

GUIDANCE IN THE RULEMAKING PROCESS: EVALUATING PREAMBLES, REGULATORY TEXT, AND FREESTANDING DOCUMENTS AS VEHICLES FOR REGULATORY GUIDANCE



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Introduction

In the past two decades, the use of guidance—nonbinding statements of interpretation, policy, and advice about implementation—by administrative agencies has prompted considerable interest from executive branch officials, committees in Congress, agency officials, and commentators. Most of this attention has been directed toward “guidance documents,”¹ freestanding, nonbinding policy and interpretive statements issued by agencies. Policymakers and commentators have expressed concern that agencies are relying on guidance documents in ways that circumvent the notice-and-comment rulemaking process; in particular, the worry is that with the increased analytical and justificatory burdens of notice-and-comment rulemakings, agencies have turned to guidance as a way to establish norms without the participation benefits and explanatory burdens of the notice-and-comment process.²

¹ OFFICE OF MANAGEMENT AND BUDGET, FINAL BULLETIN FOR AGENCY GOOD GUIDANCE PRACTICES, 72 FED. REG. 3432, 3439 (Jan. 25, 2007) (defining a “guidance document” 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.”) [hereinafter *OMB’s Good Guidance Bulletin*].

² For instance, in 1992, the Administrative Conference of the United States (ACUS) recommended that agencies provide affected persons an opportunity to challenge the wisdom of a guidance document or policy statement before the statement is applied to persons affected. Admin. Conf. of the United States, Agency Policy Statements, Recommendation 92-2, 57 Fed. Reg. 30,103 (June 18, 1992). The ACUS Recommendation commented, “The Conference is concerned . . . about situations in where agencies issue policy statements which they treat or which are reasonably regarded by the public as binding . . . [but these pronouncements do] not offer the opportunity for public comment . . .”). In 2007, President Bush issued an executive order which subjected significant guidance documents to regulatory review based on similar concerns. See Exec. Order No. 13,422, 3 C.F.R. § 191 (2008). President Obama revoked Executive Order 14,422, see Exec. Order No. 13,497, 3 C.F.R. § 218 (2010), but as discussed below, see Memorandum from Peter Orzag, Dir. Office of Mgmt. & Budget, to Heads and Acting Heads of Exec. Dep’ts and Agencies (Mar. 4, 2009) [hereinafter “Orzag Memorandum”] (available at http://www.whitehouse.gov/sites/default/files/omb/assets/memoranda_fy2009/m09-13.pdf), significant guidance is still subject to regulatory review. In 2007, OMB issued a “Final Bulletin for Agency Good Guidance Practices” which requires agencies to provide a means for comment on certain significant guidance documents, see *OMB’s Good Guidance Bulletin*, *supra* note 1, and this Bulletin remains in effect. Committees in Congress have expressed concerns that agencies are inappropriately relying on guidance. See, e.g., COMM. ON GOV’T REFORM, 106TH CONG., NON-BINDING LEGAL EFFECT OF AGENCY GUIDANCE DOCUMENTS, H.R. REP. NO. 106-1009, at 9 (2000) (“[A]gencies have sometimes improperly used guidance documents as a backdoor way to bypass the statutory notice-and-comment requirements for agency rulemaking . . .”); cf. The Regulatory Accountability Act of 2013, S. 1029, 113th Cong. (2013) (Section 706(d) would overrule *Auer* deference to agency interpretations of their own regulations); Todd D. Rakoff, *The Choice Between Formal and Informal Modes of Administrative Regulation*, 52 ADMIN. L. REV. 159, 166 (2000) (arguing that agencies are avoiding ossified rulemaking process by use of nonbinding guidance). For a concise overview of the legal and policy debates over guidance documents, see Nina A. Mendelson, *Regulatory Beneficiaries and Informal Agency Policymaking*, 92 CORNELL L. REV. 397, 397-414 (2007). As I discuss below, recent empirical research calls into question empirical basis for the theory of strategic substitution of guidance documents for rules. See *infra* Part II.B.

Concern about agency reliance on guidance is also evident in the Supreme Court’s doctrines governing the standards of judicial review of agency action. Based in part on the preference for policy formulation through rulemaking and other more formal processes, in 2001, the Supreme Court announced a general presumption that to qualify for *Chevron* deference,³ agency interpretations of the statutes the agency administers must be issued through relatively formal processes, such as notice-and-comment rulemaking.⁴ That 2001 decision, *United States v. Mead Corp.*,⁵ gives agencies incentives to act through notice-and-comment as opposed to guidance documents if they seek to trigger *Chevron* deference in review of their actions. In addition, in the last two years, three members of the Supreme Court have announced their interest in reconsidering the longstanding doctrine identified with *Bowles v. Seminole Rock & Sand Co.*⁶ and *Auer v. Robbins*,⁷ under which the reviewing courts must accept agency interpretation of their regulations unless plainly erroneous or inconsistent with the regulation.⁸ In the same time period, the Supreme Court denied deference to an agency interpretation of its own regulation that appeared in a litigation brief.⁹ These decisions suggest a narrowing of deference available to agencies when they take interpretive positions or issue guidance informally and *post hoc*.

This multi-decade debate about guidance and its relationship to notice-and-comment rulemaking has largely passed over the function and varieties of *contemporaneous guidance*—that is, guidance that agencies provide about the meaning of their rules in the rulemaking process. Contemporaneous guidance appears in three main forms. First, agencies provide guidance about the meaning and application of their rules in explanatory “statement[s] of their basis and purpose,”¹⁰ statements which constitute the bulk of the regulatory “preambles” issued with final rules. Second, they provide guidance about the application and interpretation of their regulations in the Code of Federal Regulations, in notes and examples, and appendices to rules that are published in the Code

³ *Chevron U.S.A. Inc. v. Natural Resources Defense Council*, 467 U.S. 837, 843-44 (1984).

⁴ *United States v. Mead Corp.*, 533 U.S. 218, 230-31 (2001) (noting that agency decisions decided in notice-and-comment qualify for review under *Chevron*).

⁵ *Id.*

⁶ 325 U.S. 410 (1945).

⁷ 519 U.S. 452 (1997). While this doctrine was traditionally associated with *Seminole Rock*, since 1997 the Supreme Court and other courts have frequently attributed it to *Auer*, see, e.g., *Talk Am., Inc. v. Mich. Bell Tel. Co.*, 131 S. Ct. 2254, 2265–66 (2011) (Scalia, J., concurring) (noting that the *Seminole Rock* doctrine has recently been attributed to *Auer*), despite the fact that *Auer* involved a straightforward application of *Seminole Rock*, see *Auer*, 519 U.S. at 461 (relying on *Seminole Rock* with little ado).

⁸ *Decker v. Northwest Env’tl Def. Center*, 133 S. Ct. 1326 (2013); *id.* at 1338 (Roberts, C.J., and Alito, J., concurring) (noting that it “may be appropriate to reconsider” *Seminole Rock/Auer* in another case); *id.* at 1339, 1442 (Scalia, J.) (concurring in part and dissenting in part) (urging the Court to overturn *Seminole Rock/Auer*).

⁹ See *Christopher v. SmithKline Beecham Corp.*, 132 S. Ct. 2156, 2166–68 (2012) (concluding that “general rule” of granting *Auer* deference to interpretations in litigation briefs did not apply in these circumstances of the case in view of fair notice concerns).

¹⁰ 5 U.S.C. § 553 (2012).

of Federal Regulations. Third, at the same time that agencies promulgate their regulations, they sometimes issue freestanding guidance documents. Contemporaneous guidance has a fundamental fair-notice benefit: It furnishes the public and regulated entities the agency’s understanding of the regulation at the time of issuance, reducing some of the uncertainty incident to any new regulatory change, as opposed to later in time or in the context of an enforcement proceeding.¹¹

The neglect of contemporaneous guidance in debates about guidance practices and rulemaking has practical implications along four dimensions. First, and at a most basic level, there has been little dialogue among policymakers or commentators about the best practices for providing guidance in the rulemaking process. Agencies have adopted a diverse set of practices. While uniformity is not necessary or a value to unreflectively demand of a practice as diverse and wide-ranging as rulemaking, the self-conscious choices that some agencies make about how to issue contemporaneous guidance can be a source of information and insight to other agencies. One aim of this Report is to catalogue the variety of agency practices, and legal regime that governs them, as a prompt to reflection about those that best suit particular rulemaking environments.

Second, while many agencies openly embrace the guidance function of preambles, other agencies treat their preambles as unrelated to, and performing an entirely different function than, their “guidance documents.” But by treating preambles as occupying a functionally and conceptually distinct silo from guidance, some agencies neglect the basic guidance function of the “statement of [] basis and purpose,” exclude preambles from their general policies on guidance, fail to include reference to preambles in their official compilations of guidance, and web postings of guidance. Many agencies could also do more to make guidance they provide in preambles easier to locate, for instance, by organizing them to make it easier for the reader to locate the most salient discussions of each element of the regulation, limiting the extent to which they rely on discussions of the rule in notice of proposed rulemaking (NPRM) which can require the reader to integrate two separate statements of the rule, and/or by including hyperlinks to the preambular guidance on electronic versions of their regulatory texts. A second aim of this Report is to suggest reasons why contemporaneous guidance deserves a place at the table in debates and agency choices about guidance practices and rulemaking, and to make several specific supporting recommendations in this regard.

¹¹ This is not to say that a broad variety of circumstances—uncertainty about how a regulation will affect those subject to it, changes in technological, business, environmental or other conditions, newly acquired expertise or studies, constraints on agency staff time, etc.—all provide a justification for issuing *post hoc* guidance. But if all other considerations are equal, contemporaneous guidance has a fair notice benefit.

Third, at the other extreme, in some cases, agencies treat the text of their preambles and the text of their rules as functional equivalents. Thinking about preambles as a source of guidance also prompts inquiry into the boundaries of appropriate use of the preamble. A third aim of the Report is to identify the residual need to insist on the distinctions between preamble and regulatory text.

Fourth, agencies have unrealized opportunities for including notes and examples in the Code of Federal Regulations (CFR) or more extensive guidance published as appendices to the CFR. Where the agency knows that the regulated public relies primarily on the CFR to understand its obligations, there is a strong need for uniformity in guidance, and that guidance does not need to be frequently amended including notes and examples in the CFR or more extensive guidance in an appendix to the CFR can enhance the visibility of this agency advice. The Report also seeks to identify some of those opportunities.

This Report is organized as follows. Part I defines guidance and discusses the scope of the inquiry and methodology of the Report. Part II gives a brief overview of notice-and-comment rulemaking and the role of guidance in the rulemaking process. Part III describes the legal regime governing guidance in preambles, regulatory text, and contemporaneous, separately issued documents. The summary provided in Part III illustrates the continuities between guidance issued in a preamble, regulatory text, and separate documents, highlighting the need for self-conscious choice by agencies about the forms in which they issue guidance. Part IV offers a description of the varieties of contemporaneous guidance that agencies issue. Part V makes several recommendations to federal agencies. Given that regulations have long since outnumbered statutes,¹² it is worth examining the promise and challenges that contemporaneous guidance faces.

I. Definition of Guidance and Scope of Inquiry

A. Definition and Dimensions of Guidance

It is first important to define what is meant by the word “guidance” in this Report. By “guidance” this Report refers to (i) *agency statements outside of those appearing in regulatory text that pertain to the meaning or interpretation of the agency’s regulations or to advice about how to comply with the agency’s regulations*, and (ii) *agency statements*

¹² See CORNELIUS M. KERWIN & SCOTT P. FURLONG, RULEMAKING: HOW GOVERNMENT AGENCIES WRITE LAW AND MAKE POLICY 13-21 (4th ed. 2011) (documenting, in both number of rules and pages of the *Federal Register* devoted to federal regulations, a level of production that far exceeds comparable measures for federal legislation).

appearing in regulatory text that are designed to guide the application or interpretation of the regulation, such as examples or official commentaries.

This definition departs from the most prominent definition of guidance which appears in the Office of Management and Budget's *Final Bulletin on Agency Good Guidance Practices* ("*OMB's Good Guidance Bulletin*")¹³ in two important respects. Under *OMB's Good Guidance Bulletin*, a "guidance document" is "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."¹⁴ In contrast, this Report addresses only guidance about the meaning or application of *regulations*, not guidance about statutes or other sources of law. In that respect, this Report focuses on a narrower class of guidance that falls within the Bulletin's definition.

Second, this Report includes statements that appear in the regulation's text or are published in an appendix to the regulation's text as forms of guidance. Because some of these statements might qualify as "regulatory action[s]" under *OMB's Good Guidance Bulletin's* definition of guidance, they would be excluded from its scope. Because statements that are similar in content can appear in a regulation's preamble, text, or a separately issued document, the broader definition used in this Report does not preclude consideration of these forms of guidance, and agencies' justifications for using them. But because "guidance" is so frequently associated with documents issued outside of rulemaking, it is worth expressly emphasizing that under the definition of "guidance" used here, the guidance may appear in a preamble or the text of a regulation, not merely in separately issued documents.¹⁵

With guidance so defined, guidance can be classified on three dimensions:

1. Timing. Guidance can be provided at the time of the regulation's issuance or at a later time. Contemporaneous guidance would include guidance that appears in a

¹³ *OMB's Good Guidance Bulletin*, *supra* note 1. The definition of "guidance document" adopted in *OMB's Good Guidance Bulletin* is the same as that used in President Bush's Executive Order, Further Amendments to Executive Order 12866 on Regulatory Planning and Review, Executive Order 13,422, 72 Fed. Reg. 2763, 2762 (Jan. 23, 2007) (inserting Section 3(g) with this definition), which President Obama revoked. *See* Exec. Order No. 13,497, 3 C.F.R. § 218 (2010).

¹⁴ *See OMB's Good Guidance Bulletin*, *supra* note 1, at § I.3.

¹⁵ It is worth also emphasizing that statements in preambles could be considered guidance documents even under the definition of guidance in *OMB's Good Guidance Bulletin* because they are "an agency statement[s] of general applicability and future effect, other than a regulatory action, that sets forth a policy on a . . . regulatory or technical issue or an interpretation of . . . a regulatory issue." *Id.*

preamble, the regulation's text, or documents issued at the same time as the regulation, such as compliance guides.¹⁶ All other guidance is *post hoc*.

2. Content. Guidance can take innumerable forms, including: providing (1) general advice about the meaning of particular words or provisions, (2) answers to frequently asked questions, (3) announcement of priorities of the agencies with regard to the enforcement of their regulations, (4) examples of calculations required under the regulations, and (5) examples of model forms.

3. Location. As noted above, guidance can also appear as part of different documents, most obviously including: (1) the regulation's preamble, (2) portions of the agency's reasoning stated in a Notice of Proposed Rulemaking (NPRM) adopted in the regulation's preamble, (3) the regulation text, such as in notes and examples, (4) an appendix to the regulation's text whether published in the Code of Federal Regulations (CFR) or not, or (5) documents issued separately from these core rulemaking documents.

B. Scope of Inquiry and Methodology

This Report focuses on this third dimension—the location of guidance. In almost every rulemaking, agencies face a choice regarding guidance. They can issue virtually identical advice and text in the regulation's preamble, the regulation's codified text or appendix, or in a separate document issued alongside the rule; guidance that appears in preambles in some rulemakings appears in regulatory text or separately issued documents in other rulemakings. The variation is not itself a cause for concern; the difference in the content of regulations, their audience, duration, and interaction with the surrounding legal landscape among many other factors may justify these different choices, even for a single agency. But because these different locations can have different legal effects, different modes of publication, and different ability to reach the regulated, it is worth examining the constraints on the agency's choices and the considerations that inform their best practices with regard to issuing contemporaneous guidance. Those questions are the focus of this Report.

The Report was conducted primarily through legal research and research on agencies' practices in providing contemporaneous guidance. As to agency practices, the research had two components. First, it involved text-based word searches of rulemakings conducted in the last five years by executive agencies that had promulgated economically

¹⁶ Small Business Regulatory Enforcement Fairness Act, Pub. L. No. 104-121, § 212(a), 110 Stat. 873, codified at 5 U.S.C. § 601 nt. (2012).

significant regulations in the last 15 years. The focus on the last five years was to ensure study of current practices. The set of executive agencies that had issued an economically significant rule in the last 15 years is drawn from David Lewis and Jennifer Selin’s *Sourcebook of the United States Executive Agencies*.¹⁷ This sample was chosen because it reflects a cross-section, at least of executive agencies, engaged in the most significant rulemakings. Second, with the assistance of Staff Counsel at the Administrative Conference of the United States (ACUS), I also conducted half-hour phone interviews with counsel working on rulemaking in 12 agencies in January and February, 2014.¹⁸ The Report includes discussion of examples of rulemakings from those agencies even if they were not among those identified for the word searches of agency practices. On February 10, 2014, I presented an overview of the project for brown bag discussion at ACUS headquarters attended by more than thirty other government lawyers working on rulemaking. The experience and insight of the lawyers with whom I spoke informed the recommendations and coverage of this Report.

II. Guidance and Rulemaking: A Brief Overview

To assess the appropriate role of guidance in rulemaking today, it first makes sense to begin with some background understanding of the place and prominence of guidance within and outside of notice-and-comment rulemaking proceedings.

A. The APA’s Vision: The Dual Role of the Statement of Basis and Purpose -- Justification and Guidance

The Administrative Procedure Act (APA) provides a simple structure for notice-and-comment rulemaking, especially given the scope of federal lawmaking that now emerges through this process. Section 553 of the APA sets out three basic elements of notice-and-comment rulemaking.¹⁹ First, section 553 requires publication of a “[g]eneral notice of proposed rulemaking” in the *Federal Register*, commonly referred to as an

¹⁷ DAVID E. LEWIS & JENNIFER L. SELIN, SOURCEBOOK OF UNITED STATES EXECUTIVE AGENCIES 132 (Table 20) (December 2012 First Edition). The following agencies fall in this category: USDA, DOC, DOD, DOED, HHS, DHS, HUD, DOI, DOJ, DOL, STAT, DOT, DTRS, DVA, EPA, EEOC, OMB, OPM, RRB, SBA, and SSA.

¹⁸ These agencies included the Board of Governors of the Federal Reserve System, Consumer Financial Protection Bureau, Department of Education, Department of Health and Human Services, Department of the Interior, Department of Transportation, Department of the Treasury, Equal Employment Opportunity Commission, Merit Systems Protection Board, Occupational Health & Safety Review Commission, Social Security Administration, and U.S. Coast Guard.

