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Restoring Good Guidance Practices

How to restrain the administrative state and make government better

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Executive summary

Federal agency guidance documents form a large and expanding part of the administrative state's regulatory universe. These informal documents including memoranda, bulletins, and circulars, greatly outnumber the statutes enacted by Congress and the legislative rules which, because they carry the force of law, are required to go through the notice and comment procedures of the Administrative Procedure Act (APA) and, for significant regulations, review by the Office of Management and Budget.

Guidance documents escape the APA's procedural safeguards because they technically have no legal force and are not binding. But it is widely acknowledged that as a practical matter, many guidance documents do bind regulated entities and can have a large economic impact. Agencies frequently use guidance documents to effectively change the law or expand the scope of their delegated regulatory authorities. This is often done with little or no input from the public and sometimes in an opaque manner that leaves regulated entities and the public ignorant of new or changed guidance.

This paper examines Good Guidance Practices (GGPs) – such as notice and public comment, centralized review, and searchable databases – that attempt to subject significant guidance to public and stakeholder scrutiny, improve final guidance documents with stakeholder input, and to inform interested parties of relevant guidance.

Guidance documents strongly influence private behaviors. For practical purposes, guidance documents are often as binding as legislative rules on regulated entities. Even experienced observers and jurists sometimes have difficulty distinguishing between the categories of rules. Increasingly, agencies are relying on guidance to circumvent the notice-and-comment rulemaking process, central review, and Congressional scrutiny under the Congressional Review Act.

Over several decades, multiple efforts to institute good guidance practices for agencies have been tried and failed. The Food and Drug Administration's GGP regulation is a notable exception. The latest effort – President Trump's 2019 Executive Order 13891 entitled "Promoting the Rule of Law Through Improved Agency Guidance Documents – directed each agency to promulgate regulations setting forth procedures for issuing guidance documents and to set up searchable databases that would allow easy access by members of the public to agency guidance. Thirty-two departments and agencies issued guidance regulations. The most prominent was the Department of Health and Human Services (HHS) December 2020 regulation. Unfortunately, on his first day in office, President Biden revoked EO 13891 with his EO 13992 that directed departments and agencies to rescind their guidance regulations.

Why it matters: Guidance allows agencies to bind the regulated public without adequate notice and public input, without an opportunity for regulated entities to know the full range of rules relevant to their actions. Agencies have even used guidance to avoid enforcing existing laws. Should the Supreme Court overturn or substantially limit its longstanding Chevron doctrine, as many expect it will, agencies will likely increasingly rely on guidance to evade notice and comment rulemaking.

As evidenced by HHS's regulation rescinding its GGP regulation, the agency and the Biden administration view GGP as a burden rather than a benefit. They are most concerned with maximizing administrative powers and flexibility unimpeded by oversight. They ignore the democratic accountability and improved policy that result from GGP. They assume, with scant evidence, that bureaucratic experts know best and would not benefit from public and stakeholder input. HHS's rejection of interference with its autonomy was so absolute that it objected to the requirement that each guidance document contain the disclaimer that it is guidance and may not carry the force and effect of law.

The revocation of the GGP rules seemed to have less to do with reasoned decision-making than with a political decision to reverse a political opponent's accomplishments and to remove restraints on the expanding administrative state. Without the re-establishment of GGPs, guidance is likely to be increasingly used to expand agencies' powers without any democratic constraints.

Policy suggestions: Ideally, Congress would pass a statute with many or all of the GGP requirements found in EO 13891. But Congress has, thus far, been unable to pass GGP legislation. Good guidance

regulations will have to await a new administration willing to advance GGPs at the outset of its term so they can become embedded before there is an opportunity for rapid revocation.

Introduction

It is often said that America is a nation of laws.[1] Over the past one hundred years or so, America has become a nation of administrative agency diktats. Some of these rules and directives are issued with notice to and input from the public. Many more are issued with limited public knowledge or input.

We now live in a so-called administrative state resulting from a proliferation of federal agencies that make up the executive branch – such as the Environmental Protection Agency, the Department of Transportation, and the Food and Drug Administration – which, pursuant to authority granted from Congress, issue an ever expanding array of rules and regulations, as well as several independent agencies that operate without direct oversight from the president.[2] Their administrative rules touch on every aspect of our lives and are far more numerous than the statutes enacted by Congress.

Legislative rules are rules or regulations issued by federal administrative agencies that carry the force of law. They are required to undergo the notice and comment procedures of the Administrative Procedure Act (APA). But as Wayne Crews of the Competitive Enterprise Institute has documented, agencies issue far more informal documents such as letters, memoranda, bulletins, and circulars than they issue formal regulations. He labels this mass of agency output as "regulatory dark matter."

These documents are often general statements of policy or interpretive[3] rules advising the public of how the agency interprets the statutes and regulations it administers. Collectively, these policy and interpretive documents are usually referred to as agency "guidance."

Guidance documents are technically not legally binding[4] and are exempted under the APA from notice and comment requirements.[5] While many guidance documents deal with minor, mundane matters, some guidance can have a substantial economic impact on regulated entities that alter their conduct to conform to the guidance. In fact, agencies often use guidance documents to effectively change the law or expand the scope of their delegated regulatory authorities. This is often done with little or no input from the public and sometimes in an opaque manner that leaves regulated entities and the public ignorant of new or changed guidance.

Ideally, the public and regulated entities would be notified about significant proposed guidance documents in advance and have the opportunity to comment on them. In addition, centralized review of proposed guidance by experienced regulatory overseers such as the Office of Management and Budget (OMB) to assess the economic impact of the proposal and determine how it interacts with other laws, regulations and guidance would be helpful. Public notice and comment and informed review would ensure democratic accountability, prevent executive overreach, and improve the final guidance. Once finalized, guidance documents need to be readily available in an easy to access format so that regulated entities and the public can be informed of agency expectations.

These procedural safeguards are in place for legislative rules or regulations. Unfortunately, none of these so-called Good Guidance Practices (GGP) – notice and public comment, centralized review, and searchable databases – are widely employed for guidance in the administrative state. Efforts to institute them have been incomplete, ignored, and actively resisted.

This paper sets out to explore the administrative landscape, discuss the value of GGPs, examine when GGPs have been utilized and why they have generally

[1] The phrase derives from John Adams's statement that philosophers "define a republic to be a government of laws, and not of men. …bound by fixed laws, which the people have a voice in making, and a right to defend." It expresses the importance of following laws enacted through proper constitutional processes, even if that sometimes hampers the adoption of policies or programs that seem good or helpful. John Adams, *The Letters of Novanglus*, February 6, 1775, https://www.let.rug.nl/usa/presidents/john-adams/novanglus-text-february-6-1775.php.

[2] Susan E. Dudley, "Milestones in the Evolution of the Administrative State," 150(3) *Dædalus* 33-48 (Summer 2021), https://direct.mit.edu/daed/article/150/3/33/102568/Milestones-in-the-Evolution-of-the-Administrative.

[3] The APA uses "interpretative," but most people use the more common spelling interpretive. Both will be used interchangeably in this paper since both are used in the legal literature.

[4] See, e.g., *Shalala* v. *Guernsey Mem'l Hosp.,* 514 U.S. 87, 99 (1995).

[5] 5 USC 553(b)(A).

failed or been resisted, and suggest how they might be utilized in the future. In the first section, I discuss the topology of the administrative state and rulemaking in the US. This will consider the legal bases for different government powers under the Constitution and how they have changed over time to allow broad delegations of power to executive branch agencies. Various safeguards have evolved to regulate and review the regulations these agencies publish including notice and comment rulemaking under the Administrative Procedure Act, centralized review by the Office of Regulatory Affairs (OIRA) within OMB, and the ability to review and reverse final rules by Congress under the authority of the Congressional Review Act.

Next, I describe what guidance is and how it differs from the legislative rules that are subject to these various procedural safeguards. Even experienced observers and jurists sometime have difficulty distinguishing between the categories of rules.

The following section describes how guidance has proliferated so that it greatly outnumbers statutes and formal regulations. While guidance is technically distinguished from legislative rules by not having legal force, many guidance documents strongly influence private behaviors and have tremendous economic impact. Often guidance, for practical purposes, is as binding as a legislative rule on regulated entities. Increasingly, agencies are relying on guidance to circumvent the notice-and-comment rulemaking process, central review and Congressional scrutiny.

Since guidance often has binding effect that makes it difficult to distinguish from legislative rules, it probably makes the most sense to base the regulation and use of procedural safeguards for rules, including guidance, on the importance or significance of the rule. Various, largely unsuccessful, attempts that have been made over the years to institute GGPs are outlined.

In 1997, for example, Congress established good guidance practices for the FDA in the law.[6] While these have largely been successful, there have been problems in FDA's implementation. A decade later, OMB published a final "Bulletin for Agency Good Guidance Practices" in 2007. But this OMB effort was undermined by the incoming Obama administration and was essentially ignored.

A major, recent attempt to bring good guidance to departments and agencies was President Trump's 2019 Executive Order 13891 entitled "Promoting the Rule of Law Through Improved Agency Guidance Documents."[7] It directed each agency to promulgate regulations setting forth processes and procedures for issuing guidance documents and to set up searchable databases that would allow easy access by members of the public to agency guidance. Thirty-two departments and agencies responded by issuing guidance regulations. Unfortunately, immediately upon assuming office, President Biden revoked EO 13891 with his own EO 13992 that directed departments and agencies to rescind their guidance regulations, which they did.

The next section uses the guidance regulation issued by the Department of Health and Human Services (HHS) in December 2020 in response to EO 13891 and its subsequent revocation in response to EO 13992 as a case study. HHS was selected because it is the largest civilian department in the federal government with a $1.6 trillion budget. Its component divisions regulate a large swath of the economy, are the nation's most important health-related regulators, and were deeply involved in the then-ongoing response to the COVID-19 pandemic. Guidance issuance in general escalated during the COVID-19 pandemic, but especially within the various health care components of HHS. Importantly, unlike other agencies' revocations of their guidance regulations pursuant to EO 13992, the HHS regulation revoking its guidance regulation provided detailed discussions of the various elements in the guidance regulation and the rationales for revoking them. This creates the opportunity to study whether the guidance regulation or its revocation is the better policy.

HHS exaggerated the purported burdens of the guidance rule and minimized the benefits of GGP. The Department seemed to be solely concerned with preserving its flexibility to act free of public oversight or procedural requirements. And it expressly worried that good guidance practices might burden and slow Biden administration actions "advancing equity for all."

[6] Food and Drug Administration Modernization Act of 1997, 21 U.S.C. §371(h).

[7] Executive Order 13891 of October 9, 2019, 84 FR 55235, https://www.federalregister.gov/documents/2019/10/15/2019-22623/promoting-the-rule-of-law-through-improved-agency-guidance-documents.

The final section concludes that any action to reinstate the HHS good guidance regulation or extend GGP across the government in the near future will likely have to originate with Congress. Regrettably, repeated failures to pass proposals to improve the use of guidance and increase congressional oversight of administrative rules make this prospect unlikely.

