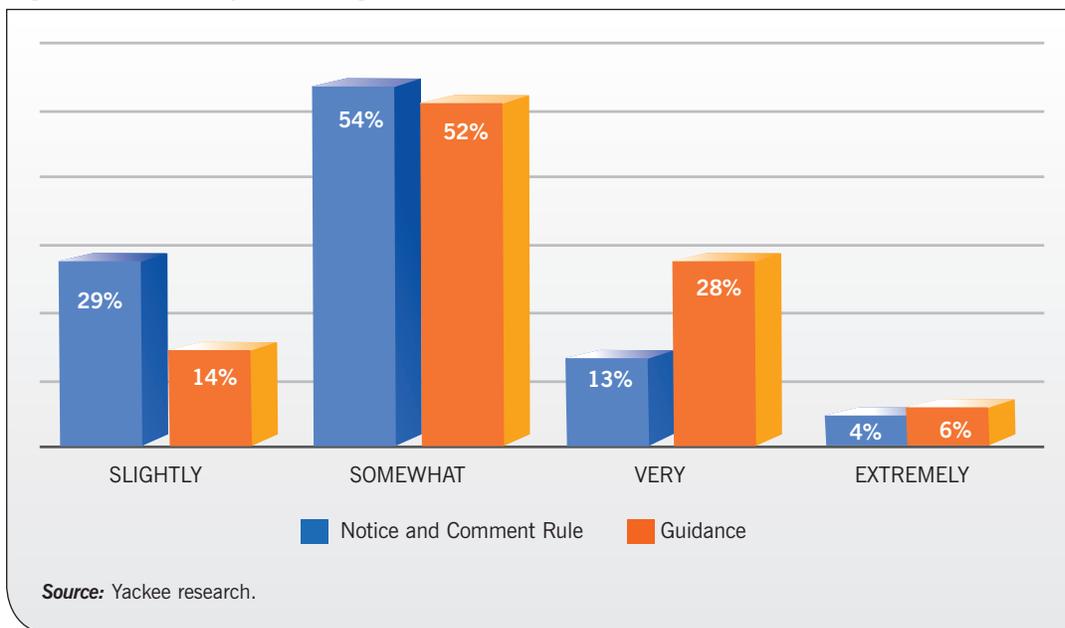
The next general survey question asked:



*How likely is it that organizations, like yours, will have a better chance of influencing the content of [an FDA guidance statement OR an FDA notice and comment regulation]? Would you say slightly likely, somewhat likely, very likely, or extremely likely?*

Figure 2 presents these results. The organizations answering “guidance statement” to the earlier question appear in orange, while those answering “notice and comment regulations” appear in blue. Several findings stand out. First, not only are participants more likely to believe that they hold greater influence on guidance, but they also perceive that influence to have greater impact. When comparing the “very” and “extremely” replies, 34 percent of guidance respondents answered this high degree of influence, as opposed to only half this amount (17 percent) of notice and comment respondents.

**Figure 2: FDA Policy Tools: Degree of Influence**



A final general survey question queried:

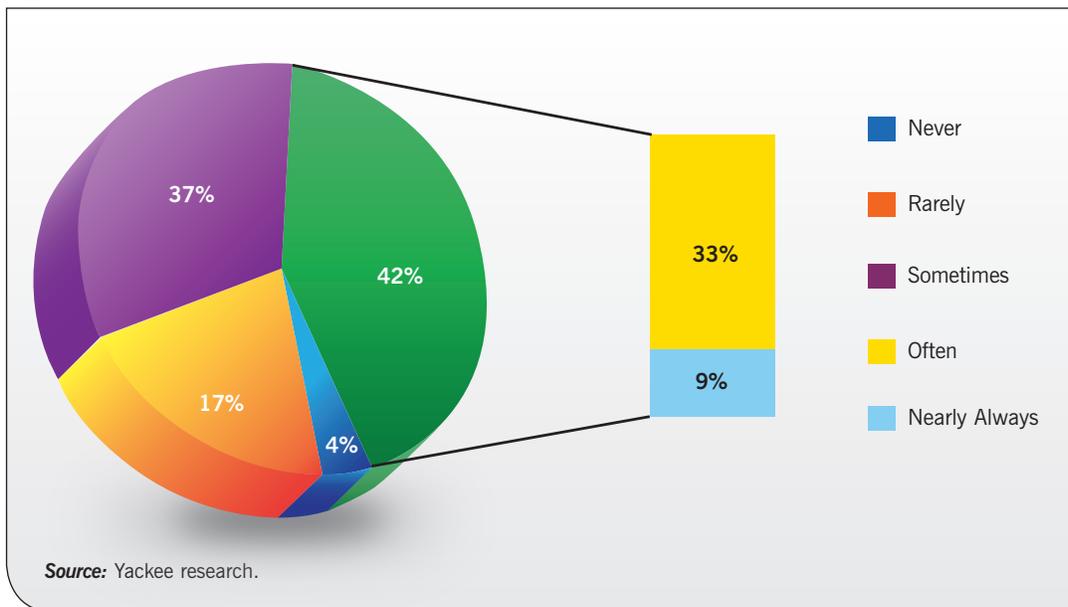


*How often does the FDA use guidance statements to issue policy decisions when it should use notice and comment regulations instead? Would you say: never, rarely, sometimes, often, or nearly always?*

Figure 3 displays the results. The pie chart shows the results for the first three categories, including the four percent of respondents who replied “never” to the question and the 17

percent responding “rarely.” Approximately 37 percent of the respondents suggested that the FDA “sometimes” uses guidance when it should employ notice and comment rules. The stacked bar breaks out the last finding of 42 percent further: 33 percent of organizations replied that the FDA “often” uses guidance when it ought not to, while nine percent said it “nearly always” does. Furthermore, difference-of-means tests suggest that organizations that have more experience submitting public comments during federal rulemaking were statistically more likely to reply that FDA “often” or “nearly always” relies on guidance.

**Figure 3: FDA Guidance: Perception of Over Reliance**



Overall, three conclusions emerge from this public engagement-related research:

- Organizational commenters to FDA guidance documents often perceived—and achieved—policy success during the guidance document development process. Indeed, such guidance commenters appeared to have greater success than those who participated in notice and comment rulemaking at the FDA. This suggests that public engagement during the FDA’s guidance process is associated with government responsiveness on the top issues brought up during the public comment period.
- Figures 1 and 2 show that organizational participants in FDA policy decision making generally agree that engagement during the FDA guidance process is more likely to be influential than participation during the notice and comment regulatory process. Engagement with FDA guidance is viewed as particularly efficacious by select interests, including representatives from the pharmaceutical industry.
- Figure 3 displays survey evidence that engaged participants in FDA policymaking processes frequently believe that the agency substitutes guidance when it should use the notice and comment process. More experienced participants with regulatory lobbying were more likely to draw this conclusion. Overall, this implies that the guidance process is already being used—and will continue to be used—to make meaningful policy decisions at the agency.

# RECOMMENDATIONS

This report provides a roadmap for enacting government management reforms that improve the development of agency guidance documents by fostering a more citizen-driven process.

Two critical tensions are balanced in these recommendations:

- Agency leaders and managers must retain nimbleness within the guidance process, and guidance should continue to provide a flexible and timely tool for agency policy decision making. Any reform efforts must avoid the risks associated with overly complex processes.
- There is a clear need for government reforms that increase the transparency of—and public engagement with—the agency guidance development process. Doing so will systematize and modernize government operations, while also furthering critical rule-of-law principles.

The report makes five recommendations to include in future guidance reform. The first three recommendations further the public value of transparency, while the last two advance public engagement.



## Develop Standardized Definitions for Guidance and Major Guidance

New guidance reforms could establish a standardized definition for a guidance document, as well as a standardized definition for a major guidance document. As highlighted above, guidance documents are presently often hard to identify. This remains true even as OMB's GGP and EO 13891 attempted to provide governmentwide definitions for the constructs.

The report recommends that a guidance document be defined as *any nonbinding general statement of policy or interpretive rule issued by a government agency intended to clarify existing statutes or existing notice and comment rules*.<sup>118</sup> This definition matches the common use of the term. Drawing on past reform efforts, the government could also require that all guidance documents use the term “guidance” in their title to increase visibility.