¹⁹ 5 U.S.C. § 553 (2012). Section 553 provides a default process for rulemaking except in the rare case of a statute that requires the rulemaking be conducted through the APA’s formal rulemaking procedure, *see id.* § 553 (noting that § 556 & § 557 apply when the rules are required by statute “to be made on the record and after opportunity for an agency hearing”), or when a statute specifies its own rulemaking procedure.

“NPRM.”²⁰ Second, after publication of that required notice, the agency “shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments.”²¹ Third, after consideration of these comments, “the agency shall incorporate in the rules adopted a concise and general statement of their basis and purpose.”²² The APA exempts from these notice and consideration requirements “interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice,” among other exceptions, which are sometimes referred to as nonlegislative rules or guidance documents.²³

Early understandings of the APA suggest that the statement of basis and purpose, which comprises much of what is commonly referred to as the regulation’s “preamble,” was intended to have a dual role: not only identifying the legal and factual basis for the rule, but also providing guidance on its meaning and import for the public and the courts. This message comes through clearly in the *Attorney General’s Manual on the Administrative Procedure Act*.²⁴ Of the statement of basis and purpose, the Manual opines, “[t]he required statement will be important in that the courts and the public will be expected to use such statements in the interpretation of the agency’s rules.”²⁵ And the Manual goes on, “the statement is intended to advise the public of the general basis and purpose of the rules.”²⁶ The APA’s legislative history also includes support for this understanding. “The required statement of basis and purpose of rules issued,” as both the House and Senate Judiciary Committee Reports commented on S.7 which became the APA, “should not only relate to the date so presented but with reasonable fullness explain the actual basis and objectives of the rule.”²⁷

²⁰ 5 U.S.C. § 553(b) (2012).

²¹ *Id.* § 553(c).

²² *Id.*

²³ *Id.* § 553(b)(3)(A); see Mendelson, *supra* note 2, at 406 (describing process applicable to guidance documents).

²⁴ UNITED STATES DEPARTMENT OF JUSTICE, ATTORNEY GENERAL’S MANUAL ON THE ADMINISTRATIVE PROCEDURE ACT (1947).

²⁵ *Id.* at 32.

²⁶ *Id.*

²⁷ H.R. REP. NO. 79-1980, at 259 (1946); S. REP. NO. 79-752, at 201 (1945), as available in ADMINISTRATIVE PROCEDURE ACT, LEGISLATIVE HISTORY, 79TH CONG., S. Doc. No. 79-248, 1944-46, 225 (1944-46). The Senate Report also contains as an appendix to the Attorney General’s 1945 report on Senate Bill 7. The Attorney General’s report stated the following in regards to the statement of basis and purpose:

Section 4 (b), in requiring the publication of a concise general statement of the basis and purpose of rules made without formal hearing, is not intended to require an elaborate analysis of rules or of the detailed considerations upon which they are based but is designed to enable the public to obtain a general idea of the purpose of, and a statement of the basic justification for, the rules. The requirement would also serve much the same function as the whereas clauses which are now customarily found in the preambles of Executive orders.

The idea that the statement of basis and purpose was meant to apprise the public of the purpose and effect of the rule—that is, that it serve a guidance function—in addition to disclosing the basis for the rule has sound logic. The statement of basis and purpose is necessary for the procedural validity of the rule,²⁸ and constitutes the agency’s authoritative statement of the rule’s purposes and basis. Because the statement of basis and purpose is part and parcel of the agency’s rulemaking, it makes sense these documents would help inform the public about the meaning and application of the rules they accompany, and that the public and courts would turn to them for those purposes.²⁹ As this Report documents, while many agencies rely extensively on statements of basis and purpose to apprise the public of the application of their rules, the guidance function of these statements has had not had prominence in policy on guidance nor received much attention from government bodies or commentators.³⁰

B. The Expanding Preamble, Ossification, and Separately Issued Guidance

Part of the explanation for the relative neglect of the guidance function of preambles is that agencies have come to devote more and more attention in their preambles to justifying the legal sufficiency of their rules. For some agencies, a clear legal division of labor has taken hold: The preamble is devoted almost entirely to the legal sufficiency of the regulation, and guidance is something the agency provides outside the rulemaking, in separately issued documents.

This development has been conventionally understood as a consequence of heightened judicial scrutiny review of the rationality of agency regulations that took hold in the late 1960s and early 1970s in the form of “hard look review” and has persisted ever since. Hard look review developed as a combination of two doctrinal elements. First, hard look review adopts the pre-APA administrative law requirement associated with *SEC v.*

S. REP. NO. 752, at 225 (1945) (also available in ADMINISTRATIVE PROCEDURE ACT, LEGISLATIVE HISTORY, 79TH CONG., 2D SESS., Doc. No. 248, 1944-46, 225 (1946).

²⁸ See *Indep. U.S. Tanker Owners Comm. v. Dole*, 809 F.2d 847, 852 (1987) (vacating a rule for inadequate statement of basis and purpose).

²⁹ See Kevin M. Stack, *Interpreting Regulations*, 111 Mich. L. Rev. 355 (2012) (defending reliance on agency preambles to interpret regulations).

³⁰ A few more comprehensive commentaries observe that agencies include statements of basis and purpose to explain their rules, but do not give the practice focused attention. See, e.g., JEFFREY S. LUBBERS, A GUIDE TO FEDERAL AGENCY RULEMAKING 337 (5th ed., 2012) (“Agencies often use the statement [of basis and purpose] to advise interested persons how the rule will be applied.”); Richard J. Lazarus, *Meeting the Demands of Integration in the Evolution of Environmental Law: Reforming Environmental Criminal Law*, 83 GEO. L.J. 2407, 2437 (1995) (noting that lengthy preambles are just one sources of “underground environmental law” which also includes extensive guidance).

*Chenery Corp.*³¹ (known as *Chenery I*), which stated that a reviewing court will uphold an agency’s action based only on “the grounds upon which the agency acted in exercising its powers.”³² Second, hard look review embraces a relatively high standard for the quality of the reasons provided by the agency, despite statements by courts that arbitrary and capricious review is lenient or narrow.³³ When the *Chenery I* requirement for a contemporaneous statement of reasons is combined with a high standard for the quality of those reasons, the consequences for the agency are clear: For rules to survive judicial review, the agency must provide an extremely detailed justification of their grounds. The place for the agency to do so is in the rule’s statement of basis and purpose.

The Supreme Court’s decision in *Motor Vehicle Manufacturers Ass’n v. State Farm Mutual Automobile Insurance Co.*³⁴ still provides the classic statement and illustration of hard look review. In *State Farm*, the Court set a high standard for the agency’s level of express justification in its statement of basis and purpose in the rule. To avoid being arbitrary or capricious under section 706 of the APA, the agency must “examine the relevant data and articulate a satisfactory explanation for its action, including a ‘rational connection between the facts found and the choice made.’”³⁵ An agency rule would normally be arbitrary and capricious if “the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.”³⁶ In *State Farm*, the Supreme Court reversed the agency’s decision to rescind a rule under this standard, in part because the agency provided no consideration of one of the viable options within the ambit of the existing rule.³⁷ Since the *State Farm* decision, both the Supreme Court and the Courts of Appeals have emphasized that the vesting of wide power for agencies “carries with it a correlative responsibility for the agency to explain the rationale and factual basis for its decision,”³⁸ a duty that agencies discharge in their statements of basis and purpose. This duty not only includes evaluation of alternatives and explanation of the basis for the regulations adopted, but also a duty to discuss salient comments.³⁹ As a result, the agency’s articulation of the grounds of its

³¹ 318 U.S. 80 (1943).

³² *Id.* at 95.

³³ *See, e.g.,* *Citizens to Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971) (describing the standard as a “narrow” one); *Muwekma Ohlone Tribe v. Salazar*, 708 F.3d 209, 220 (D.C. Cir. 2013) (same).

³⁴ 463 U.S. 29 (1983).

³⁵ *Id.* at 43.

³⁶ *Id.*

³⁷ *Id.* at 51

³⁸ *Bowen v. Am. Hosp. Ass’n*, 476 U.S. 610, 627 (1986); *see also, e.g.,* *Detsel by Detsel v. Sullivan*, 895 F.2d 58, 63 (2d Cir. 1990).

³⁹ *See, e.g.,* *Am. Mining Cong. v. EPA*, 965 F.2d 759, 771 (9th Cir. 1992).

action and engagement with commentators in its statement of basis and purpose is necessary to the validity of the rule.

As these doctrines of judicial review congealed in the contemporary hard look doctrine, the length of regulatory preambles has grown as measured by the average number of pages per final rule published in the *Federal Register*. Based on a study performed by the Congressional Research Service, the average number of *Federal Register* pages per final rule in 1976, 1977, 1978 was 1.7, 2.07, 2.2 respectively, whereas the averages in 2009, 2010, and that 2011 were 5.93, 6.97, and 6.91 respectively.⁴⁰ The common sense explanation is that the prospect of stringent judicial review, which requires the agency to “show it’s work,” has prompted agencies to devote more energy to writing elaborate statements of the legal sufficiency of their regulations in their preambles.⁴¹ Other analysis requirements imposed on agencies also add to the explanatory obligations the agency must discharge in their preambles, including the analysis requirements imposed by Executive Order 12,866,⁴² the Regulatory Flexibility Act,⁴³ the Paperwork Reduction Act of 1995,⁴⁴ the National Environmental Policy Act of 1969,⁴⁵ and the Unfunded Mandates Reform Act of 1995,⁴⁶ among other analysis and consultation requirements.

At the same time that the agency’s duties of explanation—and actual explanations—of the basis for their rules in preambles has grown, the need for guidance as to the meaning and application of agency regulations has not gone away.

⁴⁰ MAEVE P. CAREY, CONG. RES. SERV. R43056, COUNTING REGULATIONS: AN OVERVIEW OF RULEMAKING, TYPES OF FEDERAL REGULATIONS, AND PAGES IN THE FEDERAL REGISTER, 17-18 (2013) (calculations produced by dividing the number of pages per final rule by the number of final rules, information reported in Table 6).

⁴¹ See, e.g., Richard J. Pierce, Jr. *Seven Ways to Deossify Agency Rulemaking*, 47 ADMIN. L. REV. 59, 65 (1997) [hereinafter “*Seven Ways*”] (suggesting that the stringent judicial gloss on the APA has “transform[ed] the simple, efficient notice and comment process into an extraordinarily lengthy, complicated, and expensive process,” discouraging agency use of rulemaking); Thomas O. McGarity, *Some Thoughts on “Deossifying” the Rulemaking Process*, 41 DUKE L.J. 1385, 1401 (1992) (attributing the “Herculean effort of assembling the record and drafting a preamble” to heightened judicial scrutiny of rulemaking); Mark Seidenfeld, *Demystifying Deossification: Rethinking Recent Proposals to Modify Judicial Review of Notice and Comment Rulemaking*, 75 TEX. L. REV. 483, 492-98 (1997) (providing account of ways in which hard look review has increased burdens of explanation and evidence production on agencies).

⁴² Exec. Order No. 12,866, 3 C.F.R. 638 (1994). For a copy of this Regulatory Planning and Review Executive Order as amended, see 5 U.S.C. § 601 nts. (2012).

⁴³ 5 U.S.C. § 604(a)(2) (2012) (requiring agencies to state changes made in rule in response to comments).

⁴⁴ 44 USC §§ 3501-3521 (2006) (requiring in § 3505 approval by Director of OMB that rules minimize federal information collection burdens).

⁴⁵ 42 USC § 4321 et seq. (2006) (requiring in § 4332 preparation of environmental impact statement for significantly effecting the quality of the human environment).

⁴⁶ 2 U.S.C. § 1532(a)(5)(A) (2012) (requiring agencies to respond to comments from state and local governments).

A common suspicion is that the increased costs associated with notice-and-comment rulemaking has given agencies incentives to look for alternative, less costly ways to establish policy or advise the public of the agency's understanding of the law. In particular, several commentators suggested that the high cost of notice-and-comment rulemaking has caused agencies to rely to a greater extent on separately issued guidance documents which need not proceed through notice-and-comment rulemaking,⁴⁷ effectively substituting guidance documents for rulemaking.⁴⁸ Recent empirical investigations call into question this suggestion that agencies rely on guidance documents to avoid the burdens of notice-and-comment rulemaking. In a study of the Environmental Protection Agency (EPA), Food and Drug Administration (FDA), Federal Communications Commission (FCC), Occupational Safety and Health Administration (OHS), and the Internal Revenue Service (IRS), between 1996 and 2006, Connor Raso found that agencies do not increase their issuance of guidance strategically,⁴⁹ and that the body of significant legislative rules issued still dwarfs that of significant guidance.⁵⁰ In an extensive study of the Department of the Interior, Jason and Susan Webb Yackee also found no support for increased reliance on nonlegislative rules between 1950-1990.⁵¹ More generally, Anne Joseph O'Connell also found that the volume of agency notice-and-comment rulemaking remains significant, and thus does not appear to be so costly that it is no longer a viable option for agencies.⁵²

⁴⁷ See 5 U.S.C. § 553(b) (2012) (excepting interpretative rules and general statements of policy from notice and comment requirements).

⁴⁸ See, e.g., Robert A. Anthony, *Interpretive Rules, Policy Statements, Guidances, Manuals, and the Like—Should Federal Agencies Use Them to Bind the Public?*, 41 DUKE L.J. 1311, 1316-17(1992) (arguing that with the increased cost of notice-and-comment rulemaking, agencies are increasingly willing to rely on forms of nonlegislative rules, such as interpretative rules and general statements of policy to implement their statutes); Pierce, *Seven Ways*, *supra* note 41, at 86 (same).

⁴⁹ Connor Raso did not find evidence that agencies issued guidance documents more often as presidential terms waned, nor more frequently during periods of divided government. See Connor N. Raso, Note, *Strategic or Sincere? Analyzing Agency Use of Guidance Documents*, 119 YALE L.J. 782, 806-07 (2010).

⁵⁰ See Raso, *supra* note 49, at 813-14 (Table 3 showing that the ratio of significant guidance documents to significant legislative rules ranges from .00 and .01 (Defense and Energy) to .31 and .35 (Education and Homeland Security)).

⁵¹ Jason Webb Yackee & Susan Webb Yackee, *Testing the Ossification Thesis: An Empirical Examination of Federal Regulatory Volume and Speed, 1950-1990*, 80 GEO. WASH. L. REV. 1414, 1461 (2012). The Yackees' article includes interim final rules and guidance documents in a category on "no-comment regulations," drawn from searches of the *Federal Register*. With regard to guidance published in the *Federal Register*, this methodological choice means that their findings of no increased reliance on guidance is very conservative because they are counting interim final rules in this category. However, their study does not capture guidance that is not published in the *Federal Register*, so may also understate agency reliance on it.

⁵² See Anne Joseph O'Connell, *Political Cycles of Rulemaking: An Empirical Portrait of the Modern Administrative State*, 94 VA. L. REV. 889, 936 (2008) (suggesting that volume of agency rulemaking shows it is not ossified). Interestingly, Anne Joseph O'Connell's study reveals that agencies have increased issuance of direct final rules and interim final rules. See *id.* Both direct final rules and interim final rules include statements equivalent to statements of basis and purpose, but they do not undergo a pre-publication comment period. NAT'L ARCHIVES & RECORDS ADMIN., FEDERAL REGISTER DRAFTING DOCUMENT HANDBOOK, 2-6 to 2-8 (1998) (noting that direct final rules and interim final rules should include preambles explaining the

These studies complicate and may undermine the view that agencies have increasingly relied on separately issued guidance documents in response to the greater demands on, and costs of, notice-and-comment rulemaking. But these studies do not address the extent to which the agency preambles have been devoted to justifying the legal sufficiency of the regulations as opposed to serving a guidance function. The increased legal demands saddled upon the agency’s preamble have all been directed toward legal sufficiency or analysis requirements, not their guidance function.⁵³ To the extent those increased justificatory and analysis requirements have had an effect on agency’s activities in rulemaking—and the lengthening of agency preambles is a good indication that they have an effect—they have augmented the prominence of the justificatory role of the preamble. At the same time, even as policymakers and commentators have devoted more attention to agencies’ use of guidance, that attention has been almost exclusively directed to separately issued guidance documents, not guidance provided within rulemaking documents. We need a better understanding of the guidance function these documents do—and must—serve.

III. The Law Governing Contemporaneous Guidance

Assessment of best practices for providing guidance in rulemakings—that is, best practice for contemporaneous guidance—requires understanding the legal regime and constraints that apply to providing guidance in regulatory preambles, the regulatory text (including any appendices), or in separately issued documents. Despite the ubiquity of contemporaneous guidance,⁵⁴ there are few, if any, resources that draw together the legal regime applicable to contemporaneous guidance. From the perspective of the agency and the public, there are a host of questions about how the general law of guidance applies to contemporaneous guidance, including:

- What, if any, process requirements apply to issuing contemporaneous guidance?
- What, if any, process requirements apply to revising contemporaneous guidance?

rule’s purpose and grounds). Agencies’ increased reliance on these forms suggests that at least the “notice-and-comment rulemaking has significant costs that the agencies want to avoid.” Joseph O’Connell, *supra*, at 936.

⁵³ See, e.g., Unfunded Mandates Reform Act, 2 U.S.C. § 1523(a) (2006); Small Business Regulatory Enforcement Fairness Act, 5 U.S.C. § 609, Pub. L. No. 104-121, 110 Stat. 857 (1996); Regulatory Flexibility Act, 44 U.S.C. §§ 301-612 (2006); Congressional Review Act, 5 U.S.C §§ 801-08 (2006); Paperwork Reduction Act, 44 U.S.C. §§ 3501-20 (2006); 44 U.S.C. § 3504(c) (2006).

⁵⁴ See *infra* Part IV.

- When is contemporaneous guidance subject to OIRA review?
- What, if any, guidance must be included in a regulatory preamble or regulatory text, or separately issued document?
- What, if any, guidance may not be included in a regulatory preamble or regulatory text?
- What forms of contemporaneous guidance are reviewable?
- What standards of judicial review apply?