Topology of rulemaking in the administrative state

The US Constitution cedes the power to pass laws to Congress (Article I), directs the executive branch to administer and enforce those laws (Article II), and gives the judicial branch ultimate responsibility for interpreting the laws and the Constitution (Article III). Over the past 100 years, the lines between the Article I Article II, Article III powers have been blurred. There is now what has been referred to as the "fourth branch" of the federal government – federal agencies, located within the executive branch, that combine legislative, executive, and judicial powers.[8]

Congress created a few independent agencies in the 19th century, but the New Deal brought a huge expansion of the number of agencies in the executive branch during the 1930s.[9] The Supreme Court had held in 1892 "that Congress cannot delegate legislative power to the President is a principle universally recognized as vital to the integrity and maintenance of the system of government ordained by the Constitution."[10] The Court modified this "nondelegation doctrine" in 1928, allowing Congress to delegate legislative power as long as the statute included an "intelligible principle" to guide executive action.[11] But, with the exception of two cases in 1935 in which the Court invoked the nondelegation doctrine to invalidate provisions of the National Industrial Recovery Act, the Court has always been able to discern an intelligible principle to avoid limiting Congressional delegation of power to the executive branch.[12]

By essentially abandoning the nondelegation doctrine, the Supreme Court allowed broad delegations of authority to executive branch agencies that permitted the assignment of substantial discretion over regulatory policy to executive branch officials.[13] Nevertheless, debate on the proper role of administrative agencies continued over the ensuing decade leading to passage of the Administrative Procedure Act (APA) in 1946.[14]

The APA represented a compromise between those who valued bureaucratic expertise and flexibility in the modern state and those who demanded accountability to democratic values and legislative entities. The statute required agencies to provide public notice of all rules, an opportunity for public comment, and a response to those comments to accompany publication of final rules. Final rules would be subject to judicial review to determine whether they are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."[15] The APA defined a rule as, "the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy."[16]

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[8] Peter L. Strauss, "The Place of Agencies in Government: Separation of Powers and the Fourth Branch," *Columbia Law Review* 573, 582 (1984).

[9] "Congress created the first modern regulatory agency, the Interstate Commerce Commission (ICC), in 1887. … In the decades that followed, Congress established a variety of agencies to regulate interstate trade, water and power, communications, commodity exchanges, and other areas of activity. These agencies were often outside of executive departments and structured to be somewhat independent of presidential control. Their members could only be dismissed 'for cause' ('inefficiency, neglect of duty, or malfeasance in office') in contrast to political appointees in executive departments who served 'at the pleasure of the president.'" Dudley, "Milestones in Administrative State," p. 34.

The ICC was primarily created not to remedy market failure, but to satisfy shippers seeking government intervention to establish stable rates from the railroads. Fred L. Smith, Jr. and Marc Scribner, *Reviving Capitalism: Lessons from the Near-Death and Rebirth of American Railroads,* Competitive Enterprise Institute, *Profiles in Capitalism* No. 2, November 2015, pp. 11-13, https://cei.org/wp-content/uploads/2015/11/Fred-Smith-and-Marc-Scribner-Reviving-Capitalism.pdf.

[10] *Field v. Clark,* 143 U.S. 649 (1892).

[11] *J. W. Hampton, Jr. & Co. v. United States,* 276 U.S. 394 (1928).

[12] *Panama Refining Co. v. Ryan,* 293 U.S. 388 (1935) and *A. L. A. Schechter Poultry Corp. v. United States,* 295 U.S. 495 (1935).

[13] Cass R. Sunstein, "Constitutionalism After the New Deal," 101 *Harvard Law Review* 421, 477-478 (1987) The "disintegrat[ion]" of challenges to executive agencies on nondelegation grounds led to a "working compromise in which broad delegations of power [to the executive branch] were tolerated".

Cf. Keith E. Whittington & Jason Iuliano, "The Myth of the Nondelegation Doctrine," 165 *University of Pennsylvania Law Review* 379, 383 (2017) arguing that "[t]he prevalent vision of the pre–New Deal nondelegation doctrine is a myth." After reviewing every federal and state nondelegation challenge before 1940, the authors conclude that "that the nondelegation doctrine never actually constrained expansive delegations of power."

[14] Dudley, "Milestones in Administrative State," p. 35.

[15] Dudley, "Milestones in Administrative State," pp. 36-37. "Arbitrary and capricious" is a relaxed standard of review that only invalidates agency determinations that fail to "examine the relevant data and articulate a satisfactory explanation for [the] action including a 'rational connection between the facts found and the choice made.'" *Motor Vehicle Manufacturers Association v. State Farm Auto Mutual Insurance Co.,* 463 U.S. 29, 43 (quoting *Burlington Truck Lines v. United States,* 371 U.S. 156, 168 (1962)) (1983).

[16] 5 U.S.C. §551(4).

There are clear reasons behind requiring notice and comment rule-making. Democratic values suggest that before public officials promulgate policies that effectively bind the people they presumably serve, those officials should hear from the people the policies will affect.[17] Moreover, obtaining public comment will actually improve agency planning and decision-making.[18] Involving the public,

> *helps to elicit "the information, facts, and probabilities which are necessary to fair and intelligent action" by those responsible for promulgating administrative rules. Since an agency's own accumulated knowledge and expertise are rarely sufficient to provide all the needed data upon which rulemaking decisions should be based, agency communication with interested parties on the subject of proposed regulations is essential.*[19]

Federal rule making under the APA was tempered by President Reagan's EO 12291 in 1981 which introduced centralized review and cost-benefit analysis into the process.[20] EO 12291 required that all proposed regulations be submitted to the Office of Management and Budget (OMB), the largest component within the Executive Office of the President, prior to sign off by agency officials and publication in the Federal Register. It also required that agencies prepare and submit to OMB a Regulatory Impact Analysis (RIA) including a cost-benefit analysis for all major rules—rules with an annual economic impact of $100 million or more, that would lead to a major increase in costs or prices, or that would have significant adverse effects on competition, employment, investment, productivity, or innovation. The recently created Office of Information and Regulatory Affairs (OIRA) became the central authority for regulatory review within OMB.[21] The EO instructed that "Regulatory action shall not be undertaken unless the potential benefits to society for the regulation *outweigh* the potential costs to society." (emphasis added)[22]

The EO 12291 rule making regime was replaced by President Clinton's 1993 Executive Order 12866.[23] The new EO expressed the view that regulations should only be issued if required by law or a "compelling public need."[24] Yet it was also more deferential to agencies, including within its objectives "to reaffirm the primacy of Federal agencies in the regulatory decision-making process" and to conduct the regulatory process "with due regard to the discretion that has been entrusted to the Federal agencies."[25]

EO 12866 narrowed the types of rules subjected to OIRA review. All agencies, including independent agencies, must submit a list of all draft and proposed final regulatory actions to OIRA as part of the semi-annual Unified Regulatory Agenda.[26] However, the EO limits OIRA review to "significant" draft rules from agencies (other than independent

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[17] Most proposed rules attract little or no public interest. But the advent of the internet and computer algorithms has led to episodes (most significantly, a proposal to rescind the net neutrality rule) with massive amounts of computer-generated comments or even fraudulently attributed comments. Reeve T. Bull, "Democratizing and technocratizing the notice-and-comment process," *Brookings Institution Commentary*, Oct. 12, 2021, https://www.brookings.edu/articles/democratizing-and-technocratizing-the-notice-and-comment-process/.

[18] Cass R. Sunstein, *Valuing Life*, University of Chicago Press (2014), https://press.uchicago.edu/ucp/books/book/chicago/V/bo5872162.html.

[19] Arthur Earl Bonfield, "Public Participation in Federal Rulemaking Relating to Public Property, Loans, Grants, Benefits, or Contracts," 118 *University of Pennsylvania Law Review* 540 (1970), https://www.acus.gov/sites/default/files/documents/1969-08%20Elimination%20of%20Certain%20Exemptions%20from%20the%20APA%20Rulemaking%20Requirements.pdf.

[20] 46 FR 13193, 3 CFR, 1981 Comp., p. 127, https://www.archives.gov/federal-register/codification/executive-order/12291.html. The EO aimed to "to reduce the burdens of existing and future regulations, increase agency accountability for regulatory actions, provide for presidential oversight of the regulatory process, minimize duplication and conflict of regulations, and insure well-reasoned regulations."

[21] OIRA was established by the 1980, Paperwork Reduction Act. 44 U.S.C. § 3501, et seq.

"Although the executive order did not specifically mention OIRA, shortly after its issuance the Reagan Administration decided to integrate OMB's regulatory review responsibilities under the executive order with the responsibilities given to OMB (and ultimately to OIRA) by the PRA [Paperwork Reduction Act of 1980]." Congressional Research Service, "Federal Rulemaking: The Role of the Office of Information and Regulatory Affairs," March 21, 2011 (RL32397). https://www.everycrsreport.com/reports/RL32397.html#_Ref202772357.

[22] Executive Order 12291, sec 2(a).

[23] Executive Order 12866, Regulatory Planning and Review, 58 FR 51,735, Oct. 4, 1993.

[24] "Federal agencies should promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling public need, such as material failures of private markets to protect or improve the health and safety of the public, the environment, or the well-being of the American people." EO 12866, § 1(a).

[25] EO 12866, preamble.

[26] EO 12866, § 4(b).

regulatory agencies[27]), as determined by the agency or as identified by OIRA itself, at both the proposed and final rulemaking stages. Significant rules – defined as meeting at least one of four categories including: having "an annual effect on the economy of $100 million or more[28] or adversely affect[ing] in a material way the economy, a sector of the economy, productivity, competition, [or] jobs"; creating an inconsistency with other law or other agency actions; materially altering the budgetary impacts of various government programs; or "rais[ing] novel legal or policy issues" — were similar to but slightly different (adding the categories of inconsistencies or conflicts across agencies and programs and "novel legal or policy issues") than the major rules found in EO 12291. OIRA can approve the rule, suggest changes and later approve the rule with changes, or suggest the agency withdraw the rule.

The changes in EO 12866 resulted in a substantial drop in the number of rules reviewed by OIRA each year. OIRA designates and reviews 500-700 regulatory actions as significant each year,[29] down from between 2,000 and 3,000 per year under EO 12291.[30]

Agencies must also identify "economically significant" rules – a subset of significant rules meeting the $100 million economic effect threshold – for which agencies must prepare a Regulatory Impact Analysis (RIA) identifying alternative regulatory approaches with a benefit-cost analysis for each one.[31] OIRA reviews the economic analyses.[32] OMB Circular A-4 describes "best practices" for agencies' regulatory impact analyses to provide guidance on what agencies should include and consider in their cost-benefit analyses of rules and alternative regulatory approaches.[33] It should be noted that a recent re-write of Circular A-4 changes the analytic parameters in a way that encourages more regulations.[34] OIRA reviews all significant and economically significant rules and, in consultation with the agency, makes changes before the final draft regulations are published in the federal register.

According to OMB[35], the purpose of an RIA is to ensure that regulatory actions are based on "reasoned determination that the benefits justify the costs." This is consistent with the language in EO 12866 directing executive branch agencies to "propose or adopt a regulation only upon a reasoned determination

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[27] Administrative Conference of the United States, Benefit-Cost Analysis at Independent Regulatory Agencies, June 13, 2013, https://www.acus.gov/recommendation/benefit-cost-analysis-independent-regulatory-agencies#_ftn7.

But,

> Virtually all independent regulatory agencies are subject to certain crosscutting statutes that may require some type of regulatory analysis, such as the Regulatory Flexibility Act and the Paperwork Reduction Act. In addition, some independent regulatory agencies' organic acts or other statutes require them to conduct benefit-cost analyses or to consider certain economic effects of their regulations, although the requirements vary significantly from agency to agency. *Ibid.*

[28] EO 14094 "Modernizing Regulatory Review," changed this threshold to $200 million. 88 FR 21879-21881, April 6, 2023, https://www.govinfo.gov/content/pkg/FR-2023-04-11/pdf/2023-07760.pdf.

