

**2018, 2019, and 2020 Report to Congress on
the Benefits and Costs of Federal Regulations
and Agency Compliance with the Unfunded
Mandates Reform Act**



2018, 2019, 2020

OFFICE OF MANAGEMENT AND BUDGET
OFFICE OF INFORMATION AND REGULATORY AFFAIRS

**2018, 2019, AND 2020 REPORT TO CONGRESS
ON THE BENEFITS AND COSTS OF FEDERAL REGULATIONS AND
AGENCY COMPLIANCE WITH THE UNFUNDED MANDATES REFORM ACT**

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EXECUTIVE SUMMARY

This Accounting Statement and Report, issued pursuant to the Regulatory Right-to-Know Act, presents estimates of cost and benefits from agency-reported analyses for major rules issued in Fiscal Year (FY) 2017, FY 2018, and FY 2019. It does not purport to demonstrate all costs or benefits from federal regulation; instead, the report summarizes the anticipated costs and benefits that the Regulatory Impact Analyses (RIAs) of individual final rules reported for those rules. None of these estimates reflect retrospective evaluation of their impacts. This report covers a time period that includes some regulations issued before the change in administration, and does not imply an endorsement by the current Administration of all of the assumptions made and analyses conducted at the time these regulations were finalized.

For this Report's review of the full FY 2017,¹ extending into the prior Administration, executive agencies promulgated 60 major rules, of which 26 were "transfer" rules – rules that primarily caused income or wealth transfers. Most transfer rules implement Federal budgetary programs as required or authorized by Congress, such as rules associated with the Medicare Program and the Federal Pell Grant Program. More information about the FY 2017 major rules follows:

- For 20 rules, we report the issuing agencies' quantification and monetization of both benefits and costs.
- For one rule, the issuing agency quantified and monetized only benefits.
- For ten rules, we report the issuing agencies' quantification and monetization of costs, which in some cases was only partial.
- For three rules, the issuing agencies were able to quantify and monetize neither costs nor benefits.

During FY 2018, executive agencies promulgated 32 major rules, of which 18 were transfer rules. More information about the FY 2018 major rules follows:

- For five rules, we report the issuing agencies' quantification and monetization of both benefits and costs.
- For two rules, the issuing agency quantified and monetized only benefits.
- For four rules, we report the issuing agencies' quantification and monetization of costs, which in some cases was only partial.
- For three rules, the issuing agencies were able to quantify and monetize neither costs nor benefits.

During FY 2019, executive agencies promulgated 55 major rules, over half of which were transfer rules. More information about the FY 2019 major rules follows:

¹ Fiscal years run from October 1 (of the preceding calendar year) to September 30.

- For five rules, we report the issuing agencies’ quantification and monetization of both benefits and costs.
- For one rule, the issuing agency quantified and monetized only benefits.
- For 14 rules, we report the issuing agencies’ quantification and monetization of costs, which in some cases was only partial.
- For seven rules, the issuing agencies were able to quantify and monetize neither costs nor benefits.

The historically independent regulatory agencies, whose regulations have not been previously subjected to OMB review under Executive Order 12866, issued 15 major rules in FY 2017, 11 major rules in FY 2018, and 15 major rules in FY 2019. The majority of these rules were regulations of the financial sector.

It is important to emphasize that the estimates used here have limitations. Insufficient empirical information and data is a continuing challenge to agencies when assessing the likely effects of regulation. In some cases, the quantification of various effects may be speculative and may not be complete. For example, the value of particular categories of benefits (such as protection of homeland security or personal privacy) may be sizable but quantification can present significant challenges. In spite of these difficulties, careful consideration of currently-available data and methods for assessing costs and benefits is best understood as a pragmatic way of providing insights regarding the prospects for individual regulations to improve social welfare.

Chapter I summarizes the benefits and costs of major Federal regulations issued in FY 2017, FY 2018, and FY 2019. Chapter II discusses regulatory impacts on State, local, and tribal governments, small business, wages, and economic growth. Chapter III provides recommendations for reform—including in relation to Executive Order 13891, “Promoting the Rule of Law Through Improved Agency Guidance Documents,” which reiterates long-standing principles regarding agency use of guidance documents and sets forth concrete new requirements designed to enhance transparency and facilitate public input. Chapter IV provides an update on the implementation of OMB’s Information Quality initiatives.

This Report is being issued along with OMB’s Annual Report to Congress on Agency Compliance with the Unfunded Mandates Reform Act of 1995.² OMB reports on agency compliance with Title II of UMRA, which generally requires that each agency conduct a cost-benefit analysis, identify and consider a reasonable number of regulatory alternatives, and select the least costly, most cost-effective, or least burdensome alternative that achieves the objectives of the rule before promulgating any proposed or final rule that includes a Federal mandate that may result in expenditures of more than \$100 million (adjusted for inflation) in at least one year by State, local, and tribal governments, or by the private sector. Each agency must also seek input from State, local, and tribal governments.

OMB regularly reassesses and welcomes feedback on how best to provide the information required by law in this Report as well as recommendations for, or information on,

² 2 U.S.C. § 1538.

deregulatory opportunities in sectors, trading relationships, or other situations where multiple agencies share regulatory jurisdiction as outlined in Chapter III. New circumstances provide an opportunity to take a fresh look at how analyses are conducted, and whether OMB is providing the public with the optimal level and scope of information, given the status of the final rules covered in this Report. For example, OMB is sharing data in this report via electronic spreadsheets to allow the public to better use and analyze the information.³

³ As discussed in more detail below, the spreadsheets—available on the White House website and in this Report’s docket at www.regulations.gov—may facilitate calculation of impact subtotals that potentially hold interest for various readers.

**PART I: 2018, 2019, AND 2020 REPORT
TO CONGRESS ON THE BENEFITS AND
COSTS OF FEDERAL REGULATIONS**

Chapter I: The Benefits and Costs of Federal Regulations

The Regulatory Right-to-Know Act calls for the Office of Management and Budget (OMB) to submit to Congress each year “an accounting statement and associated report” including:

- (A) an estimate of the total annual costs and benefits (including quantifiable and nonquantifiable effects) of Federal rules and paperwork, to the extent feasible:
 - (1) in the aggregate;
 - (2) by agency and agency program; and
 - (3) by major rule;
- (B) an analysis of impacts of Federal regulation on State, local, and tribal government, small business, wages, and economic growth; and
- (C) recommendations for reform.⁴

The Regulatory Right-to-Know Act does not define “major rule.” For the purposes of this Report, we define major rules to include all final rules promulgated by an Executive Branch agency that meet at least one of the following three conditions:

- Rules designated as major under 5 U.S.C. § 804(2);⁵
- Rules designated as meeting the analysis threshold under the Unfunded Mandates Reform Act of 1995 (UMRA);⁶ or
- Rules designated as “economically significant” under § 3(f)(1) of Executive Order 12866.⁷

⁴ 31 U.S.C. § 1105 note. The Regulatory Right-to-Know Act was enacted as part of the of Treasury and General Government Appropriations Act, 2001, Pub. L. No. 106-554 (2000), *available at* <https://www.govinfo.gov/content/pkg/PLAW-106publ554/html/PLAW-106publ554.htm>.

⁵ A major rule is defined in Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 as a rule that has resulted in or is likely to result in: “(A) an annual effect on the economy of \$100,000,000 or more; (B) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or (C) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.” 5 U.S.C. § 804(2). Under the statute, agencies submit a report to each House of Congress and GAO and make available “a complete copy of the cost-benefit analysis of the rule, if any.” *Id.* § 801(a)(1)(B)(i). See also footnote 23 of OMB M-19-14 “Guidance on Compliance with the Congressional Review Act,” *available at* <https://www.whitehouse.gov/wp-content/uploads/2019/04/M-19-14.pdf#page=6>.

⁶ Generally, a written statement containing a qualitative and quantitative assessment of the anticipated benefits and costs of the Federal mandate is required under section 202(a) of the Unfunded Mandates Reform Act of 1995 for all rules that include a Federal mandate that may result in: “the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” 2 U.S.C. § 1532(a).

⁷ A regulatory action is considered “economically significant” under § 3(f)(1) of Executive Order 12866 if it is likely to result in a rule that may have “an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities.”

As has been the practice for many years, all estimates presented in this chapter are agency estimates of benefits and costs, or minor modifications of agency information prepared by OMB.⁸ This chapter also includes a discussion of major rules issued by independent regulatory agencies, although OMB does not review these rules under Executive Order 12866.⁹ This discussion is based solely on data provided by these agencies to the Government Accountability Office (GAO) and OMB under the Congressional Review Act.¹⁰

As in previous reports, we have adjusted estimates to 2001 dollars (2001\$), the requested format in OMB Circular A-4. We also report estimates that reflect a recent annual GDP deflator.¹¹

Aggregating benefit and cost estimates of individual regulations may produce results that are neither precise nor complete, nor, in some cases, conceptually sound. Several points deserve emphasis.

1. Individual regulatory impact analyses vary in rigor and may rely on different assumptions, including baseline scenarios, methods (including models), data, and measures of welfare changes (including approximations thereof). Summing across estimates involves the aggregation of analytical results that may not be comparable.¹²
2. The benefits and costs presented as presented in this report, including the accompanying spreadsheet, are not necessarily correlated. In other words, when interpreting the meaning of these ranges, the reader should not assume that when benefits are on the low end of their range, costs will also tend to be on the low end of their range. This is because, for some rules, there are factors that affect costs that have little correlation with factors that affect benefits (and vice-versa). Accordingly, to calculate the range of net benefits (i.e., benefits minus costs), one should not simply subtract the lower bound of the benefits range from the lower bound of the

⁸ OMB used agency estimates where available. We note that those estimates were typically subject to internal review (through the interagency review process) and external review (through the public comment process). OMB did not independently estimate benefits or costs when agencies did not provide quantified estimates. We do not update or recalculate benefit and cost numbers based on current understanding of science generally and economics in particular. Please see Appendices A and C for discussion of some of the estimates appearing in this Report.

⁹ These executive orders can be found at <https://www.archives.gov/files/federal-register/executive-orders/pdf/12866.pdf> and <https://www.gpo.gov/fdsys/pkg/FR-2011-01-21/pdf/2011-1385.pdf>. Section 3(b) of Executive Order 12866 excludes “independent regulatory agencies as defined in 44 U.S.C. 3502(10)” from OMB’s regulatory review purview.

¹⁰ 5 U.S.C. 801–808.

¹¹ Unless otherwise noted, all benefit and cost estimates are adjusted to 2001 dollars using the latest Gross Domestic Product (GDP) deflator, available from the Bureau of Economic Analysis at the Department of Commerce. (See *National Income and Product Accounts*, Table 1.1.9, Implicit Price Deflators for Gross Domestic Product, available at <http://www.bea.gov>.) In instances where the nominal dollar values the agencies use for their benefits and costs is unclear, we assume the benefits and costs are presented in nominal dollar values of the year before the rule is finalized. In periods of low inflation such as the past few years, this assumption does not affect the overall totals.

¹² Please see past Reports for further discussion about lack of comparability.

cost range and similarly for the upper bound. It is possible that the true benefits are at the higher bound and that the true costs are at the lower bound, as well as vice-versa.

3. As we have noted, it is not always possible to quantify or to monetize relevant benefits or costs of rules in light of limits in existing information. For purposes of policy, non-monetized benefits and costs may be important. Some regulations have significant non-quantified or non-monetized benefits (such as protection of privacy, human dignity, and—see point 5 below—distributive impacts) that are relevant under governing statutes and that may serve as a key factor in an agency’s decision to promulgate a particular rule. (Analogously, to the extent that rules encroach upon privacy or human dignity, there may be important non-monetized costs of regulation.)
4. Prospective analyses—such as the agency RIAs that form the basis for the estimates in this Report—may overestimate or underestimate both benefits and costs; retrospective analysis can be important as a corrective mechanism.¹³ Executive Order 12866 requires, and Executive Orders 13771 and 13777 reiterate the importance of, such analysis, with the goal of improving relevant regulations through modification, streamlining, expansion, or repeal.¹⁴ The aims of retrospective analysis are to improve technical understanding, which would indirectly bolster the accuracy of prospective analysis, and to provide a basis for potentially modifying rules as a result of ex post evaluations.¹⁵ Rules should be written and designed to facilitate retrospective analysis of their effects, including consideration of the data that will be needed for future evaluation of the rules’ ex post costs and benefits.
5. OMB Circular A-4 recognizes that “those who bear the costs of regulation and those who enjoy its benefits often are not the same people.”¹⁶ In consequence, agencies are encouraged to provide separate descriptions of distributive effects. For example, some research indicates that energy efficiency regulations adversely affect lower-

¹³ See Greenstone (2009). References listed in Appendix D of this report include, in footnote citations, the author and year of publication.

¹⁴ Executive Order (EO) 13771 requires federal departments and agencies to: (1) issue two deregulatory actions for each new regulatory action; and (2) not exceed a regulatory cost allowance. OIRA issues separate annual reports on agencies’ regulatory reform results under this executive order. Links to those reports can be found at <https://www.reginfo.gov/public/do/eAgendaEO13771>. The values reported in those reports are not comparable to the values reported in this Report, including because they are associated with a different (partially overlapping) set of regulations. Additionally, this Report presents the highest-magnitude regulatory impacts—which could be transfers, benefits, or costs—whereas the EO 13771 accounting focuses on costs and savings (that is, negative costs). For example, if a regulation causes \$500 million in transfers and \$1 million in paperwork costs, the \$1 million would be tallied for EO 13771 purposes but would receive little or no attention in this Report, which would instead highlight the \$500 million transfer impact (an amount that is omitted from EO 13771 accounting). It is also worth noting that the two sets of reports may present different summary calculations, even for impacts that both qualify as costs or savings under EO 13771 and are large enough to be relevant to the major status of the rule (and thus for inclusion in this Report); the EO 13771 accounting prioritizes consistency across regulatory analyses and therefore reports the present value of costs and cost savings across a uniform perpetual time horizon, while this Report lists the cost of each rule annualized across the (typically finite) time period over which the agency chose to analyze the rule.

¹⁵ Retrospective review has shown that both costs and benefits can be overestimated or underestimated. See Harrington, Morgenstern & Nelson (2000) and Harrington (2006).

¹⁶ Office of Mgmt. & Budget, Exec. Office of the President, OMB Circular A-4, at 14 (2003), available at <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf> or <https://perma.cc/CA6P-PNUY>.

income consumers more than those who earn a higher income.¹⁷ If a regulation would disproportionately help or hurt particular groups of people, relevant law may require or authorize agencies to consider that fact. While analysis of these types of impacts is more limited, efforts to examine the distributive impacts of regulations is increasing. Additional analyses of this type could prove illuminating.¹⁸

6. The most fundamental purpose of a regulatory impact analysis is to inform policy options at the time a regulatory decision is being made; however, analytic approaches that serve this purpose may not readily lend themselves to aggregation. For example, in order to evaluate the expected costs and benefits of a regulation when it is put in place, agencies often assume there will be full compliance with the regulation. If this later turns out to be not the case and a second regulation is being contemplated to increase compliance, it would be appropriate to analyze the expected costs and benefits of the second regulation relative to the then current conditions of less-than-full compliance to determine whether that second regulation is likely to be cost-beneficial. However, summing the estimated costs and benefits of these two rules without taking account of their overlapping estimated effects would result in an overestimate of both the aggregate costs and the aggregate benefits of the two rules.¹⁹

Estimates of the Benefits and Costs of Major Rules Issued in FY 2017, FY 2018, and FY 2019

1. Major Rules Issued by Executive Departments and Agencies

In this section and in Table A-1 of each of the accompanying spreadsheets, we examine in more detail the estimated benefits and costs of the major final rules for which OMB concluded review during the 12-month periods beginning October 1, 2016, and ending September 30, 2017; beginning October 1, 2017, and ending September 30, 2018; or beginning October 1, 2018, and ending September 30, 2019.²⁰ (Note that in two of the three fiscal years covered by this Report over half of the major rules are transfer rules.²¹) Major rules represent approximately one-fourth of the final rules reviewed by OMB.²²

¹⁷ See, e.g., Levinson (2019), Jacobsen (2013), and Metcalf (2019).

¹⁸ See, e.g., Kahn (2001).

¹⁹ Although this example relates to an action meant to increase compliance with an earlier rule, the caveats associated with aggregation apply more broadly to any regulations that have interacting effects.

²⁰ Table numbers have been assigned so as to maintain consistency with analogous tables in the most recent past reports. Although these tables, along with the Report more generally, note some instances in which rules are not in effect due to being vacated or enjoined by federal courts or due to subsequent agency rulemaking, such notes are not necessarily comprehensive. Aggregating impact estimates for rules that are in effect at a particular point in time, rather than for all major rules regardless of legal status, is the type of option that we hope may be facilitated by the spreadsheet presentation of much of the Report's content.

²¹ These counts exclude rules that were withdrawn from OMB review. Also, joint rules are counted once each, even if they were submitted to OMB separately for review.