This Part addresses these questions, and then provides a summary of the answers in Table 1.⁵⁵

A. Process Requirements for Issuing Contemporaneous Guidance

One of the distinctive features of separately issued guidance documents is that they are exempt from the requirements of notice-and-comment under APA § 553(b)(A).⁵⁶ But this does not mean that there are no applicable procedural requirements. The APA requires that interpretive rules and general statements of policy be published in the *Federal Register*,⁵⁷ and that other forms of guidance be publically available.⁵⁸ Preambles and regulatory text obviously must meet that publication requirement.

The more involved and less explored process issue for contemporaneous guidance arises from those agencies covered by *OMB's Good Guidance Bulletin*.⁵⁹ As noted at the outset, this *Bulletin* defines “guidance documents” to exclude regulatory actions,⁶⁰ so it would not apply to any guidance the agency provided in the text of its regulations. But under the definition in the *Bulletin*, agency preambles (as well as separately issued documents) could qualify as guidance documents within the *Bulletin* because they may be statements of “general applicability and future effect . . . that set[] forth a policy on a . . . regulatory issue or interpretation of a . . . regulatory issue.”⁶¹ Likewise, statements in an agency preamble could also constitute “significant guidance” which includes guidance leading to an annual effect on the economy of more than \$100 million, creating serious

⁵⁵ See *infra* Section III(H).

⁵⁶ 5 U.S.C. § 553(b)(A) (2012).

⁵⁷ See *id.* § 552(a)(1)(D).

⁵⁸ See *id.* § 552(a)(2)(B) (2012).

⁵⁹ *OMB's Good Guidance Bulletin*, *supra* note 1. The *Bulletin* applies only to executive agencies. See *id.* § I.2 (defining “agency” as agencies other than those considered to be independent regulatory agencies under 44 U.S.C. § 3205(5)).

⁶⁰ *Id.* § I.3 (“The term ‘guidance document’ means an agency statement of general applicability and future effect, other than a regulatory action (as defined in Executive Order 12866, as further amended by, section 3(g)), that sets forth a policy on statutory, regulatory, or technical issue or an interpretation of a statutory or regulatory issue.”).

⁶¹ *Id.*

inconsistencies with another agency's actions or planned actions, altering budget impacts on entitlements, or raising novel legal issues arising out of legal requirements or the president's priorities or Executive Order 12,866.⁶²

Accordingly, for executive agencies, to the extent any statements in an agency preamble as well as those in separately issued documents would be considered "significant guidance documents" or even "economically significant guidance documents" under the Bulletin, the agency would have to comply with the procedural requirements the Bulletin imposes.⁶³ Most interesting for their application to preambles are the requirement that: (1) there be a designation of the statement as "guidance" (or its equivalent),⁶⁴ (2) the agency maintain on its web site a list of significant guidance documents,⁶⁵ and (3) the agency structure a means for the public to submit comments on significant guidance documents.⁶⁶ While many agencies provide extensive guidance about the meaning and operation of their regulations in their preambles, few agencies appear to treat their preambles as subject to the procedural requirements of *OMB's Good Guidance Bulletin* which, by its own terms, could apply to guidance provided in preambles.

Consider in particular *OMB's Good Guidance Bulletin's* requirement that each agency maintain on its web site a list of its current significant guidance documents in effect, including a link to the document.⁶⁷ Based on a review of the web sites of the 21 executive branch agencies that have issued an economically significant regulation in the last 15 years,⁶⁸ only the Department of Transportation's web site on guidance mentions preambles as a source of guidance.⁶⁹

In sum, while guidance provided in agency preambles or in regulatory text clearly meet the APA's publication requirements, these same statements, if their effects are significant, could require compliance with *OMB's Good Guidance Bulletin*. That would require the agency to be conscientious about how it designated those guidance portions, to

⁶² *Id.* § I.4(a)(i)-(iv).

⁶³ *Id.* § II.2-3 (outlining basis procedures for significant guidance). The Bulletin's imposition of procedural requirements for issuing guidance builds upon ACUS Recommendation 92-2 on Agency Policy Statements. That recommendation urged agencies to provide procedures to challenge the legality and wisdom of the statements prior to these policies being applied. See Admin. Conf. of the United States, Agency Policy Statements, Recommendation 92-2, ¶ II(B), 57 Fed. Reg. 30,103 (June 18, 1992).

⁶⁴ *Id.* § II.2 (setting out requirement elements for significant guidance).

⁶⁵ *Id.* § III.1 (providing for Web posting of significant guidance).

⁶⁶ *Id.* § III.2 (setting forth requirements for public to submit comments and complaints about its guidance).

⁶⁷ *Id.* § III.1.

⁶⁸ This list of agencies is drawn from LEWIS & SELIN, *supra* note 17, at 132 (Table 20). It includes: USDA, DOC, DOD, DOED, HHS, DHS, HUD, DOI, DOJ, DOL, STAT, DOT, DTRS, DVA, EPA, EEOC, OMB, OPM, RRB, SBA, and SSA.

⁶⁹ The web sites on guidance for the agencies noted did not include mention of preambles or a rule's statement of basis and purpose, except for DOT (websites on guidance visited March 2014).

post or mention preambles alongside other significant guidance on their web sites, and even to provide an opportunity to comment on the significant guidance in preambles, among other requirements.

B. Process Requirements for Revising Contemporaneous Guidance: The Impact of *Alaska Professional Hunters*

The process requirements that apply to an agency decision to revise contemporaneously issued guidance are even clearer than those that apply to issuing contemporaneous guidance. Clearly guidance issued as part of a regulatory text can only be revised through a new notice-and-comment proceeding. Based on the rule adopted by the D.C. Circuit in *Alaska Prof'l Hunters Ass'n v. FAA*⁷⁰ and *Paralyzed Veterans of America v. D.C. Arena*,⁷¹ in some cases, agencies must also proceed through notice-and-comment to revise guidance provided in their preambles.

The “*Alaska Hunters*” rule, also known as the “one-bite” rule,⁷² states that “[w]hen an agency has given its regulation a definitive interpretation, and later significantly revises that interpretation, the agency has in effect amended its rule, something it may not accomplish without notice and comment.”⁷³ As the D.C. Circuit recently clarified in *Mortgage Bankers Ass'n v. Harris*,⁷⁴ this rule involves two basic inquiries: whether the interpretation is definitive (“definitiveness”), and whether there has been a significant change in the interpretation (“significant change”), but does not require substantial and justified reliance on the prior interpretation.⁷⁵

In *Paralyzed Veterans*, the D.C. Circuit characterized a change in an interpretation of a rule as an “amendment” to a regulation.⁷⁶ The court then turned to APA § 551(5), which defines “rulemaking” as including “formulating, amending, or repealing a rule.”⁷⁷ On this basis, the court concluded that amendments in the form of changes to interpretations must go through notice-and-comment.⁷⁸ As commentators have pointed out, the *Paralyzed Veterans* court neglected to consider that § 553, which sets forth the

⁷⁰ 177 F.3d 1030, 1035-36 (D.C. Cir. 1999).

⁷¹ 117 F.3d 579, 588 (D.C. Cir. 1997).

⁷² Stack, *supra* note 29, at 415–16.

⁷³ 177 F.3d at 1034.

⁷⁴ 720 F.3d 966 (D.C. Cir. 2013), *petition for cert. filed*, Nos. 13-1041, 13A636 (Feb 28, 2014).

⁷⁵ *Id.* at 969; Matthew P. Downer, Note, *Tentative Interpretations: The Abracadabra of Administrative Rulemaking and the End of Alaska Hunters*, 67 VAND. L. REV. (forthcoming 2014) (exploring distinction between definitive and tentative interpretations).

⁷⁶ See *Paralyzed Veterans*, 117 F.3d at 586.

⁷⁷ *Id.*

⁷⁸ *Id.*; 5 U.S.C. 551(5) (2012).

requirements for notice-and-comment rulemaking, specifically exempts “interpretative rules” from notice-and-comment.⁷⁹

Alaska Hunters formalized *Paralyzed Veterans* into a doctrine.⁸⁰ At issue in *Alaska Hunters* was a thirty-year-old practice of the Federal Aviation Administration’s Alaska regional office that uniformly advised hunting and fishing guides flying clients on Alaskan hunting tours that they were not considered “commercial operators,” a treatment that resulted in exempting these businesses from some FAA regulations.⁸¹ In 1997, FAA officials in Washington, D.C. published a “Notice to Operators” announcing that it would interpret these hunting businesses as “commercial operators” subject to commercial operator regulations going forward.⁸² Relying on *Paralyzed Veterans*, the *Alaska Hunters* court held that the “Notice to Operators” was procedurally invalid because it effectively amended a regulation by changing a definitive interpretation without notice-and-comment.⁸³ The prior interpretation, the court noted, had become “an authoritative departmental interpretation, an administrative common law.”⁸⁴ In subsequent decisions, the D.C. Circuit has narrowed the scope of this rule somewhat, holding that when an administrative interpretation includes conditional language (e.g., “may use,” “can be used”) or did not establish an “express, direct, and uniform interpretation,”⁸⁵ it is not definitive. While roundly criticized by commentators as inconsistent with the APA § 553,⁸⁶ the D.C. Circuit and several other Circuits continue to apply this doctrine.⁸⁷

⁷⁹ Jon Connolly, Note, *Alaska Hunters and the D.C. Circuit: A Defense of Flexible Interpretive Rulemaking*, 101 COLUM. L. REV. 155, 160, 165 (2001).

⁸⁰ Alaska Prof’l Hunters Ass’n, 177 F.3d at 1034 (citing *Paralyzed Veterans*, 117 F.3d at 586) (“‘Rule making,’ as defined in the APA, includes not only the agency’s process of formulating a rule, but also the agency’s process of modifying a rule.”).

⁸¹ *Id.* at 1031-32.

⁸² *Id.* at 1033.

⁸³ *Id.* at 1034.

⁸⁴ *Id.* at 1035.

⁸⁵ *MetWest Inc. v. Sec’y of Labor*, 560 F.3d 506, 509 (D.C. Cir. 2009) (conditional statement, “circumstances may exist,” in guidance does not establish a definitive agency interpretation); *Darrell Andrews Trucking, Inc. v. Fed. Motor Carrier Safety Admin.*, 296 F.3d 1120, 1126 (D.C. Cir. 2002) (presence of language “can be used” or “could be used” rendered guidance ambiguous and thus did mark a definitive interpretation); *Ass’n of Am. R.R.s v. Dep’t of Transp.*, 198 F.3d 944, 949 (D.C. Cir. 1999) (agency interpretations not sufficiently authoritative or uniform).

⁸⁶ Richard W. Murphy, *Hunters for Administrative Common Law*, 58 ADMIN. L. REV. 917, 918 (2006) (“Academic commentary on [the *Alaska Hunters* doctrine] has been scathing.”); see also William Funk, *A Primer on Nonlegislative Rules*, 53 ADMIN. L. REV. 1321, 1329 (2001) (criticizing the D.C. Circuit’s reasoning in *Alaska Hunters*); Pierce, *Seven Ways*, *supra* note 41, at 566 (same); Peter L. Strauss, *Publication Rules in the Rulemaking Spectrum: Assuring Proper Respect for an Essential Element*, 53 ADMIN. L. REV. 803, 846 (2001) (same); Connolly, *supra* note 79, at 157 (same).

⁸⁷ See *Mortg. Bankers Ass’n v. Harris*, 720 F.3d 966 (D.C. Cir. 2013) (reaffirming the *Alaska Hunters* doctrine). The Third, Fifth and Sixth Circuits have adopted the *Alaska Hunters* doctrine. See *SBC Inc. v. FCC*, 414 F.3d 486, 498 (3d Cir. 2005); *Dismas Charities, Inc. v. U.S. Dept. of Justice*, 401 F.3d 666, 682 (6th Cir. 2005); *Shell Offshore Inc. v. Babbitt*, 238 F.3d 622, 629 (5th Cir. 2001). In contrast, the First, Seventh, and Ninth Circuits have rejected the *Alaska Hunters* doctrine. See *Abraham Lincoln Mem’l Hosp. v.*

The *Alaska Hunters* rule has clear implications for preambles. It seems clear that guidance provided in a preamble to a regulation could be definitive under *Alaska Hunters*. Guidance provided in a preamble is clearly authoritative; it is the agency as an institution that issues it. So long as it was not conditional or ambiguous, it would qualify as a definitive interpretation. As a result, under *Alaska Hunters*, for the agency to significantly change its definitive guidance provided in a preamble would require the agency to undergo a new notice-and-comment proceeding.

The idea that a notice-and-comment proceeding is required to change guidance given in a preamble to a regulation may strike many as an odd result in part because it appears to blur the distinction between rule and preamble. That blurring follows from *Alaska Hunters*, but also has an important implication for agencies: For definitive guidance, there may be less procedural difference that would initially appear between statements in the preamble and in the regulatory text. So long as the statements in the preamble are definitive, then they can be changed, like regulatory text, only through notice-and-comment. So the difference in procedural requirements is only a difference in the processes that govern their issuance: Regulatory text is subject to notice-and-comment under the APA, whereas guidance in a preamble, like separately issued guidance, is at most subject to the notice obligations imposed by *OMB's Good Guidance Bulletin* (which in turn involves notice and comment for economically significant guidance).

C. When Is Contemporaneous Guidance Subject to OIRA Review?

For agencies that are not independent regulatory agencies,⁸⁸ preambles to significant final rules, the text of those rules, as well as significant guidance documents are all subject to some oversight by the Office of Information and Regulatory Affairs under Executive Order 12,866.⁸⁹

Executive Order 12,866 defines regulatory actions as “any substantive action by an agency (normally published in the *Federal Register*) that promulgates or is expected to lead to the promulgation of a final rule or regulation . . . advanced notices of proposed rulemaking, and notices of proposed rulemaking.”⁹⁰ Preambles to final rules and

Sebelius, 698 F.3d 536 (7th Cir. 2012); Erringer v. Thompson, 371 F.3d 625 (9th Cir. 2004); Warder v. Shalala, 149 F.3d 73 (1st Cir. 1998). The Tenth Circuit appeared to criticize the *Alaska Hunters* decision, but did not either formally adopt or reject it. See *United States v. Magnesium Corp. of Am.*, 616 F.3d 1129 (10th Cir. 2010).

⁸⁸ Exec. Order. No. 12,866 § 3(b), 3 C.F.R. 638 (1994) (defining agencies, unless otherwise noted, as excluding independent regulatory agencies as listed in 44 U.S.C. § 3502(10)).

⁸⁹ *Id.* at § 3(e).

⁹⁰ *Id.*

regulatory text are clearly “regulatory actions.” As such, under the Executive Order’s Centralized Review provisions, for regulations that are “significant,”⁹¹ covered agencies must provide the text of the preamble and the regulatory text to OIRA for review.⁹²

In addition, “significant” guidance documents are also subject to OIRA review. While President Obama revoked President Bush’s Executive Order which formally subjected guidance documents to review,⁹³ that did not remove significant guidance documents from OIRA review. As former OIRA Administrator Cass Sunstein reports, “Across multiple administrations, OIRA has long reviewed such [guidance] documents . . . so long as they count as ‘significant.’”⁹⁴ This understanding was confirmed by then-OMB Director Peter Orzag in a March 2009 memorandum that made clear that the revocation of President Bush’s Executive Order formally including guidance in regulatory review restored regulatory review to the process between 1993 and 2007.⁹⁵ “During that period,” Director Orzag wrote, “OIRA reviewed all significant proposed final agency actions, including significant policy and guidance documents.”⁹⁶

D. What Contemporaneous Guidance is Required?

While the law does not require including particular guidance in regulatory text,⁹⁷ there are minimum obligations for contemporaneous guidance to be included in regulatory preambles as well as in separate guidance documents called “compliance guides” for rules that have “a significant impact on a substantial number of small entities,” as required by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA).⁹⁸

⁹¹ *Id.* § 3(e).

⁹² *Id.* § 6(a)(3)(B).

⁹³ Exec. Order No. 13,497, 3 C.F.R. § 218 (2010), revoking Exec. Order No. 13422, 3 C.F.R. § 191 (2008) (revoked) (subjecting guidance to regulatory review).

⁹⁴ Cass R. Sunstein, *The Office of Information and Regulatory Affairs: Myths and Realities*, 126 HARV. L. REV. 1838, 1853 (2013).

⁹⁵ See Orzag Memorandum, *supra* note 2. The issuance of this memorandum, Sunstein reports, “reflects broad support for such review within the Executive Office of the President,” notwithstanding the fact that guidance might strictly fit within Executive Order 12,866’s definition of “regulatory action.” See Sunstein, *supra* note 94, at 1853 n.60. For a description of the character of OIRA’s review of guidance documents during that period, see Jennifer Nou, *Agency Self-Insulation Under Presidential Review*, 126 HARV. L. REV. 1755, 1785 (2013).

⁹⁶ See Orzag Memorandum, *supra* note 2.

⁹⁷ President Clinton’s directive on plain language, which includes plain language in final rules, remains in effect. See Memorandum for the Heads of Executive Departments and Agencies on “Plain Language in Government Writing” (June 1, 1998), 63 Fed. Reg. 31,885 (June 10, 1998).

⁹⁸ 5 U.S.C. § 601 notes, § 212 (requiring the production of compliance guides whenever the agency must produce a regulatory flexibility analysis under 5 U.S.C. § 605(b) and quoting § 605(b)).

1. Preambles

The near exclusive focus on the justificatory function of statements of basis and purpose in regulatory preambles also completely occludes the question of what minimum level of guidance preambles must provide. There are two legal sources that could be understood to impose a minimum guidance obligation on the agency: the requirement of APA § 553 that the agency issue a “statement of [] basis and purpose,” and the Regulatory Flexibility Act’s requirement that agencies engaged in rulemaking under § 553 provide a “statement of the need for, and objective of, the rule.”⁹⁹

These requirements ensure that a minimum guidance function is served by the preamble. *Independent U.S. Tanker Owners Committee v. Dole*¹⁰⁰ provides the established formulation of the necessary requirements for an agency’s statement of basis and purpose to be procedurally valid. While the statement need not “be an exhaustive, detailed account of every aspect of the rulemaking proceedings,” the statement “should indicate the major issues of policy that were raised in the proceedings and explain why the agency decided to respond as it did, particularly in light of the statutory objectives that the rule must serve.”¹⁰¹ Under this standard, the *Independent U.S. Tankers* court concluded that the agency’s statement did not explain how the rule furthered statutory objectives, and accordingly vacated the rule.¹⁰²

Requiring this articulation in the statement of basis and purpose clearly helps a reviewing court assess whether the agency has taken a hard look at the problem in light of its statutory objectives. But it just as clearly serves a guidance function. It requires the agency to provide an independent articulation of the purpose of the rule and its place in the implementation of the statute. The fact, as *Independent Tankers* held, that issuing a statement of basis and purpose with an adequate explanation of how the rule furthers the statute’s purposes is *procedurally* necessary for a notice-and-comment rulemaking¹⁰³ suggests that guidance is one of the purposes—and minimum obligations imposed on—these statements. In other words, part of what makes a statement of basis procedurally valid is providing a minimum level of guidance that explains how the rule implements the statute’s purpose. From this perspective, statement of basis and purpose that falls short of this minimum requirement does not perform its necessary guidance function of stating the rule’s purposes in light of statutory objectives.¹⁰⁴

⁹⁹ 5 U.S.C. § 604(a)(1) (2012)

¹⁰⁰ 809 F.2d 847 (D.C. Cir. 1987).