[29] Office of Information and Regulatory Affairs; Office of Management and Budget, Reginfo.gov. https://www.reginfo.gov/public/jsp/Utilities/faq.myjsp#:~:text=A%20regulatory%20action%20is%20determined%20to%20be%20%22economically%20significant%22%20if,environment%2C%20public%20health%20or%20safety%2C

[30] Congressional Research Service, "Federal Rulemaking: The Role of the Office of Information and Regulatory Affairs," March 21, 2011 (RL32397). https://www.everycrsreport.com/reports/RL32397.html#_Ref202772357.

[31] The term "economically significant" never appears in EO 12866 or in statute. It has become a term of art, adopted by OMB, to reflect the additional requirements imposed in sec. 6(a)(3)(C) of the EO on "significant regulatory action within the scope of section 3(f)(1)." Section 3(f)(1) sets out the first of the four categories that can qualify for the significant rule designation—the $100 million economic impact threshold. Clyde Wayne Crews, "Classifying regulations is now more confusing thanks to Biden administration," Competitive Enterprise Institute, *OpenMarket blog*, March 28, 2024, https://cei.org/blog/the-new-significance-of-a-significant-regulatory-action/.

[32] One complaint about RIAs and their economic analyses is that they only include paperwork compliance costs or clerical costs which are less than ten percent of the overall cost of regulation and do not account for actual economic costs which include resource and opportunity costs. Testimony of Casey B. Mulligan, Hearing on "Death by a Thousand Regulations: The Biden Administration's Campaign to Bury America in Red Tape" June 14, 2023, Committee on Oversight and Accountability, U.S. House of Representatives, https://oversight.house.gov/wp-content/uploads/2023/06/hoc_testimony_mulligan_20230614-1.pdf.

[33] Maeve P. Carey, Congressional Research Service, "Counting Regulations: An Overview of Rulemaking, Types of Federal Regulations, and Pages in the Federal Register," R43056 (updated Sept. 3, 2019) p.4.

[34] Circular No. A-4, November 9, 2024, https://www.whitehouse.gov/wp-content/uploads/2023/11/CircularA-4.pdf. The new Circular supersedes and rescinds the 2003 Circular A-4, effective March 1, 2024. Its three most important changes include: 1. Drastically lowering the discount rate so that proposals with possible future benefits and current costs are more likely to be judged as cost justified than under the higher discounts rates applied by the original A-4; 2. Requiring a distributional analysis where agencies consider the distributional effects of proposed rules and a suggestion that benefits to lower income people be weighted more highly than benefits to higher income people; and 3. An instruction that agencies conduct a global analysis that considers the effects of regulation with the U.S. (as the old A-4 did) as well as the benefits and costs abroad that affect US citizens and residents residing abroad and, in some cases, effects on non-citizens residing abroad. Whether these new analytic standards will withstand judicial review remains to be seen. William R. Levi and Jeremy Rozansky, "Sidley Austin Regulatory Litigation Update: New Circular A-4: A Revolution in Cost-Benefit Analysis," November 20, 2023, https://www.sidley.com/en/insights/newsupdates/2023/11/new-circular-a4-a-revolution-in-cost-benefit-analysis#:~:text=On%20November%209%2C%20the%20Biden,as%20the%20Environmental%20Protection%20Agency.

[35] Office of Management and Budget, "Regulatory Impact Analysis: A Primer," OMB Circular A-4 (Washington, D.C.: Office of Management and Budget, 2011), https://www.reginfo.gov/public/jsp/Utilities/circular-a-4_regulatory-impact-analysis-a-primer.pdf.

that the benefits of the intended regulation justify its costs." Hence, EO 12866 changed the Reagan EO 12291 wording requiring benefits to "outweigh" costs to the lower threshold of requiring that benefits "justify" costs. OMB also states that, "[r]egulatory analysis also has an important democratic function; it promotes accountability and transparency and is a central part of open government."[36]

Congress installed additional oversight over rules in 1996 by passing the Congressional Review Act.[37] The CRA requires an agency promulgating a rule to submit it to Congress and the Government Accountability Office (GAO) before it can take effect. The CRA gives Congress the opportunity, within strict time limits, to invalidate a new federal agency rule (or interim final rule) and block the issuing agency from creating a similar rule in the future. In the nearly 30 years of its existence, the CRA has only "been used to overturn a total of 20 rules: one in the 107th Congress (2001-2002), 16 in the 115th Congress (2017-2018), and three in the 117th Congress (2021-2022)."[38] This suggests recent, increased willingness to utilize the CRA, especially when an outgoing administration of one party is followed by unified control of the executive and legislative branches by another party.[39]

What is guidance? How is it different?

The APA requirement for public notice-and-comment for rulemaking, since supplemented with OIRA review for significant and economically significant (now "S3F1") rules and potential Congressional review under the CRA, apply to so-called "legislative rules" that carry the force of law.[40] But there are many more agency actions that escape these procedural safeguards.[41]

My colleague at the Competitive Enterprise Institute, Wayne Crews, has written extensively about the proliferation of what he calls "regulatory dark matter" to describe executive branch and federal agency actions that have regulatory effects but are not subject to the same scrutiny as formal regulations (APA notice & comment requirements) or statutes that must be enacted by Congress and signed by the President. Like the Dark Matter in physics (hypothetical matter that is invisible because it does not absorb, reflect or emit light) that has far greater mass than the visible universe, regulatory "dark matter" largely remains invisible to most observers other than the most interested parties and is far more common than visible laws and regulations.

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[36] Office of Management and Budget, "Regulatory Impact Analysis."

[37] 5 U.S.C. §§801- 808.

[38] Congressional Research Service, "The Congressional Review Act (CRA): A Brief Overview," (updated February 27, 2023), p. 1, https://sgp.fas.org/crs/misc/IF10023.pdf.

In fact, there have been more than 200 joint resolutions of disapproval for more than 125 rules introduced since the CRA's enactment in 1996. Most of these did not pass or if they passed were vetoed by the president.

National Conference of State Legislatures (NCSL), Congressional Review Act | Overview and Tracking (updated March 06, 2024), https://www.ncsl.org/state-federal/congressional-review-act-overview-and-tracking.

[39] The 16 revocations during the 115th Congress were primarily against rules from late in the Obama administration plus two rules issued later by the Bureau of Consumer Financial Protection. The three in the 117th Congress were revocations of rules from late in the Trump administration. GW Regulatory Studies Center, Congressional Review Act: CRA Tracker, https://regulatorystudies.columbian.gwu.edu/congressional-review-act.

[40] 5 U.S.C. § 553(b). "The APA does not specifically assign a label to the sorts of rules that are subject to notice and comment, but they have come to be known colloquially as "legislative" or "substantive" rules." Adam J. White, "*Perez v. Mortgage Bankers*: Heralding the Demise of Auer Deference?" *Cato Supreme Court Review 2015*, chap. 12, Washington: Cato Institute, 2015), 333, 335-336, https://www.cato.org/sites/cato.org/files/serials/files/supreme-court-review/2015/9/2015-supreme-court-review-chapter-12.pdf.

"Although the notice-and-comment rulemaking procedures of § 553 of the APA represent the most commonly followed process for issuing legislative rules, agencies may choose or may be required to use other rulemaking options, including formal, hybrid, direct final, and negotiated rulemaking." For example, under APA § 553(c) (5 U.S.C. § 553(c)) "when rules are required by statute to be made on the record after opportunity for an agency hearing" the formal, trial-like, rulemaking requirements of § 556 and § 557 apply. Hybrid rulemaking is required when Congress expressly directs an agency to follow specific procedural requirements in addition to those required by the informal rulemaking procedures of the APA § 553, but that fall short of formal rulemaking. Direct-final rulemaking allows an agency to bypass notice and comment requirements for rules for which the agency does not expect opposition by publishing the rule in the Federal Register along with a notice that the rule will become effective as a final rule on a specific date unless an adverse comment is received by the agency. Negotiated rulemaking allows agencies to consult with persons and groups with significant interest in the subject matter of the rule, before ordinary notice and comment procedures, to more expeditiously reach a rule that is acceptable to the relevant parties. (5 U.S.C. §§ 561-70).

Congressional Research Service, "A Brief Overview of Rulemaking and Judicial Review," R41546, March 27, 2017, https://www.everycrsreport.com/reports/R41546.html#Content.

[41] The APA contains several exceptions to Section 553's procedural requirements: (1) Certain subject areas are exempt: e.g. rules pertaining to "a military or foreign affairs function of the United States" or a matter relating to "public property, loans, grants, benefits, or contracts." 5 U.S.C. § 553(a); (2) the APA's "good cause" exception permits agencies to forego notice and public comment if "the agency for good cause finds" that compliance would be "impracticable, unnecessary, or contrary to the public interest" 5 U.S.C. § 553(b)(3)(B) and to bypass the requirement to publish a rule 30 days before its effective date if good cause exists 5 U.S.C. § 553(d)(3); and (3) rules that do not have the "force of law" such as rules concerning "agency organization, procedure, or practice" as well as interpretive rules and general statements of policy (guidance). 5 U.S.C. § 553(b)(3)(A).

The Government Accountability Office (GAO) found that between 2003 and 2010 federal agencies did not publish a notice of proposed rulemaking (NPRM), enabling the public to comment on a proposed rule, for more than a third of their rules, most often citing the APA's "good cause" exception. Government Accountability Office, Federal Rulemaking: Agencies Could Take Additional Steps to Respond to Public Comments (December 2012).

These documents, proclamations, memoranda, bulletins, circulars, letters, etc., greatly outnumber formal regulations that themselves greatly outnumber statutes. During calendar year 2022, while agencies issued 3,168 rules, Congress enacted 247 laws. Thus, agencies issued 13 rules for every law enacted by Congress. The average ratio over the past 10 years is 22 rules for every law. The amount of regulatory dark matter greatly exceeds the number of formal rules.[42] Administrative agencies often issue statements or publications that are not considered legally binding such as interpretive rules, which advise the public of an agency's interpretation of the statutes and regulations it administers; and general statements of policy, which advise the public about an agency's intended use of its discretionary authority. These interpretive rules and policy statements are generally referred to as "guidance documents"[43] and often provide necessary clarifications. In mid-2022, Crews estimated there are more than 107,000 guidance documents in effect, but the true number is likely higher since agency records are incomplete.[44]

OMB defined guidance documents as "an agency statement of general applicability and future effect, other than a regulatory action (as defined in Executive Order 12866, as further amended, section 3(g)), that sets forth a policy on a statutory, regulatory or technical issue or an interpretation of a statutory or regulatory issue."[45] As OMB noted "Guidance documents often come in a variety of formats and names, including interpretive memoranda, policy statements, guidances, manuals, circulars, memoranda, bulletins, advisories, and the like."[46] Yet, despite their diverse forms, they fall into the two broad categories of policy statements (non-binding agency pronouncements "'issued . . . to advise the public prospectively of the manner in which the agency proposes to exercise a discretionary power.'") and interpretive rules ("'statements issued by an agency to advise the public of the agency's construction of the statutes and rules which it administers.'").[47]

Thus, the APA divides agency action into three categories: legislative rules, interpretive rules, and general statements of policy.[48] The APA explicitly exempts interpretative rules and general statements of policy – collectively guidance – from notice and comment requirements[49] and from the requirement that final substantive rules must be published in the Federal Register at least 30 days before becoming effective.[50]

There are other important differences. "[L]egislative rules and sometimes even interpretive rules may be subject to pre-enforcement judicial review, but general statements of policy are not."[51]

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[42] Clyde Wayne Crews, Jr., "Ten Thousand Commandments 2023: An Annual Snapshot of the Federal Regulatory State.,"Competitive Enterprise Institute, 2023, p. 4.

