Policies that Bind? The Use of Guidance Documents by Federal Agencies

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Abstract

Each year, agencies issue thousands of pages of regulations through the notice and comment process. Given the extensive involvement of the federal government, the health and human services field is particularly affected by this kind of policymaking. Over the past decade, this process has drawn significant scholarly attention. However, policy creation via its close cousin—the agency guidance document development process—is largely unexplored within the fields of public administration and policy. Yet, over time, the utilization and importance of agency guidance has grown enormously. Indeed, in some areas, such as food and drug regulation, agency guidances are now the policy tool of choice for government regulators. This article provides an overview of agency guidance and its important role in the policymaking process. Additionally, it details an October 2019 U.S. presidential executive order on the subject, while also contextualizing the existing literature. The article then reviews select survey results drawn from a study of 41 U.S. Food and Drug Administration (FDA) regulations—20 of which were promulgated using the notice and comment process and 21 via the guidance process—to further illustrate the topic. The results imply a clear need for additional quantitative scholarship to better understand the political and policy underpinnings attached to regulating via agency guidance documents, particularly as they related to health and human services.

Keywords Regulation, Policy Tools, Rulemaking, Notice and Comment, Guidance

Points for Practitioners

- The vast majority of policymaking today occurs through rules issued by administrative agencies and not by statutes passed by legislatures.
- Notice and comment rulemaking has received some scholarly attention, but much less is known about another way that agencies issue policies: the guidance process.
- While we lack comprehensive empirical data, there are good reasons to believe that guidances play an important and growing role in policymaking in the health and human services field.
- We illustrate the importance of rulemaking via the notice and comment and guidance processes with examples from the U.S. Food and Drug Administration, a prolific regulator with a vast area of responsibility.

Over the past several decades, more and more lawmaking in the United States has shifted from the legislative to the administrative arena, with a concordant elevation of agency rulemaking over legislative policymaking. Yet within the rulemaking framework, agencies have a number of policy instruments at their disposal, all of which are governed by the Administrative Procedure Act of 1946 (APA). The most well-known of these instrument is the so-called notice and comment rulemaking process (Kerwin & Furlong, 2018; West, 1995; S. W. Yackee, 2006). In it, agencies cite congressionally-passed statutes for the delegated authority to issue legally binding regulations that implement, interpret, or prescribe public policies (Rosenbloom, 2018). Agencies generally initiate this process by

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issuing a draft policy proposal (also called a Notice of Proposed Rulemaking or NPRM). This draft is subsequently made available to the public as the agency solicits public comments. Agencies must then consider these comments before issuing a Final Rule. Crucially, Final Rules hold the power of law and are thus "legally binding" (i.e. they are similar to laws passed by Congress and signed by the president). This form of rulemaking is wide-spread and well-recognized within the public administration and public policy literatures (Balla, 1998; Golden, 1998; Haeder & Yackee, 2018; Jewell & Bero, 2007; Naughton, Schmid, Yackee, & Zhan, 2009; J. W. Yackee & Yackee, 2006).

Importantly, while "rulemaking is ubiquitous" across the federal government (Kerwin & Furlong, 2018, p. 3), it is particularly common in the area of health and human services. Indeed, the U.S. Department of Health and Human Services is one of the most prolific issuers of rules (Haeder & Yackee, 2020b). Both the shift from legislative to administrative lawmaking and the crucial role regulation plays in the health and human services area are nicely illustrated by the Affordable Care Act of 2010. A recent study found that by the end of 2019, the federal government had initiated 265 rulemakings and issued more than 9,000 pages of rules in response to this one public law (Haeder & Yackee, 2020a). Moreover, the Affordable Care Act also highlights the intergovernmental nature of many rulemakings. That is, given the extensive use of shared-governance arrangements of health and human services programs, often federal and state governments have to coordinate their rulemaking activities with state-level regulators (Haeder & Weimer, 2015; Haeder, Weimer, & Mukamel, 2019b).