¹⁰¹ *Id.* at 852.

¹⁰² *Id.*

¹⁰³ *Id.*

¹⁰⁴ Direct Final Rules and Interim Final rules should also include the functional equivalent of a preamble, *see* FEDERAL REGISTER DRAFTING DOCUMENT HANDBOOK, *supra* note 52, at 2-6 to 2-8 (1998) (noting that direct

The Regulatory Flexibility Act (RFA) requires that when an agency promulgates a final rule through notice-and-comment, the agency must provide a “regulatory flexibility analysis” that includes “a statement of the need for, and objectives of, the rule,”¹⁰⁵ published in the *Federal Register*.¹⁰⁶ The RFA’s requirements are “[p]urely procedural” and so “requires nothing more than that the agency file a [final regulatory flexibility analysis] demonstrating a ‘reasonable, good-faith effort to carry out [RFA’s] mandate’.”¹⁰⁷ Still, RFA sets out “precise, specific steps the agency must take.”¹⁰⁸ And reviewing courts will assess whether the agency’s analysis “addressed all of the legally mandated subject areas.”¹⁰⁹ Substantial compliance is not authorized.¹¹⁰ Accordingly, where an agency fails to address one of those mandated subjects, a reviewing court will remand to the agency to conduct the analysis required by RFA.¹¹¹

While courts deferentially review the substance of an agency’s final regulatory flexibility analysis for the purposes of assessing compliance with RFA, the fact remains that the agency must state the need for and objectives of the rule. That requirement also enforces discipline on the agency, requiring it to have a clearly stated objective and rationale for its rules. The requirement of publication in the *Federal Register* suggests that there is a minimum guidance function enforced by RFA as well.

At a minimum, both the APA and the RFA require the agency to provide a statement of the need for the rule and the rule’s objectives in light of the authorizing statute’s aims. Preambles that do not include those statements do not satisfy their guidance function and thus should be procedurally invalid.

2. Separately Issued Documents

Section 212 of SBREFA requires agencies to publish a “small entity compliance guide” at the same time as the publication of the final rule (or as soon as possible

final rules and interim final rules should include preambles explaining the rule’s purpose and grounds); Ronald M. Levin, *Direct Final Rulemaking*, 64 GEO. WASH. L. REV. 1, 16-18 (1995) (noting direct final rules and interim final rules include functional equivalent of statement of basis and purpose), which could also be viewed as having the same minimum guidance function.

¹⁰⁵ 5 U.S.C. § 604 (2012).

¹⁰⁶ 5 U.S.C. § 604(a)(6)(b) (2012).

¹⁰⁷ *United States Cellular Corp. v. FCC*, 254 F.3d 78, 88 (D.C. Cir. 2001).

¹⁰⁸ *Nat’l Tel. Co-op. Ass’n v. FCC*, 563 F.3d 536, 539-40 (D.C. Cir. 2009).

¹⁰⁹ *Id.*

¹¹⁰ *Aeronautical Repair Station Ass’n v. FAA*, 494 F.3d 161, 178 (D.C. Cir. 2007) (remanding to FAA inadequate FRFA but not staying effect of rule).

¹¹¹ *See id.* at 177-78.

thereafter) and no later than when the rule becomes effective.¹¹² These guides shall “explain the actions a small entity is required to take to comply with a rule,”¹¹³ which “shall include a description of actions needed to meet the requirements of a rule, to enable a small entity to know when such requirements are met,”¹¹⁴ and include descriptions of procedures that “may assist a small entity in meeting” the rule’s requirements.¹¹⁵ These guides must be written “using sufficiently plain language likely to be understood by the affected small entities.”¹¹⁶ These compliance guides must be easily accessible on the web site of the agency, and distributed to known industry contacts, such as affected associations.¹¹⁷

E. What May Not Be Included in Contemporaneous Guidance?

1. Restrictions on Guidance in the Code of Federal Regulations

Only those rules that have “general applicability and legal effect” may be codified in the regulatory text of the Code of Federal Regulations.¹¹⁸ The regulations implementing this statutory requirement define documents that have “general applicability and legal effect” to mean “any document issued under proper authority prescribing a penalty or course of conduct, conferring a right, privilege, authority, or immunity, or imposing an obligation.”¹¹⁹ Thus, the codified text of the CFR may not include guidance, though agencies may include notes and examples with their codified text, or guidance in appendices to codified text.¹²⁰

2. Preamble-Specific Restrictions

a. Restriction on Preemption Statements. Perhaps the most straightforward and recent restriction on the guidance statements that may be made in preambles is President Obama’s Memorandum for the Heads of Executive Departments and Agencies

¹¹² Small Business Regulatory Enforcement Fairness Act, Pub. L. No. 104-121, § 212(a), 110 Stat. 873, codified at 5 U.S.C. § 601 nt. (2012).

¹¹³ *Id.* § 212(a)(4).

¹¹⁴ *Id.* § 212(a)(4)(B)(i).

¹¹⁵ *Id.* § 212(a)(4)(B)(ii).

¹¹⁶ *Id.* § 212(a)(5). The Plain Writing Act of 2010, Pub. L. No. 111, 124 Stat. 2861, codified at 5 U.S.C. § 301 nt. (Supp. V 2011), also imposes a plain writing requirement on documents that “explain[] to the public how to comply with a requirement the Federal Government administers or enforces.” *Id.* § 3.

¹¹⁷ *Id.* § 212(a)(2).

¹¹⁸ 44 U.S.C. § 1510(a) (2006); 1 C.F.R. § 8.1 (2013) (the Code of Federal Regulations shall contain each Federal regulation of general applicability and legal effect); *see also* Wilderness Soc. v. Norton, 434 F.2d 584, 596 (D.C. Cir. 2006) (the CFR may contain only documents having general applicability and legal effect).

¹¹⁹ 1 C.F.R. § 1.1 (2013).

¹²⁰ FEDERAL REGISTER DRAFTING DOCUMENT HANDBOOK, *supra* note 52, at 7-9 (discussing use of appendices to clarify but not to impose substantive obligations).

on Preemption.¹²¹ This Memorandum directs executive agencies not to include statements in regulatory preambles to the effect that the agency intends the regulation to preempt state law unless preemption provisions are also codified in the regulation's text.¹²²

b. Statements Without Corresponding Rules. There is some authority supporting the principle that statements in the preamble to a final rule that do not pertain to any aspect of the rules adopted are nullities in the sense that they are not validity issued even as explanatory statements. This principle arose in a D.C. Circuit decision's review of a drafting error in an EPA rule. The D.C. Circuit was confronted with a statement in the preamble referring to EPA's "final rule concerning high wind events" which states that "ambient particulate matter concentrations due to dust being raised by unusually high winds will be treated as due to uncontrollable natural events."¹²³ The final regulatory text, however, did not make any reference to high wind events or "ambient particulate matter concentrations,"¹²⁴ an oversight that EPA characterized as a drafting error. The court held that in view of this error, "the high winds event section of the preamble is a legal nullity."¹²⁵ While it is unclear how broad this principle is, at a minimum, the principle appear to apply to statements that refer to rules that do not exist. Such statements are nullities in the sense not being validly issued. It would seem a reasonable extension of this principle to apply it to statements exceed the scope of the rules adopted, for instance, by suggesting compliance obligations that extend beyond the scope of the rules.

2. Restrictions Applicable to Preambles and Separately Issued Documents

a. Subterfuge Legislative Rules. Neither a preamble nor a separately issued guidance document may contain a legislative rule. As a matter of blackletter law, under APA § 553, a "legislative" rule must be subject to notice-and-comment whereas interpretative statements and general statements of policy are not.¹²⁶ Thus, if a preamble or guidance document includes a statement that is a legislative rule, the rule is procedurally invalid under section 553. While the differences in legal effect and procedural requirements for legislative and nonlegislative rules are straightforward, distinguishing

¹²¹ Preemption: Memorandum for the Heads of Executive Departments and Agencies, 74 Fed. Reg. 24,693, 24,693-94 (May 20, 2009), available at <http://www.gpo.gov/fdsys/pkg/FR-2009-05-22/pdf/E9-12250.pdf#page=1>.

¹²² *Id.* at ¶ 1.

¹²³ *Natural Res. Def. Council v. EPA*, 559 F.3d 561, 565 (D.C. Cir. 2009) (quoting the preamble).

¹²⁴ *Id.*

¹²⁵ *Id.*

¹²⁶ 5 U.S.C. § 553(b)(3)(A); 5 U.S.C. § 553(b)(3)(A) (2012). "Legislative" or "substantive" rules are those that "grant rights, impose obligations, or produce other significant effects on private interests," or which "effect a change in existing law or policy." *Am. Tort Reform Ass'n v. OSHA*, 738 F.3d 387, 395 (D.C. Cir. 2013) (citations omitted).

between legislative and nonlegislative rules is a notoriously difficult issue.¹²⁷ Courts rely on a collection of doctrinal factors, including the “agency’s label,”¹²⁸ the practical impact on those covered by the rule,¹²⁹ and a legal effect test,¹³⁰ which looks to whether the rule imposes legal rights or obligations.¹³¹ Numerous formulations of these and other factors are found in the courts of appeals.¹³²

With regard to statements in preambles challenged as legislative rules, courts must wade into those same muddy waters. Interestingly, despite numerous challenges to language in preambles as improper legislative rules, courts have consistently held that statements in preambles are interpretive rules or general statements of policy, and thus procedurally valid.¹³³ Because of the blurry lines of the distinction between legislative and nonlegislative rules, it is difficult to tell whether this consistent practice is a result of the caution exercised by agencies in their preambles to avoid any mandatory or binding statements or simply a more relaxed judicial review of statements in preambles than in separately issued guidance documents. Given that courts frequently invalidate separately issued guidance documents, the trend is notable.

¹²⁷ See, e.g., David L. Franklin, *Legislative Rules, Nonlegislative Rules, and the Perils of the Short Cut*, 120 YALE L.J. 276, 278 (2010) (suggesting there is perhaps “no more vexing conundrum in the field of administrative law than the problem of defining a workable distinction between legislative and nonlegislative rules.”).

¹²⁸ See, e.g., *Warshauer v. Solis*, 577 F.3d 1330, 1337 (11th Cir. 2009) (the agency’s “characterization of the rule is relevant”).

¹²⁹ *Cent. Tex. Tel. Coop., Inc. v. FCC*, 402 F.3d 205, 214 (D.C. Cir. 2005) (noting that court had used a substantial impact test); see also William Funk, *A Primer on Nonlegislative Rules*, 53 ADMIN. L. REV. 1321, 1325 (2001) (noting strain of cases looking to substantive impact on the regulated).

¹³⁰ See, e.g., *Miller v. Cal. Speedway Corp.*, 536 F.3d 1020, 1033 (9th Cir. 2008) (legislative rules “create rights, impose obligations, or effect a change in the law”).

¹³¹ *Troy Corp. v. Browner*, 120 F.3d 277, 287 (D.C. Cir. 1997).

¹³² See, e.g., *Am. Mining Cong. v. Mine Safety & Health Admin.*, 995 F.2d 1106 (D.C. Cir. 1993) (listing the following factors: “(1) whether in the absence of the rule there would not be an adequate legislative basis for enforcement action or other agency action to confer benefits or ensure the performance of duties, (2) whether the agency has published the rule in the Code of Federal Regulations, (3) whether the agency has explicitly invoked its general legislative authority, or (4) whether the rule effectively amends a prior legislative rule.”).

¹³³ See, e.g., *Troy Corp. v. Browner*, 120 F.3d 277, 287 (D.C. Cir. 1997) (EPA’s preambular statement “merely informed the public that the agency would exercise its discretion by considering exposure only for low toxicity chemicals” and thus was a general policy statement); *Fertilizer Institute v. EPA*, 935 F.2d 1303, 1308-09 (D.C. Cir. 1991) (holding that EPA’s rule in its preamble was interpretive because it represents “the agency’s attempt to interpret the meaning of a statutory provision”); *Barrick Goldstrike Mines, Inc. v. Whitman*, 260 F. Supp. 2d 28, 38 (D.D.C. 2003) (“In this case, the interpretation [contained within the preamble] . . . is within the scope of the regulation”); *Bd. of Trustees of Knox Cnty. Hosp. v. Shalala*, 959 F. Supp. 1026, 1031 (S. D. Ind. 1997) (“Rather than create or destroy substantive rights, the [preambular] policy simply clarifies what the Secretary believes the regulation means and explains how the Agency will apply it.”); *OSG Bulk Ships v. United States*, 921 F. Supp. 812, 824 n.11 (D.D.C. 1996) (explaining that an interpretation within the preamble does not transform the preamble into a legislative rule); *Comité de Apoyo a los Trabajadores Agrícolas v. Solis*, No. 09-240, 2010 U.S. Dist. LEXIS 90155 at 47 (E.D. Pa. Aug. 30, 2010) (holding that the preambular language was an interpretation because the language was “very closely tied” to the definition included in the regulation and “expressly purports to be an interpretation of that definition”).

b. Consistency with Regulations and Statutes. Most obviously, statements in preambles (as well as separately issued documents) must be consistent with the regulations they explain and the statutes they implement. Both of these points are illustrated in *Cuomo v. Clearing House Association, LLC*.¹³⁴ There, the Court held that the interpretation of a regulation in the Comptroller of the Currency’s statement of basis and purpose was inconsistent with the regulation’s text as well as the underlying statute, and therefore invalid. “This passage in the statement of basis and purpose,” the Court commented, “resting upon neither the text of the regulation nor the text of the statute, attempts to do what Congress declined to do: exempt national banks from all state banking laws, or at least state enforcement of those laws.”¹³⁵

F. Reviewability of Contemporaneous Guidance

Contemporaneous guidance is reviewable in court if it constitutes “final agency action”¹³⁶ and satisfies the requirements of ripeness.¹³⁷ Statements in regulatory text presumably would not face distinctive reviewability issues. Likewise, the reviewability of separately issued guidance is solely a matter of application of general principles of finality and ripeness, for which there are existing treatments.¹³⁸ But what about guidance provided in preambles? Is preamble guidance reviewable?

The short answer is that guidance in preambles has been found to be both final and ripe, and thus subject to review. Perhaps the most prominent example of a decision concluding that language in a preamble is reviewable is the Supreme Court’s decision in *Whitman v. American Trucking Associations*.¹³⁹ While the statements at issue concerned the agency’s interpretation of a statute, not its own regulations, the decision reveals clearly that statements in regulatory preambles, just like other forms of guidance, may be reviewable if they are final and ripe.¹⁴⁰ After soliciting comment on an interim

¹³⁴ 557 U.S. 519, 129 S. Ct. 2710 (2009).

¹³⁵ *Id.* at 2720; *see also* Home Concrete & Supply, LLC v. United States, 634 F.3d 249, 256–57 (4th Cir. 2011) (rejecting the IRS’s interpretation contained in the preamble to a regulation because it was “contrary to the clearly and unambiguously expressed intent of Congress and must fail”); *Barrick*, 260 F. Supp. 2d at 36 (“Because the preamble to the 1988 rulemaking is inconsistent with the plain language of the regulation, *see* Auer, 519 U.S. at 461, it is invalid. Accordingly, subject to the concentrations of toxic chemicals it contains, Barrick’s waste rock may be eligible for the de minimis exemption.”).

¹³⁶ 5 U.S.C. § 704 (providing that final agency action is reviewable).

¹³⁷ There are, of course, elements to the availability of review, including standing, but finality and ripeness are the post germane to assessing reviewability of contemporaneous guidance.

¹³⁸ *See, e.g.*, Lubbers, *supra* note 30, at 398-402 (discussing whether guidance is “final” agency action); Mendelson, *supra* note 2, at 421-24 (identifying heightened obstacles for regulatory beneficiaries to obtain review of guidance documents).

¹³⁹ 531 U.S. 457 (2001).

¹⁴⁰ *See id.* at 478.

implementation policy for national ambient air quality standards (NAAQS) under the Clean Air Act, the EPA published an explanatory preamble to its final ozone NAAQS, including a section entitled “Final decision on preliminary standard.” In that section of the preamble, the EPA stated that it had reconsidered its proposed interpretation and “now believes that the Act should be interpreted such that the provisions of subpart 2 continue to apply” to certain areas of the country that fall below ambient air quality standards. “As a consequence,” the preamble stated “the provisions of subpart 2 . . . will continue to apply as a matter of law for so long as an area is not attaining [requisite air quality standard].”¹⁴¹

In *Whitman*, the Supreme Court had no difficulty concluding that these statements were reviewable. As to finality, the Court concluded that these statements marked “the consummation of the agency’s decisionmaking process,” a decision bolstered by the fact that in subsequent rulemakings, the EPA had denied requests to reconsider the issue, explaining “to disappointed commentators that it’s earlier decision was conclusive.”¹⁴² As to ripeness, under the standard of *Abbott Laboratories v. Gardner* looking to the “fitness of the issues for judicial decision” and the “hardship to the parties of withholding court consideration,”¹⁴³ the Court concluded that the issue of statutory interpretation presented and the hardship on states that would be imposed justified review under the Clean Air Act’s special authorization for preenforcement review,¹⁴⁴ and declined to opine on whether the statement would be ripe in a case brought under APA § 704.¹⁴⁵

The standard for final agency action under APA § 704 is well established: “A final agency action is one that marks the consummation of the agency’s decisionmaking process and that establishes rights and obligations or creates binding legal consequences.”¹⁴⁶ Applying this standard to statements in preambles, the D.C. Circuit has commented that “[w]hile preamble statements may in some unique cases constitute binding, final agency action susceptible to judicial review, . . . that is not the norm.”¹⁴⁷ Still, the D.C. Circuit has

¹⁴¹ 62 Fed. Reg. 38873 (1997), discussed in *Whitman*, 531 U.S. at 478.