[43] Congressional Research Service, "Legal Sidebar, Agency Use of Guidance Documents," April 19, 2021, p. 1, https://www.everycrsreport.com/files/2021-04-19_LSB10591_9477746a9161f3ee6f2d127a70eb84cdcec6e4df.pdf.

[44] Clyde Wayne Crews, "Federal Agency Guidance Document Inventory Tops 107,000 Entries," Competitive Enterprise Institute, *OpenMarket* blog, August 9, 2022, https://cei.org/blog/federal-agency-guidance-document-inventory-tops-107000-entries/.

[45] OMB, Final Bulletin for Agency Good Guidance Practices, 72 Fed. Reg. 3432, section I(3), (Jan. 25, 2007). https://www.federalregister.gov/documents/2007/01/25/E7-1066/final-bulletin-for-agency-good-guidance-practices#citation-17-p3433.

This definition echoes the definition found in the Bush administration executive order that accompanied the OMB Bulletin: "an agency statement of general applicability and future effect, other than a regulatory action, that sets forth a policy on a statutory, regulatory, or technical issue or an interpretation of a statutory or regulatory issue." EO 13422, 3 C.F.R. 191, 192 (2007).

[46] OMB Final Bulletin, 72 FR 3432, 3434.

[47] Administrative Conference of the United States, "Agency Guidance Through Policy Statements," December 22, 2017 (citing Attorney General's Manual on the Administrative Procedure Act 30 n.3 (1947)), https://www.acus.gov/recommendation/agency-guidance-through-policy-statements.

[48] *National Min. Ass'n v. McCarthy,* 758 F.3d 243, 251 (D.C. Cir. 2014)

[49] 5 U.S.C. § 553 (b)(A). *See e.g., Perez v. Mortgage Bankers Ass'n,* 575 U.S. 92, 97 (2015), unanimously holding that interpretive rules that "advise the public of the agency's construction of the statutes and rules which it administers," (quoting *Shalala v. Guernsey Memorial Hospital,* 514 U.S. 87, 99 (1995)) may be amended or repealed by agencies without following the APA's notice and comment procedures.

In total, the § 553 exemptions from notice and comment requirements are applied to "interpretative rules, general statements of policy, [and] rules of agency organization, procedure, or practice," § 553(b)(A), and when the agency "for good cause" finds "that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest," § 553(b)(B).

[50] 5 U.S.C. § 553(d).

[51] *National Min.* 758 F.3d at 251. In addition, "Legislative rules generally receive *Chevron* deference [from reviewing courts], but interpretive rules and general statements of policy often do not." *Id.* Guidance documents are generally accorded *Skidmore* deference instead. *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944) (Holding that courts should defer to an agency interpretation to the extent that it is persuasive. The weight accorded to an administrative judgment "will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control."). *See also, United States v. Mead Corp.,* 533 U.S. 218 (2001) (Administrative implementation of a statutory provision qualifies for *Chevron* deference when Congress delegated authority to the agency to make rules carrying the force of law and the agency interpretation claiming deference was promulgated in the exercise of such authority via notice-and-comment rulemaking or formal adjudication. In the absence of *Chevron* deference, agency interpretations are still entitled to *Skidmore* deference). Both legislative rules and guidance remain subject to review under the APA's arbitrary and capricious standard. *See* 5 U.S.C. § 706(2).

Nevertheless, the distinctions between these different agency actions are not always clear. As then Judge Kavanaugh opined in 2014, "given all of the consequences that flow, all relevant parties should instantly be able to tell whether an agency action is a legislative rule, an interpretive rule, or a general statement of policy—and thus immediately know the procedural and substantive requirements and consequences." Unfortunately, he wrote, "[t]hat inquiry turns out to be quite difficult and confused."[52]

The trouble with guidance

Guidance serves an important purpose but is increasingly being abused. As Paul R. Noe, former Counselor to the OIRA Administrator, observed,

> *guidance can and often does play a beneficial role in regulatory programs. When properly used, guidance can reasonably channel the discretion of agency employees, provide the public with clear notice of the line between permissible and impermissible conduct and ensure equal treatment of similarly-situated parties. Unfortunately, concerns have been raised that agency guidance practices should be better managed and be more transparent, consistent and accountable. Moreover, there is growing concern that, in some cases, guidance documents are being used in lieu of regulations – without following the procedural safeguards required for regulations.*[53]

While guidance does not technically have legal force, there is little question that it strongly influences private behaviors.[54] This gives agencies the ability to issue rules that have important regulatory impact and economic consequences without the time consuming statutorily prescribed process of notice and comment rule that enables public input, without advance judicial review, and without publication in the Federal Register. Unsurprisingly, agency guidance has proliferated.

As US Court of Appeals for the DC Circuit observed:

> *The phenomenon we see in this case is familiar. Congress passes a broadly worded statute. The agency follows with regulations containing broad language, open-ended phrases, ambiguous standards and the like. Then as years pass, the agency issues circulars or guidance or memoranda, explaining, interpreting, defining and often expanding the commands in the regulations. One guidance document may yield another and then another and so on. Several words in a regulation may spawn hundreds of pages of text as the agency offers more and more detail regarding what its regulations demand of regulated entities. Law is made, without notice and comment, without public participation, and without publication in the Federal Register or the Code of Federal Regulations. With the advent of the Internet, the agency does not need these official publications to ensure widespread circulation; it can inform those affected simply by posting its new guidance or memoranda or policy statement on its web site. An agency operating in this way gains a large advantage. "It can issue or amend its real rules, i.e., its interpretative rules and policy statements, quickly and inexpensively without following any statutorily prescribed procedures." Richard J. Pierce, Jr., Seven Ways to Deossify Agency Rulemaking, 47 Admin. L. Rev. 59, 85 (1995). The agency may also think there is another advantage — immunizing its lawmaking from judicial review.*[55]

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[52] *National Min.*, 758 F.3d at 251.

[53] Paul R. Noe, "Shining the Light on Regulatory Dark Matter: Due Process and Management for Agency Guidance Documents," American Forest and Paper Association: Update in Brief. February 6, 2018, https://www.afandpa.org/news/2018/shining-light-regulatory-dark-matter-due-process-and-management-agency-guidance-documents. In contrast, Connor Raso, "Strategic or Sincere? Analyzing Agency Use of Guidance Documents," 119 *Yale Law Journal* 782, https://openyls.law.yale.edu/bitstream/handle/20.500.13051/9823/24_119YaleLJ782_January2010_.pdf?sequence=2&isAllowed=y , claims that "agencies do not frequently use guidance documents to avoid the rulemaking process."

[54] As OMB observed in its Bulletin for Agency Good Guidance Practices:

Guidance can have coercive effects or lead parties to alter their conduct. For example, under a statute or regulation that would allow a range of actions to be eligible for a permit or other desired agency action, a guidance document might specify fast track treatment for a particular narrow form of behavior but subject other behavior to a burdensome application process with an uncertain likelihood of success. Even if not legally binding, such guidance could affect behavior in a way that might lead to an economically significant impact. Similarly, an agency might make a pronouncement about the conditions under which it believes a particular substance or product is unsafe. While not legally binding, such a statement could reasonably be anticipated to lead to changes in behavior by the private sector or governmental authorities such that it would lead to a significant economic effect.

72 FR 3232, at 3435.

[55] *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1020 (D.C. Cir. 2000).

As the Court recognized:

> *Only "legislative rules" have the force and effect of law. (citation omitted) A "legislative rule" is one the agency has duly promulgated in compliance with the procedures laid down in the statute or in the Administrative Procedure Act. … But we have also recognized that an agency's other pronouncements can, as a practical matter, have a binding effect. (citation omitted). If an agency acts as if a document issued at headquarters is controlling in the field, if it treats the document in the same manner as it treats a legislative rule, if it bases enforcement actions on the policies or interpretations formulated in the document, if it leads private parties or State permitting authorities to believe that it will declare permits invalid unless they comply with the terms of the document, then the agency's document is for all practical purposes "binding."* [56]

If an agency treats guidance as dispositive of the issue it addresses and applies its given interpretation to enforcement actions or in determining applications (e.g. for permits, licenses, accreditation) then, as a practical matter, the agency's guidance is binding on the regulated entities. Private parties who fail to adhere to the guidance do so at considerable risk.[57]

Whether the agency intends its guidance to be binding or not, businesses often face "overwhelming pressure" to follow agency guidance because of the structure of regulation. This is particularly true when a statute requires agency pre-approval—"… think of FDA approvals for drug manufacturers or Medicare reimbursements to healthcare providers, which determine their very survival."[58] Drug and device development is so expensive, time consuming and uncertain (only one in ten drugs make it through to FDA approval) that FDA officials, manufacturers' executives and attorneys, and public watchdog groups all agree that drug and device makers seeking premarket approval feel bound to follow FDA guidance.[59]

Affected private parties often do not challenge guidance that binds them as a practical matter because they cannot afford the cost or the delay of litigation, or because they are loath to antagonize an agency they will have to deal with in the future. This can be because of anticipated future pre-approvals or because the legislative scheme may subject the regulated party to agency monitoring and evaluations and possibly to ex-post enforcement actions. Following guidance is a way of staying on the agency's good side and avoiding costly conflict with the agency.[60]

These strong structural incentives to follow guidance erase, as a practical matter, the primary distinction between legislative rules which are legally binding and guidance documents which, in practice, are binding as well. Consequently, guidance allows agencies to bind the regulated public without adequate notice and public input and without an opportunity for regulated entities to know the full range of rules relevant to their actions.

As far back as 1992, one legal commentator observed that, "…it is manifest that nonobservance of APA rulemaking requirements is widespread. Several agencies rely in major part upon nonlegislative issuances to propagate new and changed elements in their regulatory or benefit programs."[61] And the Administrative Conference of the United States – an independent federal agency that develops recommendations to improve administrative processes – has noted that "commentators and the Administrative Conference have expressed

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[56] *Appalachian Power*, 208 F.3d at 1020-1021.

[57] Robert A. Anthony, "Interpretive Rules, Policy Statements, Guidances, Manuals, and the Like: Should Federal Agencies Use Them to Bind the Public?" 41 *Duke Law* Journal 1311 (1992).

Some courts have held that agencies must use notice-and-comment type procedures before they issue purported policy statements that are "practically binding," since they are more like legislative rules that are fixed and firm, and limit agency discretion. This distinction between guidance that is practically binding and guidance that is a more general interpretative rules or policy statement has been followed by the nation's most important administrative law court, the United States Court of Appeals for the District of Columbia Circuit (*Nat. Res. Def. Council v. EPA*, 643 F.3d 311, 313 (D.C. Cir. 2011). *Elec. Privacy Info. Ctr. v. Dep't of Homeland Sec.*, 653 F.3d 1, 3, 5-6 (D.C. Cir. 2011)) as well as other Circuit Courts of Appeals (*See, e.g., Texas v. United States*, 809 F.3d 134, 171 (5th Cir. 2015), affirmed by an equally divided court, 136 S.Ct. 2271 (2016); *Iowa League v. EPA*, 711 F.3d 844, 877 (8th Cir. 2013)).