²² Counts of OMB-reviewed rules are available through the "review counts" and "search" tools on the Office of Information and Regulatory Affairs (OIRA) regulatory information website (www.reginfo.gov). We discussed the relative contribution of major rules to the total impact of Federal regulation in detail in the "response-to-comments" section on pages 26–27 of the 2004 Report. Our evaluation of a few representative agencies found that major rules

Overall, HHS promulgated the largest number of major rules in FY 2017 (eighteen), FY 2018 (fourteen), and FY 2019 (23), some of which were joint with one or more other Departments. In a typical year, at least ten HHS regulations are annual budget rules (*i.e.*, rules that involve changes in the federal government’s outlays, such as Medicare funding, or receipts, such as passport fees), largely transferring income from one group of entities to another without directly imposing significant costs on the private sector as a whole, while the others have significant direct economic impact on the private sector. Multiple major HHS rules (sometimes issued jointly with the Departments of Labor and the Treasury) were issued in accordance with the Patient Protection and Affordable Care Act; relevant RINs include 0938-AS95, 0938-AT14, 0938-AT08, 0938-AT48, 0938-AT65, 0938-AT37 and 0938-AT66.²³

The rules from FY 2017, FY 2018, and FY 2019 for which agencies estimated both monetized costs and benefits are in the spreadsheets accompanying this report, aggregated by agency in Table 1-5 and listed in Table 1-6(a). There were 20 such rules in FY 2017, 5 in FY 2018, and 5 in FY 2019. For FY 2017, the issuing agencies estimate a total of \$5.2 billion to \$8.3 billion in annual benefits and \$1.9 billion to \$2.8 billion in annual costs (in 2001\$).²⁴ For FY 2018, the issuing agencies estimate a total of \$0.1 billion to \$0.5 billion in annual benefits and \$0.0 billion to \$0.2 billion in annual costs (in 2001\$).²⁵ For FY 2019, the issuing agencies estimate a total of \$0.2 billion to \$2.6 billion in annual benefits and up to \$0.4 billion in annual costs (in 2001\$).²⁶ We emphasize an often-overlooked detail—that the totals listed in this paragraph include only the benefits and costs for the minority of rules for which both those categories of impacts were estimated.²⁷

Spreadsheet tabs containing Tables 1-6(a), 1-6(b), 1-6(c), and 1-6(d) list each of the non-“transfer” rules and, where available, provide information on their monetized benefits and costs. Table 1-6(a) lists the rules for which agencies estimated both costs and benefits, Tables 1-6(b)

represented the vast majority of the benefits and costs of all rules promulgated by these agencies and reviewed by OMB. Based on our ongoing review of rules that are and are not major, we believe this trend is still true today.

²³ In 2010, OMB issued a memorandum on “Increasing Openness in the Rulemaking Process – Use of the Regulation Identifier Number (RIN),” which is available at https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/assets/inforeg/IncreasingOpenness_04072010.pdf. The memorandum provides that agencies should use the RIN on all relevant documents throughout the entire “lifecycle” of a rule. We believe that this requirement helps members of the public to find regulatory information at each stage of the process and is promoting informed participation.

²⁴ Equivalent to \$6.9 to \$11.0 billion in annual benefits and \$2.5 to \$3.7 billion in annual costs in 2016 dollars. “Annual” costs and benefits are agency estimates annualized, generally using three and seven percent discount rates, across the time horizon over which the agency chose to analyze the rule. For discussion of the mechanics of present and annualized value calculation, please see the Regulatory Impact Analysis FAQ, available at https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/assets/OMB/circulars/a004/a-4_FAQ.pdf.

²⁵ Equivalent to \$0.2 to \$0.6 billion in annual benefits and \$0.1 to \$0.3 billion in annual costs in 2017 dollars.

²⁶ Equivalent to \$0.2 to \$3.7 billion in annual benefits and up to \$0.6 billion in annual costs in 2018 dollars.

²⁷ The spreadsheets that contain much of this Report’s content may facilitate the calculation of other aggregates that are of interest to readers. For yet another approach to aggregation—this one focused on costs and cost savings—please see the results reported in association with Executive Order 13771, available at <https://www.reginfo.gov/public/do/eAgendaEO13771>.

and 1-6(c) list the rules for which agencies at least partially estimated costs and benefits, and Table 1-6(d) lists rules for which the agencies estimated neither costs nor benefits.²⁸

Table 1-7(a) in each spreadsheet lists Federal “budget” rules and provides information on the estimated income transfers. Table 1-7(b) lists the non-budget transfer rules for FY 2017 or FY 2019 (there were no such rules issued in FY 2018); the primary economic impact of each of these rules is to cause transfers between parties outside the Federal Government, and the table includes agencies’ estimates of these transfers, if available.²⁹

Table I. Major Rules on which OMB Concluded Review in FY 2017, FY 2018 or FY 2019

<i>Agency</i>	<i>Rule Title</i>	<i>RIN</i>	<i>Year</i>
Architectural and Transportation Barriers Compliance Board	Information and Communication Technology Standards and Guidelines	3014-AA37	FY17 (2018 Report)
Office of Personnel Management	Federal Employees Health Benefits Program; Tribes and Tribal Organizations	3206-AM40	FY17 (2018 Report)
Federal Acquisition Regulation Council	Federal Acquisition Regulation (FAR); FAR Case 2017-015, Removal of Fair Pay and Safe Workplaces Rule	9000-AN52	FY17 (2018 Report)
Department of Education	Open Licensing Requirement for Direct Grant Programs	1894-AA07	FY17 (2018 Report)
Department of Education	Borrower Defense	1840-AD19	FY17 (2018 Report)
Department of Education	Title I of the Elementary and Secondary Education Act of 1965—Accountability and State Plans	1810-AB27	FY17 (2018 Report)
Department of Education	Priorities, Requirements, Definitions, and Selection Criteria—Striving Readers Comprehensive Literacy Program	1810-AB25	FY17 (2018 Report)
Department of the Treasury	Treatment of Certain Interests in Corporations	1545-BN40	FY17 (2018 Report)
Department of the Treasury	Updated Mortality Tables for Determining Present Value	1545-BM71	FY17 (2018 Report)

²⁸ In some instances, agencies have been unable to quantify the benefits and costs of rules because existing information does not permit reliable estimates. In these cases, agencies generally have followed the guidance of Circular A-4 and have provided detailed discussions of the non-quantified benefits and costs in their analysis of rules in order to help decision-makers understand the significance of these factors. We continue to work with agencies to improve the quantification of the benefits and costs of regulations and to make progress toward quantifying impacts that have thus far been discussed only qualitatively.

²⁹ We recognize that transfers change relative prices of goods and services, and hence, transfer rules may create social benefits or costs. For example, they may impose real costs on society to the extent that they cause people to change behavior, including “deadweight losses” associated with the transfer. Rules that reduce distortions may result in analogous gains. The Regulatory Right-to-Know Act requires OMB to report the costs and benefits of these rules, and OMB encourages agencies to report these costs and benefits for transfer rules; OMB will consider incorporating any such estimates into future Reports. Transfer rules can also entail direct compliance costs; where such costs have been estimated by agencies, estimates appear in the accompanying spreadsheets.

Agency	Rule Title	RIN	Year
Department of Commerce (DOC)	Setting and Adjusting Patent Fees During Fiscal Year 2017	0651-AD02	FY17 (2018 Report)
Department of the Interior (DOI)	Migratory Bird Hunting; 2017–2018 Migratory Game Bird Hunting Regulations	1018-BB40	FY17 (2018 Report)
DOI	Waste Prevention, Production Subject to Royalties, and Resource Conservation	1004-AE14	FY17 (2018 Report)
Environmental Protection Agency (EPA)	Renewable Fuel Volume Standards for 2017 and Biomass Based Diesel Volume (BBD) for 2018	2060-AS72	FY17 (2018 Report)
EPA	Accidental Release Prevention Requirements: Risk Management Programs under the Clean Air Act	2050-AG82	FY17 (2018 Report)
Department of Energy (DOE)	Energy Conservation Standards for Miscellaneous Refrigeration Products	1904-AC51	FY17 (2018 Report)
DOE	Energy Conservation Standards for Ceiling Fans	1904-AD28	FY17 (2018 Report)
DOE	Energy Conservation Standards for Central Air Conditioners and Heat Pumps	1904-AD37	FY17 (2018 Report)
DOE	Energy Conservation Standards for Dedicated-Purpose Pool Pumps	1904-AD52	FY17 (2018 Report)
DOE	Energy Conservation Standards for Walk-In Coolers and Walk-In Freezers	1904-AD59	FY17 (2018 Report)
DOE	Energy Conservation Standards for Commercial Packaged Boilers	1904-AD01	FY17 (2018 Report)
DOE	Energy Conservation Standards for Portable Air Conditioners	1904-AD02	FY17 (2018 Report)
DOE	Energy Conservation Standards for Uninterruptible Power Supplies	1904-AD69	FY17 (2018 Report)
Department of Health and Human Services (HHS)	Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; Extension of Compliance Date; Request for Comments	0910-ZA48	FY17 (2018 Report)
HHS	ONC Health IT Certification Program: Enhanced Oversight and Accountability	0955-AA00	FY17 (2018 Report)
HHS	Merit-Based Incentive Payment System (MIPS) and Alternative Payment Models (APMs) in Medicare Fee-for-Service (CMS-5517-FC)	0938-AS69	FY17 (2018 Report)
HHS	CY 2017 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; and Home Health Quality Reporting Requirements (CMS-1648-F)	0938-AS80	FY17 (2018 Report)
HHS	CY 2017 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS-1656-FC)	0938-AS82	FY17 (2018 Report)
HHS	CY 2017 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B (CMS-1654-F)	0938-AS81	FY17 (2018 Report)
HHS	Eligibility Notices, Fair Hearing and Appeal Processes for Medicaid, and Other Provisions Related to Eligibility and Enrollment for Medicaid and CHIP (CMS-2334-F2)	0938-AS27	FY17 (2018 Report)
HHS	Third Party Payments for Coverage under Qualified Health Plans (CMS-3337-P)	0938-AT11	FY17 (2018 Report)

<i>Agency</i>	<i>Rule Title</i>	<i>RIN</i>	<i>Year</i>
HHS	CY 2018 Notice of Benefit and Payment Parameters (CMS-9934-F)	0938-AS95	FY17 (2018 Report)
HHS	Medicare Program; Changes to Advancing Care Coordination through Episode Payment Models; Cardiac Rehabilitation Incentive Payment Model; and Comprehensive Care for Joint Replacement Payment Model	0938-AS90	FY17 (2018 Report)
HHS	Conditions of Participation for Home Health Agencies; Delay of Effective Date (CMS-3819-F2)	0938-AG81	FY17 (2018 Report)
HHS	The Use of New or Increased Pass-Through Payments in Medicaid Managed Care Delivery Systems (CMS-2402-F)	0938-AT10	FY17 (2018 Report)
HHS	Patient Protection and Affordable Care Act; Market Stabilization (CMS-9929-F)	0938-AT14	FY17 (2018 Report)
HHS	FY 2018 Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities (SNFs), SNF Value-Based Purchasing Program, SNF Quality Reporting Program (CMS-1679-F)	0938-AS96	FY17 (2018 Report)
HHS	FY 2018 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Requirements (CMS-1675-F)	0938-AT00	FY17 (2018 Report)
HHS	Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2018 Rates (CMS-1677-F)	0938-AS98	FY17 (2018 Report)
HHS	Federal Policy for the Protection of Human Subjects; Final Rules	0937-AA02	FY17 (2018 Report)
HHS	World Trade Center Health Program: Amendments to Definitions, Appeals, and Other Requirements	0920-AA56	FY17 (2018 Report)
Department of Veterans Affairs (VA)	Diseases Associated With Exposure to Contaminants in the Water Supply at Camp Lejeune	2900-AP66	FY17 (2018 Report)
VA	Tiered Pharmacy Copayments for Medications	2900-AP35	FY17 (2018 Report)
Department of Labor (DOL)	Walking Working Surfaces and Personal Fall Protection Systems (Slips, Trips, and Fall Prevention)	1218-AB80	FY17 (2018 Report)
DOL	Occupational Exposure to Beryllium	1218-AB76	FY17 (2018 Report)
DOL	Definition of the Term Fiduciary--Delay of Applicability Date	1210-AB79	FY17 (2018 Report)
Department of Agriculture (USDA)	Colorado Roadless Rule--North Fork Coal Mining Exception (Rule)	0596-AD26	FY17 (2018 Report)
USDA	Eligibility, Certification, and Employment and Training Provisions	0584-AD87	FY17 (2018 Report)
USDA	NOP; Organic Livestock and Poultry Practices	0581-AD44	FY17 (2018 Report)
USDA	Clarification of Scope	0580-AB25	FY17 (2018 Report)
Department of Homeland Security (DHS)	Retention of EB-1, EB-2, and EB-3 Immigrant Workers and Program Improvements Affecting Highly-Skilled H-1B Nonimmigrant Workers	1615-AC05	FY17 (2018 Report)
DHS	Definition of Form I-94 to Include Electronic Format	1651-AA96	FY17 (2018 Report)
DHS	U.S. Citizenship and Immigration Services Fee Schedule	1615-AC09	FY17 (2018 Report)
Department of Transportation (DOT)	National Goals and Performance Management Measures 3 (MAP-21)	2125-AF54	FY17 (2018 Report)

<i>Agency</i>	<i>Rule Title</i>	<i>RIN</i>	<i>Year</i>
DOT	Sound for Hybrid and Electric Vehicles	2127-AK93	FY17 (2018 Report)
DOT	Commercial Driver's License Drug and Alcohol Clearinghouse (MAP-21)	2126-AB18	FY17 (2018 Report)
DOT	Entry-Level Driver Training	2126-AB66	FY17 (2018 Report)
Department of Housing and Urban Development (HUD)	Establishing a More Effective Fair Market Rent (FMR) System; Using Small Area Fair Market Rents (SAFMRs) in Housing Choice Voucher Program Instead of the Current 50th Percentile FMRs (FR-5855)	2501-AD74	FY17 (2018 Report)
HUD	Instituting Smoke-Free Public Housing (FR-5597)	2577-AC97	FY17 (2018 Report)
HUD	Federal Housing Administration (FHA): Strengthening the Home Equity Conversion Mortgages (HECM) Program to Promote Sustained Homeownership (FR-5353)	2502-AI79	FY17 (2018 Report)
HUD	Home Equity Conversion Mortgage Program: Mortgage Insurance Premium Rates and Principal Limit Factors Mortgagee Letter	2502-ZA15	FY17 (2018 Report)
Department of Defense	TRICARE; Reimbursement of Long-Term Care Hospitals and Inpatient Rehabilitation Facilities	0720-AB47	FY18 (2019 Report)
Department of Justice (DOJ)	Implementation of the Comprehensive Addiction and Recovery Act of 2016 and the Department of Health and Human Services Regulations Relating to the Dispensing of Narcotic Drugs for Opioid Use Disorder	1117-AB42	FY18 (2019 Report)
Department of State	Schedule of Fees for Consular Services, Department of State and Overseas Embassies and Consulates—Passport and Documentary Services Fee Changes	1400-AD81	FY18 (2019 Report)
DOI	Migratory Bird Hunting; 2018–2019 Migratory Game Bird Hunting Regulations	1018-BB73	FY18 (2019 Report)
DOI	Waste Prevention, Production Subject to Royalties, and Resource Conservation; Revision or Rescission of Certain Requirements	1004-AE53	FY18 (2019 Report)
EPA	Renewable Fuel Volume Standards for 2018 and Biomass Based Diesel Volume (BBD) for 2019	2060-AT04	FY18 (2019 Report)
DOC	Setting and Adjusting Patent Fees During Fiscal Year 2017	0651-AD02	FY18 (2019 Report)
DOC	Omnibus Essential Fish Habitat Amendment 2	0648-BF82	FY18 (2019 Report)
HHS	CY 2018 Home Health Prospective Payment System Rate Update; CY 2019 Case-Mix Adjustment Methodology Refinements; Value-Based Purchasing Model; and Quality Reporting Requirements (CMS-1672-F)	0938-AT01	FY18 (2019 Report)
HHS	CY 2018 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS-1678-FC)	0938-AT03	FY18 (2019 Report)
HHS	CY 2018 Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B; Medicare Shared Savings Program Requirements; Medicare Diabetes Prevention Program (CMS-1676-F)	0938-AT02	FY18 (2019 Report)
HHS	CY 2018 Updates to the Quality Payment Program (CMS-5522-FC)	0938-AT13	FY18 (2019 Report)
HHS	Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2019 (CMS-4182-F)	0938-AT08	FY18 (2019 Report)

