

Notices

Federal Register

Vol. 78, No. 132

Wednesday, July 10, 2013

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

ADMINISTRATIVE CONFERENCE OF THE UNITED STATES

Adoption of Recommendations

AGENCY: Administrative Conference of the United States.

ACTION: Notice.

SUMMARY: The Administrative Conference of the United States adopted four recommendations at its Fifty-eighth Plenary Session. The appended recommendations address ways to improve the adjudication of Social Security disability benefits, best practices for use of benefit-cost analysis in rulemaking by independent regulatory agencies, transparency in agencies' scientific decisionmaking, and best practices for agencies with respect to the administrative record in informal rulemaking.

FOR FURTHER INFORMATION CONTACT: For Recommendation 2013-1, Amber Williams; for Recommendations 2013-2 and 2013-3, Reeve Bull; for Recommendation 2013-4, Stephanie Tatham. For all four recommendations the address and phone number are: Administrative Conference of the United States, Suite 706 South, 1120 20th Street NW., Washington, DC 20036; Telephone 202-480-2080.

SUPPLEMENTARY INFORMATION: The Administrative Conference Act, 5 U.S.C. 591-596, established the Administrative Conference of the United States. The Conference studies the efficiency, adequacy, and fairness of the administrative procedures used by Federal agencies and makes recommendations for improvements to agencies, the President, Congress, and the Judicial Conference of the United States (5 U.S.C. 594(1)). For further information about the Conference and its activities, see <http://www.acus.gov>.

At its Fifty-eighth Plenary Session, held June 13-14, 2013, the Assembly of the Conference adopted four recommendations. Recommendation

2013-1, "Improving Consistency in Social Security Disability Adjudications," identifies ways to improve the adjudication of Social Security disability benefits claims before administrative law judges and the Appeals Council, suggests changes to the evaluation of opinion evidence from medical professionals, and encourages the agency to enhance data capture and reporting.

Recommendation 2013-2, "Benefit-Cost Analysis at Independent Regulatory Agencies," highlights a series of best practices directed at independent regulatory agencies in the preparation of benefit-cost analyses that accompany proposed and final rules.

Recommendation 2013-3, "Science in the Administrative Process," promotes transparency in agencies' scientific decision-making, including: articulation of questions to be informed by science information; attribution for agency personnel who contributed to scientific analyses; public access to underlying data and literature; and conflict of interest disclosures for privately funded research used by the agencies in licensing, rulemaking, or other administrative processes.

Recommendation 2013-4, "The Administrative Record in Informal Rulemaking," offers best practices for agencies in the compilation, preservation, and certification of records in informal rulemaking, and supports the judicial presumption of regularity for agency administrative records except in certain limited circumstances.

The Appendix (below) sets forth the full texts of these four recommendations. The Conference will transmit them to affected agencies and to appropriate committees of the United States Congress. The recommendations are not binding, so the relevant agencies, the Congress, and the courts will make decisions on their implementation.

The Conference based these recommendations on research reports that it has posted at: <http://www.acus.gov/meetings-and-events/plenary-meeting/58th-plenary-session/>. A video of the Plenary Session is available at the same web address, and a transcript of the Plenary Session will be posted once it is available.

Dated: July 3, 2013.

Paul R. Verkuil,

Chairman.

APPENDIX—RECOMMENDATIONS OF THE ADMINISTRATIVE CONFERENCE OF THE UNITED STATES

Administrative Conference Recommendation 2013-1

Improving Consistency in Social Security Disability Adjudications

Adopted June 13, 2013

The Administrative Conference of the United States (Conference) has undertaken many studies over the years relating to the Social Security disability benefits system.¹ It has issued a number of recommendations specifically directed at improving the Social Security Administration's (SSA's) initial application and appeals processes,² as well as other recommendations more generally designed to improve agency adjudicatory procedures.³ The Conference last issued a recommendation on the Social Security disability benefits system over twenty years ago. The system has grown substantially since that time. Approximately 3.3 million disability claims are now filed annually,⁴ which represents a 57% increase since 1990.⁵ In a program of this size, adjudicating disability benefits claims in a fair, consistent,

¹ The Social Security Act created two programs—Social Security Disability Insurance and Supplemental Security Income—to provide monetary benefits to persons with disabilities who satisfy these programs' respective requirements. See 42 U.S.C. 401(b), 1381 (2011).

² These recommendations include: Recommendation 91-3, *The Social Security Representative Payee Program*, 56 FR 33847 (July 24, 1991); Recommendation 90-4, *Social Security Disability Program Appeals Process: Supplementary Recommendation*, 55 FR 34213 (Aug. 22, 1990); Recommendation 89-10, *Improved Use of Medical Personnel in Social Security Disability*, 55 FR 1665 (Jan. 18, 1990 (as amended)); Recommendation 87-7, *A New Role for the Social Security Appeals Council*, 52 FR 49143 (Dec. 30, 1987) [hereinafter ACUS Recommendation 87-7]; and Recommendation 78-2, *Procedures for Determining Social Security Disability Claims*, 43 FR 27508 (June 26, 1978).

³ See, e.g., Recommendation 2011-4, *Agency Use of Video Hearings: Best Practices and Possibilities for Expansion*, 76 FR 48789 (Aug. 9, 2011); Recommendation 89-8, *Agency Practices and Procedures for the Indexing and Public Availability of Adjudicatory Decisions*, 54 FR 53495 (Dec. 29, 1989); Recommendation 86-7, *Case Management as a Tool for Improving Agency Adjudication*, 51 FR 46989 (Dec. 30, 1986); Recommendation 73-3, *Quality Assurance Systems in the Adjudication of Claims of Entitlement to Benefits or Compensation*, 38 FR 16840 (June 27, 1973).

⁴ Soc. Sec. Admin., Annual Performance Plan for FY 2013 and Revised Performance Plan for FY 2012, at 11 (2012).

⁵ Soc. Sec. Advisory Bd., Aspects of Disability Decision Making: Data and Materials 6 tbls. 1a & 1b (Feb. 2012) [hereinafter SSAB 2012 Report].

and timely manner is a monumental challenge.

Those cases flow through a nationwide, multi-step process, by which SSA determines whether a claimant is disabled and eligible for benefits. State agencies make initial disability determinations using federal guidelines. Claimants may file (and pursue) their own claims or they may choose to enlist the assistance of a representative, who may or may not be a lawyer.⁶ If benefits are denied, claimants may request reconsideration (in most states). If benefits are denied after reconsideration, claimants may request a hearing before an Administrative Law Judge (ALJ). ALJs adjudicate nearly 800,000 cases a year.⁷ In FY 2011, about 56% of disability benefits claims were allowed at the ALJ hearing stage,⁸ though more recent figures show a decline in this rate.⁹ ALJ hearings, which may be in-person or by video teleconferencing, are conducted using a de novo standard of review, and generally follow the Administrative Procedure Act's adjudication procedures. Although ALJs preside at the hearings, decisionwriters typically write decisions for ALJs based on instructions from them. Usually, decisionwriters are not assigned to specific ALJs, but serve instead as part of a "pool" in each hearing office from which writing assignments for decisions are made.

Appeals Council review is the final step in the administrative process. The Appeals Council is comprised of about 125 appellate adjudicators who typically take action—without oral argument—individually or in two-member panels.¹⁰ The Appeals Council has discretionary authority to grant, deny, or dismiss a claimant's request for review, as well as remand the case back to an ALJ or issue a decision.¹¹ In FY 2012, the Appeals

Council processed over 166,000 requests for review, a 30.7% increase from FY 2011.¹² In addition to processing requests for review, the Appeals Council has authority to review all types of unappealed decisions (i.e., allowances or benefit denials) on its "own motion" through use of random or selective sampling techniques.¹³ Currently, the Appeals Council's "own motion" review docket draws from a national random sample of ALJ allowance decisions as a quality assurance mechanism; the Appeals Council has not yet reviewed unappealed ALJ denial decisions, and has declined to use its selective sampling authority to identify and review unappealed cases with a high likelihood of error in recent years.¹⁴ In FY 2012, the Appeals Council completed random review of 7,074 ALJ allowance decisions.¹⁵ The Appeals Council publishes its decisions only rarely, in the form of Appeals Council Interpretations (ACIs), and its decisions sometimes serve as the basis for Social Security Rulings. Claimants who disagree with the final administrative decision may seek initial judicial review in federal district court.

Adjudicators and other agency employees at both the ALJ hearing level and Appeals Council level use electronic case

management systems to help manage their workflow and to provide case-related management information. The current system in use at the hearing level is the Case Processing Management System (CPMS), while the Appeals Council level uses the Appeals Council Review Processing System (ARPS). Not only do adjudicators and other staff use CPMS and ARPS in their day-to-day work, but the agency also uses data from these systems to identify and address trends and anomalies existing at the various levels of agency adjudication. While SSA has endeavored to build effective data reporting systems, limitations still exist that relate to data capture and linking the various systems.