¹⁴² 531 U.S. at 478-79.

¹⁴³ *Id.* at 479 (quoting *Abbott Labs. v. Gardner*, 387 U.S. 136, 149 (1967)).

¹⁴⁴ 531 U.S. at 479.

¹⁴⁵ *Id.* at 479.

¹⁴⁶ *Natural Res. Def. Council v. EPA*, 559 F.3d 561, 564 (D.C. Cir. 2009) (citing *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997)).

¹⁴⁷ *Id.* (citing *Kennecott Utah Copper Corp. v. Department of Interior*, 88 F.3d 1191, 1222-23 (D.C. Cir. 1996); *see also* *Natural Res. Def. Council v. EPA*, 706 F.3d 428, 432 (D.C. Cir. 2013) (affirming same). For decisions denying review of statements in preambles on finality or ripeness grounds, *see, e.g.*, *Nat’l Env’tl. Dev. Ass’n. Clean Air Project v. EPA*, 686 F.3d 803, 808-09 (D.C. Cir. 2012) (preamble not final); *Natural Res. Def. Council v. EPA*, 559 F.3d 561, 565 (D.C. Cir. 2009) (preamble not ripe); *Clean Air Implementation Project v. EPA*, 150 F.3d 1200, 1208 (D.C. Cir. 1998) (preamble not final nor ripe); *Kennecott Utah Copper Corp.*, 88 F.3d at 1222-23 (extensive discussion of preamble not being final nor ripe); *Florida Power & Light Co. v. EPA*, 145 F.3d 1414, 1420 (D.C. Cir. 1998) (preamble neither final nor ripe).

held that statements in preambles are final and ripe for review on numerous occasions, including with regard to statements of regulatory interpretation.¹⁴⁸ A critical factor in making this determination is the language of the preamble. On the one hand, language that is not definitive (such as “may,” “might” and “could”),¹⁴⁹ hypothetical or non-specific,¹⁵⁰ conjectural,¹⁵¹ or characterizes the views as preliminary,¹⁵² or promises future binding action,¹⁵³ all counsel against reviewability. On the other hand, language which is clear, not conjectural, and not qualified, makes it “fair to infer that [the agency] intended the statements to create binding legal consequences.”¹⁵⁴

Thus, the appearance of the statement within a preamble does not bar review.¹⁵⁵ Rather, the reviewability of guidance within a preamble, like the reviewability of guidance generally, depends upon the finality and ripeness analysis, which for these purposes often “converge.”¹⁵⁶ Ultimately, then, it is the content of the guidance, not its regulatory location, that determines its reviewability.

G. Standard of Judicial Review

For many years, there was little movement in the judicial doctrine first associated with *Bowles v. Seminole Rock & Sand Co.*¹⁵⁷ and now more consistently identified with *Auer v. Robbins*¹⁵⁸ that an agency’s construction of its own regulation is “controlling unless ‘plainly erroneous or inconsistent with the regulation.’”¹⁵⁹ While *Auer* still provides the general standard applicable to an agency’s interpretation of its regulations—regardless of the document type in which those interpretations appear—the Supreme Court has carved out an exception for *post hoc* interpretive positions, and several Justices have indicated an interest in revisiting the merits of the doctrine altogether. The fact that the

¹⁴⁸ See, e.g., *Natural Res. Def. Council v. EPA*, 571 F.3d 1245, 1252 n.2 (D.C. Cir. 2009) (holding that statements in EPA’s preamble final because they represented a consummation of the agency’s process, have binding consequences); *La. Env’tl. Action Network v. EPA*, 172F.3d 65, 69 (D.C. Cir. 1999) (holding language in preamble final under RCRA, 42 U.S.C. § 6976(a)(1)); *Chem. Waste Mgmt. v. EPA*, 869 F.2d 1526, 1533 (D.C. Cir. 1989) (holding that regulatory interpretation in preamble was final); see also *Cent. & Sw. Servs. v. EPA*, 220 F.3d 683, 689 n.2 (5th Cir. 2000) (concluding EPA preamble interpreting a statute was final action and ripe); *Select Specialty Hosp.-Akron, LLC v. Sebelius*, 820 F. Supp. 2d 13, 26 (D.D.C. 2011) (preamble binding and reviewable).

¹⁴⁹ *Kennecott Utah Copper*, 88 F.3d at 1222.

¹⁵⁰ *Id.* at 1223.

¹⁵¹ *Nat’l Env’tl. Dev.*, 686 F.3d at 808.

¹⁵² *Natural Res. Def. Council*, 706 F.3d at 433.

¹⁵³ *Am. Petroleum Inst. v. EPA*, 684 F.3d 1342, 1354 (D.C. Cir. 2012).

¹⁵⁴ *Natural. Res. Def. Council*, 571 F.3d at 1252 n.2.

¹⁵⁵ *Kennecott Utah Copper*, 88 F.3d at 1223.

¹⁵⁶ *Id.*

¹⁵⁷ 325 U.S. 410 (1945).

¹⁵⁸ 519 U.S. 452 (1997); see *supra* note 7 (discussing naming conventions for this doctrine).

¹⁵⁹ *Auer*, 519 U.S. at 461.

recent limitations on *Auer* have all been directed to *post hoc* guidance suggests that contemporaneous guidance—whether provided in a preamble, appendix, or separately issued document—has a stronger footing for maintaining *Auer* deference.

While there has been a longstanding critique of *Seminole Rock/Auer* deference,¹⁶⁰ current interest in the doctrine comes from the disjunction between the scope of application of *Auer* deference and *Chevron* deference created by the Supreme Court’s decision in *Mead*. In *Mead*, the Court constricted the application of *Chevron* deference to statutes that grant lawmaking authority to the agency and to agency actions which exercise that authority.¹⁶¹ Under *Mead*, notice-and-comment rulemaking is presumptively eligible for *Chevron* deference, whereas guidance documents are not.¹⁶² *Mead* thus denies deference to an agency’s statutory interpretation that appears in a guidance document or litigation brief, whereas a guidance document or litigation brief interpreting an agency regulation would still qualify for deference under *Auer*. This disjuncture has prompted a call for constricting the scope of application of *Auer* so that it would apply only to those documents to which *Chevron* would apply under *Mead*, that is, those produced by relatively formal processes.¹⁶³

Despite the logic that an agency’s regulatory interpretation issued informally should not receive deference if its statutory interpretation would not, the Supreme Court has generally accorded *Seminole Rock/Auer* deference to agency interpretations advanced in litigation briefs. As recently as 2011, for instance, the Court concluded twice that agency amicus briefs qualify for *Seminole Rock/Auer* deference, rejecting the argument that under *Mead* and *Christensen* they should not.¹⁶⁴ But, in 2012, in *Christopher v. SmithKline Beecham Corp.*,¹⁶⁵ the Court declined to grant *Seminole Rock/Auer* deference to an agency’s position taken in a litigation brief based in part on the concern that doing so

¹⁶⁰ John F. Manning, *Constitutional Structure and Judicial Deference to Agency Interpretations of Agency Rules*, 96 COLUM. L. REV. 612, 618 (1996) (challenging *Seminole Rock* deference and proposing a model of independent judicial evaluation of regulations that would place greater reliance on agencies’ explanatory statements)

¹⁶¹ *United States v. Mead Corp.*, 533 U.S. 218, 226-27 (2001).

¹⁶² *Id.* at 229.

¹⁶³ Thomas W. Merrill & Kristin E. Hickman, *Chevron’s Domain*, 89 GEO. L.J. 833, 900 (2001) (“*Seminole Rock* deference should at a minimum be subject to the same limitations that apply to the scope of *Chevron* deference.”); Matthew C. Stephenson & Miri Pogoriler, *Seminole Rock’s Domain*, 79 GEO. WASH. L. REV. 1449, 1484-96 (2011) (arguing that *Mead*’s logic for constraining *Chevron*’s scope of application extends to *Seminole Rock*).

¹⁶⁴ *See Pliva, Inc. v. Mensing*, 131 S. Ct. 2567, 2575 n.3 (2011) (relying on brief of United States); *Chase Bank USA, N.A. v. McCoy*, 131 S. Ct. 871, 883–84 (2011) (rejecting argument that agency amicus brief was not entitled to deference under *Auer*, and according deference to the interpretation contained in the brief).

¹⁶⁵ 132 S. Ct. 2156 (2012).

would undermine fair notice of the regulation’s requirements.¹⁶⁶ The Court reasoned that reliance on *Auer* in these circumstances would “frustrat[e] the notice and predictability purposes of rulemaking,” quoting Justice Scalia’s concurrence in *Talk America, Inc. v. Michigan Bell Telephone Co.*,¹⁶⁷ in which Justice Scalia first declared his interest in reconsidering *Auer*. The Court’s explanation suggested that it viewed the distinction between guidance issued *ex ante* and *post hoc* as meaningful, at least with regard to interpretations announced in enforcement proceedings:

It is one thing to expect regulated parties to conform their conduct to an agency’s interpretations once the agency announces them; it is quite another to require regulated parties to divine the agency’s interpretations in advance or else be held liable when the agency announces its interpretations for the first time in an enforcement proceeding and demands deference.¹⁶⁸

In March 2013, three Supreme Court Justices publically indicated an interest in reconsidering *Auer* in *Decker v. Northwest Environmental Defense Center*.¹⁶⁹ There, Chief Justice Roberts and Justice Alito announced they would be receptive to reconsideration of *Auer* deference in an appropriate case,¹⁷⁰ and Justice Scalia filed an opinion concurring in part and dissenting in part arguing for overruling *Auer* deference.¹⁷¹

But even if the Court were to revisit the doctrine, based on the reasoning in *Christopher v. SmithKline Beecham Corp.*, the Court appears to view guidance rendered contemporaneously with the issuance of the rule (or even guidance offered prior to enforcement) as standing on a different footing than *post hoc* interpretations produced in litigation. If this is right, then contemporaneous guidance—especially that in a preamble, regulatory text or appendix—stands in the strongest stead for deference under *Auer*: It furnishes the agency’s authoritative interpretation at the time the rule become effective, and thus allows parties as much fair notice as they receive about the rule itself.

It is worth noting that an assumption underlying this discussion is that *Auer*, not *Chevron*, provides the currently governing standard of review for an agency’s statements in its preamble to a final rule about the purpose and effect of its regulations. At least one

¹⁶⁶ See *id.* at 2166–68 (concluding that “general rule” of granting *Auer* deference to interpretations in litigation briefs did not apply in these circumstances of the case in view of fair notice concerns).

¹⁶⁷ 131 S. Ct. 2245, 2266 (2011).

¹⁶⁸ *Id.*

¹⁶⁹ 133 S. Ct. 1326 (2013).

¹⁷⁰ *Id.* at 1338 (Roberts, C.J., and Alito, J., concurring) (noting that it “may be appropriate to reconsider” *Seminole Rock/Auer* in another case); *id.* at 1339, 1442 (Scalia, J., concurring in part and dissenting in part) (arguing that the Court to overturn *Seminole Rock/Auer*).

¹⁷¹ *Id.*

court of appeals, however, has concluded that a statement’s about the application of its regulations in a preamble to a final rule are entitled to receive *Chevron* deference under *Mead*.¹⁷² If statements of this sort in a preamble receive *Chevron* deference just as statements in regulatory text does, there would be little need for courts to invoke *Auer* as a standard of review for statements about the meaning of regulations in preambles because those statements would be reviewable directly under *Chevron*.

H. Summary Table

Table 1 (below) provides a summary of the legal regime applicable to contemporary guidance addressed thus far. Readers may draw different inferences from this compilation, but one striking feature is the extent of the overlap in the requirements applicable to contemporaneous guidance, whether it appears in a preamble, regulatory text, or separately issued document. In Table 1, cells on each row that are identical are highlighted; but even where the requirements are not identical, in many cases there is significant practical overlap.

To illustrate the scope of overlap in requirements, use Table 1 to compare economically significant guidance issued in a preamble (column 1) and in a separately issued document (column 3). The requirements of issuance are the same (row 1); the requirements for revision are the same (row 2); they are both subject to OIRA review (row 3); and the same standards of judicial review (rows 6 & 7); the only difference is what content must be included or excluded.

Table 1: Summary of Legal Regime Applicable to Contemporaneous Guidance

	Guidance in Preamble	Guidance Published in the Code of Federal Regulations (in notes, examples, or appendices)	Guidance Separately Issued
1: Process Requirements for Issuance	For covered agencies, if “significant,” or “economically significant” under <i>OMB’s Good Guidance Bulletin</i> , then it must comply with the GGP, including notice and comment for	Notice-and-comment required	For covered agencies, if “significant,” or “economically significant” under <i>OMB’s Good Guidance Bulletin</i> , then it must comply with the GGP, including notice and comment for

¹⁷² See *Tibble v. Edison Int’l*, 711 F.3d 1061, 1071 (9th Cir. 2013), *amended by* 729 F.3d 1110 (9th Cir. 2013) (“As for *Mead’s* second consideration [that the agency have exercised its authority to bind with the force of law], we do not view the fact that the interpretation appears to in a final rule’s preamble as disqualifying it from *Chevron* deference.”).

	economically significant guidance.		economically significant guidance.
2: Process Requirements for Revision	If “definitive,” then revision must proceed through notice-and-comment under <i>Alaska Prof. Hunters</i> .	Notice-and-comment required	If “definitive,” then revision must proceed through notice-and-comment under <i>Alaska Prof. Hunters</i> .
3: Subject to OIRA Regulatory Review?	Yes, for covered agencies for all significant regulatory actions.	Yes, for covered agencies for all significant regulatory actions.	Yes, for covered agencies for all significant regulatory actions.
4: What must be included?	i. Under the APA, a statement of the purpose of the rule in light of statutory objectives, and ii. Under RFA, a statement of the need for the rule and its objectives.	No requirements other than those with a statutory basis.	Agency must publish compliance guide for rules with significant effects on small entities under SBREFA.
5: What may not be included?	i. Statements preempting state law without regulatory text that preempts. ii. Interpretations without corresponding regulatory text. iii. Statements that are binding legislative rules iv. Statements that contradict the regulatory text or statute.	The CFR text may contain only statements of general applicability and legal effect, as defined by 1 CFR 1.1.	i. Statements that are binding legislative rules, or including mandatory language ii. Statements that contradict the regulatory text or statute.
6: Is it reviewable in court?	Yes, if “final agency action” and ripe for review.	Yes, pre-enforcement review routinely available.	Yes, if “final agency action” and ripe for review.
7: What standard of review applies?	<i>Auer</i> deference (with a stronger basis than <i>post hoc</i> guidance)	<i>Auer</i> deference (with a stronger basis than <i>post hoc</i> guidance)	<i>Auer</i> deference (with a stronger basis than <i>post hoc</i> guidance)

IV. Agency Practices for Providing Contemporaneous Guidance

Given the significant overlap in the legal requirements governing contemporaneous and guidance, agencies will frequently have significant discretion as to whether to include the same statement in a preamble, regulatory text (or appendix), or in a guidance document issued alongside the rule. How do agencies make this choice? More specifically, what forms of contemporaneous guidance do agencies actually provide? This Part provides a description and illustrative compilation of the ways in which agencies use each of these

forms of contemporaneous guidance. It first introduces, in Table 2, a menu of agency practices with illustrative examples. These categories are relatively straightforward; the text following Table 2 provides a narrative description of examples that fall within these categories.

The scope of federal rulemaking is vast, and it is important to note that this Report makes no claim to be a completely comprehensive identification of the ways in which agencies issue contemporary guidance. Rather the Report identifies the most significant uses of contemporaneous guidance, isolating a menu of types of contemporaneous guidance with illustrative examples. Such a menu is sufficient to provide a means for agencies to consider their own practices in relation to those of other agencies, and also identify some problems and outliers in agency practices. The Report also makes no attempt to quantitatively assess the frequency with which agencies use particular forms of contemporaneous guidance.

Table 2: Menu of Agency Contemporary Guidance Practices

Type	Location	Format	Discussion
Guidance in Preamble			
	Background Discussion		
		Primarily Narrative Statement	Some agencies provide long narrative discussions without structuring them in accordance with the rule's structure.
		Includes Section-by-Section Analysis	In addition to general discussion, some preambles include analysis that matches the structure of rule.
		Relying Primarily on Grounds Stated in NPRM	Some preambles incorporate portions of the discussion in the NPRM or other prior notices.
		Purpose Stated in View of Statutory Objectives	Most preambles provide an independent assessment of the rule's purposes in relation to statutory objectives
		Purpose Statement Solely Mirroring Statutory Language (or Otherwise Inadequate)	Some agencies give this statement short shift, stating the purpose solely by

Type	Location	Format	Discussion
			parroting statutory language.
	Response to Comments		
		General Responses	Some preambles provide general narrative discussions of comments without much organizational structure.
		Section-by-Section Analysis	Some preambles structure the response to comments in section-by-section.
		Question-and-Answer	Some structure preambles response to comment questions in a Q & A format.
		Detailed Examples	Some preambles provide detailed examples to illustrate how the rule applies.
	Preamble as Rule		Some preambles treat the preamble and regulatory text interchangeably.
Guidance included in the CFR			
	Regulatory Text		
		Notes and Example Applications	Some regulatory text includes examples to guide application.
	Appendix		
		Official Commentary in Appendix	Some appendices include an official interpretive commentary
		Examples in Appendix	Some appendices include example applications.
		Question-and-Answer Format in Appendix	Some appendices are structure with Q & A
		Technical Guidance in Appendix	Some appendices include technical guidance.
Separately Issued, Contemporaneous Guidance			
	Compliance Guides, FAQs, and Other Documents		

B. Preambles as a Vehicle for Guidance

Agencies have long treated the preambles to their regulations, which “statements of their basis and purpose,” as a means of providing guidance about the meaning and application of their rules. Agencies organize their preambles—and the guidance they provide—in different formats, many of which are familiar to agency lawyers and practitioners of administrative and regulatory law.