<i>Agency</i>	<i>Rule Title</i>	<i>RIN</i>	<i>Year</i>
HHS	CY 2019 Notice of Benefit and Payment Parameters (CMS-9930-P)	0938-AT12	FY18 (2019 Report)
HHS	Durable Medical Equipment Fee Schedule, Adjustments to Resume the Transitional 50/50 Blended Rates to Provide Relief in Non-Competitive Bidding Areas (CMS-1687-IFC)	0938-AT21	FY18 (2019 Report)
HHS	Ratification and Reissuance of the Methodology for the HHS-operated Permanent Risk Adjustment Program under the Patient Protection and Affordable Care Act (CMS-9920-F)	0938-AT65	FY18 (2019 Report)
HHS	Short-Term Limited Duration Insurance (CMS-9924-F)	0938-AT48	FY18 (2019 Report)
HHS	Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2019 (CMS-1688-F)	0938-AT25	FY18 (2019 Report)
HHS	FY 2019 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Requirements (CMS-1692-F)	0938-AT26	FY18 (2019 Report)
HHS	FY 2019 Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities (SNFs) (CMS-1696-F)	0938-AT24	FY18 (2019 Report)
HHS	Hospital Inpatient Prospective Payment System for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and FY 2019 Rates (CMS-1694-F)	0938-AT27	FY18 (2019 Report)
HHS	Food Labeling: Revision of the Nutrition and Supplement Facts Labels and Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments; Proposed Extension of Compliance Dates	0910-AH92	FY18 (2019 Report)
DOL	18-Month Extension of Transition Period and Delay of Applicability Dates; Best Interest Contract Exemption; Class Exemption for Principal Transactions; PTE 84-24	1210-ZA27	FY18 (2019 Report)
DOL	Definition of an 'Employer' Under Section 3(5) of ERISA—Association Health Plans	1210-AB85	FY18 (2019 Report)
USDA	Crops, Trees, Bushes, and Vines Assistance for Losses Due to Hurricanes and Wildfires	0560-AI39	FY18 (2019 Report)
USDA	Seed Cotton Changes to Agriculture Risk Coverage (ARC) and Price Loss Coverage (PLC) Programs, and Marketing Assistance Loans (MAL)	0560-AI40	FY18 (2019 Report)
USDA	Market Facilitation Program (MFP)	0560-AI42	FY18 (2019 Report)
USDA	Agricultural Trade Promotion Program (ATP)	0551-AA92	FY18 (2019 Report)
USDA	NOP: Organic Livestock and Poultry Practices	0581-AD75	FY18 (2019 Report)
VA	Reimbursement for Emergency Treatment	2900-AQ08	FY18 (2019 Report)
VA	Expanded Access to Non-VA Care Through the Veterans Choice Program	2900-AP60	FY18 (2019 Report)
DHS	Air Cargo Advance Screening (ACAS)	1651-AB04	FY18 (2019 Report)
Department of the Treasury	Additional First-Year Depreciation Allowance	1545-BO74	FY19 (2020 Report)
Department of the Treasury	Application of Various Provisions of Section 2711 of the Public Health Service Act, the Affordable Care Act, and the Internal Revenue Code to Health Reimbursement Arrangements	1545-BO46	FY19 (2020 Report)

Agency	Rule Title	RIN	Year
Department of the Treasury	Guidance Related to Section 951A (Global Intangible Low-Taxed Income Regulations)	1545-BO54	FY19 (2020 Report)
Department of the Treasury	State and Local Tax (SALT) Credits and Charitable Contributions	1545-BO89	FY19 (2020 Report)
Department of the Treasury	Guidance Under Section 199A	1545-BO71	FY19 (2020 Report)
Department of the Treasury	Rules Relating to Section 965 Transition Tax	1545-BO51	FY19 (2020 Report)
Department of the Treasury	Modernized Drawback	1515-AE23	FY19 (2020 Report)
Department of Education	Institutional Accountability	1840-AD26	FY19 (2020 Report)
Department of Education	Program Integrity; Gainful Employment	1840-AD31	FY19 (2020 Report)
HHS	Apprehension, Processing, Care, and Custody of Alien Minors and Unaccompanied Alien Children	0970-AC42	FY19 (2020 Report)
HHS	Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction (CMS-3346-F)	0938-AT23	FY19 (2020 Report)
HHS	Revisions to Requirements for Discharge Planning for Hospitals, Critical Access Hospitals, and Home Health Agencies (CMS-3317-F)	0938-AS59	FY19 (2020 Report)
HHS	Medicaid Disproportionate Share Hospital (DSH) Allotment Reductions (CMS-2394-F)	0938-AS63	FY19 (2020 Report)
HHS	FY 2020 Inpatient Rehabilitation Facility (IRF) Prospective Payment System Rate Update and Quality Reporting Requirements (CMS-1710-F)	0938-AT67	FY19 (2020 Report)
HHS	Medicaid Provider Payment Reassignment (CMS-2413-F)	0938-AT61	FY19 (2020 Report)
HHS	Medicare Shared Savings Program; Accountable Care Organizations (CMS-1701-F)	0938-AT45	FY19 (2020 Report)
HHS	Regulation to Require Drug Pricing Transparency (CMS-4187-F)	0938-AT87	FY19 (2020 Report)
HHS	Protecting Statutory Conscience Rights in Health Care; Delegations of Authority	0945-AA10	FY19 (2020 Report)
HHS	Program Integrity Enhancements to the Provider Enrollment Process (CMS-6058-F)	0938-AS84	FY19 (2020 Report)
HHS	CY 2019 Home Health Prospective Payment System Rate Update and CY 2020 Case-Mix Adjustment Methodology Refinements; Value-Based Purchasing Model; Quality Reporting Requirements (CMS-1689-F)	0938-AT29	FY19 (2020 Report)
HHS	Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals; the Long-Term Care Hospital Prospective Payment System; and FY 2020 Rates (CMS-1716-F)	0938-AT73	FY19 (2020 Report)
HHS	FY 2020 Hospice Wage Index, Payment Rate Update, and Quality Reporting Requirements (CMS-1714-F)	0938-AT71	FY19 (2020 Report)
HHS	FY 2020 Skilled Nursing Facility (SNFs) Prospective Payment System Rate Update and Quality Reporting Requirements (CMS-1718-F)	0938-AT75	FY19 (2020 Report)
HHS	CY 2019 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B and the Quality Payment Program (CMS-1693-F)	0938-AT31	FY19 (2020 Report)

<i>Agency</i>	<i>Rule Title</i>	<i>RIN</i>	<i>Year</i>
HHS	Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out of Pocket Expenses (CMS-4180-F)	0938-AT92	FY19 (2020 Report)
HHS	Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020 (CMS-9926-F)	0938-AT37	FY19 (2020 Report)
HHS	Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2020 (CMS-4185-F)	0938-AT59	FY19 (2020 Report)
HHS	Covered Outpatient Drug; Line Extension Definition and Delay in Including U.S. Territories in Definitions of States and U.S.; Changes to the Rebate Calculation for Line Extension Drugs (CMS-2345-F2)	0938-AT09	FY19 (2020 Report)
HHS	Patient Protection and Affordable Care Act; Adoption of the Methodology for the HHS-Operated Permanent Risk Adjustment Program for the 2018 Benefit Year Proposed Rule (CMS-9919-F)	0938-AT66	FY19 (2020 Report)
HHS	CY 2019 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS-1695-F)	0938-AT30	FY19 (2020 Report)
HHS	CY 2019 Changes to the End-Stage Renal Disease (ESRD) Prospective Payment System, Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) (CMS-1691-F)	0938-AT28	FY19 (2020 Report)
HHS	Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, Extension of Compliance Dates for Subpart E	0910-AH93	FY19 (2020 Report)
DOI	Migratory Bird Hunting; 2019–2020 Migratory Game Bird Hunting Regulations	1018-BD10	FY19 (2020 Report)
DOJ	Bump-Stock-Type Devices	1140-AA52	FY19 (2020 Report)
DOL	Defining and Delimiting the Exemptions for Executive, Administrative, Professional, Outside Sales and Computer Employees	1235-AA20	FY19 (2020 Report)
DOL	Definition of an "Employer" Under Section 3(5) of ERISA—Association Retirement Plans and Other Multiple Employer Plans	1210-AB88	FY19 (2020 Report)
USDA	Agricultural Disaster Assistance Indemnity Programs	0560-AI52	FY19 (2020 Report)
USDA	Market Facilitation Program	0560-AI51	FY19 (2020 Report)
DHS	Apprehension, Processing, Care and Custody of Alien Minors and Unaccompanied Alien Children	1653-AA75	FY19 (2020 Report)
DHS	Inadmissibility on Public Charge Grounds	1615-AA22	FY19 (2020 Report)
EPA	Review of Dust-Lead Hazard Standards and the Definition of Lead-Based Paint	2070-AJ82	FY19 (2020 Report)
EPA	Emission Guidelines for Greenhouse Gas Emissions From Existing Electric Utility Generating Units; Revisions to Emission Guideline Implementing Regulations; Revisions to New Source Review Program	2060-AT67	FY19 (2020 Report)
EPA	Renewable Fuel Volume Standards for 2019 and Biomass-Based Diesel (BBD) Volume for 2020	2060-AT93	FY19 (2020 Report)
EPA	Definition of "Waters of the United States"—Recodification of Preexisting Rule	2040-AF74	FY19 (2020 Report)
VA	Veterans Community Care Program	2900-AQ46	FY19 (2020 Report)
VA	Urgent Care	2900-AQ47	FY19 (2020 Report)

<i>Agency</i>	<i>Rule Title</i>	<i>RIN</i>	<i>Year</i>
VA	VA Claims and Appeals Modernization	2900-AQ26	FY19 (2020 Report)
VA	Economic Growth, Regulatory Relief, and Consumer Protection Act (the Act), Public Law 115-174, 132 Stat. 1296.	2900-AQ42	FY19 (2020 Report)
DOI	Revisions to the Blowout Preventer Systems and Well Control Rule	1014-AA39	FY19 (2020 Report)
DHS	Registration Requirement for Petitioners Seeking To File H-1B Petitions on Behalf of Cap Subject Aliens	1615-AB71	FY19 (2020 Report)
USDA	Dairy Margin Coverage (DMC) Program	0560-AI37	FY19 (2020 Report)
USDA	National Bioengineered Food Disclosure Standard	0581-AD54	FY19 (2020 Report)
DOT	Passenger Equipment Safety Standards Amendments (RRTF)	2130-AC46	FY19 (2020 Report)
DOT	Odometer Disclosure Requirements	2127-AL39	FY19 (2020 Report)
DOT	49 CFR Part 578, Civil Penalties	2127-AL94	FY19 (2020 Report)

2. *Major Rules Issued by Historically Independent Agencies*

The Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA)³⁰ requires the Government Accountability Office (GAO) to submit to Congress reports on major rules, including rules issued by agencies not subject to Executive Order 12866.³¹ In preparing this Report, we reviewed the information contained in GAO reports on benefits and costs of major rules issued by independent agencies for the period of October 1, 2016, to September 30, 2019.³² GAO reported that seven agencies issued a total of fifteen major rules during FY 2017, eleven major rules during FY 2018, and fifteen major rules during FY 2019. (Rules by independent agencies have not historically been subject to OMB review under Executive Order 12866.) The Table 1-10 tabs in the spreadsheets accompanying this report list each of these major rules and the extent to which GAO reported benefit and cost estimates for the rule. The majority of rules were issued to regulate the financial sector.

Twelve of the fifteen FY 2017 rules, ten of the eleven FY 2018 rules, and ten of the fifteen FY 2019 rules provided some information on the benefits and costs of the regulation. The independent agencies still have challenges in providing monetized estimates of benefits and costs of regulation. The costs associated with disclosure related provisions have been largely monetized because of the requirements of the Paperwork Reduction Act; the costs associated with provisions that change how the markets are regulated are not generally monetized. In light of the limited information provided by the GAO, the Office of Management and Budget does not know whether the rigor of the analyses conducted by these agencies is similar to that of the analyses performed by agencies subject to OMB review.

Existing Executive Orders generally do not require historically independent agencies to submit their regulations for review or to engage in analysis of costs and benefits. We emphasize,

³⁰ Pub. L. No. 104-121, Title II, Subtitle E.

³¹ 5 U.S.C. 801(a)(2)(A). This provision is commonly referred to as the Congressional Review Act.

³² In practice, a rule was considered “major” for the purposes of the Congressional Review Act if (a) it was estimated to have either annual costs or benefits of \$100 million or more or (b) it was likely to have a significant impact on the economy. *See* 5 U.S.C. 804(2).

however, that for the purposes of informing the public and obtaining a full accounting, it would be highly desirable to obtain better information on the benefits and costs of the rules issued by independent agencies. The absence of such information continues to be an obstacle to transparency, and it might also have adverse effects on public policy. Consideration of costs and benefits is a pragmatic instrument for ensuring that regulations will improve social welfare; an absence of information on costs and benefits can lead to inferior decisions.

Chapter II: The Impact of Federal Regulation on State, Local, and Tribal Governments, Small Business, Wages and Employment, and Economic Growth

The Regulatory Right-to-Know Act requires OMB to present an analysis of the impacts of Federal regulation on State, local, and tribal governments, small business, wages, and economic growth.

A. Impacts on State, Local, and Tribal Governments

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA, or “the Act”) describes specific analyses and consultations that agencies must undertake for rules that may result in expenditures of over \$100 million (adjusted annually for inflation) in any year by State, local, and tribal governments in the aggregate, or by the private sector. Over the past ten fiscal years, the following rules have imposed costs of more than \$100 million per year in 1995 dollars (1995\$) on State, local, and tribal governments and have been classified as public sector mandates under the Act:³³

- *EPA’s National Emission Standards for Hazardous Air Pollutants from Coal- and Oil-Fired Electric Utility Steam Generating Units and Standards for Performance for Electric Utility Steam Generating Units [MATS] (2011)*: The MATS rule will reduce emissions of hazardous air pollutants (HAP), including mercury, from public and private fossil fuel-powered electric power generating units, by setting maximum achievable control technology standards. The annualized net compliance cost to state, local, and tribal government entities was estimated to be approximately \$294 million in 2015.
- *USDA’s Nutrition Standards in the National School Lunch and School Breakfast Programs (2012)*: This rule updates the meal patterns and nutrition standards for the National School Lunch and School Breakfast Programs to align them with the Dietary Guidelines for Americans. This rule requires most schools to: (1) increase the availability of fruits, vegetables, whole grains, and fat-free and low-fat fluid milk in school meals; (2) reduce the levels of sodium, saturated fat and *trans* fat in meals; and (3) meet the nutrition needs of school children within their calorie requirements. USDA estimates \$479 million in annual costs for the Local School Food Authorities and training, technical assistance, monitoring, and compliance costs for the State Education Agencies.

³³ We note that EPA’s rules setting air quality standards for ozone and particulate matter may ultimately lead to expenditures by State, local, or tribal governments of \$100 million or more. However, Title II of the Unfunded Mandates Reform Act provides that agency statements of compliance with section 202 must be conducted “unless otherwise prohibited by law.” 2 U.S.C. § 1532 (a). The conference report to this legislation indicates that this language means that the section “does not require the preparation of any estimate or analysis if the agency is prohibited by law from considering the estimate or analysis in adopting the rule.” H.R. Conf. Rep. No. 104-76, at 39 (1995). EPA has stated, and the courts have affirmed, that under the Clean Air Act, the criteria air pollutant ambient air quality standards are health-based, and EPA is not to consider costs in setting the standards.

- *CMS’s Patient Protection and Affordable Care Act; Benefit and Payment Parameters for 2014 (issued FY 2013), for 2015 (issued FY 2014), for 2016 (issued FY 2015), and for 2017 (issued FY 2016)*: These final rules provide detail and parameters related to various aspect of Affordable Care Act implementation, including: the risk adjustment, reinsurance, and risk corridors programs; cost-sharing reductions; user fees for Federally-facilitated Exchanges; advance payments of the premium tax credit; the Federally-facilitated Small Business Health Option Program; and the medical loss ratio program. Although HHS has not been able to quantify the user fees that will be associated with these rules, the combined administrative cost and user fee impact may be high enough to constitute a State, local, or Tribal government mandate under UMRA.
- *DOL’s Defining and Delimiting the Exemptions for Executive, Administrative, Professional, Outside Sales, and Computer Employees (2016)*: The Department of Labor divides salaried workers into three categories: low-paid workers who must be paid overtime (1.5 times the standard hourly pay rate for any hours over 40 worked in a week) under all conditions; highly compensated workers who are never subject to overtime requirements; and those in the middle who are exempt from overtime if their duties are executive, administrative, or professional (and non-exempt otherwise). DOL’s 2016 final rule revises the salary thresholds that separate the three categories—at the low end, raising it from \$23,660 to \$47,476 per year, and at the high end, raising it from \$100,000 to \$134,004—and newly requires that the thresholds be indexed every three years to account for inflation. Employee remuneration impacts and compliance costs are estimated to be well over \$100 million annually. In addition to certain private sector industries, some local government entities will be substantially affected by the rulemaking.³⁴

Although these rules were the only ones over the past ten-year period to require public sector mandates under UMRA on State, local, and tribal governments exceeding \$100 million (adjusted for inflation), they were not the only rules with impacts on other levels of governments. For example, even for rules with monetary impacts lower than the \$100 million threshold, agencies are required to consider the federalism implications of rulemakings under Executive Order 13132.