[58] Nicholas R. Parrillo, "Federal Agency Guidance and the Power to Bind: An Empirical Study of Agencies and Industries," 36 *Yale Journal on Regulation* 165, 166, 185 (2019).

[59] Parillo, "Federal Agency Guidance," pp. 186-187.

[60] Parillo, "Federal Agency Guidance," pp. 184-200.

[61] Anthony, "Interpretive Rules, Policy Statements," p. 1316.

concern that agencies too often rely on guidance in ways that circumvent the notice-and-comment rulemaking process."[62]

If the Supreme Court overturns or substantially limits its longstanding *Chevron* doctrine in the currently pending case of *Loper Bright Enterprises v. Raimondo,*[63] it is possible that agencies will increasingly rely on guidance in place of notice and comment rulemaking. Under the judicial doctrine of *Chevron* deference, reviewing courts grant deference to a reasonable agency interpretation of its statutory authority in regulations if the underlying statute is ambiguous.[64] If that deference disappears or is substantially limited, agencies will likely turn to accomplishing their regulatory policy goals by influencing stakeholder actions through "non-binding" guidance documents. Unlike regulations/legislative rules that may be subject to pre-enforcement judicial review, agency guidance usually must be involved in a particular agency action that qualifies as "final agency action" before courts have jurisdiction under the APA to review a challenge. Generally, an individual stakeholder would have to do something that is contrary to guidance and then challenge an agency determination based on that guidance through the administrative process to conclusion. The stakeholder could then seek judicial review of the final agency action.[65] Many stakeholders will be loath to undertake such a lengthy and uncertain process.

Guidance also enables agencies to avoid congressional supervision under the CRA. In theory, the CRA is broad enough to authorize Congress to disapprove guidance because the statute adopts the APA's expansive definition of "rule."[66] Therefore, "[t]he CRA applies to more than just notice-and-comment rules; it also encompasses a wide range of other regulatory actions, including, inter alia, guidance documents, general statements of policy, and interpretive rules."[67] Indeed, some commentators have suggested that the drafters of the CRA intended the statute to cover guidance because of the "widespread practice of agencies avoiding the notification and public participation requirements of APA notice-and-comment rulemaking by utilizing the issuance of other, non-legislative documents as a means of binding the public, either legally or practically."[68]

In practice though, agencies generally do not submit covered guidance documents to Congress and CRA disapproval procedures are not available until rules are submitted.[69] The Senate has developed a procedure allowing it to employ the CRA's review mechanisms for unsubmitted rules: a GAO determination that an agency action satisfies the CRA definition of rule can substitute for the agency's submission of the rule and enable Congress to use the CRA's fast-track procedures for disapproval. However, this alternative process was used for the first and only time to disapprove an unsubmitted rule—also the only time Congress has used the CRA to disapprove guidance—when the

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[62] Administrative Conference of the United States, "Guidance in the Rulemaking Process," June 10, 2014 (citing a recommendation from 1992), https://www.acus.gov/recommendation/guidance-rulemaking-process.

[63] *Loper Bright Enterprises v. Raimondo*, argued Jan. 17, 2024, https://www.oyez.org/cases/2023/22-451.

[64] *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984).

[65] 5 U.S.C. § 704. There are however instances under Supreme Court precedent where a party would not be required challenge guidance through an administrative process before seeking judicial relief if the agency action "marks the consummation of the agency's decisionmaking process" because there is no further agency action to invoke or to exhaust and "from which legal consequences will flow." *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997). *Ipsen Biopharmaceuticals, Inc. v. Azar,* 943 F.3d 953, 957 (D.C. Cir. 2019), for example, holds that "in view of the character of the agency action at issue [a letter instructing a company to change pricing information it had submitted to the agency], that increased risk of prosecution and penalties constitutes a 'legal consequence' under *Bennett*" making the agency action final and subject to judicial challenge.

[66] The CRA could apply to guidance documents because the statute adopts the broadest definition of a rule contained in § 551 of the APA, which is broader than the category of rules subject to the APA's notice-and-comment rulemaking procedures contained in §553, which excludes interpretive rules and policy statements. Congressional Research Service, "The Congressional Review Act (CRA): Frequently Asked Questions," R43992 (Updated November 12, 2021), p. 7, https://crsreports.congress.gov/product/pdf/R/R43992.

[67] Russell T. Vought, "Guidance on Compliance with the Congressional Review Act," OMB Memorandum M-19-14, p. 4, April 11, 2019, https://www.whitehouse.gov/wp-content/uploads/2019/04/M-19-14.pdf. This OMB memorandum has been superseded by OMB memorandum M-24-09, but the newer memorandum confirms that "The CRA provides that agencies must submit to Congress and the Government Accountability Office (GAO) the agency's "rule[s]," a term that that is defined for purposes of the CRA to include not only rules subject to the notice-and-comment procedures of the Administrative Procedure Act (APA), but also certain other agency statements, subject to several exceptions." Shalanda D. Young,"Guidance on Compliance with the Congressional Review Act," OMB Memorandum M-24-09, February 16, 2024. https://www.whitehouse.gov/wp-content/uploads/2024/02/M-24-09-Guidance-on-Compliance-with-the-Congressional-Review-Act.pdf.

[68] Morton Rosenberg, "Whatever Happened to Congressional Review of Agency Rulemaking?: A Brief Overview, Assessment, and Proposal for Reform," *Administrative Law Review,* (American Bar Association), Vol. 51, No. 4, 1051-1092 (Fall 1999), at pp. 1066-1067. http://www.jstor.org/stable/40710052.

[69] Congressional Research Service, "CRA: Frequently Asked Questions," pp. 7, 12. *See also,* Congressional Research Service, "The Congressional Review Act: Determining Which 'Rules' Must Be Submitted to Congress," R45248, March 6, 2019, which states in its Summary that agency actions, such as guidance documents, that are not subject to notice-and-comment rulemaking procedures may still be considered rules under the CRA and thus could be overturned using the CRA's procedures. … however, the expedited procedures for considering legislation to overturn the rule only become available when the agency submits the rule to Congress. In many cases in which agencies take actions that fall under the scope of a "rule" but have not gone through notice-and-comment rulemaking procedures, agencies fail to submit those rules.

115th Congress in 2018 overturned guidance issued by the Consumer Financial Protection Bureau in a 2013 bulletin.[70] All of the other 19 times the CRA has been used to overturn agency actions, the disapproved actions were regulations that were adopted through the APA's rulemaking process, published in the Federal Register, and submitted to Congress under the CRA.[71]

Perhaps the most egregious misuse of guidance has come when agencies have used guidance to not enforce existing laws. During the Obama administration the Treasury Department unilaterally delayed the Affordable Care Act's (ACA) employer mandate and its accompanying tax penalty for non-compliance, first by blog post, then by IRS guidance. Similarly, the ACA requirement that insurers only sell ACA compliant health insurance policies in the individual market was delayed by a pronouncement from President Obama and HHS guidance material.[72]

Providing oversight of guidance

The fact that guidance can sometimes have, for practical purposes, as much legal force as legislative rules and the difficulty that many experienced observers and sophisticated judges have in distinguishing between the two categories of rules, suggest that the procedures for issuing guidance should be changed. It probably makes the most sense to base the regulation and use of procedural safeguards for rules, including guidance, on the importance or significance of the rule rather than the difficult distinction between legislative rules and guidance.

There have been some scattered attempts to establish standards for the initiation, development, and issuance of guidance documents to raise their quality and transparency. The American Bar Association, for example, recommended in 1993 that, "Before an agency adopts a nonlegislative rule that is likely to have a significant impact on the public, the agency provide an opportunity for members of the public to comment on the proposed rule and to recommend alternative policies or interpretations...."[73] Eight years later it recommended that agencies create searchable websites to include their governing statutes, rules and regulations, and guidance documents that might be of interest to members of the public.[74]

Congress has also expressed concern about guidance over the years.[75] This was translated into the FDA Good Guidance Practices (GGP) in 1997.

On February 27, 1997, the FDA, in response to a citizen petition submitted by the Indiana Medical Devices Manufacturers Council, Inc., published a document entitled "Good Guidance Practices" setting out the agency's policies and procedures for the development, issuance, and use of guidance documents.[76] The Food and Drug Administration Modernization Act of 1997 (FDAMA; Public Law No. 105–115) established aspects of the FDA good guidance practices document as law.[77] As one of the nation's busiest regulatory agencies, the FDA issues a lot of guidance. In fiscal year (FY) 2023, the FDA issued more than 190 guidance documents, either as draft or final, roughly the same as the year before and between 2011-2019 it averaged 173 annually.[78]

FDA's GGP[79] require the agency to provide an opportunity for public comment prior to implementation for all Level 1 guidance documents—guidance documents that set forth initial interpretations of a statute or regulation or changes in interpretation or policy that are of more than a minor nature, include complex scientific issues,

[70] S.J. Res. 57 was signed into law on May 21, 2018, and became P.L. 115-172. P.L. 115-172 overturning the Consumer Financial Protection Bureau, Indirect Auto Lending and Compliance with the Equal Credit Opportunity Act, March 21, 2013, https://files.consumerfinance.gov/f/201303_cfpb_march_-Auto-Finance-Bulletin.pdf.

[71] Congressional Research Service, "CRA: Frequently Asked Questions,"Appendix A, pp. 28-29.

[72] Clyde Wayne Crews, Jr., "Mapping Washington's Lawlessness: An Inventory of 'Regulatory Dark Matter,'" 2017 Edition, Competitive Enterprise Institute *Issue Analysis* 2017 No. 4, March 2017, p. 5.

[73] American Bar Association, Annual Report Including Proceedings of the Fifty-Eighth Annual Meeting, August 10–11, 1993, Vol. 118, No. 2, at 57.

[74] American Bar Association, "Recommendation on Federal Agency Web Pages," August 2001.

[75] "Food and Drug Administration Modernization and Accountability Act of 1997," S. Rep. 105–43, at 26 (1997) (raising concerns about public knowledge of, and access to, FDA guidance documents, lack of a systematic process for adoption of guidance documents and for allowing public input, and inconsistency in the use of guidance documents); House Committee on Government Reform, "Non-Binding Legal Effect of Agency Guidance Documents," H. Rep. 106–1009 (106th Cong., 2d Sess. 2000) (criticizing "back-door" regulation)

[76] Notice, "The Food and Drug Administration's Development, Issuance, and Use of Guidance Documents," 62 FR 8961 (Feb. 27, 1997), https://www.federalregister.gov/documents/1997/02/27/97-4852/the-food-and-drug-administrations-development-issuance-and-use-of-guidance-documents.

[77] 21 U.S.C. 371(h).

[78] US Food and Drug Administration, "Background: FDA Good Guidance Practices," current as of 12/28/2023, https://www.fda.gov/about-fda/reports/background-fda-good-guidance-practices.

[79] 21 CFR 10.115.

or cover highly controversial issues[80]—unless FDA determines that prior public participation is not feasible or appropriate.[81] The agency says "to date, with the exception of guidances issued in response to the COVID-19 PHE, FDA has issued only a small portion of Level 1 guidance documents 'for immediate implementation'" without prior public comment.[82]

FDA provides public notice of draft Level 1 guidance by posting documents on its website and by publishing a Notice of Availability (NOA) in the Federal Register. It sets out a comment period (usually 60 days) to receive public input and may also hold public meetings or workshops. Once the agency reviews any comments and incorporates those it deems helpful, it publishes the final guidance document online and in the Federal Register and implements the guidance.