While rulemaking through the notice and comment process has attracted some attention, fewer scholars and practitioners may be aware that rules are also promogulated via the agency guidance document development process. Guidance documents (also called guidances or guidance statements) include agency statements of policy and interpretive rules that are intended to clarify existing statutes or regulations (Funk, 2001). As such, guidances often provide the policy detail necessary for the implementation and enforcement of public policies by agency officials (Anthony, 1992; Hwang, Avorn, & Kesselheim, 2014; Manning, 1996). However, curiously, there are few studies of this policy tool or the underlying development process, also referred to as "quasi-rulemaking" (Gluck, O'Connell, & Po, 2015, p. 1803), within the public administration and policy literatures (but see Haeder & Yackee, 2020a; Shapiro, 2014; S. W. Yackee, 2020).

This lack of attention by public administration and policy scholars is surprising for three key reasons. First, guidances can be substantive and powerful policy instruments. Take, for example, an Obama Administration guidance document issued in May 2016 (see Hersher & Johnson, 2017). It detailed the Administration's plan to allow transgender students to use locker-rooms and bathrooms that corresponded with the students' gender identity, which was a new policy interpretation of Title IX of the Education Amendments of 1972. This action, which was rescinded by the Trump Administration less than a year later, illustrates how guidance documents can be used as meaningful policy instruments to address key policy issues. This is especially true in the area of health and human services regulation. Parrillo (2017, pp. 34-35), who interviewed over 130 experts, quoted one former federal government official as stating that operating Medicare would be "impossible" without guidance, while a former U.S. Food and Drug Administration (FDA) official shared, "I

cannot imagine a world without guidance." Notably, the importance of guidance documents is not confined to the health and human services policy sphere. As a former official noted, they are "the bread and butter" of the U.S. Environmental Protection Agency's (EPA) practice, while a former U.S. Occupational Safety and Health Administration (OSHA) official suggested that guidances are an "essential responsibility" of the agency (Parrillo, 2017, pp. 34-35).

Second, agencies use guidance on a "massive" scale across the federal government (Mendelson, 2007, p. 398). For instance, Lewis (2011, p. 508) explains that "to achieve its regulatory objectives" the FDA uses "guidance as its policymaking weapon of choice." Guidance documents have also been extensively used in the implementation of the Affordable Care Act (Bagley & Levy, 2014; Haeder, 2014; Haeder & Yackee, 2020a) and the Dodd-Frank Act (Greve & Parrish, 2014). However, as we highlight below, the true extent of policymaking by guidances remains empirically unexplored due to a lack of transparency and data availability.

Third, there is a large literature within the administrative law tradition that explores guidances (see for example Anthony, 1992; Gluck et al., 2015; Levin, 2018; Sunstein, 2016). Crucially from a public policy perspective, much of this literature focuses on questions of jurisprudence, legal doctrine, and the appropriate court review standards for guidance documents. In particular, there are few quantitative studies of the political or policy implications attached to the guidance process leaving many important questions largely unaddressed (but see Raso, 2010, 2015).

In the remainder of this article, we discuss the use of guidances across the federal government. We contribute to the literature by highlighting the advantages and disadvantages associated with agency reliance on guidance as a policymaking tool instead of the more traditional notice and comment rulemaking approach. We also bring attention to a recent executive order by President Trump seeking to implement significant reforms to the guidance development process. These reforms may impact the way agencies use guidances as policy instruments. We then illustrate the role of guidances in policymaking by reviewing new survey results attached to a study of interest group participants in the FDA's notice and comment rulemaking and guidance document development processes. We close with suggestions for further scholarly inquiry.