B. Impact on Small Business, Wages and Employment, and Economic Growth

In past Reports, we have included an extensive review of the literature related to regulatory impacts on small business, wages, employment, and economic growth.³⁵ Here, we focus on several recent contributions to this literature.³⁶

³⁴ A federal judge issued a preliminary injunction blocking implementation of the rule, and the Department of Labor filed an unopposed motion to stay its own appeal; this rule is therefore not in effect. In 2019, DOL issued a new final rule, with state, local, and tribal impacts estimated to fall below the \$100 million threshold.

³⁵ See, for example, the 2017 report, available at https://www.whitehouse.gov/wp-content/uploads/2019/12/2019-CATS-5885-REV_DOC-2017Cost_BenefitReport11_18_2019.docx.pdf or <https://perma.cc/P8GT-BT5F>.

³⁶ We will continue, in future reports, to seek feedback on whether readers prefer the consolidated approach featured in past reports or this approach of more succinctly updating on recent contributions.

If producers can fully pass through costs of regulations to consumers via price increases, then wage and employment effects could be negligible, although consumers would pay more for consumer products. Miller, Osborne, and Sheu (2017) estimate that, in the case of the portland cement industry, producers bear approximately 11 percent of the burden of market-based CO₂ regulation (implying that consumers bear the remaining 89 percent). Another study in the environmental regulation context, Curtis (2018), estimates that the NO_x cap-and-trade program has decreased employment in the manufacturing sector by 1.3 percent overall and by 4.8 percent in the most energy-intensive industries, with employment declines mostly taking the form of decreased hiring rather than increased separation of incumbent workers. Although focused on a very different industry, Hazlett and Wright (2017) reach a qualitatively similar conclusion regarding the effect of regulation; they examine the Federal Communication Commission's 2015 common carrier regulation and find that reduction of the regulatory requirements has led to growth in the broadband Internet and mobile services industries. More generally, using 1998–2011 data from the Statistics of US Businesses (a survey conducted by the Census Bureau), Bailey and Thomas (2017) find that more heavily regulated industries experience fewer new firm births and slower employment growth than less heavily regulated industries, and that small firms are more likely to exit an industry in response to regulation than large firms.

Dixon, Rimmer, and Waschik (2018) simulate the effects of a local content policy in which domestic suppliers are favored in public sector contracting; the results show the abandonment of such a policy leading to a decrease in domestic manufacturing employment that is more than offset by an increase in employment in the rest of the economy.

As shown elsewhere in this Report, much regulatory activity relates to health care, and a number of studies investigate the links between health care policy and employment outcomes. Leung and Mas (2018) find no impact on employment of Medicaid expansion under the Affordable Care Act, whereas Callison and Sicilian (2018) find state Medicaid expansions to be associated with “improved labor market autonomy for white men and white women,” with results mixed for the black and Hispanic/Latino populations. Dague, DeLeire, and Leininger (2017), drawing upon a natural experiment in Wisconsin, “find enrollment into public insurance leads to sizable and statistically meaningful reductions in employment.” Shi (2016) observes that wage workers and the self-employed adjust their incomes in order to qualify for health insurance subsidies.

Rissing and Castilla (2016) examine a U.S. immigration program which requires that foreign workers only be offered employment positions when no willing and qualified U.S. workers are available. If the policy has been achieving its intended effects on job availability in the U.S., high U.S. unemployment in an occupation should be correlated with a low rate of approvals of immigrant labor certifications. However, this study finds the opposite, on net, and attributes this outcome partly to employer self-attestations of compliance with the certification policy.

Chapter III: Recommendations for Reform

The Regulatory Right-to-Know Act charges OMB with making “recommendations to reform inefficient or ineffective regulatory programs.” This year’s set of recommendations reflects initiatives that are underway in association with Executive Order (EO) 13891, “Promoting the Rule of Law Through Improved Agency Guidance Documents,” and also the encouragement of soliciting public input through Requests for Information.³⁷

Executive Order 13891

The Administrative Procedure Act (APA) generally requires agencies in the executive branch, when imposing legally binding requirements on the public, to engage in notice-and-comment rulemaking so as to provide public notice of proposed regulations and to allow interested parties an opportunity to comment.³⁸ As part of this process, agencies must consider and respond to significant comments, and publish final regulations in the *Federal Register*.

Agencies may clarify existing obligations through non-binding guidance documents, which the APA exempts from notice-and-comment requirements. Yet agencies have sometimes used this authority inappropriately in attempts to regulate the public without following the rulemaking procedures of the APA. Even when accompanied by a disclaimer that it is non-binding, a guidance document issued by an agency may carry the implicit threat of enforcement action if the regulated public does not comply. Moreover, the public frequently has insufficient notice of guidance documents, which are not always published in the *Federal Register* or distributed to all regulated parties.

Executive Order 13891 reiterates that it is the policy of the executive branch, to the extent consistent with applicable law, that agencies: (a) treat guidance documents as non-binding both in law and in practice; (b) take public input into account in formulating guidance documents; and (c) make guidance documents readily available to the public. Motivated by these principles, EO 13891 and subsequent implementation guidance set forth several actions that agencies are to take over the next several months or quarters.³⁹ These actions include but are not limited to:

- Each agency or agency component, as appropriate, is to establish on its website, and maintain going forward, a single, searchable, indexed database that contains or links to all guidance documents in effect from such agency or component. The website shall note that guidance documents lack the force and effect of law, except as authorized by law or as incorporated into contracts.
- Each agency is to review its guidance documents and, consistent with applicable law, rescind those guidance documents that it determines should no longer be in effect.

³⁷ <https://www.federalregister.gov/documents/2019/10/15/2019-22623/promoting-the-rule-of-law-through-improved-agency-guidance-documents>

³⁸ 5 U.S.C. § 553.

³⁹ OMB’s implementation guidance is available at <https://www.whitehouse.gov/wp-content/uploads/2019/10/M-20-02-Guidance-Memo.pdf>.

- Each agency, consistent with applicable law, is to finalize regulations, or amend existing regulations, to set forth processes and procedures for issuing guidance documents and for the public to petition for withdrawal or modification of a particular guidance document. Moreover, for significant guidance documents (as determined by the Administrator of OMB's Office of Information and Regulatory Affairs), the default processes and procedures are to include:
 - a period of public notice and comment of at least 30 days before issuance of a final guidance document, and a public response from the agency to major concerns raised in comments, except when the agency for good cause finds and publicly states that notice and public comment are impracticable, unnecessary, or contrary to the public interest;
 - review by the Office of Information and Regulatory Affairs under Executive Order 12866, before issuance; and
 - compliance with the applicable requirements for regulations or rules, including significant regulatory actions, set forth in EOs 12866, 13563 (Improving Regulation and Regulatory Review), 13609 (Promoting International Regulatory Cooperation), 13771 (Reducing Regulation and Controlling Regulatory Costs), and 13777 (Presidential Executive Order on Enforcing the Regulatory Reform Agenda).

On October 31, 2019, OMB issued M-20-02 as the implementing memorandum for EO 13891. The implementing memorandum further clarifies how agencies are required to comply with EO 13891. The memorandum provides a detailed definition of what is considered a “guidance document” under the EO, which helps clarify for agencies which documents need to be publicly posted on the agency’s guidance portal and which documents will be subject to OIRA significance determinations and review under the EO. In addition, the implementing memorandum provides instructions to agencies about how to conduct an economic analysis of the potential effects of a guidance document, including how to estimate behavior changes, how to calculate a baseline, and what level of rigor of analysis is needed for different categories of guidance documents. Another requirement that is clarified in the implementing memorandum are the minimum standards for what must be included in new guidance documents moving forward, including a disclaimer that makes clear to the public that guidance documents are not binding and do not have the force and effect of law in the same way that regulations do. The implementing memorandum also outlines the process that agencies should follow for submitting guidance documents to OIRA for significance determinations under the EO.

EO 13891 gives agencies deadlines keyed off the date of publication of OMB’s implementing memorandum to accomplish various requirements in order to fully implement the EO. By February 28, 2020, agencies are required to establish a single, searchable, indexed website that contains, or links to, all of the agency’s respective guidance documents currently in effect. If a guidance document that the agency considers to be currently in effect is not posted to the new guidance portal by June 27, 2020, then the agency must follow the new issuance requirements of EO 13891 in order to reestablish that guidance document as being in effect.

Agencies are also required to finalize implementing regulations for EO 13891 and M-20-02 in their own section of the Code of Federal Regulations (CFR) by August 26, 2020.

Public Input

OMB encourages the public to contribute its ideas for regulatory reform. After all, regulated entities and individuals may offer insight into regulatory redundancy, compliance inefficiencies or outdated requirements; may have information regarding difficulties for small- or medium-sized enterprises; or may have access to relevant data, including data on regulatory compliance costs.

In order to facilitate the process of obtaining public input, OMB has issued two Requests for Information (RFIs)—one on Maritime Regulatory Reform and the other on issues related to the United States-Canada Regulatory Cooperation Council, both discussed in more detail below—and we are likely to issue more in the future.

*Maritime Regulatory Reform RFI*⁴⁰

The maritime sector is subject to regulation by multiple federal agencies—including, but not limited to, the Federal Maritime Commission, the Department of Transportation, the Department of Homeland Security, the Department of Defense, the Department of Labor, the Department of Commerce, the Environmental Protection Agency, the Council on Environmental Quality, and the Department of the Interior. Although some agencies that regulate the maritime sector have previously sought regulatory reform ideas, OMB's RFI seeks broader input. The RFI also expresses our interest in understanding how regulations from the United States might be better coordinated with the regulations and requirements of other countries, especially Canada and Mexico, governing shared bodies of water.

*United States-Canada Regulatory Cooperation Council RFI*⁴¹

The United States and Canada created the Regulatory Cooperation Council (RCC) in 2011 in order to identify, and reduce or eliminate, unnecessary regulatory differences and duplicative procedures, as well as to increase regulatory transparency. Although the United States and Canada share many policy objectives, divergent regulatory approaches can hinder national and cross-border economic activity, and impose unnecessary costs on citizens, businesses, and economies. Even when the two countries opt to address a policy objective in the same way, implementation may be characterized by duplicative paperwork requirements or procedures. OMB's Regulatory Cooperation Council RFI seeks

⁴⁰ 83 Fed. Reg. 22,993 (May 17, 2018), available at <https://www.federalregister.gov/documents/2018/05/17/2018-10539/maritime-regulatory-reform>.

⁴¹ 83 Fed. Reg. 50,689 (Oct. 9, 2018), available at <https://www.federalregister.gov/documents/2018/10/09/2018-21765/request-for-information>.

to identify opportunities to align regulatory systems, streamline bilateral cooperation, and improve stakeholder engagement.

OMB may issue future RFIs, with the goal of aiding in the coordination of interagency and international streamlining of regulatory requirements. More generally, the current Administration will be continuing its emphasis on deregulation, and OMB will seek, in this Report and other venues, to facilitate communication to and from the affected public.

CHAPTER IV: OMB'S INFORMATION QUALITY INITIATIVES

Objective and high-quality analysis can improve regulatory decisions. OMB and the regulatory agencies have taken a number of steps to improve the rigor and transparency of analysis supporting public policy decisions. Of particular importance in the context of regulatory analysis is OMB's Circular A-4, "Regulatory Analysis," which was issued in 2003 after public comment, interagency review, and peer review. Circular A-4 defines good regulatory analysis and standardizes how benefits and costs of Federal regulatory actions are measured and reported.⁴² In this chapter of the Report, we highlight OMB's continuing efforts to improve government information quality and transparency, as well as provide a brief update on the Agency reporting.

Background:

The Information Quality Act (IQA), 44 U.S.C. § 3516 note, requires OMB to develop government-wide standards "for ensuring and maximizing" the quality of information disseminated by Federal agencies.

To implement the IQA, on February 22, 2002, OMB issued final government-wide guidelines⁴³ (the IQ Guidelines) and charged each Federal agency with promulgating its own Information Quality Guidelines. OMB has facilitated the development of these agency guidelines, working with the agencies to ensure consistency with the principles set forth in the government-wide guidelines. By October 1, 2002, almost all agencies released their final guidelines and were all compliant shortly thereafter. Agencies' final guidelines became effective immediately. The OMB government-wide guidelines direct agencies to establish administrative mechanisms that facilitate the public review process to seek and obtain correction of information that does not comply with OMB or agency guidelines. Each agency is required to report annually to OMB on the number and nature of information correction requests received by the agency and how such correction requests were resolved.

In our 2003 Report, OMB presented a detailed discussion of the IQA and its implementation, including a discussion of perceptions and realities, legal developments, methods for improving transparency, suggestions for improving correction requests.⁴⁴ In August 2004, the OIRA Administrator issued a memorandum to the President's Management Council requesting that agencies post all Information Quality correspondence on agency web pages to

⁴² This guidance is available at <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf> or at <https://perma.cc/CA6P-PNUY>.

⁴³ Office of Mgmt. & Budget, Exec. Office of the President, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies*, 67 Fed. Reg. 8452 (Feb. 22, 2002) (final guidelines), available at <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/assets/OMB/fedreg/reproducible2.pdf>.

⁴⁴ See Office of Mgmt. & Budget, Exec. Office of the President, *Information Quality, a Report to Congress FY 2003* (2003), available at https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/assets/OMB/inforeg/fy03_info_quality_rpt.pdf.

increase the transparency of the process.⁴⁵ In their FY 2004 Information Quality Reports to OMB, agencies provided OMB with the specific links to these web pages and OMB began providing this information to the public in our 2005 update on Information Quality.⁴⁶ This increase in transparency allowed the public to view all correction requests, appeal requests, and agency responses to these requests. The web pages also allow the public to track the status of correction requests that may be of interest.

On December 16, 2004, OMB issued the Final Information Quality Bulletin for Peer Review (the “Peer Review Bulletin”),⁴⁷ which provided additional guidance on peer review of influential scientific and technical information.

Executive Order 13777,⁴⁸ promulgated on February 24, 2017, highlights the current Administration’s commitment to the Information Quality Act and the importance of enforcing the guidance promulgated pursuant to the Act. The Executive Order requires agencies to evaluate existing regulations for consistency “with the requirements of [the IQA] (44 U.S.C. § 3516 note), and the guidance issued pursuant to that provision.” In particular, the Executive Order asks agencies to identify “regulations that rely in whole or in part on data, information, or methods that are not publicly available or that are insufficiently transparent to meet the standard for reproducibility.”

In May 2019 we disseminated OMB M-19-15⁴⁹ to reinforce, clarify, and interpret agency responsibilities with regard to responsibilities under the IQA and the IQ Guidelines. The principles and core responsibilities described in the IQ Guidelines remain sound and relevant for agency practice; however, additional guidance is required to address changes in the information landscape and to incorporate best practices developed over time.⁵⁰ OMB M-19-15 updates implementation of the IQ Guidelines to reflect recent innovations in information generation,

⁴⁵ See Office of Mgmt. & Budget, Exec. Office of the President, *Memorandum for the President’s Management Council* (Aug. 30, 2004), available at

https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/assets/OMB/infocore/infocore_quality_posting_083004.pdf.

⁴⁶ See Office of Mgmt. & Budget, Exec. Office of the President, *Validating Regulatory Analysis: 2005 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities* (2005), available at

https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/assets/OMB/infocore/2005_cb/final_2005_cb_report.pdf or at <http://perma.cc/R8LX-BQMJ>.

⁴⁷ See Office of Mgmt. & Budget, Exec. Office of the President, , OMB M-05-03, Issuance of OMB’s “Final Information Quality Bulletin for Peer Review” (Dec. 16, 2004), available at

<https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2005/m05-03.pdf>.

⁴⁸ <https://www.federalregister.gov/documents/2017/03/01/2017-04107/enforcing-the-regulatory-reform-agenda>.

⁴⁹ Office of Mgm’t & Budget, Exec. Office of the President, OMB M-19-15, *Improving Implementation of the Information Quality Act* (Apr. 24, 2019), available at <https://www.whitehouse.gov/wp-content/uploads/2019/04/M-19-15.pdf>.

⁵⁰ 67 Fed. Reg. at 8458 (contemplating the evolution of standards with experience and the need for additional implementation guidance); cf. *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated by Federal Agencies*, 66 Fed. Reg. 49,718, 49,723 (Sept. 28, 2001) (final guidelines with request for comment); Office of Mgm’t & Budget, Exec. Office of the President, *Executive Branch Implementation of the Information Quality Act* (Oct. 4, 2002), available at https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/assets/OMB/infocore/pmc_graham_100402.pdf.

access, management, and use, and to help agencies address common problems with maintaining information quality.

In the Draft of this 2018, 2019, and 2020 Report we requested public comment about whether to continue to use this Report as the mechanism to disseminate fiscal year summaries of the number of requests for correction received by agencies pursuant to the IQ Guidelines and the number of peer reviews conducted pursuant OMB’s Information Quality Bulletin for Peer Review (the Bulletin). As an alternative, we proposed to disseminate those fiscal year summaries on OMB’s web site.⁵¹ Because OMB did not receive any public comment on this issue, later this year we will begin posting the results of these data calls on OMB’s web site (beginning with the results of the FY 2019 data call).