Level 2 guidance documents – setting forth existing practices or minor changes in policy[83] – must be published on the internet but are immediately implemented. Public comments can be submitted and considered afterwards.[84]

The FDA process allows stakeholders, including industry, consumers, and other parties, to play a significant role in the development of these guidance documents. In addition, FDA maintains a searchable list of its official guidance documents.[85] This provides an easy way for regulated entities and the general public to access guidance that might affect them.

Unfortunately, while FDA has been a leader in implementing GGPs, it routinely issues draft guidance that takes months to years to finalize. During this time period the draft guidance remains on the FDA website in an uncertain status. The time draft guidance remains posted before being finalized ranges from 0 to 360 months (i.e. 30 years) with most falling between 4 to 6 years. These delays have been worsening. From 2011 to the present, the delays in finalizing guidance went from on average under 20 months to on average over 60 months.[86]

Leaving guidance on the website in draft form for years creates legal and practical uncertainties. Draft guidance is posted to facilitate public comment. It is not supposed to represent the agency's official position. Once the comment period is over, the FDA is supposed to review the comments, incorporate suggested changes if appropriate, post the final guidance in the Federal Register and on the internet, and implement the guidance[87] or issue new draft guidance.[88] Leaving the draft guidance on the agency's website after the close of the comment period leaves regulated entities in limbo. It suggests the agency means to implement the guidance even though it is barred from doing so until the guidance is finalized. Yet regulated entities have no way of knowing if or when finalization will occur or if the draft guidance still represents the agency's current policy.[89]

The FDA's proposed solution for the backlog defeats the purpose of the GGP program. In a recently released draft report, the agency proposes publishing more guidance items for immediate implementation without public comment periods. It also suggests exploring if more guidance documents can be classified as Level 2 and issued with that category's more relaxed procedures.[90]

A decade after FDA GGP was codified, on January 18, 2007, President George W. Bush issued Executive Order 13422, titled "Further Amendment to Executive Order 12866 on Regulatory Planning and Review."[91] EO 13422 changed the regulatory review process established under EO 12866 by imposing new requirements for rulemaking and by requiring agencies to obtain approval from the Office of

[80] 21 CFR 10.115(c)(1).

[81] 21 CFR 10.115(g).

[82] Food and Drug Administration, "Draft Report and Plan on Best Practices for Guidance," January 2024, p. 19 , https://insidehealthpolicy.com/sites/insidehealthpolicy.com/files/documents/2024/jan/he2024_0207.pdf.

[83] 21 CFR 10.115(c)(2).

[84] 21 CFR 10.115(g)(4).

[85] Food and Drug Administration, "Search for FDA Guidance Documents," https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

[86] Bradley Merrill Thompson, "Unpacking Averages: Analyzing FDA's Performance in Finalizing Guidance Documents," Health Law Advisor Blog. March 5, 2024, https://www.healthlawadvisor.com/unpacking-averages-analyzing-fdas-performance-in-finalizing-guidance-documents.

[87] 21 CFR 10.115(g)(iv)(D).

[88] 21 CFR 10.115(g)(v).

[89] Thompson, "Unpacking Averages," Health Law Advisor Blog,

[90] FDA: Draft Report and Plan on Best Practices for Guidance, p. 25.

[91] EO 13422, 72 FR 2763, January 23, 2007.

Information and Regulatory Affairs (OIRA) for guidance documents associated with significant economic impacts. Requiring OIRA to review significant agency *guidance* documents mirrored OIRA's existing responsibility to review economically significant *regulations* under EO 12866. The EO also included a provision permitting agencies to consider whether to use more formal rulemaking procedures in certain cases.

The Office of Management and Budget (OMB) had been concerned about guidance documents since its 2002 *Report to Congress on the Costs and Benefits of Regulations and Unfunded Mandates on State, Local and Tribal Entities*.[92] That report recognized the value of guidance documents in directing the discretion of agency employees and in giving the public notice of how the agency would interpret existing law through an interpretive rule and how it would enforce a governing legal norm through a policy statement. But in that report and subsequently, OMB was concerned that because of the ease of issuing guidance documents, they were proliferating and were often imposing legal requirements without the benefit of careful consideration and public participation provided by the notice and comment procedures of the APA and other processes for regulatory development and review.[93]

On the same day that President Bush's EO 13422 was issued, OMB, after soliciting public comments a year before, issued a final Bulletin entitled, "Agency Good Guidance Practices," to establish policies and procedures for the development, issuance, and use of significant guidance documents by executive branch departments and agencies.[94] The Bulletin expressed concerns that guidance documents "may be poorly designed or improperly implemented…[and] may not receive the benefit of careful consideration accorded under the procedures for regulatory development and review."[95]

In language that mirrored EO 13442, the Bulletin defined guidance as "an agency statement of general applicability and future effect, other than a regulatory action, that sets forth a policy on a statutory, regulatory, or technical issue or an interpretation of a statutory or regulatory issue," where "future effect" means the "intended . . . impacts due to voluntary compliance with a guidance document."[96]

Section I(4) of the Bulletin set out a definition of "significant guidance" as interpretive rules of general applicability and statements of general policy that may be reasonably anticipated to have an annual effect on the economy of $100 million or more or have a variety of other "broad and substantial impact[s] on regulated entities, the public or other Federal agencies." It was anticipated that most guidance would not be significant.

The Bulletin established basic requirements for "significant" guidance: agencies must implement written procedures for the approval of significant guidance documents by appropriate senior officials; the documents must have standard elements, such as information identifying the document as guidance, the issuing office, the activity and persons to whom it applies, the date of issuance, title and docket number; and significant guidance could not contain mandatory language such as shall or must.[97] To facilitate public access, agencies were required to maintain a current list of their significant guidance documents on their Web sites, including links to each public guidance document and an identification of which guidance documents had been added, revised or withdrawn during the previous year. Bulletin section III(2) required agencies to have procedures for public comments on significant guidance documents but did not require the agencies to formally respond to comments.[98]

Section I(5) of the Bulletin included the definition of a narrow subcategory of significant guidance documents, "economically significant guidance documents," as significant guidance "that 'may

[92] US Office of Management and Budget, *Stimulating Smarter Regulation: 2002 Report to Congress on the Costs and Benefits of Regulations and Unfunded Mandates on State, Local and Tribal Entities,* pp. 72–74, .

[93] 72 FR 3432.

[94] *See* OMB Bulletin 07–02, "Final Bulletin for Agency Good Guidance Practices," 72 FR 3432, January 25, 2007.

[95] 72 FR 3432.

[96] *See* OMB Bulletin 07–02, 72 FR 3432, 3434–35.

[97] 72 FR at 3434-3435.

[98] 72 FR at 3437.

reasonably be anticipated to lead to' an annual effect on the economy of $100 million or more or adversely affect in a material way the economy or a sector of the economy."[99] These would be subject to more formal notice and comment requirements including advance public notice, opportunity to comment on a draft, and responses to the public comments.

While some commenters questioned how guidance "which is not legally binding—could have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy or a sector of the economy" the OMB Bulletin recognized that "there are situations in which it may reasonably be anticipated that a guidance document could lead parties to alter their conduct in a manner that would have such an economically significant impact."[100]

Unfortunately, the OMB Good Guidance Practices were not widely adopted.[101]Most agencies balked at the chore of creating lists of significant and economically significant rules and were unenthusiastic about soliciting public comments and obtaining OMB/OIRA review of economically significant documents. The Bulletin was undermined when shortly after his inauguration in 2009, President Obama issued EO 13497, reversing EO 13422 that had been used as a basis for the OMB Bulletin. EO 13497 instructed agencies to "promptly rescind any orders, rules, regulations, guidelines, or policies implementing or enforcing" EO 13422.[102] Shortly thereafter, then OMB director Peter Orzag issued a memorandum "to clarify the current status of OMB review of agency actions, including guidance documents."[103] It said that EO 13497's revocation of EO 13422 "restored the regulatory review process to what it had been under Executive Order 12866." It went on to make the dubious claim that under EO 12866 "OIRA reviewed all significant proposed or final agency actions, including significant policy and *guidance documents* (emphasis added)" and that "[s]uch agency actions and documents remain subject to OIRA's review under Executive Order 12866." Since guidance documents had never been routinely reviewed by OIRA under EO 12866, it is not surprising that they remained unreviewed under the Obama administration.

Good guidance and Executive Order 13891

On October 9, 2019, President Trump signed Executive Order 13891 entitled "Promoting the Rule of Law Through Improved Agency Guidance Documents," in order "to ensure that Americans are subject to only those binding rules imposed through duly enacted statutes or through regulations lawfully promulgated under them, and that Americans have fair notice of their obligations."[104] The EO emulated the OMB Bulletin from 12 years earlier. It "require[d] that agencies treat guidance documents as non-binding both in law and in practice, except as incorporated into a contract...." and directed each agency to "review its guidance documents and... rescind those guidance documents that it determines should no longer be in effect."[105]

The EO also directed that each agency or component "establish or maintain on its website a single, searchable, indexed database that contains or links to all guidance documents in effect from such agency

[99] 72 FR at 3435.

[100] OMB, Final Bulletin at p. 3435.

[101] The US Department of Education, for example, is an exception. It takes public comments into account in the course of developing new guidance or modifying existing guidance and maintains a list of significant regulations at https://www2.ed.gov/policy/gen/guid/significant-guidance.html. In a 2015 review of guidance processes at four departments—Agriculture (USDA), Education (Education), Health and Human Services (HHS), and Labor (DOL)—and their 25 components, the GAO found there was no consistent approach or application of OMB requirements. Education and USDA had written departmental procedures for approval of significant guidance as required by OMB. DOL and HHS did not. Approaches to disseminating guidance and making it available in an easy to access, systematic way, also varied greatly. US Government Accountability Office, "Report to Congressional Requesters, Regulatory Guidance Processes: Selected Departments Could Strengthen Internal Control and Dissemination Practices," GAO-15-368, April 2015, https://www.gao.gov/assets/gao-15-368.pdf.

[102] EO 13497, "Revocation Of Certain Executive Orders Concerning Regulatory Planning And Review," January 30, 2009, https://obamawhitehouse.archives.gov/the-press-office/revocation-certain-executive-orders-concerning-regulatory-planning-and-review.

[103] Peter R. Orszag, "Guidance for Regulatory Review," OMB Memorandum M-09-13, March 4, 2009, https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/memoranda/2009/m09-13.pdf.

[104] EO 13891, October 9, 2019. Published October 15, 2019, 84 FR 55235, https://www.federalregister.gov/documents/2019/10/15/2019-22623/promoting-the-rule-of-law-through-improved-agency-guidance-documents.

[105] The companion EO 13892, issued the same day as EO 13891, instructed:

Guidance documents may not be used to impose new standards of conduct on persons outside the executive branch except as expressly authorized by law or as expressly incorporated into a contract. When an agency takes an administrative enforcement action, engages in adjudication, or otherwise makes a determination that has legal consequence for a person, it must establish a violation of law by applying statutes or regulations. The agency may not treat noncompliance with a standard of conduct announced solely in a guidance document as itself a violation of applicable statutes or regulations.

EO 13892, "Promoting the Rule of Law Through Transparency and Fairness in Civil Administrative Enforcement and Adjudication," October 9, 2019, Section 3, Published October 15, 2019, 84 FR 55239 at 55240. https://www.federalregister.gov/documents/2019/10/15/2019-22624/promoting-the-rule-of-law-through-transparency-and-fairness-in-civil-administrative-enforcement-and.

or component" by February 28, 2020. Agencies were directed to develop and assign unique identifiers to enable members of the public to easily search for and locate a specific guidance document. Guidance documents that remain in effect had to be posted on the agency website established for this purpose which "shall note that guidance documents lack the force and effect of law, except as authorized by law or as incorporated into a contract."