Not only does SSA process an extraordinary number of claims through a national, multi-tiered system, but, in doing so, the agency tries to ensure that decisionmaking is consistent and accurate at all levels of adjudication, and that legally sufficient decisions are issued that can withstand review by federal courts. Consistency and accuracy, however, have suffered under the strain of administering such a sprawling program. To be sure, an ALJ faces an enormous task in adjudicating hundreds of cases annually.¹⁶ Nonetheless, divergent allowance rates among ALJs suggest that claims are being resolved in an inconsistent, if not inaccurate, manner.¹⁷ The Appeals Council similarly struggles to fulfill its error-correction and quality-review roles. That these steps may have room for improvement is evidenced by the 45% rate at which cases are remanded back to the agency from federal courts in recent years.¹⁸ Bringing greater consistency and accuracy to the disability claims adjudication process will enhance the fairness and integrity of the program.

One area of particular concern—due to its apparent contribution to a high remand rate—is SSA's treating source rule, which generally affords "controlling weight" to the opinions of a claimant's treating physician, psychologist, or other acceptable medical source.¹⁹ In the early 1990s, SSA sought to bring greater clarity and uniformity to the assessment of medical evidence by establishing regulatory standards for such evaluations. In practice, however, this evidentiary rule has not delivered on its promise of improving consistency. In recent years, erroneous application of the treating source rule has been cited as the basis for

⁶ The administrative process for adjudication of Social Security disability claims is nonadversarial in nature. See, e.g., 20 CFR 404.900(b), 416.1400(b) (2012) (describing agency's administrative review process as "informal" and "nonadversary"); *Mathews v. Eldridge*, 424 U.S. 319, 339 (1976) ("The hearing is nonadversary and the SSA is not represented by counsel."); *Richardson v. Perales*, 402 U.S. 389, 403 (1971) ("We bear in mind that [SSA] operates essentially, and is intended so to do, as an adjudicator and not as an advocate or adversary.").

⁷ SSAB 2012 Report, *supra* note 5, at 13.

⁸ Harold Krent & Scott Morris, Statistical Appendix: Analysis of Administrative Law Judge Disposition and Favorable Rates in Fiscal Years 2009 to 2011 13, 14 tbl. A-8 (2013) [hereinafter Statistical Appendix].

⁹ Harold Krent & Scott Morris, Achieving Greater Consistency in Social Security Disability: An Empirical Study and Suggested Reforms 8 (2013) (noting a 50% allowance rate in FY 2012).

¹⁰ See 20 CFR 422.205 (2012) (prescribing Appeals Council review procedures); see also Charles H. Koch, Jr. & David A. Koplow, *The Fourth Bite at the Apple: A Study of the Operation and Utility of the Soc. Sec. Admin.'s Appeals Council*, 17 Fla. St. U. L. Rev. 199, 253-54 (1990).

¹¹ The Conference believes that its 1987 conclusion, that a "principal mandate" of the Appeals Council is "to recommend and, where appropriate, develop and implement adjudicatory principles and decisional standards for the disability determination process" remains valid today. See ACUS Recommendation 87-7, *supra* note 2.

¹² Soc. Sec. Admin., Office of Appellate Operations, Executive Director's Broadcast, at 1 (Oct. 19, 2012) [hereinafter Exec. Dir. Broadcast]. Of these 166,000 requests for review, the Appeals Council dismissed or denied 78.3% of the requests, remanded 18.6% of the cases back to ALJs, and issued decisions (i.e., fully favorable, partially favorable, or unfavorable) in 2.6% of the cases. *Id.* at 2.

¹³ As the name connotes, random sampling involves selection of hearing level cases for Appeals Council review from a national pool without regard for case characteristics or correctness, other than broad categories designed to assure randomness (e.g., allowances within a given date range). By contrast, selective sampling is specifically designed to identify cases for review that "exhibit problematic issues or fact patterns that increase the likelihood of error." 20 CFR 404.969(b)(1), 416.1469(b)(1) (2012) (detailing the Appeals Council's "own motion" review authority and procedures); see also Soc. Sec. Admin., Identification and Referral of Cases Under Appeals Council's Own Motion Review Authority, 63 FR 36560 (July 7, 1998). These procedures are established pursuant to the Social Security Act's broad grant of authority to the Commissioner to establish hearing procedures and, on his or her own motion, hold hearings or conduct other proceedings as necessary for the proper administration of the program. See, e.g., 42 U.S.C. 405(b)(1), 1383(c)(1)(A) (2011).

¹⁴ This recommendation suggests that, to enhance decisional accuracy and consistency, SSA expand the Appeals Council's use of "own motion" review of unappealed ALJ decisions through selective sampling based on announced, neutral, and objective criteria that identify problematic issues, fact patterns, or case characteristics. Under this recommendation, focused review might be warranted, for example, based on: the subject matter of a claim, the manner in which a hearing was held, or statistical analyses showing a high likelihood of error or significantly anomalous outcomes.

¹⁵ Exec. Dir. Broadcast, *supra* note 12, at 3. The Appeals Council agreed with the decisions of ALJs 82.5% of the time, and either remanded or issued corrective decisions approximately 16% of the time. At the end of the FY 2012, there were 741 "own motion" review cases still pending final action. *Id.*

¹⁶ On average, for FY 2009-FY 2011, ALJs issued 538.9 dispositions per year. See Statistical Appendix, *supra* note 8, at 6, 8 tbl. A-2.

¹⁷ In recent years, while the distribution of yearly allowance disposition rates has been approximately normal (i.e., a mean of 56%), the distribution covers a wide range of allowance rates, with 95% of the rates falling between 26% and 85%. See *id.* at 13, 14 fig. A-8 (analyzing allowance rates for FY 2009-FY 2011). The lowest allowance rate was 4% and the highest allowance rate was 98%. See *id.*

¹⁸ See *id.* at 54 tbl. A-24. Policy compliance among ALJs has improved in recent years. See Michael J. Astrue, former Comm'r, Soc. Sec. Admin., Address at the Social Security Advisory Board Forum: Straight Talk about "Disability Reform." (Mar. 8, 2013), available at <http://www.ssb.gov/Portals/0/2013Forum/Presentations/Astrue%20Speech%203-8-13.pdf>.

¹⁹ See 20 CFR 404.1527(c), 416.927(c) (2012).

remand by the Appeals Council at a 10% frequency rate, and the frequency rate with which it is cited by federal courts is even higher at 35%.²⁰ Dramatic changes in the American health care system over the past twenty years also call into question the ongoing efficacy of the special deference afforded to the opinions of treating sources. Individuals typically visit multiple medical professionals in a variety of settings for their health care needs and less frequently develop a sustained relationship with one physician.²¹ Moreover, difficulty in determining who among a wide range of medical professionals should be considered a treating source has bedeviled ALJs and reviewing courts, contributing to high remand rates.²²

This recommendation finds its genesis in SSA's request that the Conference study the role of the Appeals Council in reviewing cases to reduce any observed variances among adjudicative decisions at the hearing level, as well as the efficacy of SSA's treating source rule. These studies also revealed other areas that appear ripe for recommendation. While SSA has enacted various initiatives to increase consistency and has issued rulings to clarify its regulations, the size and complexity of the system leave more work to be done. The following recommendations reaffirm certain portions of past recommendations that remain valid and relevant and also identify new approaches to ensure consistency, accuracy, and fairness across this massive decision system.

Recommendation

ALJ Hearing Stage

1. *Improving Adjudication Effectiveness and Consistency.* In order to promote greater decisional consistency and streamline the adjudication process at the ALJ hearing stage, SSA should:

(a) Require claimant representatives (while also *permitting* claimants without representation) to submit pre-hearing briefs in a standardized format that, among other things, summarizes the medical evidence and justification for the claimant's eligibility for benefits;

(b) expand the use of video hearings in a manner consistent with sound technological practices, because such hearings promote efficiency and do not lead to a significant difference in allowance rates from in-person hearings. SSA should continue to advise claimants that opting for video hearings often results in faster scheduling of hearings (as compared to in-person hearings) and more convenient hearing locations; and

(c) assign decisionwriters and case technicians to specific ALJs in a hearing office (with Hearing Office Directors continuing to supervise such support staff), while maintaining flexibility to meet operational needs.

Appeals Council

2. *Balancing Error-Correction and Systemic Review Functions.* SSA should continue to promote the consistent application of policy to the adjudication of disability benefits claims across a nationwide program. SSA should ensure that the Appeals Council strikes an appropriate balance between its error-correction function when exercising discretionary review of individual claimants' requests for review, and its mandate to improve organizational effectiveness, decisional consistency, and communication of agency policy through use of "own motion" review (as to both allowances and unappealed denials) and other types of systemic quality assurance measures.