1. Background Sections

The preamble to federal rules typically appears under the Supplemental Information heading in the *Federal Register*.¹⁷³ Most agencies provide extensive narrative commentary on the rule, its procedural history, factual and legal grounds and aims in subsection of the Supplement Information entitled Background Discussion.¹⁷⁴ This section typically includes content that would constitute guidance, and agencies organize it in many different ways, frequently using one or more of the following formats.

a. Preamble Composed Primarily of Narrative Statement. One common format of the Background Discussion section is a narrative statement. A recent preamble produced by the Occupational Health and Safety Administration (OSHA) for a rule adopted to conform to the United Nations’ Globally Harmonized System of Classification and Labelling of Chemicals (GHS) reflects this structure.¹⁷⁵ The preamble consists of general narrative in sections entitled, for instance, “Events Leading to the Revised Hazard Communication Standard” and “Overview of the Final Rule and Alternatives Considered.”¹⁷⁶ In these sections, OSHA generally explained the impact and motivation for the rule, but did not organize its discussion in accordance with the particular sections of the rule.¹⁷⁷

b. Section-By-Section Format. Agencies also organize background discussions of preambles in a section-by-section format. While agencies also use the section-by-section format to structure a response to comments, as discussed below, in the background discussion, the section-by-section analysis is not explicitly responding to comments.

¹⁷³ See FEDERAL REGISTER DOCUMENT DRAFTING HANDBOOK, *supra* note 104, at 2-8 (directing that extended discussion of the rule belongs in the Supplemental Information section).

¹⁷⁴ See *id.* at 2-17.

¹⁷⁵ Hazard Communication, 77 Fed. Reg. 17,574, 17,574 (March 26, 2012) (to be codified at 29 C.F.R. pts. 1910, 1915, 1926).

¹⁷⁶ *Id.* at 17,577, 17,579, 17,693.

¹⁷⁷ *Id.*

The Consumer Protection Financial Bureau (CFPB) adopted this approach in a rule amending Regulation E, which implements the Electronic Fund Transfer Act.¹⁷⁸ In the preamble, the agency provides a section-by-section analysis which is subdivided numerically and by topic with subsections such as “Section 1005.2 Definitions” and “Section 1005.3 Coverage.”¹⁷⁹ In the Coverage subsection, for instance, the agency explains changes to the regulation without engaging specific comments: “Currently, § 1005.3(a) states that Regulation E generally applies to financial institutions. Section 1005.3(a) is revised to state that the requirements of subpart B apply to remittance transfer providers. The revision reflects the fact that the scope of the Dodd-Frank Act’s remittance transfer provisions is not limited to financial institutions.”¹⁸⁰

c. Agency Reliance on Grounds Stated in NPRM. Agencies vary as to how much they rely upon discussions in the NPRM (or other prior notices) to provide a statement of the rule’s basis and purpose or treat the preamble to the final rule as a freestanding document that provides a comprehensive statement of the rule’s basis and purpose. Agencies frequently refer the readers to explanations, proposals, or studies published in the NPRM. Agencies occasionally specifically incorporate particular aspects of the legal reasoning or analysis provided in the NPRM.¹⁸¹ Agencies also rely upon reasoning and discussions in the NPRM for a more comprehensive summary of the rule’s basis, purposes and effects.¹⁸² In contrast, agencies also frequently treat the preamble as a relatively comprehensive and stand-alone statement of the grounds of the rule, referring to the NPRM only as necessary to explain how the agency’s reasoning has shifted, how the agency has responded to comments, or to appreciate the procedural history of the rule.

¹⁷⁸ Electronic Fund Transfers (Regulation E), 77 Fed. Reg. 6,194, 6,194 (Feb. 7, 2012) (to be codified at 12 C.F.R. pt. 1005).

¹⁷⁹ *Id.* at 6,204–6,205.

¹⁸⁰ *Id.* at 6,205.

¹⁸¹ *See, e.g.*, Eligible Obligations, Charitable Contributions, Nonmember Deposits, Fixed Assets, Investments, Fidelity Bonds, Incidental Powers, Member Business Loans, and Regulatory Flexibility Program, 77 Fed. Reg. 31981 (May 31, 2012) (to be codified at 12 C.F.R. pts. 701, 703, 713, 721, 723, 742) (“For the reasons discussed below the Board is adopting the amendments almost exactly as proposed. As such, the Board does not restate the legal analysis it presented in the NPRM’s preamble and incorporates it by reference here in this rulemaking.”); Crewmember Identification Documents, 74 Fed. Reg. 19135, 19139 (Apr. 28, 2000) (to be codified at 33 C.F.R. pt. 1360) (“We received no public comments that would alter our assessment of impacts in the NPRM. We have adopted the assessment in the NPRM as final.”).

¹⁸² *See, e.g.*, Medicare Program: Review of National Coverage Determinations and Local Coverage Determinations, 68 Fed. Reg. 63692 (Nov. 7, 2003) (to be codified at 42 C.F.R. pts 400, 405, 426); *id.* at 63693 (“For further discussion of the claims appeal process please consult the proposed rule.”); *id.* (“For the full discussion of NCDs please consult our proposed rule at 67 FR 54535 published on August 22, 2002.”); *id.* (“The provisions described in bullets two through four above constitute coverage provisions. For further information on LMRPs please consult our proposed rule at 67 FR 54535.”); Practices and Procedures, 77 Fed. Reg. 62,350, 62,350 (Oct. 12, 2012) (to be codified at 5 C.F.R. pts. 1200, 1201, 1203, 1208, 1209) (“[r]eaders desiring a more detailed summary of the amendments proposed by the MSPB should consult the proposed rule.”).

d. Purpose Statements. Agencies typically provide a statement of the purpose of the regulation in the Summary and/or in the Supplemental Information sections of their preambles to their substantive rules, that is, those that have independent legal effect. These statements vary widely in terms of their level of specificity and clarity. Many statements clearly indicate the purpose of the regulation in light of the statute's objectives, the agency's powers, and its past regulatory history.¹⁸³

Rather than providing an independent assessment of the purpose of the rule in light of the statute, some preambles state the purpose of their regulations in terms that largely mirror statutory language. For instance, a Department of Labor rule establishing the uniform national threshold for the employment rate for veterans included a purpose statement that largely mirrored the statutory language requiring the agency to promulgate the rule.¹⁸⁴ In the preamble, the Department of Labor stated “[w]e undertook this Rulemaking in accordance with 38 U.S.C. 4102A(c)(3)(B) (as enacted by the Jobs for Veterans Act) which requires the Department to establish that threshold rate by regulation.”¹⁸⁵ Then the agency wrote “Section 4(a)(1) of the JVA amended 38 U.S.C. 4102A to require that the Secretary of Labor ‘establish, and update as appropriate, a comprehensive performance accountability system . . . and carry out annual performance reviews of veterans employment, training, and placement services provided through employment service delivery systems, including through Disabled Veterans’ Outreach Program specialists and through Local Veterans’ Employment Representatives in States receiving grants, contracts, or awards under this chapter.”¹⁸⁶

After the agency recited what it was required to do by statute, the agency turned to discussing details of the rule, such as its definition of critical terms, but did not provide an independent statement reflecting the agency's choices about how best to implement the statutory requirement.¹⁸⁷

2. Response to Comments

a. General Responses. Agencies frequently provide guidance about the meaning and application of their regulations in a dialogue with commenters in the preamble. They do this in different formats. Sometimes they do this in the course of a

¹⁸³ Exemption of Work Activity as a Basis for a Continuing Disability Review, 71 Fed. Reg. 66,840, 66,840 (Nov. 17, 2006) (to be codified at 20 C.F.R. pts. 404, 416).

¹⁸⁴ Uniform National Threshold Entered Employment Rate for Veterans, 78 Fed. Reg. 15,283, 15,283 (Mar. 11, 2013) (to be codified at 20 C.F.R. pt. 1001).

¹⁸⁵ *Id.* at 15,284.

¹⁸⁶ *Id.*

¹⁸⁷ *Id.*

general response to comments. For instance, in a Department of Veterans Affairs (DVA) rule implementing the DVA’s medical foster home program, a commenter asked whether the spouse of a married veteran could move into the medical foster home with the veteran or if the rule forced couples to live apart.¹⁸⁸ The DVA answered that “[n]othing in the regulation would preclude a spouse of a veteran from living in the same medical foster home as the veteran. Such an arrangement would be a matter of agreement between the spouse of the veteran and the medical foster home caregiver.”¹⁸⁹ In this preamble, the DVA provided this and other guidance in response to comments without topical headings.

Agencies, however, often organize their general responses to comments by topic. For example, in a Department of Treasury and U.S. Customs and Border Protection (CBP) rule defining “members of a family” for purposes of filing a customs family declaration, the agencies responded to commenters in topical sections.¹⁹⁰ In the “Definition of Resident” section, a commenter posed a question about whether the definition of “resident” as used by CBP in this context was the same as “permanent resident” as used in the immigration law context.¹⁹¹ The agencies responded that “[t]he term ‘resident’ for purposes of this regulation is not the same as ‘lawful permanent resident’ in immigration law. For customs purposes, pursuant to 19 CFR 148.2, persons arriving from foreign countries are divided into two categories: (1) Residents of the United States returning from abroad and (2) all other persons (i.e., visitors).”¹⁹²

b. Section-by-Section Analysis. Agencies also provide guidance in the course of responding to comments through a section-by-section analysis. The Equal Employment Opportunity Commission (EEOC) used this format in a rule implementing Title II of the Genetic Information Nondiscrimination Act.¹⁹³ The EEOC offered guidance pertaining to numerical sections of the regulation, including “Section 1635.1 Purpose” followed by “Section 1635.2 Definitions—General.”¹⁹⁴ In “Section 1635.3(a) Family Member,” the EEOC confronted a commenter’s suggestion that medical information obtained from one employee should not be considered family medical history of a family

¹⁸⁸ Medical Foster Homes, 77 Fed. Reg. 5,186, 5,187 (Feb. 2, 2012) (to be codified at 38 C.F.R. pt. 17); *see also* State Official Notification Rule, 77 Fed. Reg. 39112 (June 29, 2012) (to be codified at 12 C.F.R. pt. 1082) (the following statement was the closest to a statement of purpose in the summary of the final rule: “In drafting the Final Rule, the Bureau endeavored to create a process that would provide both the Bureau and, where applicable, the prudential regulators with timely notice of pending actions and account for the investigation and litigation needs of state regulators and law enforcement agencies.”).

¹⁸⁹ *Id.*

¹⁹⁰ Members of a Family for Purpose of Filing CBP Family Declaration, 78 Fed. Reg. 76,529, 76,529 (Dec. 18, 2013) (to be codified at 19 C.F.R. pt. 148).

¹⁹¹ *Id.* at 76,530.

¹⁹² *Id.*

¹⁹³ Regulations Under the Genetic Information Nondiscrimination Act of 2008, 75 Fed. Reg. 68,912, 68,912 (Nov. 9, 2010) (to be codified at 29 C.F.R. pt. 1635).

¹⁹⁴ *Id.* at 68,913.

member who also works for the same employer.¹⁹⁵ The EEOC rejected this suggestion, writing, “[w]e do not think Congress could have intended that an employee not be protected from the discriminatory use or the disclosure of his or her genetic information just because the employer obtained it from a family member who was also an employee.”¹⁹⁶

The Small Business Administration (SBA) also utilized the section-by-section analysis format in a rule defining a new category of small business investment companies (SBICs).¹⁹⁷ Under the heading of “Section 107.50—Definitions,” the SBA responded to a number of commenters that suggested changing the proposed definition of “Early Stage SBIC,” by writing “SBA . . . believes the commenters’ contrasting points of view illustrate the benefits of maintaining the flexibility that the proposed definition provided. SBA expects that some management teams will focus exclusively on early stage companies, while others will opt for a mixed portfolio.”¹⁹⁸ This rule also includes a “General Comments” section where the SBA responds to comments that impact broad issues in the rule.¹⁹⁹ Agencies frequently combine two formats in their rules as the SBA did here.

c. Question-And-Format. Another method agencies use to respond to comments is the question and answer format. The Railroad Retirement Board (RRB) used this approach in a rule that removes a listing of impairments from its regulations and explains how the RRB will determine disability.²⁰⁰ The preamble is divided into sections including, “What Programs Will the Final Rule Affect?” and “How Is Disability Defined?”²⁰¹ In the section, “How Does This Final Rule Address That Problem?”, the RRB responds to commenters by stating “[t]he Board has reviewed the comments and the amendments to section 220.178(c)(1) and agrees that the second sentence could be confusing. We have modified that sentence to make it clear that in a continuing disability review, the claimant's current severity will be compared to the standard that was used to make the original, or ‘comparison point decision.’”²⁰² Unlike the SBA rule, question and answer format is the only format used in this preamble.

¹⁹⁵ *Id.* at 68,915.

¹⁹⁶ *Id.* at 68,916.

¹⁹⁷ Small Business Investment Companies—Early Stage SBICs, 77 Fed. Reg. 25,042, 25,042 (April 27, 2012) (to be codified at 13 C.F.R. pt. 107).

¹⁹⁸ *Id.* at 25050.

¹⁹⁹ *Id.* at 25043.

²⁰⁰ Removal of Listing of Impairments and Related Amendments, 74 Fed. Reg. 63,598, 63,598 (Dec. 4, 2009) (to be codified at 20 C.F.R. pt. 220).

²⁰¹ *Id.*

²⁰² *Id.* at 63,599–63,600.

A Social Security Administration (SSA) rule revising medical criteria used for evaluating digestive disorders utilized a combination of the question and answer format, section-by-section analysis, and general response to comments format.²⁰³ The preamble begins with sections entitled, “Why are we revising the listings for digestive disorders?” and “What general changes are we making that affect both the adult and childhood listings for digestive disorders?”²⁰⁴ Then, within these larger sections, SSA includes subsections with questions associated with particular regulatory text sections, such as “5.00D—How do we evaluate chronic liver disease?”²⁰⁵ Next, SSA includes a “Public Comments” section that is a general response to comments.²⁰⁶ Guidance appears throughout these different formats. For instance, in the “Public Comments” section, one commenter suggested that all individuals who require feeding through intravenous or gastrostomy tubes should be considered not able to work under the rule, but the SSA responded that “we do not think it appropriate to presume disability in all individuals who need such treatment; we must evaluate most situations on a case-by-case basis.”²⁰⁷

d. Detailed Examples. A fourth method that agencies use to provide guidance in preambles while responding to comments is through the use of detailed examples. These can be incorporated within any of the other three formats discussed above. The Department of Education included detailed examples in a rule amending the Direct Loan Program.²⁰⁸ The agency wrote “[t]he following two examples illustrate the operation of the final regulations” and then “Example 1: Borrower A and Borrower B are both enrolled half-time and both enrolled in the fall term only. Borrower A receives a Direct Subsidized Loan in the amount of the annual loan limit and Borrower B receives a loan for less than the annual loan limit.”²⁰⁹ Following this introduction to the example, the Department of Education included a chart and a few paragraphs explaining how the hypothetical borrowers would be impacted by the regulation.²¹⁰

The Centers for Medicare and Medicaid Services (CMS) also used detailed examples in the preamble to a rule establishing guidelines for Accountable Care Organizations (ACOs).²¹¹ For instance, commenters expressed confusion over a proposed

²⁰³ Revised Medical Criteria for Evaluating Digestive Disorders, 72 Fed. Reg. 59,398, 59,398 (Oct. 19, 2007) (to be codified at 20 C.F.R. pts. 404, 416).

²⁰⁴ *Id.*

²⁰⁵ *Id.* at 59,399.

²⁰⁶ *Id.* at 59,407.

²⁰⁷ *Id.* at 59,409.

²⁰⁸ William H. Ford Federal Direct Loan Program, 79 Fed. Reg. 3,108, 3,108 (Jan. 17, 2014) (to be codified at 34 C.F.R. pt. 685).

²⁰⁹ *Id.* at 3,114 – 3,115.

²¹⁰ *Id.* at 3,115.

²¹¹ Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations, 76 Fed. Reg. 67,802, 67,802 (Nov. 2, 2011) (to be codified at 42 C.F.R. pt. 425).

requirement that the governing bodies of ACOs at least 75% controlled by Medicare-enrolled entities. CMS responded with an example: “For example, if a hospital, two physician groups, and a health plan formed an ACO, the hospital and two physician groups must control at least 75 percent of the ACO governing body.”²¹² This example is embedded in a general response to comments section, but agencies frequently use examples and incorporate them in various formats.

3. Preambles the Appear to Bind

Rather than articulating the basis and purpose of the regulatory text or providing guidance on how to comply with it, some preambles make statements that appear or purport to have legal effect.

A complex rulemaking by the Centers for Medicare and Medicaid Services (CMS) provides an example of the slippage that can occur between the preamble and the text of the rule.²¹³ In the rule, CMS revised requirements for the way in which long-term care hospitals transfer patients to hospitals within them (“hospitals within hospitals”) or affiliated satellite hospitals. In the preamble to its final rule, CMS noted in response to comments that it provided a 4-year transition prior for the implementation of the new requirements and also provide for certain hospitals to be “grandfathered,” treating the first year as “hold harmless.”²¹⁴ The preamble went on to state, “we are requiring that even for grandfathered facilities, in the first cost reporting period, the percentage of discharges admitted from the host hospital may not exceed the percentage of discharges admitted from the host hospital in its FY 2004 cost reporting period.”²¹⁵

The final rule, however, “omitted the limitation that grandfathered facilities in the first year of the transition period would not be allowed to exceed the percentage of patients admitted from the host during fiscal year 2004 cost reporting period.”²¹⁶ The preamble thus stated a requirement about the percentage of permissible admissions to hospitals within hospitals and satellite facilities that did not appear in the rule.

On its own initiative, CMS issued a correcting amendment to the rule to conform the rule to its preamble’s statement of the requirements applicable to grandfathered

²¹² *Id.* at 67,819–67,820.

²¹³ Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates, 69 Fed. Reg. 48916 (Aug. 11, 2004) (to be codified at 42 C.F.R. pts. 403, 412, 413, 418, 460, 480, 482, 483, 485, 489).

²¹⁴ *Id.* at 49196.