Guidance—A Critical Policymaking Tool for Regulators

Federal government agencies regularly use guidance documents to make policy statements and to provide interpretations of existing public policies (Mendelson, 2007). To many, this type of policy activity will sound a great deal like how agencies traditionally have used notice and comment rulemaking. The confusion is understandable. Indeed, numerous scholars have called the distinction between guidance documents and notice and comment rules "'tenuous,' 'baffling,' and 'enshrouded in considerable smog'" (Franklin, 2010, p. 276), as well as "fuzzy" (Levin, 2018, p. 266) and "blurry" (Rosenbloom, 2000, p. 60). And, while there are key differences between these policy tools, several of which we highlight below, in some agencies, such as the FDA, informed observers suggest that

government officials often use guidances as direct substitutes for notice and comment rules (Parrillo, 2017).

One of the key distinctions between these two approaches hails from the differential procedural and process requirements for writing rules. Crucially, the APA establishes a specific process for issuing notice and comment regulations; however, it does not establish a corresponding process for issuing guidance documents. Moreover, since the APA's passage in 1946, a number of additional procedural requirements have been imposed to further formalize the notice and comment process (Haeder & Yackee, 2015, 2018; J. W. Yackee & Yackee, 2010, 2016). Importantly, many of these requirements have been put into place to facilitate democratic accountability by increasing transparency and oversight of bureaucratic activities by elected officials. In contrast, agencies have far fewer requirements when issuing guidances (Romano, 2019).

The second crucial difference between notice and comment rules and guidances is that while the former has the force of law (i.e. they are "legally binding"), guidance documents do not (i.e. they are, technically speaking, not "legally binding"). At first blush, this difference appears quite important. However, in practice, it may be less so. As Shapiro (2014, p. 531) concludes, regulated entities generally comply with the requirements set forth in guidance documents "out of fear" of the agency. After all, as Mantel (2009) explains, agencies frequently use guidances as the basis for their policy enforcement actions—suggesting that "prudent" regulated entities may comply with guidances to avoid confrontations with those agency officials who hold power over them (Hickman, 2009, p. 240). Hwang et al. (2014, p. 770) add that "guidance documents remain controversial because, by providing the agency's 'thinking' on interpretive reasoning or enforcement standards, they may have regulation-like effects." Additionally, according to some scholars, bringing legal challenges to contest a guidance document is more difficult than for a notice and comment rule (Funk, 2001; Raso, 2010; Romano, 2019). When taken together, the above illustrates why some observers conclude that guidances may "bind" in practice, even if they do not, technically-speaking, bind by law (Anthony, 1992).

Given these distinctions, there are significant advantages and disadvantages to using guidance documents as policy tools. For instance, as suggested above, guidance document development is often seen as a faster, more flexible, and less proceduralized approach to policymaking than notice and comment rulemaking (Gluck et al., 2015; Mantel, 2009; Shapiro, 2014). Some observers may interpret these factors as advantages because they allow agencies to respond more nimbly to changing political circumstances or technical and scientific innovations. Less benevolent explanations may see the speed, as well as the reduced participation requirements attached to guidance documents, as a means to shield public policy development from necessary political oversight and public participation. Similarly, the ease of issuing guidance may be seen as an advantage on the one hand by allowing presidents to unilaterally move policy in the face of gridlock. However, on the other hand, as the bathroom guidance example above suggests, future presidents can relatively easily rescind previous guidances. As a result, one of the "costs" attached to policymaking via guidance documents is that they can result in a more volatile regulatory environment and with less certainty and predictability for regulated entities. In contrast, it

is much more difficult to rescind a notice and comment rule is because it requires an agency to go through the full regulatory process (Kerwin & Furlong, 2018). Another way to consider the advantages and disadvantages of policymaking via guidance documents is to look at the human capital expenditures attached to these tools. As Shapiro (2014, 582) writes, policymaking via notice and comment rulemaking is much more "costly." Agencies have to develop a robust written record to establish a political and, oftentimes, scientific basis for new regulations (West, 1995). Thus, the notice and comment process—which is closely policed by the courts—is intense in terms of agency resources. In contrast, the guidance document development process often requires less in terms of a written record and justification (Romano, 2019). This may be seen as a benefit to some, but to others, who believe that agency policymaking ought to only take place when a fully developed evidentiary record undergirds that decision-making, it may be seen as problematic.