A. Government-Wide Information Quality Guidelines

This section of the chapter provides a summary of the current status of correction requests received in FY 2017 and FY 2018, as well as an update on the status of requests that were still pending by the close of FY 2016 and FY 2017. A discussion of legal interpretations of the Information Quality Act is also provided. Our discussion of the individual correction requests and agency responses is minimal because all correspondence between the public and agencies regarding these requests is publicly available on each agency’s Information Quality web page.

1. Request for Correction Process for FY 2017

a. New Correction Requests and Appeal Requests Received by the Agencies in FY 2017

Table 3-1 below lists the departments and agencies that received requests for correction in FY 2017. In FY 2017, a total of 12 requests for correction were received by 7 different departments and agencies. At the end of FY 2017, responses had been sent for 10 of the requests and 2 were pending.

Table 3-1: Departments and Agencies that Received Information Quality Correction Requests in FY 2017

Agency	Number of FY 2017 Correction Requests
Department of Commerce	1
Department of Health and Human Services	2
Department of the Interior	1

⁵¹ Such a web dissemination would be consistent with the U.S. Government Accountability Office’s report GAO-16-110, *Actions Needed to Improve Transparency and Reporting of Correction Requests* (Dec. 21, 2015), available at <https://www.gao.gov/products/GAO-16-110>. GAO raised the concern that although OMB posts IQA information online, including links to agency-specific IQA guidelines, there is no central location on OMB’s website where a user could access all IQA data, making specific IQA data more difficult to find and hindering transparency of the process.

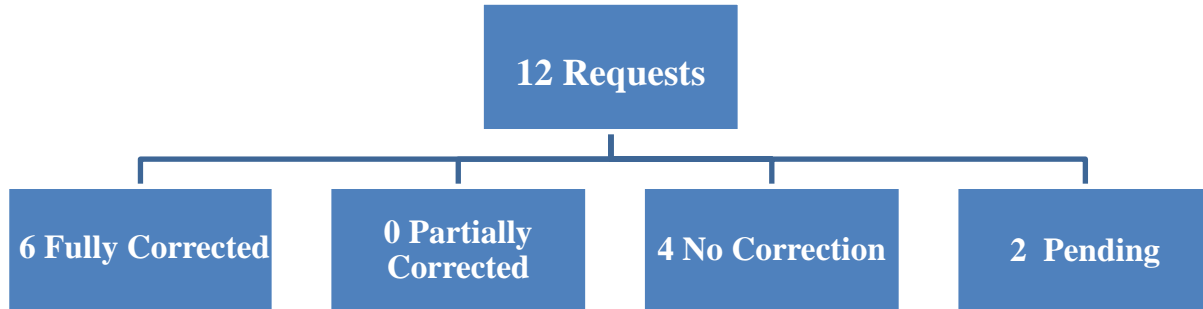
Agency	Number of FY 2017 Correction Requests
Department of Labor	4
Department of Transportation	1
Environmental Protection Agency	2
Federal Trade Commission	1
Total	12

- The requests received by the Department of Commerce’s National Oceanic and Atmospheric Administration, the Federal Trade Commission, and the Department of Transportation’s National Highway Traffic Safety Administration were fully corrected.
- One request received by the Environmental Protection Agency is still pending and one request resulted in no correction.
- The request received by the Department of the Interior’s Bureau of Safety and Environmental Enforcement resulted in no correction.
- The Department of Health and Human Services’ Centers for Disease Control and Prevention had 1 request with a full correction, and 1 request with no correction that resulted in an appeal with a resolution of no correction.

The Department of Labor’s Occupational Safety and Health Administration had 2 full corrections, 1 request still pending, and 1 determination of “no correction” that resulted in an appeal still pending. Figure 3-1 below shows the status of the 12 correction requests in FY 2017. For further details, links to all the correction requests, and the complete agency responses, we encourage readers to visit the agency Information Quality web pages.⁵² OMB continues to use the “different processes” category to describe responses that were handled by pre-existing processes at the agencies.

⁵² A listing of webpages for Agency IQ correspondence is available at: http://www.whitehouse.gov/omb/inforeq_agency_info_quality_links/.

Figure 3-1: Status⁵³ of IQ Correction Requests Received in FY 2017



As noted in previous reports, OMB cautions readers against drawing any conclusions about trends or year-to-year comparisons. However, we note that there were 48 correction requests in FY 2003; 37 in FY 2004; 24 in FY 2005; 22 in FY 2006; 21 in FY 2007; 14 in FY 2008; 17 in FY 2009; 27 in FY 2010; 16 in FY 2011; 16 in FY 2012; 20 in FY 2013; 20 in FY 2014; 35 in FY 2015; and 18 in FY 2016.

As shown below in Table 3-2, two appeals were filed in FY 2017.

Table 3-2: Departments and Agencies that Received Information Quality Appeal Requests in FY 2017

Agency	Appeals received FY 2017
The Department of Health and Human Services	1
Department of Labor	1
Total	2

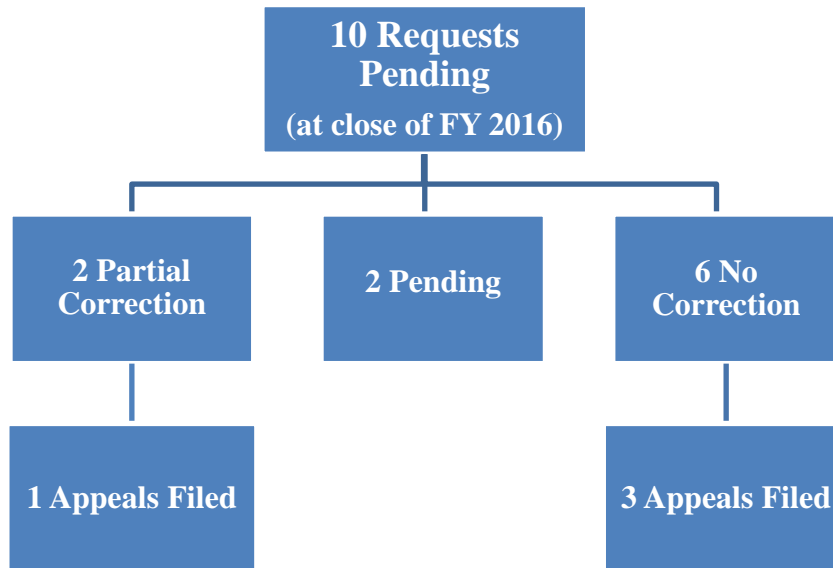
- One was received by the Department of Health and Human Services’ Centers for Disease Control and Prevention.
- One was received by The Department of Labor’s Occupational Safety and Health Administration.

b. Correction Requests Left Unresolved at the End of the Prior Fiscal Year

⁵³ Status at the close of FY 2017.

At the close of FY 2016, 10 correction requests remained outstanding. Figure 3-2 shows the status of these requests at the close of FY 2017.

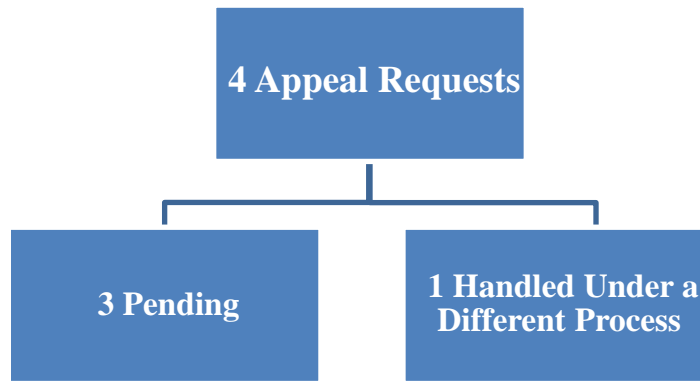
Figure 3-2: Status at the Close of FY 2017 of Correction Requests that Were Pending at the Close of FY 2016



- The Department of Interior’s Geological Survey reported 1 request with no correction and 1 request with no correction that resulted in an appeal.
- The Consumer Product Safety Commission reported 1 appeal still pending.
- The Environmental Protection Agency 1 request still pending, 4 requests resulting in no correction with 2 appeals filed, and one request resulting in partial correction with an appeal filed.
- The Department of Health and Human Services’ Centers for Disease Control and Prevention reported 1 request with partial correction.

Figure 3-3 below provides the status of the four appeals filed in FY 2017 on requests pending at the close of FY 2016. Correspondence showing the agency’s responses to these requests is publicly available on the agencies’ Information Quality web pages.

Figure 3-3: Status at the Close of FY 2017 of Appeals that Were Filed on Requests Pending at the Close of FY 2016



- One appeal request was pending at the Department of the Interior’s USGS.
- The Environmental Protection Agency had 2 appeals from FY 2016 still pending at the close of FY 2017 and a third that was handled under a different process.

2. Request for Correction Process for FY 2018

a. New Correction Requests and Appeal Requests Received by the Agencies in FY 2018

Table 3-3 below lists the departments and agencies that received requests for correction in FY 2018. In FY 2018, a total of 13 requests for correction were received by 8 different departments and agencies. At the end of FY 2018, responses had been sent for 8 of the requests and 5 are still pending.

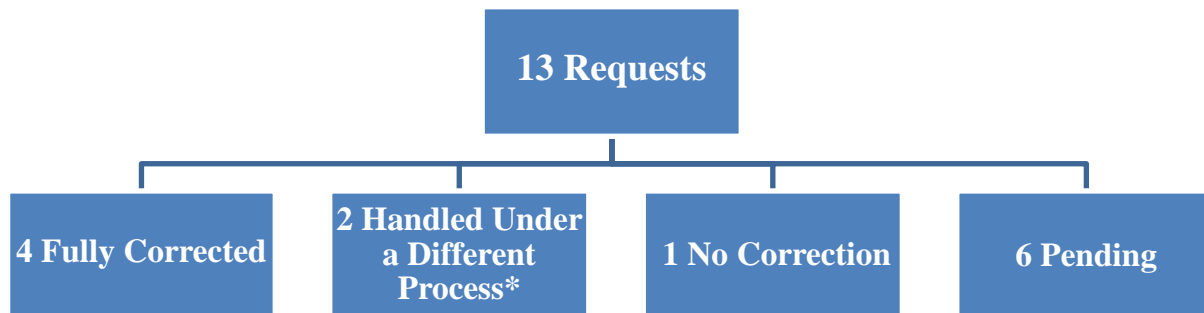
Table 3-3: Departments and Agencies that Received Information Quality Correction Requests in FY 2018

Agency	Number of FY 2018 Correction Requests
Department of Health and Human Services	1
Department of Homeland Security	1
Department of Education	3
Department of Energy	1
Department of Interior	2
Department of Justice	1
Environmental Protection Agency	3
National Endowment for the Arts	1
Total	13

- The Department of Justice, Justice Management Division, had 1 request pending at the time of reporting.
- Department of the Interior’s Geological Survey received 1 request that was fully corrected and 1 that was pending at the time of reporting.
- The National Endowment for the Arts and Department of Health and Human Services’ National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) each received 1 request that was fully corrected.
- Department of Education received 3 requests, 1 was fully corrected and the other 2 were handled under a different process (comment process under the Notice of Proposed Rulemaking), 1 of which was under appeal at the time of reporting.
- The Environmental Protection Agency received 2 requests that were pending at the time of reporting and one that was not corrected and was under appeal at the time of reporting.
- The Department of Homeland Security received one request for correction, which was pending at the time of reporting.
- The Department of Energy received one request for correction, which was pending at the time of reporting.

Figure 3-4 below shows the status of the 13 correction requests in FY 2018. For further details, links to all the correction requests, and the complete agency responses, we encourage readers to visit the agency Information Quality web pages.⁵⁴ OMB continues to use the “different processes” category to describe responses that were handled by pre-existing processes at the agencies.

Figure 3-4: Status⁵⁵ of IQ Correction Requests Received in FY 2018



* comment process under the Notice of Proposed Rulemaking.

⁵⁴ A listing of webpages for Agency IQ correspondence is available at http://www.whitehouse.gov/omb/inforeg_agency_info_quality_links/.

⁵⁵ Status at the close of FY 2018.

As noted in previous reports, OMB cautions readers against drawing any conclusions about trends or year-to-year comparisons. However, see above for the number of IQ correction requests since FY 2003.

As shown below in Table 3-4, two appeals were filed in FY 2018.

Table 3-4: Departments and Agencies that Received Information Quality Appeal Requests in FY 2018

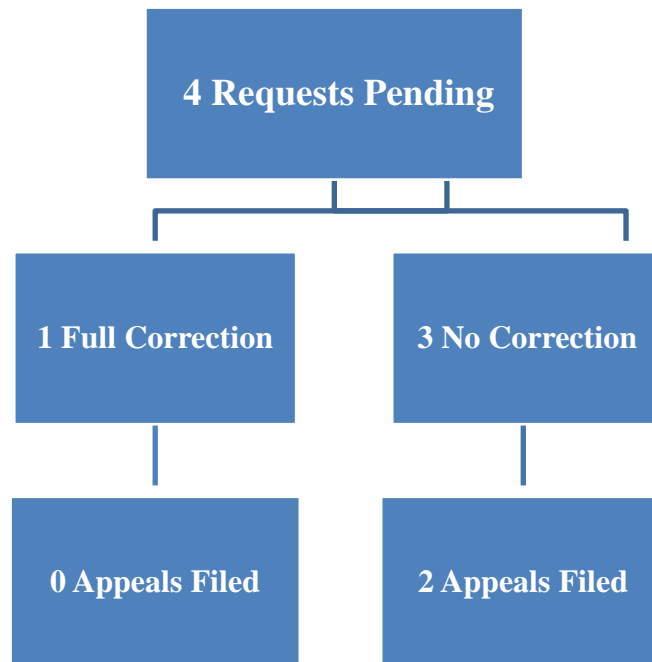
Agency	Appeals received FY 2018
Department of Education	1
Environmental Protection Agency	1
Total	2

- One was received by the Department of Education and was handled under a different process (comment process under the Notice of Proposed Rulemaking).
- One was received by the Environmental Protection Agency and is still pending.

b. Correction Requests Left Unresolved at the End of the Prior Fiscal Year

At the close of FY 2017, 4 correction requests remained open. Figure 3-5 shows the status of these requests at the close of FY 2018. Agencies closed out 3 of these correction requests in FY 2018 (2 of these correction requests led to no correction and 1 led to a full correction).

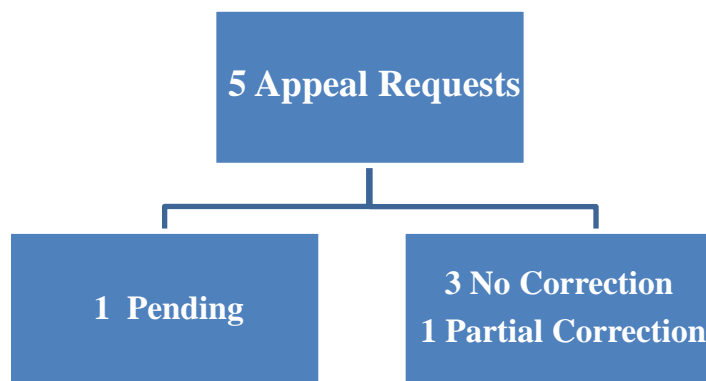
Figure 3-5: Status at the Close of FY 2018 of Correction Requests that Were Pending at the Close of FY 2017



- The Consumer Products Safety Commission completed 1 request with no correction.
- The Department of Health and Human Services’ National Center for Health Statistics (NCHS) had 1 request with no correction with an appeal filed, and the National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) responded to 1 request with a full correction.
- The Environmental Protection Agency had 1 request with no correction and an appeal still pending, and 1 request with no correction that was completed.

Figure 3-6 below provides the status of the 5 appeal requests pending at the close of FY 2017. Correspondence showing each agency’s responses to these requests is publicly available on the agencies’ Information Quality web pages.

Figure 3-6: Status at the Close of FY 2018 of Appeals that were Pending at the Close of FY 2017



- The Department of the Interior’s Geological Survey and the Department of Health and Human Services’ National Center for Health Statistic each had 1 appeal request with no correction.
- The Environmental Protection Agency had 3 appeals pending; 1 resulted in no correction with an appeal still pending which was handled under a different process (same comments were submitted during public rulemaking). One resulted in a partial correction which was appealed but no further correction was made. The third resulted in no correction and is still pending.

3. Legal Discussion

As discussed in previous reports, there has been litigation under the Information Quality Act (IQA); in addition, there has been litigation regarding the scope of judicial review under the Administrative Procedure Act (APA) in those challenges. In 2010, the United States Court of Appeals for the Ninth Circuit affirmed the district court’s dismissal of the case for lack of jurisdiction under the APA.⁵⁶ Also in 2010, the United States Court of Appeals for the District of Columbia Circuit declined to find that the IQA had been violated based on its determination that OMB’s interpretation regarding “dissemination” and, in particular, the exclusion from the definition of dissemination documents “prepared and distributed in the context of adjudicative proceedings”, was a reasonable interpretation of the statute.⁵⁷ Other courts have also dismissed IQA challenges on other grounds.⁵⁸

B. Information Quality Bulletin for Peer Review

The Peer Review Bulletin⁵⁹ requires executive agencies to ensure that all “influential scientific information” they disseminate after June 16, 2005, is peer-reviewed. “Influential

⁵⁶ *Ams. for Safe Access v. HHS*, 399 F. App’x 314, 316 (9th Cir. 2010) (holding that HHS’s decision to defer an IQA petition to an already pending alternate procedure was not a reviewable final agency action).