3. *Enhancing Communication.* SSA should make clear that an essential function of the Appeals Council is both to focus on consistent application of Social Security regulations and policies on a systemic basis, and to disseminate advice and guidance to SSA policymakers, ALJs, and other lower-level decisionmakers. The Appeals Council should advise and assist policymakers and decisionmakers by:

(a) Issuing Appeals Council Interpretations (ACIs), with greater frequency, in order to: Address policy gaps; promote greater consistency and uniformity throughout the adjudicatory process; and establish precedents upon which claimants and their representatives may rely. Such ACIs should be circulated within the agency and made publicly available through posting on SSA's Web site or other similar means of public dissemination;

(b) publishing selected ALJ or Appeals Council decisions to serve as model decisions (e.g., they are well-reasoned and clear), or to provide needed policy clarifications. Consistent with statutory obligations to maintain the privacy of sensitive information, such publications should not include personally identifiable information;

(c) continuing, to the greatest extent feasible, to send cases that have been remanded from the Appeals Council or federal courts back to the same ALJs who initially adjudicated such claims for additional proceedings as required. If an ALJ who initially decided a claim will not be presiding over a case post-remand, SSA should nonetheless ensure that he or she still receives notification of the remand decision. Decisionwriters who were involved in drafting a remanded decision should also receive notification of remand decisions; and

(d) developing a program for ALJs to serve extended voluntary details on the Appeals Council in order to introduce a measure of peer review, enrich ALJ understanding of the appeals process, and benefit the Appeals Council by introducing the perspectives and insights of ALJs. In support of that effort, SSA should seek a waiver from the Office of Personnel Management (OPM) of its durational (120-day) limit on details, which, if granted, would enable detailed ALJs to gain a deeper knowledge of the Appeals Council than is possible under a shorter detail period. OPM should give favorable consideration to such a request.

4. *Expanding Focused "Own Motion" Review.* In order to focus attention on the

unappealed decisions that most warrant review, thereby enhancing both accuracy and consistency, SSA should expand the Appeals Council's use of its "own motion" review by using selective review in a manner consistent with ALJ decisional independence. The Appeals Council should use announced, neutral, and objective criteria, including statistical assessments, to identify problematic issues or fact patterns that increase the likelihood of error and, thereby, warrant focused review. In addition, SSA should review unappealed decisions that raise issues whose resolution likely would provide guidance to ALJs and adjudicators. In expanding its "own motion" review, SSA must ensure that (i) selection-of-review criteria are developed in a neutral fashion without targeting particular ALJs or other decisionmakers, and that (ii) inclusion of cases in such review does not serve as the basis for evaluation or discipline. Thus, if necessary, SSA should revise its regulations through notice-and-comment rulemaking to clarify and expand the Appeals Council's use of selective sampling to identify for review decisions that:

(a) Raise issues for which resolution by the Appeals Council would provide policy clarifications to agency adjudicators or the public;

(b) appear, based on statistical or predictive analysis of case characteristics, to have a likelihood of error or lack of policy compliance; or

(c) otherwise raise challenging issues of fact or law, or have case characteristics, that increase the likelihood of error.

Use of Opinion Evidence From Medical Professionals (Treating Source Rule)

5. *Evaluating Medical Source Opinions.* SSA should revise its regulations through notice-and-comment rulemaking to eliminate the controlling weight aspect of the treating source rule in favor of a more flexible approach based on specific regulatory factors. SSA should give ALJs greater discretion and flexibility when determining the appropriate weight to afford opinions from treating sources (which may or may not be determinative), consistent with the factors enumerated in the current regulatory scheme for evaluation of opinions of acceptable medical sources who are not deemed "treating" sources. Such factors should include: (i) Length of the treatment relationship and frequency of examination; (ii) nature and extent of the treatment relationship; (iii) supportability of the medical source's opinion; (iv) consistency of the medical source's opinion; (v) specialization of the medical source; and (vi) any other factors that may support or contradict a medical source's opinion. In all cases, ALJs should articulate the bases for the weight given to opinions from medical sources.

6. *Recognizing the Value of Other Medical Sources.* SSA's existing regulatory scheme, which assigns second-tier evidentiary value to the opinions of nurse practitioners (NPs), physician assistants (PAs), and licensed clinical social workers (LCSWs) because they are not considered "acceptable medical sources," should be reconsidered to reflect

²⁰ See Office of the Chairman, Administrative Conference of the United States, *SSA Disability Benefits Programs: Assessing the Efficacy of the Treating Physician Rule*, Appendix B, at A-4, A-8 (2013).

²¹ See *id.* at 25-33.

²² See *id.* at 23-24, 33-35.

the realities of the current health care system. For many Social Security disability claimants, these medical professionals are the de facto “treating source” of medical care for physical and mental illnesses. SSA should:

(a) Revise its regulations through notice-and-comment rulemaking to add NPs, PAs, and LCSWs as “acceptable medical sources,” consistent with their respective state law-based licensure and scopes of practice; or

(b) issue a new Social Security ruling or other interpretive policy statement that makes clear, for agency adjudicators, federal courts, and the public, the value of, as well as the weight to be afforded, the opinions of these three types of medical professionals.

Statistical Quality Assurance Measures

7. *Enhancing Data Reporting Systems.* SSA should enhance its current data reporting systems in order to develop a more robust statistical quality assurance program. To enhance its current data reporting systems, such as the Case Processing Management System (CPMS) and the Appeals Council Review Processing System (ARPS), or any respective follow-on systems, SSA should determine how to associate types of cases and issues, regions, hearing offices, adjudicators, procedural elements and benchmarks, and decisional outcomes together. The goal of such systems should not only be objective evaluation of the agency’s case processing operation, but also the effective utilization of data to inform policy formation and operational consistency.

8. *Capturing Additional Data.* SSA should specifically address the limitations of CPMS, ARPS, and any respective follow-on systems by ensuring that these data reporting systems capture (as appropriate):

(a) Information related to any prior hearings;

(b) whether a decision involved a hearing or on-the-record decision;

(c) whether new evidence was submitted by a claimant after his or her hearing to the ALJ or to the Appeals Council; and

(d) data or other tracking mechanisms enabling ARPS and CPMS data to be related to a single claim through all case processing stages, including hearings, Appeals Council review, and remand by the Appeals Council or federal courts.

9. *Encouraging Employee Feedback.* SSA should encourage feedback from SSA employees to identify other types of case-related data that should be captured and to suggest ways to facilitate the linking of SSA’s multiple data reporting systems in order to improve overall data quality and quality assurance capabilities.

Administrative Conference Recommendation 2013–2

Benefit-Cost Analysis at Independent Regulatory Agencies

Adopted June 13, 2013

Benefit-cost analysis (also known as cost-benefit analysis) is one of the primary tools used in regulatory analysis to anticipate and evaluate the likely consequences of rules.¹

Although some regulatory benefits and costs are difficult to quantify or monetize, those preparing such analyses generally attempt to estimate the overall benefits that a proposed or final rule would create as well as the aggregate costs that it would impose on society, and then determine whether the former justify the latter. Some observers have disputed its utility in rulemaking,² but benefit-cost analysis (and other forms of regulatory analysis) can help ensure that decisionmakers fully contemplate the risks and rewards of any proposed regulatory strategy.³ Benefit-cost analysis can also improve transparency, helping to ensure that the public and Congress understand why regulatory decisions are made.

For more than 30 years, Cabinet departments and other executive agencies like the Environmental Protection Agency (but not independent regulatory agencies⁴ such as the Federal Trade Commission (FTC)) have been required by executive orders to conduct benefit-cost or other types of regulatory analyses for their “major” or

www.whitehouse.gov/omb/circulars_a004_a-4/ [hereinafter “OMB Circular A–4”]. Much of the literature on regulatory analysis, including prior recommendations of the Administrative Conference, uses the term “cost-benefit analysis” in lieu of, or in addition to, “benefit-cost analysis.” Circular A–4 uses the term “benefit-cost analysis,” and this recommendation will therefore utilize the same terminology.

² Critics of benefit-cost analysis contend that it ignores values that cannot be easily quantified, that benefits can often be difficult to monetize, that it tends to overestimate costs, and that it undervalues future benefits through the application of discounting methodologies. See, e.g., Frank Ackerman & Lisa Heinzerling, *Pricing the Priceless: Cost-Benefit Analysis of Environmental Protection*, 150 U. Pa. L. Rev. 1553, 1557–60, 1580–81 (2001).

³ See Administrative Conference of the United States, Recommendation 79–4, *Public Disclosure Concerning the Use of Cost-Benefit and Similar Analyses in Regulation*, 44 FR 38826 (July 3, 1979) (“Wise decisionmaking presupposes that the potential benefits and costs of the actions under consideration will be identified, will be quantified if feasible, and will be appraised in relation to each other.”); Cass R. Sunstein, *The Office of Information & Regulatory Affairs: Myths and Realities*, 126 Harv. L. Rev. 1838, 1846 (2013) (“Cost-benefit analysis can be exceedingly important, and in the Obama Administration, several steps were taken to strengthen it, contributing to a situation in which the net benefits of economically significant rules were extraordinarily high.”); cf. Richard L. Revesz & Michael A. Livermore, *Retaking Rationality: How Cost-Benefit Analysis Can Better Protect the Environment and Our Health* 10 (2008) (“Although cost-benefit analysis, as currently practiced, is . . . biased against regulation, those biases are not inherent to the methodology. If those biases were identified and eliminated, cost-benefit analysis would become a powerful tool for neutral policy analysis.”).

⁴ As a general matter, “independent regulatory agencies” are those whose heads possess “for cause” removal protection and that enjoy some degree of independence from the executive branch. David E. Lewis & Jennifer L. Selin, ACUS Sourcebook of United States Executive Agencies 49 (1st ed., 2d Printing Mar. 2013). Under Executive Order 12,866, 58 FR 51735 (Oct. 4, 1993), the term “agency” excludes independent regulatory agencies. *Id.* § 3(b). However, independent regulatory agencies are covered by the planning requirements in section 4 of the executive order.