The Trump Administration and the Future of Guidance Documents

Yet, recent developments may cause the differences between guidance documents and notice and comment rules to shrink even further in the future. Issued by President Trump in October 2019, the Executive Order on *Promoting the Rule of Law Through Improved Agency Guidance Documents* (E.O. 13891) seeks to increase public participation opportunities during the formulation of guidances. Specifically, it requires all cabinet agencies to seek public comment on "significant" guidance documents. This action builds on existing practices at the FDA based on the Food and Drug Administration Modernization Act of 1997, which required the agency to take public comments on all important guidance documents. Since that point, the FDA has been a leader in formalizing its guidance process. Yet, the new order extends even beyond the FDA's current practices because, while the FDA is required to *solicit* comments on important guidance, it is not required to *respond* to the comments it receives (Lewis, 2011). In contrast, E.O. 13891 specifically requires agencies to *consider and formally respond* to all significant comments when issuing agency guidances. Thus, with the implementation of these requirements in 2020, there will be an increased formalization of the guidance process, as well as new opportunities for public engagement and feedback across many federal agencies.

Additionally, E.O. 13891 further attempts to increase public scrutiny of guidances by systematizing and making more transparent how government agencies issue guidance documents. To do this, it requires all cabinet agencies to create a searchable database of their active guidance documents on their websites. For instance, in the past, due to significant variation in agency practice, guidance documents were "difficult-to-monitor" by the public and thus "more difficult for elected officials to oversee" (Shapiro, 2014, p. 526). The executive order's new database requirements will, if fully implemented, unquestionably increase the visibility and trackability of the process. The databases, which will also come into effect in 2020, will also allow researchers to provide the first aggregate-level count of agency guidance documents across most government agencies. This development is crucial because currently there is no way to systematically account for all agency guidances across federal agencies. Hamstrung by a dearth of data, scholars have been unable to even

descriptively outline the extent of guidance usage, let alone assess empirically its implications. Thus, with these new data in hand, scholars will be able to undertake important research into the political and policy underpinnings attached to regulating via agency guidance documents.

FDA Guidance and Public Participation Data

As described above, rulemaking plays an important role in the policymaking process across all sectors and at all levels of government. This holds particularly true for health and human services policies. For instance, rules govern issues such as setting standards for Medicare Advantage plans (Haeder, 2019b, 2019c), establishing contraception coverage (Haeder & Yackee, 2020a), determining the adequacy of provider networks (Haeder, Weimer, & Mukamel, 2019a), and regulating nursing homes (Mukamel, Haeder, & Weimer, 2014) and hospitals (Haeder, 2019a).

Yet even in the regulation-intensive health and human services sector, the FDA stands out as one of the most important regulators in the United States (Carlson et al., 2020; Carpenter, Chattopadhyay, Moffitt, & Nall, 2012; Lavertu & Weimer, 2008). Its mandate is huge—spanning cosmetics, pet food, vending machines, medical devices, tobacco, pharmaceuticals, and more. According to the FDA, the agency's policy reach is so extensive that it regulates products accounting for about 20 cents of each dollar spent by American consumers (FDA 2011). In making its forward-looking regulatory policy decisions, the FDA has increasingly turned to the use of guidance documents over time (Lewis, 2011). Recent in-depth interviews confirm its importance as a policy tool. For instance, one industry official told Parrillo (2017, p. 182) that the FDA uses notice and comment rules infrequently to regulate in modern times, and instead often relies on guidance documents to make important policy decision. Another interviewee of Parrillo shared that the FDA's regulatory practice can be frustrating because it often uses a guidance document when it should have used a notice and comment regulation in their opinion.