For the definition of *major guidance*, the report recommends following a similar standard as created in the Congressional Review Act of 1996 (CRA) to define a *major rule*, which is: “one that has resulted in or is likely to result in (1) an annual effect on the economy of \$100 million or more; (2) a major increase in costs or prices for consumers, individual industries, federal, state, or local government agencies, or geographic regions; or (3) significant adverse effects on competition, employment, investment, productivity, or innovation, or on the ability

118. Haeder and Yackee 2020.

of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.” The Congressional Research Service writes that the CRA’s definition of a major rule already applies to major guidance; as a result, this definition exists under current law.<sup>119</sup>

These definitions could be further supported by language inspired by FDA practice,<sup>120</sup> such as: *The agency may not use documents or other means of communication that are excluded from the definition of guidance document to informally communicate new or different regulatory expectations. These definitions must be followed whenever regulatory expectations that are not readily apparent from the statute or regulations are communicated to a broad public audience.*

Clear and codified definitions—alongside a statement of expectations on agency guidance usage—would provide new transparency guardrails for guidance practice, while largely retaining the agency’s nimbleness when using guidance as a regulatory policy tool.



### Create a Centralized Repository for Current Federal Government Guidance

Reform efforts could include the creation of a centralized repository for all federal government guidance in effect. At present, there is no governmentwide means for cataloguing or tracking guidance. Yet the analysis above suggests that past efforts to create agency-specific systems have been inadequate—leading to uneven implementation across agencies and incomplete information. A standardized, consistent, and transparent system would address these challenges.

This reform would bring together federal guidance policies in one place for the first time. The report recommends that the repository take the form of an online, searchable website. This online delivery mechanism would increase the accessibility and timeliness of the documents for agency officials and members of the public. Search fields would include the guidance’s title, date issued, date posted, hyperlink to the guidance, topic, several sentences summarizing the guidance, and a field designating whether the guidance replaces a previous document. Finally, the repository could include a field marking its status as a major guidance document, and a hyperlink to a “response to comments” document for all major guidance.

A central repository could incorporate similar information to previously created agency-specific repositories, like FDA’s, to avoid confusion, redundancies, and inefficiencies. Development and management of the online repository could be given to the Office of the *Federal Register* (OFR). Given its centralized role in publishing the *Federal Register*, this office could work across government agencies to create the new guidance resource. OFR could also institute a unique identifier system for all agency guidance. Alternatively, the General Services Administration (GSA), which leads the Regulations.gov program and website, could serve as an alternate organization tasked with the development and management of an online guidance repository.

While the administrative agencies who use guidance as a policy tool would need to feed information to OFR or GSA, day-to-day management of the repository could shift to this office. Doing so would help systematize the process while relieving agency reporting and organizational burden, placing the task of guidance cataloging with OFR or GSA—organizations that have deep expertise in this area.

119. Congressional Research Service. 2020. “The Congressional Review Act (CRA): Frequently Asked Questions.” R43992.

120. See 65 *Federal Register* 56477, Sept. 19, 2000.

Action to create a centralized guidance repository is particularly timely because, as the analysis above shows, President Biden’s issuance of EO 13992 has opened a window of opportunity to reconsider and greatly improve the public’s access to guidance document information.

### **Archive Guidance at a Semiannual Interval in an Easy-to-Use, Searchable System**

New guidance reforms could require the archiving of past versions of the centralized guidance repository on a semiannual basis. At present, no governmentwide guidance archive exists. As highlighted above, this shortcoming makes it difficult to appreciate and understand agency policy change across time.

OFR or GSA could manage the web-based archive, which would consist of past versions of the searchable centralized guidance repository. The archive would house twice-a-year “snapshots” of the centralized guidance database described above, summarizing all the agency guidance in effect at that time. Implementation of this recommendation would yield a dynamic record of guidance practice. Moreover, it would place no new limitations on the flexibility or timeliness of current agency guidance practice.

### **Harness Technology to Alert Members of the Public to New Guidance Documents, as well as Rescinded Guidance**

Reform efforts could use social media platforms to notify the public, as well as raise public awareness and engagement with guidance. This recommendation responds directly to the current lack of a governmentwide alert system for new and rescinded guidance. That shortcoming creates opaqueness within the guidance process—opening it to critiques including that guidance has been called “stealth regulation” and is produced “under the radar.”<sup>121</sup>

Social media can help to communicate policy change during guidance creation, including the promulgation of new guidance and the rescission of guidance, as well as provide information on public comment opportunities. For example, OFR frequently tweets to announce the postings of new notice of proposed rulemakings and final rules. Consequently, OFR is well positioned to use social media to systematically publicize information on guidance policy change across government. The centralized guidance repository described above would already tag new guidance based on topic. This type of information could be used to create specialized social media lists for guidance topic areas, which would ensure that concerned members of the public, regulated entities, and the media would receive alerts about new guidance and guidance rescissions in their areas of interest.