“economically significant” rules.⁵ In 1981, President Ronald Reagan issued Executive Order (EO) 12,291,⁶ which instructed covered executive agencies to prepare regulatory impact analyses of their draft proposed and final major rules (including a description of benefits and costs), and to submit all of their draft rules to the Office of Information and Regulatory Affairs (OIRA) within the Office of Management and Budget (OMB) before publication in the **Federal Register**. Subsequent administrations have reaffirmed the importance of benefit-cost analysis and OIRA review. Currently, EO 12,866, issued by President William Jefferson Clinton in 1993, requires Cabinet departments and other covered executive agencies to “assess both the costs and benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs.”⁷ It also requires them to assess the costs and benefits of “significant” draft proposed and final rules submitted to OIRA for review, and to conduct more thorough analysis of economically significant draft proposed and final rules.⁸

As noted previously, independent regulatory agencies traditionally have not been subject to the formal benefit-cost analysis requirements imposed by executive order, although several recent Presidents have encouraged those agencies to voluntarily apply the principles contained in the relevant executive orders.⁹ Virtually all

⁵ “Major” and “economically significant” rules include (but are not limited to) rules likely to result in annual costs, benefits, or transfer payments of \$100 million or more. See Congressional Review Act, 5 U.S.C. 804(2); Exec. Order No. 12,866, *supra* note 4, § 3(f)(1). Transfer payments are monetary payments from one group to another that do not affect total resources available to society. See OMB Circular A–4, *supra* note 1. The most common form is the transfer of federal funds to the recipients of those funds (e.g., grants, food stamps, Medicare or Medicaid funds, and crop payments). In 2010, more than one-third of all major rules were so categorized because of the amount of transfer payments. See U.S. Cong. Research Service, *REINS Act: Number and Types of “Major Rules” in Recent Years*, R41651, Feb. 21, 2011, by Curtis W. Copeland and Maeve Carey.

⁶ Exec. Order No. 12,291, 46 FR 13193 (Feb. 17, 1981) (revoked by § 11 of EO 12,866).

⁷ Exec. Order No. 12,866, *supra* note 4, § 1(b)(6).

⁸ *Id.* § 6(a)(3); see also Exec. Order No. 13,563, 76 FR 3821 (Jan. 21, 2011) (President Obama) (stating that the benefits of proposed and final rules must “justify” the costs); Administrative Conference of the United States, Recommendation 88–9, *Presidential Review of Agency Rulemaking*, 54 FR 5207 (Feb. 2, 1989) (suggesting guidelines for the enhanced openness of executive regulatory review and recommending the reconsideration of existing rules looking toward the repeal of unnecessary regulations).

⁹ See, e.g., Exec. Order No. 13,579, 76 FR 41,587 (July 14, 2011) (stating that independent regulatory agencies “should promote” the goal, articulated in EO 13,563, of producing a “regulatory system that protects public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation” and “should comply” with the provisions in EO 13,563

Continued

¹ See Office of Management and Budget, Circular A–4 (Sept. 17, 2003), available at http://www.whitehouse.gov/omb/circulars_a004_a-4/

independent regulatory agencies are subject to certain crosscutting statutes that may require some type of regulatory analysis, such as the Regulatory Flexibility Act¹⁰ and the Paperwork Reduction Act.¹¹ In addition, some independent regulatory agencies' organic acts or other statutes require them to conduct benefit-cost analyses or to consider certain economic effects of their regulations, although the requirements vary significantly from agency to agency. For instance, some agencies (e.g., the Consumer Product Safety Commission) are required by statute to prepare a formal regulatory analysis statement that describes expected costs and benefits prior to issuing certain rules.¹² Other agencies (e.g., the Commodity Futures Trading Commission (CFTC) and the Securities and Exchange Commission (SEC)) are required by statute to "consider" costs and benefits or other factors associated with some of their rules.¹³ Still other agencies (e.g., the Federal Communications Commission and the Nuclear Regulatory Commission) are not subject to any formal regulatory analysis requirements for most of their rules.

The Administrative Conference believes that it is in the interest of the independent regulatory agencies, the executive branch, Congress, the courts, and the public that independent regulatory agencies' current practices relating to benefit-cost analysis be documented. In this light, the report supporting the recommendation examined efforts by independent regulatory agencies to analyze regulatory benefits and costs in recent major rules.¹⁴ It also examined whether the agencies factor benefits and costs into their decisionmaking. The report indicated that, in many instances, independent regulatory agencies quantify at least some of the costs (and, to a lesser extent, the benefits) created by the major rules they adopt and, in other instances, such agencies usually provide at least qualitative descriptions of the associated benefits and costs. The report also discusses several factors that the agencies said affected their ability to quantify and monetize regulatory costs and benefits. For example, several agencies mentioned the Paperwork Reduction Act approval process as inhibiting their ability to gather the data needed to prepare regulatory analyses in a timely fashion.¹⁵

regarding public participation, integration and innovation, flexible approaches, and science "[t]o the extent permitted by law").

¹⁰ 5 U.S.C. 601–12.

¹¹ 44 U.S.C. 3501–21.

¹² 15 U.S.C. 2058(f).

¹³ CFTC is required to "consider the costs and benefits" of the agency's action before issuing certain rules and orders. 7 U.S.C. 19(a). The SEC is required, when it is engaged in rulemaking under certain statutory provisions, to "consider, in addition to the protection of investors, whether the action will promote efficiency, competition, and capital formation." 15 U.S.C. 77b(b). Interpretation of these provisions has been a matter of debate.

¹⁴ See Curtis W. Copeland, *Economic Analysis and Independent Regulatory Agencies* 60–107 (Mar. 29, 2013), available at <http://acus.gov/sites/default/files/documents/Copeland%20CBA%20Report%203-29-13.pdf>.

¹⁵ Cf. Administrative Conference of the United States, Recommendation 2012–4, *Paperwork*

This recommendation encourages agencies to voluntarily adopt certain practices that some independent regulatory agencies (and other agencies) have developed when conducting regulatory analyses for major rules. The Conference recognizes that increasing the attention paid to the economic impact of proposed and final rules might well require substantial use of limited agency resources. This might require independent agencies to make significant tradeoffs among competing priorities and may delay the rulemaking process. Nevertheless, some independent regulatory agencies are already subject to benefit-cost and other types of regulatory analysis requirements, and others have voluntarily conducted such analyses, and the Conference therefore wishes to highlight innovative practices undertaken by these agencies.¹⁶

The recommendation, first, identifies various policies and practices used in several of the independent regulatory agencies and offers a series of proposals to encourage their use in other agencies. For example, it recommends that each independent regulatory agency develop written guidance on the preparation of benefit-cost and other types of regulatory analyses. Such guidance should be designed to help ensure that any regulatory analysis the agency undertakes is soundly developed, transparent, consistently conducted, and contributes to agency compliance with applicable statutes and other rulemaking requirements. Second, the recommendation highlights a series of analytical practices that OMB Circular A–4 recommends to Cabinet departments and other executive agencies for their major rules, and the recommendation encourages independent regulatory agencies to consider whether those practices may be useful in the development of their major rules. For example, it recommends that agencies' analyses be as transparent and reproducible as practicable, subject to the limitations of law and applicable policies (including preventing the disclosure of proprietary information or trade secrets, or other confidential information). The recommendation does not seek to establish a one-size-fits-all approach to regulatory analysis, and recognizes that each agency must tailor the analyses it conducts to accord with relevant statutory requirements, its own regulatory priorities, and the potential impact of the analysis on regulatory decisionmaking to ensure proper use of limited agency resources. Finally, the recommendation proposes that, to the extent Congress decides to impose or endorse new regulatory analysis requirements on independent regulatory agencies, Congress should consider giving those agencies the discretion to scale the analyses to the significance of the rules, and should consider the agency resources needed to satisfy such requirements.¹⁷

Reduction Act, ¶ 3, 77 FR 47800, 47808 (Aug. 10, 2012) (recommending that agencies "use all available processes for OMB approval for information gathering").

¹⁶ See, e.g., Copeland, *supra* note 14, at 99 (describing the Federal Communications Commission's increased usage of benefit-cost analysis in light of EO 13,579).

¹⁷ Between January 2007 and December 2012, federal agencies published 19,246 final rules, of

Recommendation

Encouraging the Diffusion of Certain Policies and Practices

1. Each independent regulatory agency should develop and keep up to date written guidance regarding the preparation of benefit-cost and other types of regulatory analyses. That guidance should be tailored to the agency's particular statutory and regulatory environment. To accomplish this goal, independent regulatory agencies may choose whether or not to adopt or adapt the regulatory analysis practices described in OMB Circular A–4 or any successor government-wide guidance.

2. If an independent regulatory agency prepares a regulatory analysis for a proposed or final rule, the analysis should be developed as early in the rulemaking process as reasonably practical. Once prepared, the analysis may need to be updated as the agency becomes aware of new information that may affect the rulemaking, or if changes are made to the substance of the rule.