While the FDA relies heavily on guidances, it also utilizes a more established and extensive process for developing those guidances than most other agencies (Mendelson, 2007). Specifically, as mentioned previously, it is required by the Food and Drug Administration Modernization Act of 1997 to solicit public comments during the creation of its significant guidance documents. Consequently, the FDA issues two types of guidances. The first type are Level-1 guidance documents which govern scenarios where the "agency believes there is a major change in policy" or for "complex or highly controversial issues" (Hwang et al., 2014, p. 772). In a similar fashion to notice and comment rulemaking, the FDA publicly issues a *Draft Guidance Document*, which it then opens up for public comments. After taking in public comments, the FDA then issues a *Final Guidance Document*. FDA Level-2 guidances are reserved for narrow and more minor matters and do not take public comments. Importantly, E.O. 13891 will extend the requirement for public participation on significant guidance documents to all cabinet-level agencies and sub-agencies in the near future. Thus, the FDA's experience with public participation during the guidance development process may provide important lessons

regarding how the executive order's procedural changes may affect regulatory policymaking across the federal government.

In order to better understand these lessons, we undertook a survey of interest group commenters to a sample of recent FDA rulemakings. We specifically focused on FDA notice and comment rules and Level-1 guidance documents. We studied 41 completed FDA rulemakings—20 of which began as an NPRM and 21 as a Draft Guidance Document; each of the rulemakings received public comments. As part of the study design, we hired a professional survey firm to implement a telephone survey of the interest group commenters to these rules. We define *interest groups* broadly to include "companies, business and trade associations, unions, other levels of government, and public interest groups" (Kerwin & Furlong, 2018, p. 180). The firm gathered 227 responses with a 38% response rate. The survey included questions about the interest group's participation on the underlying sample rule, as well as three general questions about the FDA's use of notice and comment rules and guidance documents. We report the general survey question results for the first time below.

Two survey questions inquired about how interest group respondents perceived influence across the two different policy tools. We asked: *"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?"* Over 50% of the respondents answered "guidance," approximately 35% stated "notice and comment regulation," while the remaining interest groups volunteered either "neither" or "both." These descriptive statistics, which are provided in Table 1, suggest that many interest groups believe that greater regulatory policy influence may be had when lobbying during the FDA's guidance formation process.

Table 1: Descriptive Statistics

Variables	Mean	Low	High	Observations
Better Chance of Influencing Guidance	0.510	0	1	197
Better Chance of Influencing Notice and Comment Rule	0.355	0	1	197
Federal Regulatory Lobbying Experience	3.413	1	5	223
Organizational Size	2.920	1	5	226
Located in Washington, DC	0.317	0	1	227
Pharmaceutical Company	0.079	0	1	227
Public Interest Group	0.092	0	1	227
How Likely - Better Chance of Influencing Guidance	2.263	1	4	99
How Likely - Better Chance of Influencing Notice and Comment Rule	1.928	1	4	69
Use Guidance Instead of Notice and Comment Rules	3.258	1	5	186
Use Guidance Instead of Notice and Comment Rules—Often of Nearly Always	0.419	0	1	186

Notes: The number of observations is reduced in size in some cases as a result of respondent options such as "*don't know*" and "*refused.*"

Looking specifically at those interest group participants who responded "guidance" to this question, we then implemented a series of difference-of-means tests to discern potential patterns in the responses. A summary of these assessments is shown in Table 2. For instance, we found that respondents who answered "guidance" did not have more experience participating in federal rulemaking in the past. We also did not find evidence that these respondents came from larger organizations or from the Washington D.C. area. However, differences did emerge with regard to group type. That is, pharmaceutical companies were much more likely to believe they had a better chance of influencing an FDA guidance, while public interest groups were much more likely to respond that they had a better chance of influencing an FDA notice and comment rule. Overall, these findings reinforce and extend analyses completed by one of us elsewhere, which also suggest that interest groups hold policy influence during the FDA's guidance document development process (S. W. Yackee, 2020).