Agencies could publicize guidance on their own websites and through other means as well, such as meetings and email lists. Yet by using social media systematically, OFR or GSA could establish a communications baseline for all new and rescinded guidance. Doing so would produce a quick, seamless, and cost-effective way to ensure consistent distribution of guidance changes to a broad audience.

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121. See <https://www.mercatus.org/publications/regulation/confronting-problem-stealth-regulation>, accessed 3/20/2021, see page 1.



## Establish a Public Comment Process for Major Guidance Immediately After Issuance

New reforms could establish a process for post-adoption public commenting for all major guidance. Under this system, major guidance would be effective immediately upon posting to the GSA's centralized guidance repository. After the posting of a major guidance document, it would then be open for 30 days of public comment. In a process similar to that used by the FDA for Level 2 guidance, the agency would be required to review any comments it receives and post a new version of the guidance document if revised. Unlike the FDA's Level 2 guidance process, however, agencies would generate a response-to-comments document for each major guidance document, which would be posted on the centralized guidance repository.

The recommendation of a post-adoption comment period—which is similar to the Interim Final Rule process within notice and comment regulation—would yield many advantages. It would sustain the flexible and timely nature of major guidance, allowing agencies to issue major guidance quickly and promoting the nimbleness of this policy tool.

Post-adoption comment also guarantees that public feedback and engagement would occur on important agency guidance decision making. This process would be open so that any concerned party may add her/his views. Doing so would assist agencies, who would receive new technical insights and implementation information from public participation as in the notice and comment process.<sup>122</sup> Requiring that the response-to-comment document be published on the centralized guidance repository would provide accountability to commenters and ensure that the agency justify its decision making.

Agencies could also make the post-adoption commenting process readily accessible to the public—ideally by posting all guidance for public feedback on Regulations.gov. This is the FDA's current practice for Level 2 guidance documents. Having comments submitted electronically and to a common repository, such as Regulations.gov, could also assist agencies as they sift through and make sense of public feedback. This may also be facilitated by artificial intelligence and other machine learning tools that can help to extract trends and useful information, especially when many public comments are received.<sup>123</sup>

All five of the above recommendations could be implemented via executive order or memoranda to apply to executive branch agencies, or codified in statute to also cover independent agencies.

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122. Yackee 2015a.

123. Engstrom, David Freeman, Daniel E. Ho, Catherine M. Sharkey, and Mariano-Florentino Cuéllar. 2020. "Government by Algorithm: Artificial Intelligence in Federal Administrative Agencies." Administrative Conference of the United States Report, February 2020.

# CONCLUSION

The Biden administration has an opportunity to transform the agency guidance document development process. The reforms proposed in this report are designed to modernize the issuance of guidance while retaining the policy tool's nimbleness and timeliness.

The report makes five recommendations that further the values of transparency and public engagement. Framed as advancing the public's access and rule-of-law principles in government, these recommendations are likely to find support from a broad spectrum of Americans.

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**Susan Webb Yackee** is a Collins-Bascom professor of Public Affairs and Political Science and the director of the La Follette School of Public Affairs at the University of Wisconsin-Madison. Her research and teaching interests include the public policymaking process, public management, regulation, and interest group politics. Yackee has published articles in a number of journals, including the *American Political Science Review*, *Public Administration Review*, and *Journal of Policy Analysis and Management*. Yackee received the 2019 Herbert A. Simon Mid-Career Contribution Award from the Midwest Public Administration Caucus. Her article “Clerks or Kings? Partisan Alignment and Delegation to the U.S. Bureaucracy” (with Dr. Christine Kelleher Palus) won the 2017 Beryl Radin Award for the best article published in the *Journal of Public Administration Research and Theory*. Yackee is an elected member of the National Academy of Public Administration. As a junior scholar, she received four “Emerging Scholar Awards” from various professional associations. Yackee worked as a legislative research assistant in the U.S. Senate before beginning her academic training.



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## ACKNOWLEDGEMENT

Professor Yackee would like to thank the Burroughs Wellness Fund for its generous support of her FDA research through its Innovations in Regulatory Science Award.

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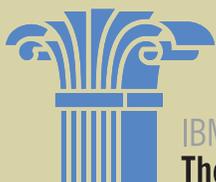
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