²¹⁵ *Id.*

²¹⁶ *Select Specialty Hosp.-Akron v. Sebelius*, 820 F.Supp.2d 13, 23-24 (D.D.C 2011).

institutions,²¹⁷ which correcting amendment was upheld from procedural and substantive challenges.²¹⁸

C. Guidance in Regulatory Text and Appendices

Agencies provide guidance about the meaning and application of their regulations in the regulatory text published in the Code of Federal Regulations (CFR) and in appendices attached to final rules. While guidance in the regulatory text appears, by definition, in the Code of Federal Regulations, guidance in appendices is sometimes only published in the *Federal Register* and other times published in the Code of Federal Regulations. Agencies use different formats to provide guidance in the regulatory text and appendix, including through official commentary, examples, notes, and technical guidance. The following sections illustrate the various ways agencies offer guidance in the regulatory text and appendix.

1. Guidance Published in the CFR

a. Examples in Regulatory Text. Agencies provide guidance in material published in the CFR, most often in the form of notes and examples. For instance, the Department of the Treasury provided illustrative examples in a rule on mergers, acquisitions, and takeovers by foreign persons.²¹⁹ In § 800.215 (a)–(b), the regulatory text defines a “foreign person” as “(a) Any foreign national, foreign government, or foreign entity; or (b) Any entity over which control is exercised or exercisable by a foreign national, foreign government, or foreign entity.”²²⁰ After this text, there are five examples

²¹⁷ *Id.*

²¹⁸ *Id.* at 27 (concluding that the agency was not required to go through another round of notice-and-comment to issue its correcting amendment and that the amendment was not arbitrary nor capricious); *see also* Natural Res. Def. Council v. EPA, 559 F.3d 561, 565 (D.C. Cir. 2009) (invalidating requirements stated in preamble that did not correspond to or interpret a section of the rule). In some cases, agencies make statements in their preambles that appear to be binding in part because they use mandatory language and do not make a reference the regulatory text, even when the regulatory text provides a basis for the obligations discussed. *See, e.g.*, Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations, 76 Fed. Reg. 67,802, 67,898-99 (Nov. 2, 2011) (to be codified at 42 C.F.R. pt. 425) (in a section headed “Final Decision” the preamble stated “if an ACO [Accountable Care Organization] fails to achieve the minimum attainment level on at least 70 percent of the measures in each domain, we will give the ACO a warning, an opportunity to resubmit and re-evaluate the following year. If the ACO continues to underperform in the following year, the agreement would be terminated,” without referring to 42 C.F.R. § 425.502(d)(2)(ii)). It is preferable to for mandatory statements of this kind in preambles to cite the regulatory provisions that give rise to those obligations.

²¹⁹ Regulations Pertaining to Mergers, Acquisitions, and Takeovers by Foreign Persons, 73 Fed. Reg. 70,702, 70,702 (Nov. 21, 2008) (to be codified at 31 C.F.R. pt. 800).

²²⁰ *Id.* at 70,720.

illuminating the “foreign person” definition.²²¹ Example 4 states that “[c]orporation A is organized under the laws of a foreign state and is owned and controlled by a foreign national. A branch of Corporation A engages in interstate commerce in the United States. Corporation A (including its branch) is a foreign person. The branch is also a U.S. business.”²²² After the examples, the rule proceeds to the next regulatory provision.²²³

The Merit Systems Protection Board (MSPB) provided guidance through examples in the regulatory text of a rule updating MSPB’s adjudicatory practices and processes.²²⁴ In its rule addressing the filing of appeals, the Board notes that “[a]n appellant is responsible for keeping the agency informed of his or her current home address[.]”²²⁵ Following the rule’s text, the Board provided examples “to illustrate the application of this rule.”²²⁶ The three enumerated examples include: “Example A: An appellant who fails to pick up mail delivered to his or her post office box may be deemed to have received the agency decision. Example B: An appellant who did not receive his or her mail while in the hospital may overcome the presumption of actual receipt. Example C: An appellant may be deemed to have received an agency decision received by his or her roommate.”²²⁷

2. Guidance in Appendices

a. Official Commentary in Appendix. Some agencies incorporate official commentary, official interpretations, or designated interpretive guidance into appendices. The Equal Employment Opportunity Commission (EEOC) included official interpretations in a rule implementing the equal employment provisions of the ADA Amendments Act of 2008.²²⁸ In the preamble to the final rule, the EEOC explained the function of the official interpretations:

The appendix addresses the major provisions of the regulations and explains the major concepts. The appendix as revised will be issued and published in the Code of Federal Regulations with the final regulations. It will continue to represent the Commission’s interpretation of the issues discussed in the

²²¹ *Id.*

²²² *Id.*

²²³ *Id.*

²²⁴ Practices and Procedures, 77 Fed. Reg. 62,350, 62,350 (Oct. 12, 2012) (to be codified at 5 C.F.R. pts. 1200, 1201, 1203, 1208, and 1209).

²²⁵ *Id.* at 62,364.

²²⁶ *Id.*

²²⁷ *Id.* (appearing in 5 C.F.R. § 1201.22 (2012)).

²²⁸ Regulations To Implement the Equal Employment Provisions of the Americans With Disabilities Act, as Amended, 76 Fed. Reg. 16,978, 16,978 (March 25, 2011) (to be codified at 29 C.F.R. pt. 1630).

regulations, and the Commission will be guided by it when resolving charges of employment discrimination under the ADA.²²⁹

The appendix entitled “Appendix to Part 1630—Interpretive Guidance on Title I of the Americans with Disabilities Act” includes a lengthy introduction on the development of the ADA followed by a section-by-section analysis of the provisions promulgated in the regulation.²³⁰ For instance, in the appendix under “Section 1630.2(l) – Regarded as Substantially Limited in a Major Life Activity”, the EEOC wrote “[c]overage under the ‘regarded as’ prong of the definition of disability should not be difficult to establish.”²³¹ The EEOC states that these interpretations will guide it when resolving employment discrimination charges under the ADA.²³²

The Consumer Financial Protection Bureau (CFPB) also included official interpretations at the end of Regulation X, a rule implementing the Real Estate Settlement Procedures Act (RESPA).²³³ After appendices with technical guidance, there is a section entitled “Supplement I to Part 1024—Official Bureau Interpretations.”²³⁴ In this supplement, the CFPB explains that “[t]his commentary is the primary vehicle by which the [Bureau] issues official interpretations of Regulation X. Good faith compliance with this commentary affords protection from liability under section 19(b) of [RESPA].”²³⁵ Like the EEOC rule above, this supplement included section-by-section interpretations of the regulation.²³⁶ For instance, in the supplement the CFPB interpreted the regulatory provision § 1024.36 on investigation and response requirements.²³⁷ Specifically, the agency interpreted “information not available” as occurring when: “(i.) [t]he information is not in the servicer’s control or possession, or (ii) [t]he information cannot be retrieved in the ordinary course of business through reasonable efforts.”²³⁸

b. Examples in Appendix. The EEOC appendix that provided interpretive guidance on the ADA Amendments Act of 2008 also incorporated examples.²³⁹ In the appendix, the EEOC wrote: “[f]or example, an individual who is denied a promotion

²²⁹ *Id.* at 16979.

²³⁰ *Id.* at 17003.

²³¹ *Id.* at 17014.

²³² *Id.* at 16978.

²³³ Mortgage Servicing Rules Under the Real Estate Settlement Procedures Act (Regulation X), 78 Fed. Reg. 10,696, 10,696 (Feb. 14, 2013) (to be codified at 12 C.F.R. pt. 1024).

²³⁴ *Id.* at 10,887.

²³⁵ *Id.*

²³⁶ *Id.*

²³⁷ *Id.* at 10,891.

²³⁸ *Id.*

²³⁹ Regulations To Implement the Equal Employment Provisions of the Americans With Disabilities Act, as Amended, 76 Fed. Reg. 16,978, 17,016 (March 25, 2011) (to be codified at 29 C.F.R. pt. 1630).

because he has a minor back injury would be ‘regarded as’ an individual with a disability if the back impairment lasted or was expected to last more than six months.”²⁴⁰ The EEOC offered numerous examples in this appendix.

A joint rule by a group of agencies (Treasury, SSA, DVA, RRB, and OPM) on garnishment of accounts containing federal benefit payments utilized examples in an appendix to the final rule.²⁴¹ For instance, one of the appendices entitled “Appendix C to Part 212—Examples of the Lookback Period and Protected Amount” stated “the following examples illustrate the definition of *protected amount*.”²⁴² There are then five examples that explain how hypothetical scenarios fit within the definition of protected amount.²⁴³ Here is an excerpt of example 4: “Since the \$2,000 sum of the two benefit payments posted to the account during the lookback period is less than the \$3,000 balance in the account when the account review is performed, the financial institution establishes the protected amount at \$2,000 and places a hold on the remaining \$1,000 in the account in accordance with State law.”²⁴⁴ The appendices were published in the CFR.²⁴⁵

c. Question and Answer Format in Appendix. Agencies provide guidance in appendices through the question and answer format. The Social Security Administration promulgated a rule revising medical criteria for evaluating visual disorders in which revisions adopted consisted almost exclusively amendments to the appendix appearing in the CFR.²⁴⁶ After the preamble, the agency posed and answered a series of questions in the appendix.²⁴⁷ Questions included, for instance, “How do we evaluate visual disorders?” and “How do we define statutory blindness?”²⁴⁸ In response to the question “What are visual disorders?”, the agency wrote “Visual disorders are abnormalities of the eye, the optic nerve, the optic tracts, or the brain that may cause a loss of visual acuity or visual fields.”²⁴⁹ These questions and answers in the appendix were published in the CFR.²⁵⁰

The Department of Education also provided guidance in an appendix through the question and answer format in a rule implementing the Family Educational Rights and

²⁴⁰ *Id.*

²⁴¹ Garnishment of Accounts Containing Federal Benefit Payments, 78 Fed. Reg. 32,099, 32,110 (May 29, 2013) (to be codified at 31 C.F.R. pt. 212).

²⁴² *Id.* at 32,109.

²⁴³ *Id.* at 32,109–32,110.

²⁴⁴ *Id.* at 32,110.

²⁴⁵ See 31 C.F.R. § 212 app. A, B & C (2013).

²⁴⁶ Revised Medical Criteria for Evaluating Visual Disorders, 78 Fed. Reg. 18,837, 18,837 (March 28, 2013) (to be codified at 20 C.F.R. pt. 404).

²⁴⁷ *Id.* at 18,839.

²⁴⁸ *Id.*

²⁴⁹ *Id.* at 18,834

²⁵⁰ 20 C.F.R. § 404, Subpart P, app. 1 (2013).

Privacy Act (FERPA).²⁵¹ After the regulatory text, the Department of Education included a document on “Guidance for Reasonable Methods and Written Agreements” in Appendix A.²⁵² The Department of Education structured this guidance document as a series of questions and answers.²⁵³ Questions included: “What is the Family Educational Rights and Privacy Act?” and “What do I do if the terms of the written agreement are violated?”²⁵⁴ In response to the latter question, the agency answered “[i]f the entity to which you have disclosed PII from education records without consent . . . violates the terms of the written agreement, you should evaluate your options under the penalty and termination provisions of the agreement”²⁵⁵ Interestingly, before the appendices to the FERPA rule, the Department of Education wrote “Note: The following appendices will not appear in the Code of Federal Regulations.”²⁵⁶ (The agency did not further explain its choice to exclude the appendices from the CFR.)

d. Technical Guidance in Appendix. Agencies sometimes include technical guidance in appendices to final rules. For instance, the CFPB utilized this approach in Regulation X discussed above.²⁵⁷ After the regulatory text, the CFPB attached appendices with model forms and sample language for use by regulated entities.²⁵⁸ Appendix MS-2 contained a model form of a notice of transfer of loan servicing for a servicer to provide to a borrower.²⁵⁹ An excerpt of this model form read: “[Name of present servicer] is now collecting your payments. [Name of present servicer] will stop accepting payments received from you after [Date].”²⁶⁰ These model forms were published in the CFR.

The Department of Education’s rule implementing FERPA also includes technical guidance in appendices.²⁶¹ FERPA requires educational institutions to annually notify parents and eligible students of their rights under FERPA.²⁶² To facilitate this requirement, Appendix B attached to the final rule includes a “Model Notification of Rights under

²⁵¹ Family Educational Rights and Privacy, 76 Fed. Reg. 75,604, 75,645 (Dec. 2, 2011) (to be codified at 34 C.F.R. pt. 99).

²⁵² *Id.*

²⁵³ *Id.*

²⁵⁴ *Id.* at 75,645, 75,653.

²⁵⁵ *Id.* at 75,653.

²⁵⁶ *Id.* at 75644. So long as the material is reasonably available, as it was in this case, this practice complies with recommended practices on incorporation by reference. See Admin. Conf. of the United States, Agency Policy Statements, Recommendation 2011-5, ¶ 1, 77 Fed. Reg. 2257, 2258 (Jan. 17, 2012) (recommending that material incorporated by reference be reasonably available).

²⁵⁷ Mortgage Servicing Rules Under the Real Estate Settlement Procedures Act (Regulation X), 78 Fed. Reg. 10,696, 10,886 (Feb. 14, 2013) (to be codified at 12 C.F.R. pt. 1024).

²⁵⁸ *Id.*

²⁵⁹ *Id.* at 10,877.

²⁶⁰ *Id.* at 10,886.

²⁶¹ Family Educational Rights and Privacy, 76 Fed. Reg. 75,604, 75,654 (Dec. 2, 2011) (to be codified at 34 C.F.R. pt. 99).

²⁶² *Id.* at 75608.

FERPA for Elementary and Secondary Schools.”²⁶³ The model form begins with “[FERPA] affords parents and students who are 18 years of age or older (‘eligible students’) certain rights with respect to the student’s education records” and then the model form enumerates those rights.²⁶⁴ As noted above, the appendices to the FERPA rule were not published in the CFR.

D. Separately Issued Contemporaneous Guidance

Agencies frequently issue guidance or draft guidance in the form of separately issued documents at the same time that they issue their rules. This practice has the benefit of giving regulated parties as much notice as possible at the time the rule promulgated about the agency’s interpretation of the rule and advice about compliance with it.

The Nuclear Regulatory Commission (NRC) provides a recent example an agency issuing detailed guidance alongside a new rule. At the time the NRC issued a rule amending its regulations regarding the security requirements for the transportation of radioactive material,²⁶⁵ it also issued an extensive guidance document to assist in the implementation of these requirements.²⁶⁶ The implementation guidance provided comprehensive treatment of the approaches and methods that the agency deemed acceptable in complying with the regulations,²⁶⁷ framing this guidance in an accessible question-and-answer format. The practice of issuing a freestanding guidance at the same time a rule is promulgated is particularly helpful where, as in the case of the NRC rule, the preamble makes reference to (and providing links to) the accompanying guidance.²⁶⁸

Even when agencies choose not to issue a separately designated guidance document, as noted above, for rules with significant impacts on small entities, SBREFA requires agencies to issue a form of contemporaneous guidance, “small entity compliance guidance,” before the regulation becomes effective to explain what actions are necessary for a small entity to comply with the regulation.²⁶⁹

²⁶³ *Id.* at 75654.

²⁶⁴ *Id.*

²⁶⁵ Nuclear Regulatory Commission, Physical Protection of Byproduct Material, Final Rule, 78 Fed. Reg. 16922 (Mar. 19, 2013).

²⁶⁶ U.S.N.R.C., Office of Federal and State Materials and Environmental Management Programs, Implementation of Guidance for 10 C.F.R. Part 37 “Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material,” NUREG-2155 (Feb. 2013).

²⁶⁷ *Id.* at 1.

²⁶⁸ *See* Physical Protection of Byproduct Material, 78 Fed. Reg. at 16922.

²⁶⁹ Small Business Regulatory Enforcement Fairness Act, § 212(a)(4)(B)(i), 5 U.S.C. § 610 (2006)

In 2001, GAO issued a report concluding that many agencies were failing to fully comply with these requirements of SBREFA.²⁷⁰ Based on an examination of rulemaking in 1999 and 2000 for seven agencies (the Department Commerce, CMS, FDA, HHS, EPA, FCC, and SEC), the GAO study concluded that agencies were applying different standards for when a rule affected small entities triggering the obligation to prepare a guide,²⁷¹ were not designating their products as “compliance guides,”²⁷² were failing to explain the compliance actions required,²⁷³ and did not meet the contemporaneous deadlines set by the Act,²⁷⁴ among other difficulties. Interestingly, there is no central clearinghouse for these compliance guides or for the agency websites on which they appear.

V. Recommendations to Federal Agencies

This Part sets forth recommendations to federal agencies with regard to the use of contemporary guidance. Some of these recommendations apply to all rulemaking agencies and others pertain to specific agencies and practices; some suggest relatively substantive reforms, such as how preamble are drafted, and others pertain to how agencies can increase the accessibility of their contemporary guidance. These recommendations are clustered under five headings: (1) preamble drafting, (2) integrating preambles into policies on guidance and collections of guidance, (3) electronic presentation of regulations, (4) tailoring the location of guidance to the practices of those regulated, and (5) small entity compliance guides.

1. Preamble Drafting

Rec. 1.1. The statement of “basis and purpose” produced in the preamble to final rules should state the purpose of the rule and how it advances statutory objectives in a way that goes beyond merely repeating statutory language.

Discussion: Recommendation 1.1 is based on the principle that an agency’s own statement of the purposes of the rule in light of statutory objectives is a necessary element of the “statement of [] basis and purpose” under APA § 553 and “a statement of the need for, and objectives of, the rule” under the Regulatory Flexibility Act (RFA).²⁷⁵ This principle follows from judicial interpretations of the APA and RFA discussed above

²⁷⁰ U.S. GOV’T ACCOUNTABILITY OFFICE, GAO 02-172, Compliance Guide Requirement Law Little Effect on Agency Practices (2001).

²⁷¹ *Id.* at 14.

²⁷² *Id.* at 23.

²⁷³ *Id.* at 24.

²⁷⁴ *Id.* at 28.

²⁷⁵ 5 U.S.C. § 604 (2012).

(Section III(D)(1)). At a basic level, a statement of a rule’s purpose and how it advances statutory objectives orients all interpretation of the rule, and demonstrates the agency’s discharge of the statutory powers with which it is vested. The vast majority of agencies and rulemakings admirably comply with this basic requirement, but not all do. Accordingly, it is worth highlighting this fundamental duty.