3. If an independent regulatory agency determines that additional analytical expertise or experience may be helpful to prepare a regulatory analysis (e.g., determining how certain costs or benefits could be quantified or monetized), it should, to the extent appropriate, consult with other governmental entities with expertise in this area.

4. Consistent with applicable laws and the procedures and flexibilities permitted in the Paperwork Reduction Act, independent regulatory agencies and OIRA should facilitate the timely collection of information necessary to develop the agencies' regulatory analyses.

Recommended Practices for Major Rules

5. Independent regulatory agencies should consider the appropriateness of the analytical guidance provided in OMB Circular A–4 when developing regulatory analyses for major rules. They should consider structuring their analyses of those rules in terms of three general principles: (a) Identify the need for the regulation; (b) examine plausible alternative regulatory approaches; and (c) estimate, to the extent possible, the benefits and costs of the proposed rule and the primary alternatives.

6. Consistent with applicable laws and agency resources, independent regulatory agencies should consider including in their regulatory analyses assessments of the impact of not only those actions that are within the agency's statutory discretion but also of those actions that are statutorily mandated. Agencies should consider showing the effects of both types of actions in order to improve regulatory transparency.

7. Subject to the limitations of law and applicable policies, independent regulatory agencies' regulatory analyses should be as

which 485 were considered "major" rules. See Copeland, *supra* note 14, at Table 1. Expanding the rules on which regulatory analysis is required from "economically significant" or "major" rules to rules considered "significant" under EO 12,866 would likely quintuple the number of analyses required. See <http://www.reginfo.gov/public/do/eoCountsSearch> for data on this issue.

transparent and reproducible as practicable. In particular, agencies should consider disclosing how the analyses were conducted, posting the analyses on their Web sites and other appropriate online fora, and summarizing the methods and results in the preambles of the notice of proposed rulemaking and the final rule.

8. Independent regulatory agencies should consider including in the preambles of the notice of proposed rulemaking and the final rule a summary statement or table concisely showing the agencies' overall estimates of the expected total benefits, costs, and transfer payments of regulatory actions and the primary alternatives, including any benefits or costs that could not be quantified or monetized.

Recommendations to Congress

9. If Congress decides to establish or endorse new requirements that independent regulatory agencies prepare benefit-cost analyses of their proposed or final rules, it should recognize that agencies need (a) the flexibility to scale the analyses to the significance of the rules and (b) the resources to satisfy such requirements.

Administrative Conference Recommendation 2013-3

Science in the Administrative Process

Adopted June 14, 2013

Over the last three decades, several authorities made recommendations for improving transparency in the use of science¹ in the administrative process.² Partially in response to these recommendations, the executive branch and Congress have made a number of reforms to the scientific process undergirding agency decisionmaking. In 2009, President Obama issued a memorandum directing that, "[t]o the extent permitted by law, there should be transparency in the preparation, identification, and use of scientific and technological information in policymaking."³ "Each agency should [also]

have appropriate rules and procedures to ensure the integrity of the scientific process within the agency."⁴ The Office of Science and Technology Policy (OSTP) elaborated upon this memorandum in 2010, instructing agencies to "communicate scientific and technological findings by including a clear explication of underlying assumptions; accurate contextualization of uncertainties; and a description of the probabilities associated with both optimistic and pessimistic projections."⁵

At base, these initiatives demand heightened transparency of agencies' use of science as a central means of ensuring the basic accountability of agency regulation. If an agency identifies the role that scientific information plays in its ultimate decision and explains how it ensured that its scientific analysis was rigorous, then the public has a basis against which it can evaluate both the scientific and policy judgments underlying the agency's decision. This transparency allows those outside the agency to assess whether the agency's policy decision comports with the authorizing law and the scientific record. A transparent decisionmaking process also advances other institutional and scientific goals, such as identifying promising areas for future research and serving as a bulwark against misuse of science for political ends.⁶

Despite these important initiatives, a study commissioned by the Administrative Conference⁷ (and public meetings that considered questions it raised) revealed that agency decisionmaking processes would benefit from further improvements. Drawing on this learning, the recommendation offers several proposals for enhancing the transparency of agencies' use of science. At the same time, the Conference recognizes that agencies' abilities to implement this recommendation may be affected by resource limitations.

First, the recommendation highlights a number of innovative practices undertaken by different federal agencies to enhance the transparency of their scientific decisionmaking processes. As a general matter, agencies should articulate the specific questions to be informed by scientific information, specify study designs for new research, and establish criteria for weighing existing studies.⁸ Agencies should identify

scientific reports or data upon which they relied and material literature that they considered, but upon which they did not rely, to the extent practicable and permitted by law.⁹ Agencies should establish checkpoints (i.e., times for closing off consideration of additional research or debate prior to making a final regulatory decision) and policies for reopening that consideration. Agencies should also consider extending attribution to individual staff who participate in the preparation of scientific reports and taking other steps to promote robust debate among agency scientists.¹⁰ In addition, agencies should share best practices with other agencies and should recommend the removal of any legal impediments to

Risk Assessment in the Federal Government: Managing the Process 7 (1983).

⁹ See Administrative Conference of the United States, Recommendation 2011-1, *Legal Considerations in E-Rulemaking*, ¶ 4, 76 FR 48789, 48789 (Aug. 9, 2011); see also Exec. Order No. 13,642, *Making Open and Machine Readable the New Default for Government Information*, 78 FR 28111 (May 14, 2013); Memorandum from John P. Holdren, Director of the Office of Science and Technology Policy, to the Heads of Executive Departments and Agencies on Increasing Access to the Results of Federally Funded Research (Feb. 22, 2013) (calling for agency plans to permit public access to research papers funded in whole or in part with federal monies). As a general matter, the agency should make publicly available any scientific literature it considered, including literature it reviewed but upon which it ultimately did not rely. For purposes of the recommendation, literature that an agency "considered" includes not only any study an agency official relied upon but also any study an agency official reviewed but ultimately determined not to rely upon (because it was deemed to be outside the scope of the scientific study at hand, was not considered sufficiently reliable, or was otherwise rejected by the agency official). Cf. Administrative Conference of the United States, Recommendation 2013-4, *The Administrative Record in Informal Rulemaking*, — FR — (providing a similar definition of "consider" in the context of the administrative record in informal rulemaking). If an agency official merely had access to a study but did not specifically analyze it to determine its relevance, that study has not been "considered" within the meaning of the recommendation for purposes of making such literature publicly available.

¹⁰ In response to President Obama's call for agencies to develop "appropriate rules and procedures to ensure the integrity of the scientific process," Obama Scientific Integrity Memo, *supra* note 3, a number of agencies have promulgated integrity policies to promote open debate among agency scientists. See, e.g., Env't Prot. Agency, Scientific Integrity Policy (Feb. 2012), available at http://epa.gov/osa/pdfs/epa_scientific_integrity_policy_20120115.pdf; Food and Drug Admin., Scientific Integrity at FDA, FDA Staff Manual Guides, Volume IV—Agency Program Directives 2 (2012), available at <http://www.fda.gov/ScienceResearch/AboutScienceResearchatFDA/ucm306446.htm>; Nat'l Oceanic and Atmospheric Admin., Scientific Integrity (Dec. 7, 2011), available at http://www.corporateservices.noaa.gov/ames/administrative_orders/chapter_202/202-735-D.pdf; Nuclear Regulatory Comm'n, Collaborative Work Environment Program, <http://www.nrc.gov/about-nrc/values.html#open> (last updated May 4, 2012); see also Francesca T. Grifo, Federal Agency Scientific Integrity Policies: A Comparative Analysis (Mar. 2013), http://www.ucsusa.org/assets/documents/scientific_integrity/SL-policies-comparative-analysis.pdf.

¹ The scope of this recommendation is limited to the "natural sciences" (e.g., chemistry, physics, medical science, geology, etc.), mathematics, statistics, computer science, and other allied fields. It is based upon a report that deals with agency research and decisionmaking related to the natural sciences. Wendy Wagner, Science in Regulation: A Study of Agency Decisionmaking Approaches (Feb. 18, 2013), available at http://www.acus.gov/sites/default/files/documents/Science%20in%20Regulation_Final%20Report_2_18_13_0.pdf.

² See e.g. Nat'l Research Council, Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde (2011); Comm. on Risk Assessment of Hazardous Air Pollutants, Nat'l Research Council, Science and Judgment in Risk Assessment (1994); Nat'l Research Council, Risk Assessment in the Federal Government: Managing the Process (1983); Bipartisan Policy Ctr., Improving the Use of Science in Regulatory Policy 16, 41-42 (2009) [hereinafter "BPC Report"]; see also Ctr. for Effective Gov't, Advancing the Public Interest through Regulatory Reform: Recommendations for President-Elect Obama and the 111th Congress 26, 34, 47 (2008).

³ Memorandum from the Admin. of Barack H. Obama for the Heads of Executive Departments and Agencies on Scientific Integrity, Daily Comp. Pres. Docs., 2009 DCPD No. 00137 (Mar. 9, 2009)

[hereinafter "Obama Scientific Integrity Memo"], available at <http://www.gpo.gov/fdsys/pkg/DCPD-200900137/pdf/DCPD-200900137.pdf>.