⁵⁷ *Prime Time Int’l Co. v. Vilsack*, 599 F.3d 678, 685 (D.C. Cir. 2010).

⁵⁸ See, e.g., *Salt Inst. v. Leavitt*, 440 F.3d 156, 159 (4th Cir. 2006); *Family Farm Alliance v. Salazar*, 749 F. Supp. 2d 1083 (E.D. Cal. 2010); *In re Operation of the Mo. River Sys. Litig.*, 363 F. Supp. 2d 1145, 1174–75 (D. Minn. 2004), *vacated in part and aff’d in part on other grounds*, 421 F.3d 618 (8th Cir. 2005).

⁵⁹ See Office of Mgmt. & Budget, Exec. Office of the President, OMB M-05-03, *Issuance of OMB’s “Final Information Quality Bulletin for Peer Review”* (Dec. 16, 2004), available at <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2005/m05-03.pdf>.

scientific information” is defined as “scientific information the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions.”⁶⁰ The term “influential” is to be interpreted consistently with OMB’s government-wide Information Quality Guidelines and the information quality guidelines of each agency.

One type of scientific information is a scientific assessment. For the purposes of the Peer Review Bulletin, the term “scientific assessment” means an evaluation of a body of scientific or technical knowledge, which typically synthesizes multiple factual inputs, data, models, assumptions, and/or applies best professional judgment to bridge uncertainties in the available information.⁶¹

The Peer Review Bulletin describes the factors that should be considered in choosing an appropriate peer review mechanism and stresses that the rigor of the review should be commensurate with how the information will be used. It directs agencies to choose a peer review mechanism that is adequate, giving due consideration to the novelty and complexity of the science to be reviewed, the relevance of the information to decision making, the extent of prior peer reviews, and the expected benefits and costs of additional review. When deciding what type of peer review mechanism is appropriate for a specific information product, agencies should consider at least the following issues: individual versus panel review, timing, scope of the review, selection of reviewers, disclosure and attribution, public participation, disposition of reviewer comments, and adequacy of prior peer review.

The Peer Review Bulletin specifies the most rigorous peer review requirements for “highly influential scientific assessments,” which are a subset of “influential scientific information.” To ensure that implementation of the Peer Review Bulletin is not too costly, these requirements for more intensive peer review apply only to the more important scientific assessments disseminated by the Federal Government—those that could have a potential impact of more than \$500 million in any one year on either the public or private sector; are novel, controversial, or precedent-setting; or have significant interagency interest.

Under the Peer Review Bulletin, agencies are granted broad discretion to weigh the benefits and costs of using a particular peer review mechanism for a specific information product. In addition to the factors noted above, agencies also have the option of employing “alternative processes” for meeting the peer review requirement (*e.g.*, commissioning a National Academy of Sciences study). Moreover, to ensure that peer review does not unduly delay the release of urgent findings, time-sensitive health and safety determinations are exempted from the requirements of the Peer Review Bulletin. There are also specific exemptions for national security, individual agency adjudication or permit proceedings, routine statistical information, and financial information. The Peer Review Bulletin does not cover information disseminated in

⁶⁰ The Bulletin notes that information dissemination can have a significant economic impact even if it is not part of a rulemaking. For instance, the economic viability of a technology can be influenced by the government’s characterization of its attributes. Alternatively, the Federal Government’s assessment of risk can directly or indirectly influence the response actions of state and local agencies or international bodies.

⁶¹ These assessments include, but are not limited to, state-of-science reports; technology assessments; weight-of-evidence analyses; meta-analyses; health, safety, or ecological risk assessments; toxicological characterizations of substances; integrated assessment models; hazard determinations; or exposure assessments.

connection with routine rules that materially alter entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof.

The Peer Review Bulletin provides two mechanisms for monitoring the progress of the agencies in meeting these peer-review requirements: a transparent peer review planning process and annual reporting, described below.

The good science and good government requirements of the Peer Review Bulletin should assist in improving the accuracy and transparency of agency science. Additionally, the peer review planning process described in the Peer Review Bulletin, which includes posting of plans on agency websites, enhances the ability of the government and the public to track influential scientific disseminations made by agencies.

On June 16, 2005, the Peer Review Bulletin became effective for all influential scientific information, including highly-influential scientific assessments. The peer review planning component of the Bulletin, discussed below, became fully effective on December 16, 2005.

1. Peer Review Planning

The Peer Review Planning component of the Peer Review Bulletin (Section V) requires agencies to engage in a systematic process of peer review planning for influential scientific information (including highly influential scientific assessments) that the agency plans to disseminate in the foreseeable future.

A key feature of the agency's peer review plan is a web-accessible listing (an "agenda") of forthcoming influential scientific disseminations that is updated on a regular basis. These postings are designed to allow the public to participate in the peer review process by providing data and comments to the sponsoring agencies, as well as to external peer reviewers. By making these agendas publicly available, agencies increase the level of transparency in their peer review processes, and also have a mechanism to gauge the extent of public interest in their proposed peer reviews.

The agenda is designed to encourage planning for peer review early in the information-generation process. Thus, the agenda should cover all information subject to the Peer Review Bulletin that the agency plans to disseminate in the foreseeable future. For instance, once an agency has established a timeline for the generation of a scientific report, the agency should include that report in its agenda. Thus, although the Peer Review Bulletin specifies that agencies should update their peer review agendas every six months, the agenda is not a six-month forecast (*i.e.*, it should not be limited to information (documents) that the agency plans to peer review in the next six months).

Readers are encouraged to visit the agendas for agencies of interest. OMB asks agencies to ensure that there is an easily identifiable hyperlink to the peer review agenda from the agency's Information Quality home page.

Several agencies have determined that they do not currently produce or sponsor information subject to the Peer Review Bulletin. Most of these agencies produce primarily

financial information or routine statistical information for which the Bulletin provides specific exemptions. Others primarily engage in management, oversight, or granting activities.

2. Summary of FY 2017 Annual Reports of Agency Peer Reviews

The Peer Review Bulletin’s annual reporting requirement is designed to provide OMB with a count of the peer reviews completed in the fiscal year as well as information about the use of waivers, deferrals, exemptions, alternative processes, and exceptions. Table 3-5 shows that for FY 2017, 6 agencies reported to OMB that they conducted a total of 184 peer reviews within the scope of the Peer Review Bulletin. The remaining agencies did not report any reviews pursuant to the Peer Review Bulletin this fiscal year. Individual agency reports are available on each agency's website.⁶²

Table 3-5: Numbers of Peer Reviews Reported by Agencies for FY 2017

Department/ Agency	Total Peer Reviews Completed	Reviews of Highly Influential Scientific Assessments	Waivers, Deferrals, or Exemptions	Potential Reviewer Conflicts
Department of Agriculture	55	0	0	0
Department of Commerce	13	0	4	4
Department of Energy	13	0	0	0
Department of the Interior	81	4	8	0
Environmental Protection Agency	6	2	0	0
Department of Health and Human Services	16	6	2	2

⁶² A listing of webpages for Agency IQ correspondence is available at http://www.whitehouse.gov/omb/inforeg_agency_info_quality_links/.

Table Details:

- The Department of Agriculture agency reporting peer reviews in FY 2017 was the Economic Research Service.
- The Department of Commerce agency reporting peer reviews and deferrals in FY 2017 was the National Oceanic and Atmospheric Administration.
- The Department of Health and Human Services agencies reporting peer reviews in FY 2017 were the Centers for Disease Control and Prevention (associated with 1 deferral and 1 alternate procedure), the Food and Drug Administration, and the National Institutes of Health.
- The Department of the Interior agencies reporting peer reviews in FY 2017 were the Fish and Wildlife Service, Bureau of Reclamation, Bureau of Safety and Environmental Enforcement, and the Geological Survey. The waivers reported here are all associated with the Fish and Wildlife Service.
- The Departments of Labor, Justice, and the National Aeronautics and Space Administration, the Consumer Product Safety Commission, and the Federal Trade Commission have reported peer reviews in the past, but reported that no peer reviews were conducted in FY 2017.

3. Summary of FY 2018 Annual Reports of Agency Peer Reviews

Table 3-6 shows that for FY 2018, 8 agencies reported to OMB that they conducted a total of 176 peer reviews within the scope of the Peer Review Bulletin. The remaining agencies did not report any reviews pursuant to the Peer Review Bulletin this fiscal year. Individual agency reports are available on each agency’s website.

Table 3-6: Numbers of Peer Reviews Reported by Agencies for FY 2018

Department/ Agency	Total Peer Reviews Completed	Reviews of Highly Influential Scientific Assessments	Waivers, Deferrals, or Exemptions	Potential Reviewer Conflicts
Department of Agriculture	36	0	0	0
Department of Commerce	9	0	1	0
Department of Energy	14	0	0	0
Department of Health and Human Services	27	6	0	3
Department of the Interior	80	3	8	0

Department of Veterans Affairs	2	0	0	0
Environmental Protection Agency	7	3	0	0
Federal Communications Commission	1	0	0	0

Table Details:

- The Department of Agriculture agency reporting peer reviews in FY 2018 was the Economic Research Service.
- The Department of Commerce agency reporting peer reviews and alternative procedures in FY 2018 was the National Oceanic and Atmospheric Administration.
- The Department of Health and Human Services agencies reporting peer reviews in FY 2018 were the Centers for Disease Control and Prevention and the National Institutes of Health.
- The Department of the Interior agencies reporting peer reviews in FY 2018 were the Fish and Wildlife Service, Bureau of Reclamation, Bureau of Safety and Environmental Enforcement, and the Geological Survey. The waivers reported here are all associated with the Fish and Wildlife Service.
- The Departments of Labor, Justice, and the National Aeronautics and Space Administration, the Consumer Product Safety Commission, and the Federal Trade Commission have reported peer reviews in the past, but reported that no peer reviews were conducted in FY 2018.

**PART II: ANNUAL REPORT TO
CONGRESS ON AGENCY COMPLIANCE
WITH THE UNFUNDED MANDATES
REFORM ACT**

Introduction

This report represents OMB’s annual submission to Congress on agency compliance with the Unfunded Mandates Reform Act of 1995 (UMRA). This report on agency compliance with the Act covers the period of October 2016 through September 2019; rules published before October 2016 are described in previous years’ reports.

Since 2001, this report has been included in our final Report to Congress on the Benefits and Costs of Federal Regulations. This is done because the two reports together address many of the same issues. Both reports also highlight the need for regulating in a responsible manner, accounting for benefits and costs, and taking into consideration the interests of our intergovernmental partners.

State and local governments have a vital constitutional role in providing government services. They have the primary role in providing domestic public services, such as public education, law enforcement, road building and maintenance, water supply, and sewage treatment. The Federal Government contributes to that role by promoting a healthy economy and by providing grants, loans, and tax subsidies to State and local governments. However, State, local, and tribal governments have expressed concerns about the difficulty of complying with Federal mandates without additional Federal resources.

In response, Congress passed the Unfunded Mandates Reform Act of 1995 (UMRA, or “the Act”). Title I of the Act focuses on the Legislative Branch, addressing the processes Congress should follow before enactment of any statutory unfunded mandates. Title II addresses the Executive Branch. It begins with a general directive for agencies to assess, unless otherwise prohibited by law, the effects of their rules on the other levels of government and on the private sector (section 201). Title II also describes specific analyses and consultations that agencies must undertake for rules that may result in expenditures of over \$100 million (adjusted annually for inflation) in any year by State, local, and tribal governments in the aggregate, or by the private sector.

Specifically, section 202 requires an agency to prepare a written statement for intergovernmental mandates that describes in detail the required analyses and consultations on the unfunded mandate. Section 205 requires that for all rules subject to section 202, agencies must identify and consider a reasonable number of regulatory alternatives, and then generally select the least costly, most cost-effective, or least burdensome option that achieves the objectives of the rule. Section 205 does not apply if the agency head explains in the final rule why such a selection was not made or if such a selection would be inconsistent with law.

Title II requires agencies to “develop an effective process” for obtaining “meaningful and timely input” from State, local and tribal governments in developing rules that contain significant intergovernmental mandates (section 204). Title II also singles out small governments for

particular attention (section 203). OMB’s guidelines assist Federal agencies in complying with the Act and are based upon the following general principles⁶³:

- Intergovernmental consultations should take place as early as possible, beginning before issuance of a proposed rule and continuing through the final rule stage, and be integrated explicitly into the rulemaking process;
- Agencies should consult with a wide variety of State, local, and tribal officials;
- Agencies should prepare an estimate of direct benefits and costs for use in the consultation process;
- The scope of consultation should reflect the cost and significance of the mandate being considered;
- Effective consultation requires trust and significant and sustained attention so that all who participate can enjoy frank discussion and focus on key priorities; and
- Agencies should seek out State, local, and tribal views on costs, benefits, risks, and alternative methods of compliance and whether the Federal rule will harmonize with and not duplicate similar laws in other levels of government.

Federal agencies have been actively consulting with states, localities, and tribal governments in order to ensure that regulatory activities were conducted consistent with the requirements of UMRA, and a description of agency consultation activities is included in Appendix B.

The remainder of this report lists and briefly discusses the regulations issued from October 1, 2016, to September 30, 2017; from October 1, 2017, to September 30, 2018; and from October 1, 2018, to September 30, 2019, that impose expenditures meeting the UMRA Title II threshold.⁶⁴ In FY 2017, as listed in Table II, Federal agencies issued eleven final rules that were subject to sections 202 and 205 of UMRA, as they required expenditures by State, local or tribal governments, in the aggregate, or by the private sector, of at least \$100 million in at least one year (adjusted annually for inflation). The Environmental Protection Agency published two, the Department of Energy published five, the Department of Health and Human Services published one in conjunction with numerous co-signatory agencies, the Department of Labor published one, the Department of the Interior published one, and the Department of the Treasury published one. In FY 2018, as also listed in Table II, one Federal agency—the Environmental Protection Agency—issued one final rule that was subject to sections 202 and 205 of UMRA. In FY 2019, the Department of Agriculture, the Environmental Protection Agency, and the Department of Labor issued one such rule each.⁶⁵

⁶³ Office of Mgmt. & Budget, Exec. Office of the President, OMB M-95-09, *Guidance for Implementing Title II of S. 1* (Mar. 31, 1995), available at <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/1995-1998/m95-09.pdf>.

⁶⁴ Please see Chapter II for a list of rules issued over the past ten years for which unfunded mandates in excess of \$100 million fell upon state, local, or tribal governments, rather than just the private sector.

⁶⁵ Interim final rules were not included in this chapter because section 202 of the Unfunded Mandates Reform Act “does not apply to interim final rules or non-notice rules issued under the ‘good cause’ exemption in 5 U.S.C. 553(b)(B).” OMB M-95-09, at 3

OMB worked with the agencies in applying the requirements of Title II of the Act to their selection of the regulatory options for these rules.

Table II. Final Rules Issued in FY 2017, FY 2018, or FY 2019 and Subject to Sections 202 and 205 of UMRA

<i>Agency</i>	<i>Rule Title</i>	<i>Description</i>
Department of Agriculture	National Bioengineered Food Disclosure Standard †	This rule mandates label disclosures of food that is or may be bioengineered.
Environmental Protection Agency	Renewable Fuel Volume Standards for 2017 and Biomass Based Diesel Volume (BBD) for 2018	This rule specifies the annual volume requirements for renewable fuels under the Renewable Fuel Standard program.
Environmental Protection Agency	Renewable Fuel Volume Standards for 2018 and Biomass Based Diesel Volume (BBD) for 2019 *	This rule specifies the annual volume requirements for renewable fuels under the Renewable Fuel Standard program.
Environmental Protection Agency	Renewable Fuel Volume Standards for 2019 and Biomass Based Diesel Volume (BBD) for 2020 †	This rule specifies the annual volume requirements for renewable fuels under the Renewable Fuel Standard program.
Environmental Protection Agency	Modernization of the Accidental Release Prevention Regulations Under Clean Air Act	This rule, in response to Executive Order 13650, includes several revisions to the accident prevention program.
Department of Energy	Energy Efficiency Standards for Miscellaneous Refrigeration Products	This final rule prescribes energy conservation standards for miscellaneous refrigeration products.
Department of Energy	Energy Conservation Standards for Ceiling Fans	This final rule prescribes energy conservation standards for ceiling fans.
Department of Energy	Energy Efficiency Standards for Central Air Conditioners and Heat Pumps	This final rule prescribes energy conservation standards for central air conditioners and heat pumps.
Department of Energy	Energy Conservation Standards for Dedicated-Purpose Pool Pumps	This final rule prescribes energy conservation standards for dedicated-purpose pool pumps.
Department of Energy	Energy Conservation Standards for Walk-In Coolers and Walk-In Freezers	This final rule prescribes energy conservation standards for walk-in coolers and walk-in freezers.
Department of Health and Human Services (and co-signatory agencies)	Federal Policy for the Protection of Human Subjects; Final Rules	This rulemaking, known as the Common Rule, revises human subjects regulations related to protections for research subjects and the facilitation of research.
Department of Labor	Walking Working Surfaces and Personal Fall Protection Systems	This final rule addresses slip, trip and fall hazards and establishes requirements for personal fall protection systems.
Department of Labor	Defining and Delimiting the Exemptions for Executive, Administrative, Professional, Outside Sales and Computer Employees †	This final rule adjusts the salary level thresholds for certain overtime pay requirements.
Department of the Interior	Waste Prevention, Production Subject to Royalties, and Resource Conservation	This final rule establishes requirements and incentives to reduce waste of gas and clarify when royalties apply to lost gas.