For those concerned about the burden this recommendation might place on agencies, it is worth emphasizing three points. First, this is a fundamental requirement of the APA and RFA, but one for which there is not active judicial enforcement for many rules. Second, compliance with this recommendation should not be unduly burdensome. For small and routine rulemakings, the agency could comply with this recommendation with a sentence or two of explanation. Third, this recommendation addresses only those rules that proceed through notice and comment. Regulations that merely restate the language of statutes they implement need not proceed through notice and comment,²⁷⁶ and therefore fall outside this recommendation (along with rules exempted from notice and comment for other reasons).

Rec. 1.2. Agencies generally should organize their preambles to include a section-by-section analysis in which the organization of the preambular analysis corresponds to the organization of the final rules to facilitate identification of the discussion the agency has provided as to each provision of the rule.

Discussion: The increased justificatory demands on preambles, as discussed above (Section II(B)), have contributed to the length and complexity of these documents. Recommendation 1.2 is the organizational equivalent of a requirement for plain language in government documents.²⁷⁷ It reflects the common sense idea that when the analysis in the preamble includes a section-by-section treatment corresponding to the sections of the rule adopted, it is easier for those reading the preamble to locate the most highly pertinent discussion. Of course, reading a section-by-section analysis is no excuse for not reading the entire preamble in order to understand its context and cross-cutting implications. But a section-by-section organizational structure reduces the search costs for those seeking to understand the operation and justification for particular aspects of an agency rule. In other words, a well-organized preamble reduces the cost of locating its guidance.

²⁷⁶ Gray Panthers Advocacy Cmm., 936 F.2d 1284, 1291 (1991) (“when regulations merely restate the statute they implement, notice-and-comment procedures are unnecessary”).

²⁷⁷ See, e.g., Memorandum for the Heads of Executive Departments and Agencies on “Plain Language in Government Writing” (June 1, 1998), 63 Fed. Reg. 31,885 (June 10, 1998); Plain Writing Act of 2010, Pub. L. No. 111, 124 Stat. 2861, codified at 5 U.S.C. § 301 nt. (Supp. V 2011) (imposing plain writing requirements on many government documents including those that explain how to comply with a requirement the federal government administers).

Rec. 1.3. Agencies should strive for preambles to their final rules to be comprehensive statements of each rule’s basis and purpose. In preambles to final rules, agencies should generally avoid relying on discussions of the basis and purpose of the rule provided in the Notice of Proposed Rulemaking (or in other prior notices) in ways that require the reader of the final preamble to integrate two or more discussions of the rule’s basis and purpose.

Discussion: Recommendation 1.3 addresses the practice of incorporating background discussions of the policy, basis, and objections provided in the Notice of Proposed Rulemaking (and other prior notices) in the final preamble. The Government Printing Office charges agencies per page they print in the *Federal Register*,²⁷⁸ so agencies have some financial incentive to incorporate prior analyses in a final preamble as opposed to restating them. Moreover, sometimes rules and their supporting analysis change very little in the comment process. Relying on prior discussions can also save agency drafters time. Notwithstanding these considerations, the practice of relying on discussion in previously published notices impedes the guidance function of the final rule’s preamble. With extensive reliance on prior statements of the rule’s basis and purpose, the final preamble can become merely a placeholder and signpost to other discussions that need to be integrated with the text of the final preamble. Requiring the public and regulated parties to integrate two or more separate and partial discussions of the basis and purposes of the rule reduces the utility of the final preamble for guidance purposes. This suggests that agencies should, at a minimum, consider whether incorporating or relying upon prior discussion will impede the guidance function of their preamble, and generally avoid such incorporation when it requires a reader to integrate two or more treatments.²⁷⁹ At a more general level, the guidance function of the final preamble is best served when the preamble provides a comprehensive statement of the rule’s basis and purpose. Accordingly, when feasible, agencies should strive for the preamble to the final rule to be a comprehensive and free-standing explanation of the rule.

Rec. 1.4. Agencies should not make statements of general applicability that are intended to have legal effect, such as statements imposing binding substantive standards or obligations, in preambles to final rules.

²⁷⁸ The fees for *Federal Register* publication in FY 2014 are as follows: MS Word submission: \$477/per page, \$159/per column; Manuscript Copy: \$522/per page, \$174/per column; Camera Copy: \$522/per page, \$174/per column. See Government Printing Office, Circular Letter No. 885 to Printing and Publishing Officials of the Federal Government (May 31, 2103) (available at <http://www.gpo.gov/pdfs/customers/cir885.pdf>) (last visited March 31, 2014).

²⁷⁹ Fewer burdens are imposed on the reader when the agency adopts the entire previous statement of the basis and purpose for the rule. In those cases, much less integration of two separate discussions is required.

Discussion: While preambles may be authoritative sources of guidance, as discussed above, under the APA, preambles should not include legislative rules; if a preamble were to include a legislative rule, that rule would be procedurally invalid under APA § 553. ACUS Recommendation 92-2 states that agencies should “not issue statements of general applicability that are intended to impose binding substantive standards or obligations upon affected persons without using legislative rulemaking procedures (normally notice-and-comment).”²⁸⁰ Recommendation 1.4 makes clear that this general prohibition on including statements that are intended to have legal effect applies to statements in preambles to final rules.

This recommendation also finds support in *OMB’s Good Guidance Bulletin*. The *Bulletin* prohibits agencies from using mandatory language in guidance documents unless “the agency is using these words to describe a statutory or regulatory requirement, or the language is addressed to agency staff and will not foreclose consideration by the agency of positions advanced by affected private parties.”²⁸¹ The *Bulletin* gives “shall,” “must,” and “requirement” as examples of prohibited mandatory language. Recommendation 1.4 highlights that the prohibition applies to all statements that purport to specify legal effects, not just those singled out by the mandatory language identified in *OMB’s Good Guidance Bulletin*.

2. Integrating Preambles into Policies on Guidance and Collections of Guidance

Rec. 2.1. Agencies should mention preambles to their final rules as sources of guidance in their general compilations of guidance and on their webpages devoted to guidance. Agencies should also develop ways to integrate the guidance content of their preambles into their general compilations of guidance and their webpages devoted to guidance.

Discussion: The preambles to final rules are often the most important sources of guidance about the rule’s meaning and effects. For agencies covered by *OMB’s Good Guidance Bulletin*, the *Bulletin* requires “each agency to maintain on its Web site . . . a current list of its significant guidance documents in effect.”²⁸² These pages typically define guidance and provide a topical and/or chronological listing of the agency’s guidance documents, with links. Based on a review of those executive agencies which have issued

²⁸⁰ Admin. Conf. of the United States, Agency Policy Statements, Recommendation 92-2, 57 Fed. Reg. 30,103 (June 18, 1992).

²⁸¹ *OMB’s Good Guidance Bulletin*, *supra* note 1, at 3440.

²⁸² *See id.* at Section III.1

an economically significant rule in the last 15 years,²⁸³ only the Department of Transportation mentions preambles as sources of guidance on its webpage devoted to guidance. Recommendation 2.1 seeks to improve the visibility of preambles as sources of guidance by recommending that, at a minimum, agencies mention preambles to final rules on their guidance web pages and integrate them into their general compilations of guidance.

There is not likely to be a uniform way to integrate the guidance content of preambles into agency's web-based summaries of guidance. (One promising format is providing hyperlinks from the regulatory text to guidance in preambles and other guidance documents, a suggestion addressed in Recommendation 3.1.) Regardless of the format, by endeavoring to integrate the guidance content of their preambles into their topical and other treatments of guidance, the agencies will not only assist the public in identifying this content but also will be spurred to consider how the guidance content of their preambles relates to the guidance they later provide. This process may encourage agencies to make self-conscious choices about the allocation of their guidance content between final preambles and later issued guidance documents, and may help to overcome perceptions that preambles concern only the legal sufficiency of rules and thus need not be considered as part of the way in which the agency provides guidance about the meaning of its regulations.

Mentioning preambles as sources of guidance and working to integrate the guidance in preambles into presentations of agency guidance will promote the visibility of this guidance regardless of the type of agency. Accordingly, this recommendation applies not only to those agencies covered by *OMB's Good Guidance Bulletin* but to all agencies that provide compilations or summaries of their guidance.

Rec. 2.2. To the extent agencies have policies on issuing guidance, those policies should address the guidance content of preambles to their final rules. For agencies covered by *OMB's Good Guidance Bulletin*, their policies should address compliance with the *Bulletin's* procedural requirements applicable to guidance documents for significant and economically significant guidance included in preambles to final rules.

Discussion: As discussed above, preambles to final rules provide an important source of guidance, and so agency policies on issuing guidance should address them. Doing so will encourage agencies to make choices about the kind of guidance that they provide in preambles and in other documents. It will also encourage agencies to consider

²⁸³ This list of agencies is drawn from LEWIS & SELIN, *supra* note 17, at 132 Table 20. The web pages for these agencies were visited in March 2014.

how they envision those affected by their regulations integrating these different sources of guidance. The recommendation does not independently suggest that agencies develop policies on guidance, only that those with policies reassess them to address guidance provided in preambles.

Agencies covered by *OMB's Good Guidance Bulletin* must have policies for the approval of guidance.²⁸⁴ As the analysis above suggests (Section II(A)), guidance that those covered agencies provide in preambles to final rules, if significant, is subject to the procedural requirements of the *Bulletin*. As a result, conscientious compliance with that *Bulletin* (or careful monitoring of compliance with it by the Office of Management and Budget) would require evaluating whether guidance provided in preambles triggers any of the process or other requirements of the *Bulletin*.

3. Electronic Presentation of Regulations

Rec. 3.1. Working in conjunction with the Office of the Federal Register and the Government Printing Office, agencies should develop electronic versions of their regulations which include hyperlinks to relevant guidance in the rules' final preambles as well as to other relevant guidance documents.

Discussion: The electronic presentation of regulations can integrate agency guidance with their regulations by providing hyperlinks to relevant guidance in preambles to final rules as well as to other relevant guidance documents. This can improve the public and regulatory entities access and understanding of agency regulations and agency guidance.

The Consumer Financial Protection Bureau has piloted a new online tool, "[eRegulations](#),"²⁸⁵ with the aim of improving access to and understanding of final rules.²⁸⁶ The tool provides navigable links to defined terms, official commentary, previous and proposed versions of the rule, as well as section-by-section analysis in regulatory preambles.²⁸⁷ This tool is an important step in realizing the possibilities of the internet and hypertext formats to improve understanding of regulations. In particular, because this tool provides links to relevant sections of preambles to final, it clearly highlights the guidance function of preambles and also reduces the costs associated with accessing this preamble

²⁸⁴ See *OMB's Good Guidance Bulletin*, *supra* note 1, at 3440.

²⁸⁵ E-Regulations, <http://www.consumerfinance.gov/eregulations/1005> (last visited Mar. 21, 2014).

²⁸⁶ See Stephanie J. Tatham, *CFPB's eRegulations tool promises to help users navigate federal regulations*, ADMINISTRATIVE FIX BLOG, (Oct. 22, 2013, 6:11 PM), <http://www.acus.gov/newsroom/administrative-fix-blog/cfpb%E2%80%99s-eregulations-tool-promises-help-users-navigate-federal>.

²⁸⁷ See *id.*

guidance. This format provides a promising way of integrating the guidance content of preambles with other guidance, and associating it with the relevant provisions of the rule.

Adoption of such hyperlink tools may also influence the way in which preambles are drafted, in particular by giving agencies incentives to write preambles with organizational structures (as suggested by Recommendation 1.2 above) that track the rule's sections so that they can support intelligible hyperlinks. Substantive knowledge of the agency's preambles and guidance is necessary to provide reliable links to the portions most relevant to each provision of a rule. Accordingly, this work will require detailed involvement and supervision by general counsel for each agency. In addition, the Office of the Federal Register and the Government Printing Office should be encouraged to work with agencies to make available electronic versions of agency regulations with these hyperlinks to supplement the official versions of the *Federal Register* and Code of Federal Regulations that the Office of the Federal Register maintains.

4. Tailoring the Location of Guidance to the Practices of Those Regulated

Rec. 4.1. Where the regulated population is (1) primarily the public and (2) is understood to rely primarily on the codified text of the regulation to understand their regulatory compliance obligations, agencies should consider including guidance (such as notes and example applications) in the text of the Code of Federal Regulations or in an appendix to the Code of Federal Regulations, as opposed to including it only in a separate guidance document or a preamble.

Discussion: Most members of the public and many regulated parties have little knowledge of administrative government, much less the distinction between a “regulation” and “guidance.” Members of the public frequently and reasonably seek the simplest way to find out what the law requires. When the agency publishes guidance in the form of examples, technical advice, or official interpretations, it can improve the accessibility of this content if it is published in the Code of Federal Regulations, either as a note or example in the text or as an appendix.

Recommendation 4.1 suggests that when the public is the primary regulated audience and the agency has reason to believe that the public relies primarily on the Code of Federal Regulations to ascertain its obligations, the agency should consider including that guidance in the Code of Federal Regulations (CFR). One possible downside of publishing guidance in the CFR is that the public will take it too seriously, treating it as

binding (not just as authoritative guidance).²⁸⁸ This is a real risk, and so agencies issuing guidance in the CFR should clearly designate that it is nonbinding.

Publishing guidance content in the CFR also imposes an additional process burden on the agency. But, as noted above, as long as *Alaska Professional Hunters* remains good law, the agency would have to proceed through notice-and-comment to revise any authoritative guidance, so issuing it in the CFR does not increase the agency's revision cost, only its cost for issuance. This recommendation encourages agencies to make case specific determinations about when the benefits of publishing guidance content in the CFR are outweighed by the increased cost, delay, or other problems that publishing it in the CFR can pose.

5. Small Entity Compliance Guides

Rec. 5.1. Agencies should reassess how they display their small entity compliance guides on their websites to ensure that these guides are in an “easily identified location”²⁸⁹ as required by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA).

Rec. 5.2. The Small Business Administration should work with agencies to develop guidelines for posting small entity compliance guides on agency websites in ways that make them easily identifiable.

Rec. 5.3. The Small Business Administration should maintain a webpage with links to agency webpages that host agency's small entity compliance guides.

Discussion of 5.1-5.3: While many agencies post the small entity compliance guides required by SBREFA in an “easily identified location” on their websites, for many other agencies these guides are difficult to find. Indeed, searching the websites of the 21 agencies that have issued an economically significant rule in the past 15 years,²⁹⁰ only four agencies (Labor, State, Transportation, and EPA) have an identified web page devoted

²⁸⁸ For instance, the Department of Energy decided to delete guidance that had appeared as an appendix in the C.F.R. and publish the same in an updated form on its web site. See *Energy Conservation Program: Test Procedures for Electronic Motors and Small Electric Motors*, 77 Fed. Reg. 26608, 26623-24 (May 4, 2012) (to be codified at 10 C.F.R. pt. 431). The Department noted that his change “does not change the legal effect or authority of appendix A as appendix A was a ‘Policy Statement’ that merely provided users with guidance as to DOE’s interpretation of existing statutes and regulations.” *Id.* Placing this content in freestanding guidance, the Department explained will allow the Department “to respond more efficiently to questions” and also “eliminate any potential confusion as to the legal effect of appendix A.” *Id.*

²⁸⁹ 5 U.S.C. § 601 nt. § 212(a)(2)(A) (2012).

²⁹⁰ See LEWIS & SELIN, *supra* note 17, at 132. Web searches of these agency websites conducted in March, April, and May 2014.

either to displaying these guides or acknowledging the responsibility of producing them. It does not make sense to require agencies to produce these guides, as SBREFA does, and not follow through on making them readily accessible. In this regard, agencies should be encouraged to evaluate where they are posting these guides on their web sites, as provided in Recommendation 5.1, to ensure they are easily located.

Recommendation 5.2 encourages the Small Business Administration (SBA) to take a leadership role in coordinating among agencies and developing policies on uniform and best practices for agencies presenting small entity compliance guides on their websites. Because these guides are directed to small entities, the Small Business Administration is a logical leader for this endeavor. The assistance of the Office of Management and Budget would also be welcome in assisting SBA in coordinating among agencies on a set of guidelines.

Recommendation 5.3 goes a step further and recommends that SBA host a clearinghouse with links to agency webpages that contain their small entity compliance guides. Such a clearinghouse would provide a backstop for small entities searching for these guides; it would allow them to easily find where these guides are located for each agency, and may also alert them to other useful guides. Because these guides are directed to small entities, and the SBA already maintains a webpage with information about SBREFA, the SBA is a logical home for this clearinghouse.

Maintaining this clearinghouse would also create a welcome additional incentive for agencies to comply with the requirements of SBREFA. As noted above, GAO's 2001 report, *Compliance Guide Requirement Law Has Little Effect on Agency Practices*,²⁹¹ found that many agency compliance guides were not complying with all the requirements of this provision of SBREFA. A collection of links to agency webpages with these guides will make it easy for agencies to compare their guides to those produced by other agencies, and may create some pressure toward greater consistency in meeting the requirements SBREFA establishes. It will also provide an informal monitoring mechanism for Recommendation 5.2 which urges SBA to work with agencies to enhance the visibility of these guides.

²⁹¹ U.S. GOV'T ACCOUNTABILITY OFFICE, GAO 02-172, COMPLIANCE GUIDE REQUIREMENT HAS HAD LAW LITTLE EFFECT ON AGENCY PRACTICES (2001).

Conclusion

Given that regulations produced through notice-and-comment account for many more binding legal norms than statutes, the interpretation of these regulations is a critical question for administrative governance. One critical source for understanding the meaning and application of regulations is agency's own guidance.

Agencies routinely provide guidance in the context of rulemaking. There is some minimum guidance function inherent in an agency's statement of basis and purpose in a regulation's preamble. But in many cases, agencies provide considerably more preamble guidance about the meaning of the regulation in the preamble. Agencies also do so in the regulatory text (including appendices that may be published in the CFR) and separate documents. Despite the ubiquity of contemporaneous guidance, it has been largely neglected in the long-running debate on the use of guidance by agencies.

This Report seeks to take some initial steps in overcoming this neglect. It does so by pursuing three goals. First, by documenting the scope of contemporaneous guidance and its varieties, the Report aims to provide agencies with resources for making deliberate choices about the use of guidance in rulemaking. Second, by describing the legal regime applicable to contemporaneous guidance the Report aims to inform and prompt evaluation of current practices. Third, by tracing the implications of the neglect of the guidance function of preambles and use of regulatory text for guidance, the Report teases out several recommendations to improve the utility and accessibility of these forms of guidance.

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