⁴ Id.

⁵ Memorandum from John P. Holdren, Director of the Office of Science and Technology Policy, to the Heads of Executive Departments and Agencies on Scientific Integrity (Dec. 17, 2010), available at <http://www.whitehouse.gov/sites/default/files/microsites/ostp/scientific-integrity-memo-12172010.pdf>. To effectuate this and a number of other responsibilities, agencies were asked to report back to OSTP on the actions taken to develop and implement their scientific integrity policies by April 2011.

⁶ BPC Report, *supra* note 2, at 3.

⁷ Wagner, *supra* note 1.

⁸ In so doing, agencies should endeavor to explain the relationship between scientific research and the policy decisions the research is intended to inform. Nat'l Research Council, Comm. on the Institutional Means for Assessment of Risks to Public Health,

promoting transparency in decisions in which science is an important element.¹¹

Second, the recommendation offers a series of proposals to bring greater congruity to the treatment of publicly and privately funded scientific research. Specifically, it encourages the disclosure of data underlying scientific research, including both privately funded and federally funded research, that an agency is considering (to the extent practicable and permitted by law).¹² Similarly, it recommends extending conflict of interest disclosure norms to private parties who submit studies used by an agency.

Recommendation

Suggested Agency Practices Regarding the Use of Science in the Administrative Process

1. Explaining Agency Scientific Decisionmaking. Agencies should explain in proposed and final decision documents how they ensured rigorous review of the scientific information underlying each science-intensive regulatory project. This includes a statement of how each agency evaluated the scientific information used in its analysis; how the agency made that information available to reviewers and the public; how the analysis was reviewed by experts and interested parties; and how the agency ensured that the final decision was supported by the scientific record.

2. Assuring Transparent Assessments. At an early stage in their decisionmaking processes, agencies should identify the specific policy questions that may be informed by science; describe the design of the assessments needed to characterize risks and inform policy decisions; and describe the criteria to be used in reviewing and weighing existing studies. When completed, assessments should: identify other appropriate analytical choices and explain why they were not chosen; provide a synthesis of the available evidence and relevant literature guided by the assessment design or criteria; identify significant assumptions and choices of analytical techniques; provide a statement of remaining uncertainties; and discuss how different plausible choices might change the results of the assessment. Where possible, agencies should also explain the relationship between their scientific findings and the final policy choice. Agencies should strive to communicate this information in a manner that is clear to the general public.

3. Disclosing Underlying Studies and Data. To the extent practicable and permitted by law and applicable policies, each agency should identify and make publicly available (on the agency Web site or some other widely available forum) references to the scientific literature, underlying data, models, and research results that it considered. In so

doing, the agency should list all information upon which it relied in reaching its conclusions, as well as any information material to the scientific analysis that it considered but upon which it ultimately did not rely. Consistent with the limitations in the Information Quality Act (IQA) guidelines issued by the Office of Management and Budget and its own IQA guidelines, each agency should ensure that members of the public have access to the information necessary to reproduce or assess the agency's technical or scientific conclusions.

4. Checkpoints and Explanations. Agencies should consider establishing explicit checkpoints for regulatory projects, defining both the conditions under which they intend to close their consideration of research or debate in order to reach a decision and when they might reopen that consideration, particularly in cases when they are not bound by judicially enforceable deadlines. In any case, agencies should explain their decisions to initiate, stop, or reopen consideration of research or debate. Such explanations should reference significant relevant ongoing research or other relevant factors.

5. Identifying Future Projects. For science-intensive projects, agencies should identify specific types of future research that may be needed to reduce significant uncertainties in order to advance understanding of the issues.

6. Attribution for Agency Personnel. Agency personnel play an important role in producing their respective agencies' scientific analyses. Agencies should consider providing their personnel with some form of consensual attribution for reports or analyses to which they contribute in a significant way. If appropriate, such attributions should be made for personnel who contributed in a significant way to a technical or scientific report, including not only scientists but also economists, lawyers, and other contributors. Reviewers and other contributors could be identified by name and general contribution.

7. Encouraging Debate. Agencies should encourage vigorous debate among agency scientists and should explore ways of incorporating the diversity of that debate in any resulting work product. Agency employees should be encouraged to publish their scientific work in the peer reviewed literature, provided that they follow applicable agency procedures and that confidential governmental deliberations are not compromised. Dissenting staff members should be protected from reprisals.

8. Sharing of Agency Best Practices. Agencies should identify and publicize the innovations they have developed for transparently incorporating science into their regulatory decisions. OSTP, an interagency group headed by OSTP, or another body should consider occasionally convening agency representatives to discuss and share best practices.

9. Addressing Legal Obstacles to Transparent Decisionmaking. Agencies should identify legal obstacles that may impede otherwise appropriate public access to the scientific information underlying agency analyses or that may prevent the agencies' development of scientifically robust decisionmaking processes. Agencies should

recommend appropriate actions to eliminate such impediments, including revisions in existing law, to the Executive Office of the President.

Agency Disclosures To Enhance the Transparency of Research

10. Data Disclosure. To the extent practicable and in compliance with applicable legal restrictions, privileges, protections, and authorities, agencies should seek to provide disclosure of data underlying scientific research, including both privately and federally funded research being considered by the agencies. Where practicable, such information should be disclosed in machine-readable format. Where such data are not subject to legal or other protections, and the data's owners nonetheless will not provide such access, agencies should note that fact and explain why they used the results if they chose to do so. Agencies should review their confidential business information policies to ensure that they include appropriate mechanisms to prevent over-claiming.

11. Conflict of Interest Disclosure. Agencies should require conflict of interest disclosures on all scientific research submitted to inform an agency's licensing, regulatory, or other decisionmaking processes. This disclosure should be similar to the conflict of interest disclosure required by some scientific journals, such as that used by the International Committee of Medical Journal Editors. The regulatory conflict of interest disclosure should also, where permitted by law, identify whether the experimenter or author had the legal right without approval of the sponsor of the research to: design the research; collect the data; interpret the data; and author, publish or otherwise disseminate the resulting report or full dataset. To the extent that a party other than the principal investigator (e.g., the study sponsor or funder) had control over the design or publication of the study, agencies should disclose this fact and specify the nature of the control such an entity exercised.

Administrative Conference Recommendation 2013-4

The Administrative Record in Informal Rulemaking

Adopted June 14, 2013

The administrative record in informal rulemaking plays an essential role in informing the public of potential agency action and in improving the public's ability to understand and participate in agency decisionmaking. As well, the administrative record can be essential to judicial review of agency decisionmaking under the Administrative Procedure Act (APA), which directs courts to "review the whole record or those parts of it cited by a party" to determine whether challenged agency action is lawful.¹ This statutory language was originally understood as referring to formal proceedings. However, the Supreme Court has long interpreted this APA provision as also encompassing the "administrative record" in informal agency proceedings,

¹¹ See Wagner, *supra* note 1, at 135–38 (identifying a number of external legal impediments to promoting transparency, including short statutory deadlines, limits on dissemination of scientific studies, resource limitations, and caps on the number of discretionary advisory committees agencies can constitute).

¹² Legal restrictions that may limit agencies' ability to provide such disclosures include, among other things, protections for personal privacy, trade secrets, and confidential business information.

¹⁵ U.S.C. 706.

whether reviewable by statute or as final agency actions under 5 U.S.C. 704.² This application to informal proceedings has given rise to uncertainty and experimentation as agencies and courts have worked to implement the administrative record concept—at times inconsistently. As a result, confusion has arisen about the compilation and uses of agency rulemaking records maintained internally, public rulemaking dockets, and administrative records for judicial review. The differences among these three types of records can be seen from their descriptions below.

The Administrative Conference therefore commissioned a study of federal agencies' current practices in the development of rulemaking records, public rulemaking dockets, and administrative records for judicial review.³ This recommendation and the supporting report address these concepts in the context of informal agency rulemaking adopted pursuant to the notice-and-comment procedures prescribed in 5 U.S.C. 553.⁴ The recommendation does not address the record for agency decisions made in other contexts, such as in adjudication, formal rulemaking, or guidance documents.

This recommendation builds upon earlier Administrative Conference work in the areas of rulemaking, recordkeeping, and technological developments in managing records. Administrative Conference Recommendation 74–4, *Preenforcement Judicial Review of Rules of General Applicability*, identified the administrative materials that should be available to a court that was evaluating, on preenforcement review, the factual basis for agency rules of general applicability.⁵ That recommendation was receptive to judicial development of the concept of a “record” on review of informal agency rulemakings. In Recommendation 93–4, *Improving the Environment for Agency Rulemaking*, the Administrative Conference advised agencies to establish and manage rulemaking files “so that maximum disclosure to the public is achieved during the comment period and so that a usable and reliable file is available for purposes of judicial review.”⁶ A number of Administrative Conference recommendations also have examined the use of technology in acquiring, releasing, and managing agency

records.⁷ Most recently, the Conference examined legal considerations associated with the use of digital technologies in the development and implementation of informal rulemakings.⁸

This recommendation synthesizes and updates the Conference's prior recommendations in these areas. It is grounded in empirical research, supported by a survey questionnaire on present agency recordkeeping practices, as well as by a review of existing agency guidance.⁹ The Conference has identified and recommends best practices for all rulemaking agencies in the areas of record compilation, preservation, and certification. The recommendation also advises agencies to develop guidance to aid agency personnel as they compile rulemaking and administrative records and public rulemaking dockets and to increase public understanding of agency recordkeeping.