Finally, the EO (section 4(a)) directed each agency to promulgate regulations that "set forth processes and procedures for issuing guidance documents."[106] An OMB memorandum issued to implement EO 13891 noted "that many of the practices specified by the EO and explained in this memorandum are identical to practices discussed in the [2007 OMB] Good Guidance Bulletin."[107]

At least 32 departments and agencies issued rules on guidance in response to EO 13891.[108] Most were final rules. At least seven were interim rules that invited comments. One from the Department of Transportation was a final rule updating all the department's regulatory procedures that had largely been formulated in response to an earlier Trump executive order (EO 13777 – "Enforcing the Regulatory Reform Agenda").[109] The only requirement it incorporated from EO 13891 that was not otherwise provided for in existing department procedures was that the comment period for significant guidance documents would be 30 days.

All the rules included the requirements, with minor variations, set out in EO 13891 including: language in guidance documents labeling the document as guidance and stating that the document does not have the force of law and is not binding; a requirement to make a good faith estimate of the guidance's economic impact; a requirement to send significant guidance documents to OMB/OIRA for coordinated review; a requirement that significant guidance documents undergo notice and an opportunity for public comment lasting at least 30 days and, in some rules, review and signature by the secretary or head of the department or agency; a system for the public to petition for modification or withdrawal of guidance; creation of unique identifiers for each guidance document and a searchable, indexed database/website the departments guidance documents; and clauses stating that in exigent circumstances or for good cause shown the department or agency did not need to follow the various good guidance procedures outlined above.

Despite the seemingly unobjectionable nature of most of these requirements, the Biden administration on its first day in office (January 20, 2021) issued EO 13992. This revoked EO 13891 (along with five other executive orders) upon which the GGP regulations were based. EO 13992 directed OMB and agency heads "to rescind any orders, rules, regulations, guidelines, or policies, or portions thereof, implementing or enforcing the Executive Orders" and to provide exemptions from enforcement until rescission could be finalized. The EO justified the revocations with the claim that "executive departments and agencies (agencies) must be equipped with the flexibility to use robust regulatory action to address national priorities. This order revokes harmful policies and directives that threaten to frustrate the Federal Government's ability to confront these problems, and empowers agencies to use appropriate regulatory tools to achieve these goals."[110]

As a result of EO 13992, most or nearly all of the various rules establishing GGP have been revoked by new agency rulemaking. Some agencies have even removed the searchable guidance websites they had established.[111]

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[106] EO 13891, section 4(a).

[107] Office of Management and Budget, "Memorandum for Regulatory Policy Officers at Executive Departments and agencies and Managing Executive Directors of Certain Agencies and Commissions, "October 31, 2019, https://www.whitehouse.gov/wp-content/uploads/2019/10/M-20-02-Guidance-Memo.pdf.

[108] Clyde Wayne Crews, "Stomping FROGs: An Updated Inventory of Biden's Elimination of Trump-Era Final Rules on Guidance Document Procedures," Competitive Enterprise Institute *OpenMarket* blog, July 26, 2022, https://cei.org/blog/stomping-frogs-an-updated-inventory-of-bidens-elimination-of-trump-era-final-rules-on-guidance-document-procedures/. The Department of Justice, for example, published two interim final rules (at 28 CFR 50.26 and 50.27) regulating the issuance and use of guidance documents by the DOJ and its components. DOJ subsequently revoked those rules pursuant to President Biden's EO 13992. https://www.justice.gov/d9/pages/attachments/2021/07/01/attorney_general_interim_final_rule_-_processes_and_procedures_for_issuance_and_use_of_guidance_documents_7.1.2021__0.pdf.

The Department of Commerce established a portal to access guidance documents, https://2017-2021.commerce.gov/guidance.html.

[109] 84 FR 71714, Dec. 27, 2019.

[110] EO 13992, Revocation of Certain Executive Orders Concerning Federal Regulation, 86 FR 7049, January 25, 2021, https://www.federalregister.gov/documents/2021/01/25/2021-01767/revocation-of-certain-executive-orders-concerning-federal-regulation.

[111] Crews, "Stomping Frogs."

It is worth examining whether EO 13992 and the GGP revocations it triggered were good policy. For reasons that will be outlined below, the good guidance rule issued by the Department of Health and Human Services (HHS) and the rule later published to revoke it provide good insight into this issue.

The HHS Good Guidance Rule and its revocation

Pursuant to EO 13891, HHS – the largest civilian department in the federal government with a $1.6 trillion budget and the Department with more than a fifth (22,865) of known guidance documents[112] – finalized its good guidance rule on December 7, 2020[113] to be effective January 6, 2021 with the stated aim of ensuring that "the public receives appropriate notice of new guidance and that the Department's guidance does not impose obligations on regulated parties that are not already reflected in duly enacted statutes or regulations lawfully promulgated under them."[114]

The rule applied to all guidance documents issued by all components of HHS, with the proviso that the FDA, which has its own good guidance practices regulations[115] as required by the Federal Food, Drug, and Cosmetic Act (FDCA),[116] will amend its regulations to conform to the HHS regulation.

Finalizing the HHS GGP regulation was particularly important in 2020. Not only is HHS the largest civilian department in the federal government, but its 12 operating divisions consist of nine agencies in the US Public Health Service – including the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), the FDA, and the Indian Health Service—all of which were deeply involved in the effort to combat the COVID-19 pandemic that began in January 2020, as well as three human services agencies, including the Centers for Medicare and Medicaid Services (CMS) which administers the Medicare, Medicaid and CHIP health programs which grew during the pandemic to insure nearly half of Americans.[117] Guidance issuance in general escalated during the COVID-19 pandemic, but especially within the various health care components of HHS.

The HHS guidance rule particularly merits attention because the regulation revoking it provided a detailed discussion of the reasons for doing so. Many of the other regulations made pursuant to EO 13992 to revoke GGP regulations provided much less discussion or explanation. Hence, the merits of the GGP rule and its revocation can be assessed.

The HHS guidance rule defined guidance documents as "any Department statement of general applicability, intended to have future effect on the behavior of regulated parties and which sets forth a policy on a statutory, regulatory, or technical or scientific issue, or an interpretation of a statute or regulation."

Significant guidance document was defined as guidance "that may reasonably be anticipated to lead to an annual effect on the economy of $100 million or more," or have a serious impact on the economy, competition, jobs, or state and local governments.[118]

The Rule prohibited HHS from issuing any guidance document that establishes a legal obligation that is not reflected in an applicable statute or regulation, or use any guidance document to require a person or entity outside HHS to take any action, or refrain from taking any action, beyond what is required by an applicable statute or regulation.[119] Each guidance document must be identified as guidance, summarize the subject matter it covers, and include language that it does not

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[112] Crews, "Federal Agency Guidance Document Inventory Tops 107,000 Entries."

[113] Final Rule, Department of Health and Human Services Good Guidance Practices, 85 FR 78770, December 7, 2020, https://www.federalregister.gov/documents/2020/12/07/2020-26832/department-of-health-and-human-services-good-guidance-practices.

[114] §1.2 at 85 FR 78785. The Department of Commerce established a portal to access guidance documents, https://2017-2021.commerce.gov/guidance.html.The Department of Justice e published two interim final rules (at 28 CFR 50.26 and 50.27) regulating the issuance and use of guidance documents by the DOJ and its components. DOJ subsequently revoked those rules pursuant to EO 13992. https://www.justice.gov/d9/pages/attachments/2021/07/01/attorney_general_interim_final_rule_-_processes_and_procedures_for_issuance_and_use_of_guidance_documents_7.1.2021__0.pdf.

[115] 21 CFR 10.115.

[116] 21 U.S.C. 371(h).

[117] US Department of Health and Human Services, HHS Agencies and Offices, https://www.hhs.gov/about/agencies/orgchart/index.html.

[118] The full definition, to be found at 45 C.F.R §1.2, at 85 FR 78785, reads as follows:

Significant guidance document means a guidance document that may reasonably be anticipated to lead to an annual effect on the economy of $100 million or more, or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights or obligations of recipients thereof; or raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles of Executive Order 12866.

[119] 45 C.F.R. § 1.3(a), at 85 FR 78785-78786.

have the force and effect of law and does not bind the public in any way.

The Rule also created a rulemaking-like process for "significant guidance documents" requiring that they be approved by the Secretary of HHS, be subject to public notice and comment with notice published in the Federal Register and at least a 30-day comment period, and be reviewed before publication by the Office of Information and Regulatory Affairs (OIRA) within OMB as under Executive Order 12866.[120]

An important feature of the Rule to increase public transparency was the requirement that HHS maintain a text searchable guidance repository on its website with links to all guidance documents in effect that have been issued by any component of the Department. Any guidance not listed on the website would be considered rescinded.[121]

Finally, the Rule established a petition process allowing an interested party to petition HHS to withdraw or modify a guidance document because it imposes binding obligations on parties or is being used by HHS officials to create additional legal obligations beyond what is required by the terms of applicable statutes and/or regulations.[122] This created a workable pathway to beneficially modify guidance and was successfully utilized.[123]

The HHS good guidance rule was revoked by a new rule made pursuant to the Biden administration's EO 13992 (repeal proposed Oct 2021 and finalized regulation issued July 2022). In its repeal regulation, HHS wrote that after reconsidering the good guidance rules:

> *We now conclude that they create unnecessary hurdles that hinder the Department's ability to issue guidance, bring enforcement actions, and take other appropriate actions that advance the Department's mission. …that the Final Rules establish procedures well beyond anything required by applicable law. Moreover, in significantly burdening the Department, these procedures are inconsistent with the policies and goals of the current Administration to ensure that HHS can appropriately leverage administrative tools to protect and advance the public health and welfare.*[124]

The Department disagreed with commenters who argued the rule was "necessary to increase transparency, accountability, and public participation in the regulatory process," and instead concluded:

> *any benefit derived from the ability to formally comment on guidance and providing the Department's responses to comments—which, by operation of law, is nonbinding and does not have the force and effect of an agency rule—is outweighed by the Department's interest in quickly and responsively communicating current thinking on its rules and policies. Further, because compliance with these provisions diverts HHS labor to time-consuming comment analysis and response, eliminating these provisions would expedite the publication of guidance, enhance agency efficiency, and reduce administrative burden.*[125]

[120] 45 C.F.R. § 1.3(b), at 85 FR 78786.

[121] 45 C.F.R. § 1.4, at 85 FR 78786.

[122] 45 C.F.R. § 1.5, at 85 F.R. 78786-78787.

[123] Prior to rescission of its good guidance rule, HHS did grant one petition seeking modification of guidance. *See* Good Guidance Petition Response 21-01, https://www.hhs.gov/sites/default/files/davita-petition-response-and-exhibit.pdf. "Your petition, attached as Exhibit A, challenges the Centers for Medicare & Medicaid Services ("CMS") Transmittal 103681 and MLN Matters No. MM118712 and asserts that through these sub-regulatory documents, CMS is unlawfully requiring dialysis facilities to report dialysis treatment time on claims. The Department agrees and CMS will be amending CMS Transmittal 10368 and MLN Matters No. MM11871 to remove this requirement.".

[124] Department of Health and Human Services, Repeal of HHS Rules on Guidance, Enforcement, and Adjudication Procedures. 87 F.R. 44002, July 25, 2022.