Table 2: Summary of Difference-of-Means Tests

First Variable	Second Variable	Statistically Significant
Better Chance of Influencing Guidance	Federal Regulatory Lobbying	No
Better Chance of Influencing Guidance	Organizational Size	No
Better Chance of Influencing Guidance	Located in Washington, DC	No
Better Chance of Influencing Guidance	Pharmaceutical Company	Yes = More Likely
Better Chance of Influencing Notice and Comment Rule	Public Interest Group	Yes = More Likely
Use Guidance Instead of Notice and Comment Rules—Often of Nearly Always	Federal Regulatory Lobbying Experience	Yes = More Likely
Use Guidance Instead of Notice and Comment Rules—Often of Nearly Always	Organizational Size	No
Use Guidance Instead of Notice and Comment Rules—Often of Nearly Always	Located in Washington, DC	No
Use Guidance Instead of Notice and Comment Rules—Often of Nearly Always	Pharmaceutical Companies	No
Use Guidance Instead of Notice and Comment Rules—Often of Nearly Always	Public Interest Group	No

Notes: Standard cut-off levels establish statistical significance.

A follow-up survey question asked: *"How likely is it that an organization, 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?"* For those interest group respondents that had previously answered "guidance," 35% replied "very likely" or "extremely likely," while for those groups that identified "notice and comment regulation," 17% replied "very likely" or "extremely likely." These statistics imply that more interest group respondents felt strongly about their ability to affect the content of guidance documents than traditional notice and comment rules.

The final survey question queried: *"How often does the FDA use guidance statements to issue policy decision when it should use notice and comment regulations instead? Would you say: never, rarely, sometimes, often, or nearly always?"* This question taps into the perception that the FDA may be using guidance to bind the public when, in theory, only notice and comment regulations can be used for this purpose. The responses demonstrate that 21% of respondents believe that the FDA "never" or "rarely" uses guidance when it should be using a notice and comment rule, and 37% answered "sometimes." A little over 33% of the respondents replied "often", while 9% stated "nearly always." We then implemented the analogous difference-of-means assessments as listed above for the 42% of respondents who answered "often" or "nearly always" versus all other

respondent types. We found that interest groups with more experience lobbying during rulemaking were statistically more likely to reply that the FDA "often" or "nearly always" uses guidances when it should have used a notice and comment regulation. However, none of the other difference-of-means tests revealed discernable patterns.

Conclusion

Anecdotally, agencies make extensive use of guidance documents when implementing public policies. And, as we have reviewed above, some government agencies, such as the FDA, have relied heavily on guidances to "broadly and prospectively" regulate the public for decades (Mendelson, 2007, p. 397). Yet, historically, few scholars outside of the administrative law field have focused their research attention on agency policymaking via the guidance development process. President Trump's recently issued E.O. 13891 provides additional reasons and opportunities for scholars of public administration and policy to engage with one of the most important regulatory policy tools used across the federal government.

This is not to say that we know little about agency guidance in general. There is a "voluminous" literature in the administrative law tradition on guidance (Levin, 2018, p. 265). However, that literature is inevitably focused on the methods and questions core to administrative law scholars—including a focus on legal doctrine, the legality of guidance, and the proper court review standards for guidance. In contrast, much more research is needed around topics and empirical methods central to our fields of public administration and policy. These include important questions related to public governance such as investigating public participation and influence patterns, transparency requirements, different levels of proceduralization across guidance and notice and comment rulemaking, the role of political accountability and responsiveness, and the potential for bias within the guidance document development process. We strongly suggest approaching these topics using the methods and tools at the heart of modern social science research.

Our exploratory empirical work above suggests that more research is particularly needed around interest group activity across the different policy tools, as well as greater investigation regarding the discretion and autonomy of public sector agencies to choose one policy tool over another. In launching into this area of research, policy and public administration scholars may be able to capitalize on the new data generated by E.O. 13891 on guidance usage, as well as the new data on public commenting on significant guidances, which will be collected across all cabinet agencies, to explore the political or policy implications attached to modern agency policymaking. As we laid out above, there are good reasons to believe that rulemaking via the guidance process is particularly important and frequent in the health and human services field. Scholarly attention from those with public administration and policy backgrounds is especially necessary to ensure that we properly understand the significance of guidance documents to government regulation today.

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