Agencies engage in informal rulemaking with differing frequencies, resources, and technological capabilities. Many agencies are in a period of transition, as they move from paper to electronic recordkeeping.¹⁰ Attention to the design of information technology resources that is mindful of the principles and best practices set forth below can aid agencies in recordkeeping, as well as facilitate greater public understanding of agency decisionmaking and more effective judicial review. For the purposes of this recommendation, the rulemaking record, public rulemaking docket, and the administrative record for judicial review are defined as follows:

“*Rulemaking record*” means the full record of materials before the agency in an informal rulemaking. The Conference contemplates that, in addition to materials required by law to be included in the rulemaking record, as well as all comments and materials submitted to the agency during comment periods, any material that the agency considered should be included as part of that record.

“*Considered*” entails review by an individual with substantive responsibilities

in connection with the rulemaking.¹¹ To say that material was considered also entails some minimum degree of attention to the contents of a document. Thus, the rulemaking record need not encompass every document that rulemaking personnel encountered while rummaging through a file drawer, but it generally should include a document that an individual with substantive responsibilities reviewed in order to evaluate its possible significance for the rulemaking, unless the review disclosed that the document was not germane to the subject matter of the rulemaking. A document should not be excluded from the rulemaking record on the basis that the reviewer disagreed with the factual or other analysis in the document, or because the agency did not or will not rely on it. Although the concept resists precise definition, the term considered as used in this recommendation should be interpreted so as to fulfill its purpose of generating a body of materials by which the rule can be evaluated and to which the agency and others may refer in the future.

“*Public rulemaking docket*” means the public version of the rulemaking record managed by the agency, regardless of location, such as online at Regulations.gov or an agency Web site or available for physical review in a docket room. The public rulemaking docket includes all information that the agency has made available for public viewing. The Conference also urges agencies to manage their public rulemaking dockets to achieve maximum disclosure to the public. However, the Conference recognizes that prudential concerns may limit agencies from displaying some information, such as certain copyrighted or indecent materials, online. It is a best practice for agencies to describe and note online those materials that are not displayed but are available for physical inspection. Another agency best practice is to include in the public rulemaking docket materials generated and considered by the agency after the close of the comment period but prior to issuance of the final rule.¹²

“*Administrative record for judicial review*” means the materials tendered by the agency and certified to a court as the record on

² *Camp v. Pitts*, 411 U.S. 138, 142 (1973); *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 419 (1971).

³ Leland E. Beck, Agency Practices and Judicial Review of Administrative Records in Informal Rulemaking (May 14, 2013) (report to the Administrative Conference of the United States) [hereinafter Beck Report].

⁴ 5 U.S.C. 553(b)–(d). It may also have application to “hybrid” rulemaking statutes that require additional procedures beyond those in § 553 but less than those in formal rulemaking under 5 U.S.C. 556–57.

⁵ Administrative Conference of the United States, Recommendation 74–4, *Preenforcement Judicial Review of Rules of General Applicability*, 39 FR 23,044 (June 26, 1974), based on consultant's report published as Paul R. Verkuil, *Judicial Review of Informal Rulemaking*, 60 Va. L. Rev. 185 (1974).

⁶ Administrative Conference of the United States, Recommendation 93–4, *Improving the Environment for Agency Rulemaking*, 59 FR 4670 (Feb. 1, 1994), correction published, 59 FR 8507 (Feb. 22, 1994).

⁷ Administrative Conference of the United States, Recommendation 2011–2, *Rulemaking Comments*, 76 FR 48,791 (Aug. 9, 2011); Administrative Conference of the United States, Recommendation 2011–1, *Legal Considerations in e-Rulemaking*, 76 FR 48,789 (Aug. 9, 2011); Administrative Conference of the United States, Recommendation 90–5, *Federal Agency Electronic Records Management and Archives*, 55 FR 53270 (Dec. 28, 1990); Administrative Conference of the United States, Recommendation 88–10, *Federal Agency Use of Computers in Acquiring and Releasing Information*, 54 FR 5209 (Feb. 2, 1989).

⁸ Recommendation 2011–1, *supra* note 7.

⁹ Beck Report, *supra* note 3, at Section III.

¹⁰ The Office of Management and Budget and the National Archives have directed federal agencies to manage all permanent electronic records in an electronic format to the fullest extent possible by December 31, 2019, and to develop plans to do so by December 31, 2013. Memorandum from Jeffrey D. Zients, Acting Director, Office of Management and Budget, and David S. Ferriero, Archivist of the United States, National Archives and Records Administration, to the Heads of Executive Departments and Agencies and Independent Agencies concerning “Managing Government Records Directive” M–12–18 (Aug. 24, 2012).

¹¹ The Conference first recommended inclusion of materials “considered” by the agency in the administrative record for judicial review in Recommendation 74–4, *supra* note 5. Courts have also relied on the concept of consideration in defining the administrative record. *Pac. Shores Subdiv., Cal. Water Dist. v. U.S. Army Corps of Engineers*, 448 F. Supp. 2d 1, 4 (D.D.C. 2006) (citations omitted); see also *Nat'l Ass'n of Chain Drug Stores v. U.S. Dep't of Health & Human Servs.*, 631 F. Supp. 2d 23, 26 (D.D.C. 2009) (citing Recommendation 74–4 in defining the administrative record); cf. *Sierra Club v. Costle*, 657 F.2d 298, 394 n. 469 (D.C. Cir. 1981) (discussing Recommendation 74–4 as an approach to defining the administrative record).

¹² The present recommendation is not limited to disclosures that the APA, as construed in widely followed case law, may require. See *Ass'n of Data Processing Serv. Orgs. v. Bd. of Governors*, 745 F.2d 677, 684 (D.C. Cir. 1984) (“[A]t least the most critical factual material that is used to support the agency's position on review must have been made public in the proceeding. . . .”). However, this case law gives agencies an additional reason to provide public disclosure of factual material in some circumstances.

review of the agency's regulatory action. The administrative record provided to the court will include an affidavit, made by a certifying official, attesting to the contents and accuracy of the record being certified.¹³ It should also include an index itemizing the contents.¹⁴ Parties often rely on this index in designating portions of the administrative record for judicial review, such as for inclusion in a joint appendix that will be presented to the court. The designated portions of the administrative record then typically serve as the basis for the court's review, as provided in the Administrative Procedure Act and as appropriate under the rules of the reviewing court.¹⁵

Some materials in an agency's rulemaking record may be protected from public disclosure by law or withheld from the public on the basis of agency privilege. For example, protected materials might include classified information, confidential supervisory or business information, or trade secrets. Other materials might be withheld on the basis of privilege, including attorney-client privilege, the attorney work product privilege, and the pre-decisional deliberative process privilege. Agency practices regarding the identification or inclusion of protected or privileged materials in administrative records and their accompanying indices vary.¹⁶ Some agencies do not include or identify deliberative or privileged materials in administrative records for judicial review.¹⁷ Other agencies identify non-disclosed materials specifically in a privilege log provided with the index of the administrative record for judicial review. Agencies have also noted redactions of protected materials in the administrative record for judicial review and moved the court to permit filing of protected materials, or a summary thereof, under seal. Many agencies do not have a policy on inclusion of protected or privileged materials in an administrative record for judicial review and manage such materials on a case-by-case basis. Case-by-case consideration may occasionally be necessary, such as when privileged materials are referenced as the basis of the agency's decision. Nonetheless, the Conference recommends that agencies develop a written policy for treatment of protected or privileged materials, including indexing, in public rulemaking dockets and in certification of the administrative record for judicial review, and that agencies make this policy publicly available.

Compilation and preparation of the administrative record for judicial review is

properly within the province of the agency and this process should be accorded a presumption of regularity by the reviewing court.¹⁸ Completion or supplementation of the administrative record for judicial review may be appropriate where a strong showing has been made to overcome the presumption of regularity in compilation. For example, courts have permitted limited discovery on the basis of a "strong showing of bad faith or improper behavior" on the part of the agency decisionmaker.¹⁹ Courts may also inquire into allegations that the agency omitted information from the administrative record for judicial review that should have been included.²⁰

Completion or supplementation of the administrative record for judicial review may also be appropriate in other circumstances not addressed in this recommendation. In a previous recommendation, the Conference has recognized that the reviewing court should not invariably be confined to the record on review in evaluating the factual basis of a generally applicable rule on preenforcement review.²¹ The Conference has also acknowledged that, on direct review by courts of appeals, the record on review "can usually be supplemented, if necessary, by means other than an evidentiary trial in a district court."²²

Recommendation

Record Contents

1. *The Rulemaking Record.* In the absence of a specific statutory requirement to the contrary, the agency rulemaking record in an informal rulemaking proceeding should include:

- (a) Notices pertaining to the rulemaking;
- (b) comments and other materials submitted to the agency related to the rulemaking;
- (c) transcripts or recordings, if any, of oral presentations made in the course of a rulemaking;
- (d) reports or recommendations of any relevant advisory committees;
- (e) other materials required by statute, executive order, or agency rule to be considered or to be made public in connection with the rulemaking; and

¹⁸ See *Citizens for Alternatives to Radioactive Dumping v. U.S. Dep't of Energy*, 485 F.3d 1091, 1097 (10th Cir. 1985) ("... designation of the Administrative Record, like any established administrative procedure, is entitled to a presumption of administrative regularity.") (citation omitted); *Amfac Resorts, LLC v. U.S. Dep't of Interior*, 143 F.Supp. 2d 7, 12 (D.D.C. 2001); see also *United States v. Chem. Found., Inc.*, 272 U.S. 1, 14–15 (1926) ("The presumption of regularity supports the official acts of public officers and, in the absence of clear evidence to the contrary, courts presume that they have properly discharged their official duties.").