[125] 87 F.R. at 44005.

It claimed that "HHS has considered that the Guidance rule requires more process for significant (and other) guidance, which may have the benefit of refining guidance to a greater extent, but also has the disadvantage of delaying, and possibly preventing, the communication of valuable information."[126] And it asserted that good guidance rules are not needed because "the Department already has a history and practice of providing adequate public notice and stakeholder participation in the guidance process."[127]

Moreover, without any real analysis or provision of evidence, HHS made the tendentious claim that the Guidance rule interferes with the Biden administration's goal of

> *advancing equity for all, including people of color and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality. …The Guidance rule frustrates this goal by imposing unnecessary, burdensome, and ambiguous requirements that slow down the guidance process and in turn delay dissemination of information needed to access Medicaid, ACA, and other HHS programs.*[128]

In fact, outside of the FDA, HHS components have done little to provide public notice or to facilitate stakeholder participation that could improve the final guidance. In repealing its final Guidance regulation, HHS seemed intent on preserving maximum administrative flexibility without the "unnecessary hurdles" of having to inform the public and take its comments into account or to risk having the Department's judgments second guessed by OMB/OIRA review. This is in line with the Biden administration's "whole of government" effort to expand the administrative state without interference from any other part of government or the public that it purports to serve.

HHS and the Biden administration view GGP as a burden rather than a benefit. They ignore the democratic accountability and improved policy that result from GGP. They assume, with scant evidence, that bureaucratic experts know best and would not benefit from input from the public and affected stakeholders.

The HHS rule repeatedly suggests that procedural safeguards are unneeded because guidance is non-binding. As discussed earlier, while this is true in theory, it is not in practice.[129] The Department of Labor was far more realistic when it wrote in its GGP rule, published August 8, 2020:

> *this rule is designed to take into account how powerful agency statements are. When agencies speak, Americans listen carefully and often change their behavior as a result. Ignorance of or failure to abide by agency regulations and the laws agencies enforce can have immense ramifications. In light of the stakes, the public often treats guidance from agencies as binding, even if it technically is not. Thus, it is vital that agencies promulgate, maintain, and use guidance carefully.*[130]

HHS's suggestion that the guidance rule would harmfully slow the formulation and promulgation of guidance ignores the fact that the guidance rule gave the Department substantial flexibility when circumstances warrant. Section 1.3(b)(2)(ii) allowed the Department to waive the 30-day public notice and comment period for proposed significant guidance documents for "good cause" if it finds "that notice and public comment are impracticable, unnecessary, or contrary to the public interest."[131] In addition, §1.3(b)(4) provided that "A significant guidance document may be exempted from any requirement otherwise applicable to significant guidance documents if the Secretary and the Administrator of OIRA agree that exigency, safety, health, or other compelling cause warrants the exemption."[132]

[126] 87 F.R. at 44020.

[127] 87 F.R. at 44011.

[128] 87 F.R. at 44006.

[129] *See* notes 54, 56-60.

[130] Department of Labor, Promoting Regulatory Openness Through Good Guidance (PRO Good Guidance), 85 F.R. 53163, https://www.govinfo.gov/content/pkg/FR-2020-08-28/pdf/2020-18500.pdf.

[131] 85 F.R. 78786.

[132] 85 F.R. 78786. All the rules issued by the 32 agencies in response to EO 13891 included exemptions from various requirements for exigent circumstances.

The Department claimed there had been real harms resulting from the rule in the brief time it had been in effect[133] including: "clearing a Medicaid guidance under the more cumbersome new processes, which took weeks longer than anticipated and delayed the timely communication of needed information to program beneficiaries"; the inconvenience of "quickly uploading guidance *documents* into the guidance repository to avoid automatic rescission (emphasis in original)"; and the burden of "preparing the analysis of the economic impact of certain significant guidance documents, which is especially challenging given the nonbinding nature of guidance."

Yet, the Department's claims of harms are, at best, misleading. Is a few *weeks* an inordinate delay to inform the public and obtain its input? Agencies routinely take months to years to make decisions, including the formulation of guidance. And if timely communication with stakeholders is so important, why object to the requirement to quickly uphold guidance documents into the guidance repository where they will be available to the public? Since significant guidance, by definition, has a major impact on stakeholders and the public, including over $100 million in effects, precisely because it in fact binds regulated entities, estimating economic impact is neither impossible nor harmful. As the Department of Transportation noted in its December 27, 2019 comprehensive reform of its regulatory procedures which was largely complete before the EO 13891 was even issued:

> *Even though not legally binding, some agency guidance may result in a substantial economic impact. For example, the issuance of agency guidance may induce private parties to alter their conduct to conform to recommended standards or practices, thereby incurring costs beyond the costs of complying with existing statutes and regulations. While it may be difficult to predict with precision the economic impact of voluntary guidance, the… [agency can], to the extent practicable, make a good faith effort to estimate the likely economic cost impact of the guidance document to determine whether the document might be significant.*[134]

HHS never explained how its 2020 guidance rule will disproportionally "harm marginalized constituencies."[135] This inflammatory claim is particularly regrettable since marginalized groups seem most likely to benefit from the ability to comment on proposed guidance and influence the final product and to petition HHS to modify or withdraw guidance documents.

Marginalized constituencies without access to specialized advisors are also most likely to benefit from the rule's searchable database requirement that will empower them to easily identify and review guidance applicable to them. HHS still maintains a guidance portal,[136] but with the repeal of the guidance rule there is no longer the assurance that there are no unposted guidance documents that remain in effect.

HHS's rejection of interference with its autonomy was so complete that it even objected to the requirement that each guidance document contain the disclaimer that it is guidance and may not carry the force and effect of law. HHS argued that such a disclaimer was unnecessary and might be confusing.[137] But it is only unnecessary because under current law guidance is not supposed to have the force and effect of law. There is no harm in alerting the public to that. And there would only be confusion when proposed guidance did, as a practical matter, carry the force of law. In those instances, agencies should consider altering the

[133] 87 F.R at 44019.

[134] Department of Transportation, Administrative Rulemaking, Guidance, and Enforcement Procedures, 84 F.R. 71714, 71727 December 27, 2019.

[135] 87 F.R. at 44017.

[136] https://www.hhs.gov/guidance/.

[137] 87 F.R at 44011-12, 44022.

guidance or turning it into a legislative rule with all the procedural protections outlined earlier in this paper.

The path forward for GGP

The recent experience with dueling administrations' executive orders as well as the historical record showing incoming administrations' reluctance to enforce the GGP rules of preceding administrations, suggest that relying on the executive branch to establish permanent procedural safeguards for guidance maybe a fruitless endeavor. The best solution would be for Congress to act.

Ideally, Congress would pass a statute with many or all of the requirements found in EO 13891 and the 2007 OMB Bulletin. But such an outcome seems unlikely in the near term. Congress has been unwilling to pass more limited and alternative measures.

Sen. Ron Johnson (R-Wisconsin) and 20 other senators wrote President Biden on February 8, 2021, objecting to his revocation of EO 13891.[138] The letter noted that revoking EO 13891 was contrary to sound policy and contrary to bipartisan support for the Guidance out of Darkness (or GOOD) Act. The GOOD Act would require agencies to post their guidance documents (such as memorandums, directives, blog posts, and speeches by agency officials) on a single website designated by the Office of Management and Budget. In much the same way that the US Code and the Code of Federal Regulations inventory and provide easy access to federal statutes and regulations, GOOD would collect and provide a portal to facilitate access to the thousands of guidance documents.

Unfortunately, this limited and common-sense bill has, thus far, not been enacted. It has been introduced in four successive Congresses starting with the 115th and passed the full House in 2018.[139] But the bill has never passed the Senate, despite as Senator Johnson's letter noted, the support of then-Senator Kamala Harris in 2019.

Similarly, the Regulations from the Executive in Need of Scrutiny Act (REINS Act) — a proposal to improve legislative oversight of administrative agency rulemaking by requiring legislative approval of agency regulations with major financial or economic impacts before the regulations take effect – has made little Congressional headway. REINS would amend the Congressional Review Act to require congressional approval of certain major agency regulations before those regulations are implemented. Unlike the CRA procedure of issuing resolutions of disapproval after a rule takes effect, the REINS Act, by requiring affirmative approval, would give Congress the preemptive authority to halt the initial enactment of certain regulations.

REINS would improve accountability by transferring responsibility for major rules from unaccountable agency bureaucrats to members of Congress who face the electorate on a regular basis. As Ryan Young of the Competitive Enterprise Institute put it, "If Members of Congress must publicly put their name to an unpopular or burdensome regulation, they are less likely to let it stand."[140]

Major agency regulations are defined as those that have financial impacts on the US economy of $100 million or more, increase consumer costs or prices, or have significant harmful effects on the economy including significant adverse effects on competition, employment, investment, productivity, or innovation. As we have seen this is broad enough to include some guidance rules.

REINS was first introduced in the House in 2009 and has been reintroduced multiple times since. It has passed the House on several occasions but never passed in the Senate.

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[138] February 8, 2021 letter from the US Senate to President Joseph R. Biden, https://www.ronjohnson.senate.gov/services/files/35fbbb20-00ef-4516-bdd2-59990f5b9807.

[139] https://www.congress.gov/bill/115th-congress/house-bill/4809/all-info.

[140] Ryan Young, "REINing In Regulatory Overreach," Competitive Enterprise Institute, Nov. 14, 2016, ; *See also*, Joseph Postell, "House to Vote to Reduce Power of Bureaucracy With REINS Act," Heritage Foundation, June 7, 2023 ("The basic idea of the REINS Act—that Congress should vote on the major rules that carry significant impact—is rooted in the core constitutional principle of self-government through elected representatives.") and Jonathan R. Siegel, "The REINS Act and the Struggle to Control Agency Rulemaking,"16 Legislation and Public Policy 131, 135 (2013) ("The REINS Act is constitutional because it would merely reclaim, for Congress, powers that Congress was not required to delegate."); For a contrary view see Sally Katzen, "Why the REINS Act Is Unwise If Not Also Unconstitutional," *The Regulatory Review*, May 3, 2011, https://www.theregreview.org/2011/05/03/why-the-reins-act-is-unwise-if-not-also-unconstitutional/.

Conclusion

Guidance documents form a large and expanding part of the administrative state's regulatory universe. They escape many procedural safeguards because they technically have no legal force and are not binding. But it is widely acknowledged that as a practical matter, many guidance documents do bind regulated entities and, as a result, have a large economic impact.

Over the years, multiple efforts to apply good guidance practices to the issuance and maintenance of guidance rules have been tried and failed. The latest—EO 13891—imposed common sense requirements that many agencies applied by issuing new regulations. These regulations were revoked by the issuance of EO 13992 on the first day of the Biden administration.

It is hard not to conclude that the revocation of the GGP rules had less to do with reasoned decision-making than with a political decision to erase all vestiges of a political opponent's administration and to remove restraints on the expanding administrative state. The various arguments advanced by HHS for its revocation of its GGP rule are unconvincing. Valuable administrative safeguards have been summarily reversed without good reason.

Going forward, good guidance regulations will have to await a new administration willing to advance good guidance regulations at the outset of its term so they can become embedded before there is an opportunity for rapid revocation. If there is a change in administration in the upcoming 2024 election, reissuing HHS's GGP regulation would be a good place to start. Alternatively, Congress, which has thus far been unwilling to act in defense of its lawmaking authority, will have to pass guidance legislation. Either path would be a welcome brake on the unfettered advance of the administrative state.

About the author

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