<i>Agency</i>	<i>Rule Title</i>	<i>Description</i>
Department of the Treasury	Treatment of Certain Interests in Corporations as Stock or Indebtedness	These final and temporary regulations establish threshold documentation that ordinarily must be satisfied in order for certain related-party interests in a corporation to be treated as indebtedness for federal tax purposes, and treat as stock certain related-party interests that otherwise would be treated as indebtedness for federal tax purposes.
* Issued in FY 2018		
† Issued in FY 2019		

APPENDIX A: RESPONSE TO COMMENTS

We wish to express our sincere appreciation for the thoughtful peer reviews and public comments we received on the Draft 2018, 2019, and 2020 Report. In particular, we would like to thank our invited peer reviewers: Jerry Ellig (George Washington University), James Gattuso (The Heritage Foundation), Clark Nardinelli (former Food and Drug Administration Chief Economist and Immediate Past President of the Society for Benefit-Cost Analysis), and Fran Sussman (independent consultant). We are grateful for their time and the thoughtfulness of their comments. For a full list of peer reviewers and public commenters please refer to the end of this appendix. For convenience, commenters are referred to by letter throughout this discussion.

In addition to the summaries that appear below, commenters made a number of other recommendations that have not been adopted in this document but may be considered for future Reports.

Structural and Presentational Recommendations

Several commenters made suggestions for structural changes in how the Report is presented. Several commenters (including Peer Reviewers W, X, Y, and Z) expressed approval for the inclusion of Excel™ files in appendixes, as it makes the Report more accessible to users, but recommended that OMB also include summary tables in the body of the Report. Peer Reviewer X suggested including at least “a listing of the year’s major rules, showing the quantified costs and benefits of each” and suggested integrating rules from independent agencies into these summary tables, as did Peer Reviewer Z. Peer Reviewer W recommended several tables for inclusion in the Report and suggested providing values in millions of dollars. Peer Reviewer Z suggested adding greater discussion of the data included with the Report to assist the public with interpretation of the data. Peer Reviewers X and Y suggested adding a summary description of each of the year’s rules, similar to what is provided for the rules included in the Report’s UMRA section. Commenters’ opinions differed somewhat about the usefulness of including a table of ten years of aggregate costs and benefits. Peer Reviewer Z argued that the table provides valuable information and should be included. Peer Reviewer X suggested adding a discussion of the year-to-year trends in the aggregate levels of regulation comparing aggregate costs, benefits and potentially the numbers of rules. Public Commenter C also recommended greater discussion of trends. Peer Reviewer W suggested discussion of additional reasons why aggregation is problematic. Peer Reviewer Y stated that returning to OMB’s previous practice of including a summary table of annual costs and benefits of rules over ten years would make it easier to compare the current year’s regulatory activity to previous years. We appreciate the recognition that our restructuring of the Report away from the format of older Reports represents an effort on our part to streamline the presentation and make the data from the reports more accessible. Consistent with several recommendations to provide more summary information in the Report body itself, and in order to make it simpler to find the major rules included in the Report, we have added a table intended to help link the main report document with the spreadsheets. In addition, we have attempted to provide a clearer explanation of why aggregation may not be appropriate in some instances. Our example focuses on regulations meant to improve enforcement of previous regulations, but we also acknowledge the

sometimes unavoidable “apples to oranges” nature of aggregation in other circumstances. Many of reviewers’ other suggestions and requests with respect to presentation seem reasonable to us, and we will consider making further changes in future years’ Reports.

Peer Reviewer Y suggested adding a spreadsheet containing year-by-year benefits and costs to show the stream of impacts after regulatory issuance (e.g., costs that are high upfront and lower later on, or benefits that grow steadily over time). The Reviewer suggests, “entries should be in current dollars and would not have to be carried out to infinity, just far enough to give an indication of the time patterns of benefits and costs.” Such a spreadsheet might be helpful in shedding light on the timeline of regulations’ effects. However, it would be difficult to develop such a spreadsheet because OMB does not collect year-by-year data from agencies, and we would have to consider whether the additional insight gained would be worth the additional recordkeeping burden.

Several commenters, including Peer Reviewers X, Y, and Z, suggested including a discussion of OMB’s recent significant reforms of the regulatory review process under Executive Order (EO) 13771. Public Commenter C suggest that OMB use the spreadsheets in this Report as a template for reporting on EO 13771 results. We produce separate annual reports on agencies’ results under EO 13771. While we have elected not to replicate those results here, we have added a more prominent reference to those annual reports, which can be found at <https://www.reginfo.gov/public/do/eAgendaEO13771>. We may consider including spreadsheets along with those reports in the future. Also, as suggested by Peer Reviewer Z, we have included a caveat to the text explaining that the values reported in those reports are not comparable to the values in the spreadsheet accompanying this Report.

Peer Reviewer W recommended that OMB consider adding “a section to the [R]eport that lists retrospective benefit and cost assessments for deregulatory initiatives undertaken under EO 13771, compar[ing] these assessments with the predictions agencies made in the RIAs when the regulations were adopted, and explain[ing] the reasons for any differences. As the reviewer notes, we have previously provided reasons why *ex ante* estimates of the costs of regulations may differ from estimates of the cost savings likely to result from their removal. In addition to unforeseen changes in technology, input prices, or other changes in the economy which change the costs of the rule, there may be sunk costs of complying with the regulation, which cannot be recouped by the regulated entities. Also, comparing the benefit and cost estimates for deregulatory rules to the estimates made when the regulations were adopted is often difficult because the deregulatory rules may be either narrower than the original rule, removing only a portion of the provisions, or may be broader, removing provisions from several rules while adding some less onerous regulatory provisions. When reviewing deregulatory rules, OIRA encourages agencies to explain fully the differences in circumstances or methodology with the RIAs for the rules that originally put the regulations in place.

Peer Reviewer W suggested that in Part II of the Report, the table of rules subject to UMRA include an indication of whether the rule has impacts on the private sector, state and local governments, or both. We agree, and have added to Part II a cross-reference to an earlier

section of the Report that lists rules for which unfunded mandates in excess of \$100 million fall on state, local, or tribal governments, rather than just on the private sector.

Public Commenter A notes that tables in previous versions of the Report listed only a high and a low value for costs and benefits of each rule, while the spreadsheet in the current Report lists a high and a low value at both 3 percent and 7 percent discount rates. For continuity, the Commenter requests more information on how the ranges were constructed in previous Reports. As noted on page 4 of the 2017 Report, “[t]he benefit and cost ranges represent lowest and highest agency estimates among all the estimates using both 3 and 7 percent discount rates.”

Public Commenter C raised questions about the inclusion and exclusion of several rules in the spreadsheet of economically significant rules in the Report. Below, as a response, we include the following table, which explains reasons for inclusion or exclusion of the rules listed in this public comment:

RIN	Title	Included or Excluded?	Reason
2132-AB23	Public Transportation Agency Safety Plans	Excluded	Final rule estimated to have cost savings < \$100M.
2137-AF22	Pipeline Safety: Underground Storage Facilities for Natural Gas	Excluded	OMB review concluded in FY 2020. Final rule estimated to have cost savings < \$100M.
0970-AC42/1653-AA75	Apprehension, Processing, Care, and Custody of Alien Minors and Unaccompanied Alien Children	Included (under RIN 1653-AA75)	Expected to have economically significant effects, however DHS was not able to quantify the costs of this rule. As of the drafting of this final Report, the rule is not in effect. A permanent injunction was issued on September 27, 2019.
1901-AB43	Small-Scale Natural Gas Exports	Excluded	Rule is not economically significant. It was inadvertently included in the list of rules and has been removed.
2127-AL39	Odometer Disclosure Requirements	Included	Published as a non-significant rule. Concurrent with finalization, DOT published a request for comment, seeking feedback on the effects of the rule. Comments received indicate that the rule is likely to have an economically significant effect. See docket (Docket No. NHTSA-2019-0092) for details on DOT's post-publication estimate of effects.

1904-AD01	Energy Conservation Standards for Commercial Packaged Boilers	Included	Excluded from the draft FY 2017 spreadsheet because it was not clear whether the rule would be issued. Included in the final FY 2017 spreadsheet.
1904-AD02	Energy Conservation Standards for Portable Air Conditioners	Included	Excluded from the draft FY 2017 spreadsheet because it was not clear whether the rule would be issued. Included in the final FY 2017 spreadsheet.
1904-AD69	Energy Conservation Standards for Uninterruptible Power Supplies	Included	Excluded from the draft FY 2017 spreadsheet because it was not clear whether the rule would be issued. Included in the final FY 2017 spreadsheet.

Miscellaneous Feedback

Several commenters, including Peer Reviewers W, Y, and Z, emphasized the importance of retrospective review. Peer Reviewer Z suggested including a review of recent literature to see what is learned from looking at retrospective review. OIRA agrees about the importance of retrospective review, both to improve the analysis of proposed regulations in the future by evaluating the accuracy of past prospective estimates of regulations’ expected effects and to help with identifying rules that are not cost-justified and should be removed or replaced. OIRA has previously included retrospective review in its recommendations for reform and continues to encourage agencies to engage in retrospective review as a part of their program of regulatory reform. We will consider a review of recent literature in this area for a future report.

Public Commenter B stated that a statement in draft Report “that ‘energy efficiency regulations tend to adversely affect lower-income consumers more than those who earn a higher income’ is misleading” and the Commenter also objects to the citation to a single paper for support of this statement. We note that there is a substantial amount of literature which supports this statement, although there is also some contrary literature. We have revised the language of the statement slightly, updated the reference to the previously cited working paper to the published version of that paper, and added two additional supporting papers.

Peer Reviewer W highlights “estimates [of] large private benefits... that appear to depend on an assumption that consumers (and in some cases businesses) apply irrationally high discount rates,” and Peer Reviewer Y more generally recommends “better assessments of the market, government, or behavioral failures that make federal regulation desirable.” We agree that market failure assessment should be an integral part of a regulatory impact analysis (RIA). Even where other motivations drive rulemaking—such as “improving the functioning of government, removing distributional unfairness, or promoting privacy and personal freedom,” per Circular A-4—it is worth considering whether innovations in economic research offer insight regarding connections between these goals and canonical market failures. If a compelling market or government failure cannot be identified in association with a policy being assessed,

then as a first principle, it is difficult to justify, from an analytical perspective, an estimate of positive net benefits elsewhere in a regulatory impact analysis. Relatedly, any claims in an RIA about failure of entities or individuals to optimize according to their self-identified self-interest (for example, estimating positive intrapersonal net benefits from requiring individuals to undertake a transaction that was freely available to them in the absence of the regulation) should be tied, as quantitatively and empirically as possible, to some market failure, such as network externalities, or grounded in scholarly literature, potentially including literature on so-called internalities. In general, there should be a process of continual refinement as quantitative and market failure sections of an impact analysis are simultaneously developed.

Peer Reviewer W discusses the interplay between incremental effects—which are the focus of regulatory impact analysis—and cumulative effects. We agree that two regulations, or other interventions in a given market, that have the same associated compliance expenditures can have quite different incremental costs or benefits, as encapsulated in consumer and producer surplus (and the related concept of deadweight loss).⁶⁶ We encourage agencies to continue improving their regulatory impact analyses, toward the goal of achieving sufficient nuance to reflect differing incremental effects as regulations accumulate.

Peer Reviewer Y discusses the use of the value of a statistical life (VSL) and the value of a statistical life-year (VSLY) for monetizing regulatory benefits, noting that the “use of a constant VSLY embodies many of the same problems as a constant VSL, such as variation across age groups [and] requires glossing over many technical problems . . . More work on VSLY separate from VSL might be in order and should be encouraged.” Public Commenter B states that alternatives to the VSL approach “should be developed very carefully and transparently, based on peer-reviewed literature and subject to public review and comment.” As noted in past Reports, we encourage agencies to use both VSL and VSLY as methods to value delayed mortality, especially when doing so would improve transparency about the length of life extension likely to be achieved by regulatory interventions. Circular A-4, released in 2003, emphasizes the “developing state of knowledge” regarding the use of VSLY, so awareness of recent contributions to the economics literature is especially important when agencies include this approach as part of their benefits analyses.

Public Commenter B suggests several revisions to the Draft Report’s discussion of health and longevity effects of particulate matter exposure. We have reviewed the relevant appendix and made substantial revisions.

We also received comments from two public commenters—Tinee Carraker and an apparent bot—that are not relevant to this Report.

List of peer reviewers and public commenters:

Peer Reviewer W: Jerry Ellig (George Washington University)

⁶⁶ A recent proposed rule for which the accompanying impact analysis lends itself to diagrammatic illustration of this phenomenon is the Department of Labor’s Tip Regulations Under the Fair Labor Standards Act (RIN: 1235-AA21).

Peer Reviewer X: James Gattuso (The Heritage Foundation)

Peer Reviewer Y: Clark Nardinelli (former FDA Chief Economist and Immediate Past President of the Society for Benefit-Cost Analysis)

Peer Reviewer Z: Fran Sussman (independent consultant)

Public Commenter A: B. Diamond (Keybridge)

Public Commenter B: Jason A. Schwartz (Institute for Policy Integrity)

Public Commenter C: Daniel Goldbeck (American Action Forum)

APPENDIX B: AGENCY CONSULTATION ACTIVITIES UNDER THE UNFUNDED MANDATES REFORM ACT OF 1995

Sections 203 and 204 of the Unfunded Mandates Reform Act require agencies to seek input from State, local, and tribal governments on new Federal regulations imposing significant intergovernmental mandates. This appendix summarizes selected consultation activities by agencies whose actions affect State, local, and tribal governments.⁶⁷

Multiple agencies subject to UMRA conducted consultation activities not only in their regulatory processes, but also in their program planning and implementation phases. These agencies have worked to enhance the regulatory environment by improving the way in which the Federal Government relates to its intergovernmental partners. Many of the departments and agencies not listed here (*e.g.*, the Departments of Justice, State, Treasury, and Veterans Affairs, the Small Business Administration, and the General Services Administration) do not often impose mandates upon States, localities, or tribes, and thus have fewer occasions to consult with these governments. Other agencies, such as the National Archives and Records Administration, are exempt from UMRA's reporting requirements, but may nonetheless engage in consultation where their activities would affect State, local, and Tribal governments.

As the following descriptions indicate, Federal agencies conduct a wide range of consultations. Agency consultations sometimes involve multiple levels of government, depending on the agency's understanding of the scope and impact of its rule or policy.

A. Department of Agriculture

Establishment of a Domestic Hemp Production Program⁶⁸

This interim final rule establishes a new part 990, Domestic Hemp Production Program, specifying the rules and regulations to produce hemp mandated by the Agriculture Improvement Act of 2018, which amended the Agricultural Marketing Agreement of 1946. This rule outlines provisions for the Department of Agriculture to approve plans submitted by U.S. States and territories of Indian tribes for the domestic production of hemp. It also establishes a Federal plan for states, territories or tribal governments that do not have their own USDA approved plan. The program includes provisions for maintaining information on the land where hemp is produced, testing the levels of delta-9 tetrahydrocannabinol (THC), disposing of plants not meeting necessary requirements, and provisions to ensure compliance with the requirements of the new part.

Because of the impact of this rule on States and Tribal Nations, USDA's Agricultural Marketing Service staff and officials met with hundreds of stakeholders from January through May 2019, ahead of publishing the interim final rule. This outreach included meetings with state

⁶⁷ The consultation activities described in this appendix are illustrative of intergovernmental consultations conducted by Federal agencies and are not limited to consultations on regulations meeting the UMRA threshold for an unfunded mandate. This should not be considered an exhaustive list of Federal consultation activities.

⁶⁸ 84 Fed. Reg. 58,522 (Oct. 31, 2019), available at <https://www.federalregister.gov/documents/2019/10/31/2019-23749/establishment-of-a-domestic-hemp-production-program>.

representatives as well as representatives from State Departments of Agriculture, the National Association of State Departments of Agriculture and several Tribal Nations. AMS hosted a Listening Session on March 13, 2019, in which more than 2,000 public stakeholders registered. Additionally, the Office of Tribal Relations organized several Tribal Consultations around the country, including one in Washington, DC.