¹⁹ *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 420 (1971).

²⁰ See, e.g., *Cape Cod Hospital v. Sebelius*, 630 F.3d 203, 211–12 (D.C. Cir. 2011); *Ad Hoc Metals Coalition v. Whitman*, 227 F. Supp. 2d 134, 139–40 (D.D.C. 2002).

²¹ Recommendation 74–4, *supra* note 5.

²² Administrative Conference of the United States, Recommendation 75–3, *The Choice of Forum for Judicial Review of Administrative Action* ¶ 5(a), 40 FR 27926 (July 2, 1975).

(f) any other materials considered by the agency during the course of the rulemaking.

2. *The Public Rulemaking Docket.*

Agencies should manage their public rulemaking dockets to achieve maximum public disclosure. Insofar as feasible, the public rulemaking docket should include all materials in the rulemaking record, subject to legal limitations on disclosure, any claims of privilege, or any exclusions allowed by law that the agency chooses to invoke. In addition, it may be prudent not to include some sensitive information online and to note instead that this material is available for physical review in a reading room.

3. *The Administrative Record for Judicial Review.* The administrative record provided to the court on judicial review of informal rulemaking should contain all of the materials in the rulemaking record as set forth in paragraph 1, except that agencies need not include materials protected from disclosure by law nor materials that the agency has determined are subject to withholding based on appropriate legal standards, including privilege.

Rulemaking Recordkeeping

4. Agencies should begin compiling rulemaking records no later than the date on which an agency publishes the notice of proposed rulemaking. Agencies should include materials considered in preparation of the notice of proposed rulemaking. For example, agencies should include materials received in response to an advance notice of proposed rulemaking or a notice of inquiry, if there is one, and considered in development of the proposed rule. The agency should continue compiling the rulemaking record as long as the rule is pending before the agency.

5. Agencies should designate one or more custodians for rulemaking recordkeeping, either on a rulemaking-by-rulemaking basis or generally. Agencies should inform agency personnel of the custodian(s) and direct them to deposit rulemaking record materials with the custodian(s), excepting if necessary confidential information to which access is restricted. The custodian(s) should document the record compilation process.

Public Rulemaking Dockets

6. To the extent practicable, agencies should index public rulemaking dockets for informal rulemaking, at an appropriate level of detail.

Record Preservation

7. The National Archives and Records Administration (NARA) should amend its agency guidance to address the official status and legal value of records relating to informal rulemaking, particularly administrative records for judicial review.

8. Agencies using electronic records management systems to manage rulemaking records, such as the Federal Document Management System or agency specific systems, should work with NARA to ensure the adequacy of such systems for recordkeeping purposes and the transfer to the National Archives of permanent records. Agencies should review their records schedules in light of developments in electronic records management.

¹³ *Beck Report*, *supra* note 3, at Section IV.A.

¹⁴ *Id.*

¹⁵ 5 U.S.C. 706 ("... the court shall review the whole record or those parts of it cited by a party. . . .").

¹⁶ The variety of agency practices is described at length in the *Beck Report*, *supra* note 3, at Section IV.A.

¹⁷ Absent a showing of bad faith or improper behavior, the agency practice of excluding pre-decisional materials from the administrative record on judicial review enjoys substantial judicial support. See *In re Subpoena Duces Tecum Served on Office of Comptroller of Currency*, 156 F.3d 1279 (D.C. Cir. 1998); *San Luis Obispo Mothers for Peace v. Nuclear Regulatory Comm'n*, 789 F.2d 26, 44–45 (D.C. Cir. 1986) (en banc).

Certification of Administrative Records for Judicial Review

9. Agencies should develop procedures for designating appropriate individuals, who may or may not be record custodians, to certify administrative records to the court in case of judicial review of agency action. Agency certifications should include an index of contents of the administrative record for judicial review.

Agency Record Policies and Guidance

10. Agencies should develop a general policy regarding treatment of protected or privileged materials, including indexing, in public rulemaking dockets and in certification of the administrative record for judicial review. Agencies should make this policy available to the public and should provide it to the Department of Justice, if the Department represents the agency in litigation.

11. Agencies that engage in informal rulemaking should issue guidance to aid personnel in implementing the above best practices. Agencies should make their guidance on informal rulemaking and administrative recordkeeping available to the public and should provide it to the Department of Justice, if the Department represents the agency in litigation. The level of detail and contents of such guidance will vary based on factors such as: The size of typical agency rulemaking records; institutional experience, or the lack thereof, with record compilation and informal rulemaking litigation; the need for consistency across agency components in the development and maintenance of rulemaking records; and agency resources. However, agencies should ensure that guidance addresses at least the following:

- (a) Essential components of the rulemaking record, public rulemaking docket, and the administrative record for judicial review;
- (b) appropriate exclusions from the rulemaking record, including guidance on whether and when to exclude materials such as personal notes or draft documents;
- (c) timing of compilation and indexing practices;
- (d) management and segregation of privileged materials, e.g., attorney work product or pre-decisional deliberative materials;
- (e) management and segregation of sensitive or protected materials, e.g., copyrighted, classified, protected personal, or confidential supervisory or business information;
- (f) policies and procedures, if any, for the protection of sensitive information submitted by the public during the process of rulemaking or otherwise contained in the rulemaking record;
- (g) preservation of rulemaking and administrative records and public rulemaking dockets;
- (h) certification of the administrative record for judicial review, including the process for identifying the appropriate certifying official; and
- (i) relevant capabilities and limitations of recordkeeping tools and technologies.

Judicial Review

12. A reviewing court should afford the administrative record for judicial review a presumption of regularity.

13. In appropriate circumstances, a reviewing court should permit or require supplementation or completion of the record on review. Supplementation or completion may be appropriate when the presumption of regularity has been rebutted, such as in cases where there is a strong showing that an agency has acted improperly or in bad faith or there are credible allegations that the administrative record for judicial review is incomplete.

[FR Doc. 2013-16541 Filed 7-9-13; 8:45 am]

BILLING CODE 6110-01-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2013-0054]

Notice of Request for Extension of Approval of an Information Collection; Interstate Movement of Fruit From Hawaii

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Extension of approval of an information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to request an extension of approval of an information collection associated with the regulations for the interstate movement of fruit from Hawaii.

DATES: We will consider all comments that we receive on or before September 9, 2013.

ADDRESSES: You may submit comments by either of the following methods:

- **Federal eRulemaking Portal:** Go to <http://www.regulations.gov/#!documentDetail;D=APHIS-2013-0054-0001>.
- **Postal Mail/Commercial Delivery:** Send your comment to Docket No. APHIS-2013-0054, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road, Unit 118, Riverdale, MD 20737-1238.

Supporting documents and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2013-0054> or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m.,

Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

FOR FURTHER INFORMATION CONTACT: For information on the regulations for the interstate movement of fruit from Hawaii, contact Mr. David Lamb, Regulatory Coordination Specialist, RPM, PPQ, APHIS, 4700 River Road, Unit 133, Riverdale, MD 20737; (301) 851-2103. For copies of more detailed information on the information collection, contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 851-2908.

SUPPLEMENTARY INFORMATION:

Title: Interstate Movement of Fruit From Hawaii.

OMB Number: 0579-0331.

Type of Request: Extension of approval of an information collection.

Abstract: The Plant Protection Act (7 U.S.C. 7701 *et seq.*) authorizes the Secretary of Agriculture to restrict the importation, entry, or interstate movement of plants, plant products, and other articles to prevent the introduction of plant pests into the United States or their dissemination within the United States. The regulations in 7 CFR part 318, State of Hawaii and Territories Quarantine Notices, prohibit or restrict the interstate movement of fruits, vegetables, and other products from Hawaii, Puerto Rico, the U.S. Virgin Islands, and Guam to the continental United States to prevent the spread of plant pests or noxious weeds.

In accordance with the regulations in § 318.13-26, breadfruit, jackfruit, fresh pods of cowpea and its relatives, dragon fruit, mangosteen, moringa pods, and melon must meet certain conditions for interstate movement from Hawaii into the continental United States. These conditions involve information collection activities, including certificates and limited permits.

We are asking the Office of Management and Budget (OMB) to approve our use of these information collection activities for an additional 3 years.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our information collection. These comments will help us:

- (1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;
- (2) Evaluate the accuracy of our estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;