Simplifying Meal Service and Monitoring Requirements in the National School Lunch and School Breakfast Programs⁶⁹

As part of ongoing efforts to support State and local Program operators, USDA held seven listening sessions and roundtable discussions with school food service staff, school district administrators, and State agency staff in 2018 (on July 11, September 20, October 2, October 23, and December 6) and 2019 (on February 25 and July 15) to solicit additional information about Program challenges and suggestions for improvement.

B. Department of Education

Alaska Native Education Program⁷⁰

In order to gather feedback about how relevant statutory amendments should be implemented, the Department conducted a Tribal consultation and several listening sessions.

C. Department of Health and Human Services

Medicaid Program; Medicaid and Children's Health Insurance Plan (CHIP) Managed Care⁷¹

The agency has conducted interactive listening sessions with various stakeholders, including state officials, and has also convened a diverse technical expert panel (TEP) to meet periodically to advise CMS on objectives, measures, and methodologies. The TEP includes representatives from state Medicaid and CHIP agencies.

Patient Protection and Affordable Care Act^{72,73,74}

⁶⁹ 85 Fed. Reg. 4,094 (Jan. 23, 2020), available at <https://www.federalregister.gov/documents/2020/01/23/2020-00926/simplifying-meal-service-and-monitoring-requirements-in-the-national-school-lunch-and-school>

⁷⁰ 83 Fed. Reg. 66,655 (Dec. 27, 2018), available at <https://www.federalregister.gov/documents/2018/12/27/2018-28130/proposed-definitions-and-requirements-alaska-native-education-program>

⁷¹ 83 Fed. Reg. 57,264 (Nov. 14, 2018), available at <https://www.federalregister.gov/documents/2018/11/14/2018-24626/medicaid-program-medicare-and-childrens-health-insurance-plan-chip-managed-care>

⁷² 84 Fed. Reg. 71,674 (Dec. 27, 2019), available at <https://www.federalregister.gov/documents/2019/12/27/2019-27713/patient-protection-and-affordable-care-act-exchange-program-integrity>

⁷³ 84 Fed. Reg. 17,454 (Apr. 25, 2019), available at <https://www.federalregister.gov/documents/2019/04/25/2019-08017/patient-protection-and-affordable-care-act-hhs-notice-of-benefit-and-payment-parameters-for-2020>

⁷⁴ 85 Fed. Reg. 7,088 (Feb. 6, 2020), available at <https://www.federalregister.gov/documents/2020/02/06/2020-02021/patient-protection-and-affordable-care-act-hhs-notice-of-benefit-and-payment-parameters-for-2021>

HHS has held a number of listening sessions with state representatives and many other groups and individuals. The agency maintains regular contact with State Exchanges through the Exchange Blueprint process and also meets with Tribal leaders and representatives.

Tobacco Products; Required Warnings for Cigarette Packages and Advertisements

There were several opportunities for tribes to engage with FDA about the proposed rule, including the impact and costs of the proposed rule on tribal manufacturers. In a “Dear Tribal Leader” letter dated August 15, 2019, FDA initiated consultation with federally recognized Indian tribes on the proposed rule and invited tribes to participate in an All Tribes’ Call on September 19, 2019. The purpose of the call was to provide an overview of the proposed rule, answer questions, and hear tribal comments on the proposed rule. FDA provided contact information in the letter and during the call to help ensure that there was a mechanism to address any further questions. FDA also encouraged tribes to submit written comments on the proposed rule and supporting documents.

Contract Support Costs

The Department of the Interior’s Bureau of Indian Affairs and the Department of Health and Human Services’ Indian Health Service (IHS) have engaged in a variety of activities concerning Contract Support Costs (CSC) as related to the FY 2014 Consolidated Appropriations Act. The agencies have held consultations and submitted short- and long-term plans to Congress, as required by the Act. Correspondence has been provided to Tribes to update them on CSC activities:

- January 22, 2015: Letter to Tribal Leaders provides update on FY 2014 and FY 2015 CSC.
- February 9, 2015: Letter to Tribal Leaders to consult on reclassifying CSC from discretionary to mandatory funding in FY 2017.
- May 22, 2015: Letter to Tribal Leaders to update on CSC activities/consultation.
- January 7, 2016: Letter to Tribal Leaders to initiate consultation to update IHS CSC policy.
- April 1, 2016: Letter to Tribal Leaders to update on CSC policy consultation.
- April 11, 2016: Letter to Tribal Leaders to announce comment period on CSC policy.
- October 31, 2016: Letter to Tribal Leaders to announce updated IHS CSC policy.
- April 26, 2017: Letter to Tribal Leaders to announce on-line training videos on updated IHS CSC policy.
- December 21, 2017: Letter to Tribal Leaders to announce IHS temporary policy decision.
- April 13, 2018: Letter to Tribal Leaders to consult on policy revision options with comment period.
- August 6, 2019: Letter to Tribal Leaders with final decision on update to IHS CSC policy.

IHS maintains several work groups, including one focused on Contract Support Costs. Information about these work groups may be found at <https://www.ihs.gov/tribalconsultation/workgroups/>.

D. Department of Homeland Security

Factors Considered When Evaluating a Governor's Request for Individual Assistance for a Major Disaster⁷⁵

On December 8 and 9, 2015, the agency held two webinars for State governors' offices, State emergency managers, and national level State associations to explain the provisions of an upcoming proposed rule and accept comments in response.

E. Department of the Interior

Procedures for Federal Acknowledgment of Alaska Native Entities⁷⁶

The Department held several listening sessions and consultations on these issues. The Department ultimately received eight written comments in response to the Tribal consultation.

Tribal Energy Resource Agreements; Education Contracts Under Johnson-O'Malley Act^{77,78}

The agency received input from Tribes on June 24, 2019, in Sparks, Nevada, at the National Congress of American Indians Mid-Year Conference and at Tribal consultation sessions on July 11, 2019, in Catoosa, Oklahoma; July 16, 2019, in Ignacio, Colorado; July 16, 2019, in Tahlequah, Oklahoma; July 18, 2019, in New Town, North Dakota; July 19, 2019, in Bismarck, North Dakota; and July 23, 2019, by teleconference.

F. Department of Energy

Indian Country Energy and Infrastructure Working Group (ICEIWG)

The ICEIWG has met several times in geographically diverse locations in the United States, including Bethel, Alaska (March 1–3, 2017); Albuquerque, New Mexico (May 7–8, 2018); Saint Paul, Minnesota (August 29, 2018); Denver, Colorado, (July 15–16, 2019); Fort McDowell, Arizona (February 24–25, 2020); and in Washington, DC on multiple occasions. The Working Group also met via teleconference several times.⁷⁹ These meetings gave Working Group members an opportunity to exchange information and updates on energy deployment opportunities, challenges, and successes with other Tribes and federal agencies.

⁷⁵ 84 Fed. Reg. 10,632 (Mar. 21, 2019), available at <https://www.federalregister.gov/documents/2019/03/21/2019-05388/factors-considered-when-evaluating-a-governors-request-for-individual-assistance-for-a-major>

⁷⁶ 85 Fed. Reg. 37 (Jan. 2, 2020), available at <https://www.federalregister.gov/documents/2020/01/02/2019-27998/procedures-for-federal-acknowledgment-of-alaska-native-entities>

⁷⁷ 84 Fed. Reg. 69,602 (Dec. 18, 2019), available at <https://www.federalregister.gov/documents/2019/12/18/2019-27399/tribal-energy-resource-agreements>

⁷⁸ 84 Fed. Reg. 30,647 (June 27, 2019), available at <https://www.federalregister.gov/documents/2019/06/27/2019-13632/education-contracts-under-johnson-omalley-act>

⁷⁹ See *ICEIWG Meeting Agendas and Summaries*, ENERGY.GOV, <http://energy.gov/indianenergy/listings/iceiwg-meeting-agendas-and-summaries> (last visited Sept. 21, 2020).

G. Environmental Protection Agency

Use of Lead-Free Pipes, Fittings, Fixtures, Solder and Flux for Drinking Water⁸⁰

EPA contacted the Association of State Drinking Water Administrators (ASDWA) for a list of representatives from states who could provide valuable input during the development of this proposed rule. Based on ASDWA's recommendations and availability of its members, EPA regularly consulted with representatives from drinking water programs within the States of Maine, Michigan, and Washington.

National Pollutant Discharge Elimination System (NPDES) Electronic Reporting Rule—Phase 2 Extension⁸¹

The EPA-state NPDES Noncompliance Report workgroup discusses how to identify, categorize, sort, and display violations on the Noncompliance Report. EPA held three listening sessions with the EPA-state NNCR workgroup, and States provided feedback.

⁸⁰ <https://www.regulations.gov/document?D=EPA-HQ-OW-2015-0680-0002>

⁸¹ 85 Fed. Reg. 11,909 (Feb. 28, 2020), available at <https://www.federalregister.gov/documents/2020/02/28/2020-02889/npdes-electronic-reporting-rule-phase-2-extension>

APPENDIX C: ASSUMPTIONS INHERENT IN THE HEALTH BENEFITS ESTIMATES ASSOCIATED WITH REDUCTIONS IN PARTICULATE MATTER EXPOSURE

Projections of the health impact of reducing particulate matter exposure are often a major part of the total monetized benefits of regulations summarized in OMB's annual reports.⁸² The estimates are based on a series of models that take into account emissions changes, resulting distributions of changes in ambient air quality, the estimated reductions in health effects from changes in exposure, and the composition of the population that will benefit from the reduced exposure. Each component includes assumptions, each with varying degrees of uncertainty.⁸³

Several key *assumptions* underpin the particulate matter benefits estimates, and our analysis of these sources of uncertainty follows.

1. Inhalation of fine particles is causally associated with premature death at concentrations near those experienced by most Americans. This assumption carries with it uncertainty. EPA has made this determination based on the weight of available evidence, which includes an assessment of potential biological mechanisms for cardiovascular- and respiratory-related effects in combination with epidemiological evidence, indicating that there is sufficient evidence to assume a causal relationship with exposure to fine particles and premature death.
2. The concentration-response function for fine particles and premature mortality is approximately linear down to the origin, and thus benefits can be estimated using a linear no-threshold model. This model is used to estimate mortality risk reductions for concentration reductions in locations where the expected baseline concentration is well below the Primary National Ambient Air Quality Standards (NAAQS), which reflects the level determined by EPA to be protective of public health with an adequate margin of safety, taking into consideration effects on susceptible subpopulations. The ACE final rule estimated that less than one percent of the estimated premature deaths avoided due to the regulation occur in locations with baseline concentrations estimated to be above the annual mean PM_{2.5} NAAQS of 12 µg/m³. EPA assessed uncertainties about this assumption in the RIA, and in the executive summary in the RIA for the ACE final rule EPA noted:

⁸² For example, in FY 2019, substantial estimated net benefits were associated with monetization of the health co-benefits of premature mortality associated with exposure to fine particulates (PM 2.5) in EPA's Affordable Clean Energy regulation (ACE; RIN 2060-AT67).

⁸³ Although the analysis of air quality rulemaking provides a useful illustration, the challenges of estimating regulatory benefits extend more broadly. As noted by one of this Report's peer reviewers: "Other examples can be found of low-level exposures and ingestions that are common in the population and are assumed to cause health risks and premature deaths, despite the apparent lack of effects among the population. . . . The use of one risk for chemically different particles has its counterpart in the use of similar outcomes for different product risks—one might call the assumption an effects transfer. Finally, the . . . longstanding use of a largely labor market value [of a statistical life], based on premia for safety risks, requires heroic assumptions to apply to everything from heart attacks among the elderly to childhood cancers."

In general, we are more confident in the size of the risks we estimate from simulated PM_{2.5} concentrations that coincide with the bulk of the observed PM concentrations in the epidemiological studies that are used to estimate the benefits. Likewise, we are less confident in the risk we estimate from simulated PM_{2.5} concentrations that fall below the bulk of the observed data in these studies.⁸⁴ Furthermore, when setting the 2012 PM NAAQS, the Administrator acknowledged greater uncertainty in specifying the “magnitude and significance” of PM-related health risks at PM concentrations below the NAAQS. As noted in the preamble to the 2012 PM NAAQS final rule, in the context of selecting and alternative NAAQS, the “EPA concludes that it is not appropriate to place as much confidence in the magnitude and significance of the associations over the lower percentiles of the distribution in each study as at and around the long-term mean concentration.”

3. All fine particles, regardless of their chemical composition, are equally potent in causing premature mortality. Although some scientific experiments have found differential toxicity among species of particulate matter, EPA, with the Clean Air Scientific Advisory Committee’s endorsement, has concluded that the scientific evidence is not yet sufficient to allow differentiation of benefits estimates by particle type.⁸⁵ The conclusions of the 2019 PM ISA support the assumption of equal toxicity. This aspect of uncertainty becomes relevant when comparing the magnitude of the PM-related benefits among past and future regulations because fine particles vary considerably in composition across sources. For instance, particulate matter indirectly produced via transported precursors emitted from electric generating units (EGUs) may differ significantly in composition from direct particulate matter released by other industrial sources. Similarly, gasoline and diesel engine emissions differ. Thus, when a given rule controls a broad range of sources, there is likely less uncertainty in the benefits estimate than if the rule controls a single type of source.
4. Full-scale photochemical air quality modeling provides the best ability to accurately estimate both the baseline (state of the world absent a rule) and the impacts of promulgating a regulation on air quality. The models used are regularly updated and have been peer-reviewed; however, the results are dependent on the quality of the model specification and input assumptions, such as the emissions inventory. It is important to document quality checks on the models, such as through model inter-comparisons; to update input data and assumptions on a regular basis to represent the most current

⁸⁴ The *Federal Register* Notice for the 2012 PM NAAQS indicates that “[i]n considering this additional population level information, the Administrator recognizes that, in general, the confidence in the magnitude and significance of an association identified in a study is strongest at and around the long-term mean concentration for the air quality distribution, as this represents the part of the distribution in which the data in any given study are generally most concentrated. She also recognizes that the degree of confidence decreases as one moves towards the lower part of the distribution.” [Enumerated as footnote 4 in the source document.]

⁸⁵ “[M]any constituents of PM_{2.5} can be linked with multiple health effects, and the evidence is not yet sufficient to allow differentiation of those constituents or sources that are more closely related to specific outcomes.” Nat’l Ctr. for Env’tl. Assessment—RTP Div., U.S. Env’tl. Protection Agency, EPA-600-R-08-139F, *Integrated Science Assessment for Particulate Matter (Final Report)* (Dec. 2009), available at <http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=216546>.

information; and to improve the quality of emissions inventories. In addition, when full-scale photochemical air quality modeling is used, as in the case of the ACE rule, to provide context for the results, it is important to provide quantitative and qualitative assessment of the uncertainties inherent in full air quality modeling. Likewise, when other approaches are used to monetize health benefits, such as reduced form approaches, the uncertainty inherent in those approaches should also be documented.

5. The value of mortality risk reduction, based largely on studies evaluating the additional compensation workers have required to accept additional on-the-job risk, is an unbiased estimate of what the population affected by changes in air pollution would be willing to pay for incremental reductions in mortality risk. Estimates from labor market studies reflect an average willingness-to-pay for the underlying study population, which are, by virtue of the labor force employed in riskier jobs, predominantly working-aged males. However, air pollution predominantly affects non-working-aged populations, including older, younger, and more diverse populations, who may hold different preferences. In addition, there is a disparity in the expected life extension experienced by the populations in the labor market studies compared with those affected by regulation. The average life extension from PM regulations tends to be measured in days or weeks whereas in labor market studies the expected life extension is measured in multiple decades.

Some studies indicate that willingness to pay for reductions in risk may change with age.⁸⁶ If VSLs do change with age, it would have an important impact on the size of the benefits associated with premature mortality because EPA's analysis shows that the median age of individuals experiencing reduced mortality is around 75 years old. However it is also worth noting that slightly more than half of the lost life years occur in populations age <65 due to the fact that the younger populations would lose more life years per death than older populations.⁸⁷

Finally, estimates from labor market studies can be unstable due to the small size of the risk changes analyzed. Changing the baseline occupational risk by 1 in 1,000 could result in a doubling or more of the value of a statistical life. In light of these issues, agencies are encouraged to supplement the existing VSL approach with alternative measures of mortality risk reduction valuation consistent with Circular A-4.

⁸⁶ See Krupnick (2007) for a survey of the literature.

⁸⁷ For discussion of partitioning life-year estimates by age, see U.S. Env'tl. Protection Agency, *Regulatory Impact Analysis for the Final Revisions to the National Ambient Air Quality Standards for Particulate Matter 5-75 to -76* [78 Fed. Reg. 3,086 (Jan. 15, 2013)], available at http://www.epa.gov/sites/production/files/2020-07/documents/naaqs-pm_ria_final_2012-12.pdf. See OMB Circular A-4 for further discussion on effectiveness metrics for public health and safety rulemakings such as "equivalent lives" (ELs) and "quality-adjusted life years" (QALYs).

APPENDIX D: REFERENCES

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