

**2018, 2019 and 2020 Draft 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 DRAFT 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 fiscal year 2017 (FY 2017),¹ extending into the prior Administration, executive agencies promulgated 57 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 17 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 fiscal year 2018 (FY 2018), executive agencies promulgated 33 major rules, of which 18 were "transfer" rules – rules that primarily caused income or wealth transfers. 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 five 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 fiscal year 2019 (FY 2019), executive agencies promulgated 55 major rules, over half of which were "transfer" rules – rules that primarily caused income or wealth transfers. More information about the FY 2019 major rules follows:

¹ October 1, 2016 – September 30, 2017.

- 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.

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 is specifically requesting comment on how best to provide the information required by law in this Report as well as recommendations for, or information on, deregulatory opportunities in sectors, trading relationships, or other situations where multiple agencies share

² 2 U.S.C. § 1538.

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 draft Report. For example, OMB is sharing data in this report via an electronic spreadsheet to allow the public to better use and analyze the information.³ As another example, we are requesting 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 OMB's *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated by Federal Agencies*⁴ and the number of peer reviews conducted pursuant OMB's *Final Information Quality Bulletin for Peer Review*.⁵ As an alternative, we are proposing to disseminate those fiscal year summaries on OMB's web site.⁶

Upon publication of this draft report, OMB will request public comment via a *Federal Register* notice and will seek input from peer reviewers with expertise in areas related to regulatory policy or cost-benefit analysis. The final version of this report will include revisions made in response to public and peer reviewer comments, and will be posted on the White House website.

³ As discussed in more detail below, the spreadsheets may facilitate calculation of impact subtotals that potentially hold interest for various readers.

⁴ *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies*, 67 FR 8452 (Feb. 22, 2002), available at <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/assets/OMB/fedreg/reproducible2.pdf>.

⁵ Office of Mgm't & Budget, Exec. Office of the President, OMB M-05-03, Memorandum for the Heads of Executive Departments and Agencies: Issuance of OMB's "Final Information Quality Bulletin for Peer Review" (2004). Available at: <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2005/m05-03.pdf>.

⁶ Such a web hosting would be consistent with "*Actions Needed to Improve Transparency and Reporting of Correction Requests*," GAO-16-110: Published: Dec 21, 2015. Publicly Released: Jan 20, 2016 (<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.

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

DRAFT

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.⁷

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);⁸
- Rules designated as meeting the analysis threshold under the Unfunded Mandates Reform Act of 1995 (UMRA);⁹ or
- Rules designated as “economically significant” under § 3(f)(1) of Executive Order 12866.¹⁰

⁷ 31 U.S.C. § 1105 note. The Regulatory Right-to-Know Act was enacted as Section 628 of FY 2000’s Treasury and General Government Appropriations Act, <https://www.govinfo.gov/content/pkg/PLAW-106publ58/html/PLAW-106publ58.htm>.

⁸ 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).

⁹ Generally, a written statement containing a qualitative and quantitative assessment of the anticipated benefits and costs of the Federal mandate is required under the 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).

¹⁰ 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 performed by OMB.¹¹ This chapter also includes a discussion of major rules issued by independent regulatory agencies, although OMB does not review these rules under Executive Order 12866.¹² This discussion is based solely on data provided by these agencies to the Government Accountability Office (GAO) and OMB under the Congressional Review Act.

As in previous reports, we have adjusted estimates to 2001 dollars, the requested format in OMB Circular A-4. We also report estimates that reflect a recent annual GDP deflator.¹³

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.¹⁴
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 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

¹¹ 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.

¹² 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.

¹³ 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*, <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.

¹⁴ Please see past Reports for further discussion about lack of comparability.

- significant non-quantified or non-monetized benefits (such as protection of privacy, human dignity, and—see point 5 below—equity) 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.¹⁵ 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. 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.¹⁶ 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 states that “those who bear the costs of regulation and those who enjoy its benefits often are not the same people.”¹⁷ In consequence, agencies are encouraged to provide separate descriptions of distributive effects. For example, energy efficiency regulations tend to adversely affect lower-income consumers more than those who earn a higher income.¹⁸ 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.¹⁹
 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, suppose the Occupational Safety and Health Administration (OSHA) issues a regulation reducing the permissible exposure level (PEL) for some toxin. OSHA estimates regulatory benefits based on a projection that the affected industries will comply by changing their production processes to entirely avoid using inputs that contain the toxin. If OSHA subsequently revises the regulation and, at the time of the revision, the best available evidence shows that exposure to the toxin has not been entirely eliminated, the RIA for the new rule would appropriately calculate benefits or forgone benefits using the more recent exposure data, even though a multi-year sum of the estimated effects of OSHA rules would yield an inaccurate cumulative total as

¹⁵ See Greenstone (2009).

¹⁶ Retrospective review has shown that both costs and benefits can be overestimated or underestimated. See Harrington, Morgenstern and Nelson (2000) and Harrington (2006).

¹⁷ OMB Circular A-4 (2003), p. 14, <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf>.

¹⁸ See Levinson (2016).

¹⁹ See, e.g., Kahn (2001).

a result. If the new rule further reduces the PEL, some health and longevity benefits that were already tallied in the first rule would be double-counted in an aggregation of the second rule's RIA with the first rule's. Analogously, if the new rule increases the PEL, forgone benefits would be substantially overestimated if the original RIA's projection of zero exposure were carried forward into the new RIA in spite of the more recent empirical evidence.²⁰

Estimates of the Benefits and Costs of Major Rules Issued in Fiscal Year 2017, Fiscal Year 2018, and Fiscal Year 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, 2019.²¹ (Note that, in all three of the fiscal years covered by this Report, over half of the major rules are transfer rules.²²) Major rules issued by their agencies represent approximately one-fourth of the final rules reviewed by OMB.^{23,24}

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, 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

²⁰ Although this example relates to the revision of an earlier rule, the caveats associated with aggregation apply more broadly, to any regulations that have interacting effects.

²¹ 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 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.

²² 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.

²³ Counts of OMB-reviewed rules are available through the "review counts" and "search" tools on OIRA's regulatory information website (www.reginfo.gov).

²⁴ 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 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.

Protection and Affordable Care Act; relevant RINs include 0938-AS95, 0938-AT14, 0938-AT08, 0938-AT48, 0938-AT65, 0938-AT37 and 0938-AT66.²⁵

The monetized costs and benefits estimates of the 17 FY 2017, five FY 2018 rules, and five FY 2019 rules for which both of those impact categories were estimated are, in the spreadsheets accompanying this report, aggregated by agency in Table 1-5 and listed in Table 1-6(a). For FY 2017, the issuing agencies estimate a total of \$4.4 billion to \$7.2 billion in annual benefits and \$1.6 billion to \$2.4 billion in annual costs (in 2001\$) or \$5.9 to \$9.5 billion in annual benefits and \$2.2 billion to \$3.2 billion in annual costs (in 2016\$). 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\$) or \$0.2 to \$0.6 billion in annual benefits and \$0.1 billion to \$0.3 billion in annual costs (in 2017\$). 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\$) or \$0.2 to \$3.7 billion in annual benefits and up to \$0.6 billion in annual costs (in 2018\$). 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. The spreadsheets that contain much of this Draft Report’s content may facilitate the calculation of other aggregates that are of interest to readers.²⁶

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) 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.²⁷

Each spreadsheet Table 1-7(a) 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.²⁸

²⁵ In 2010, OMB issued a memorandum on “Increasing Openness in the Rulemaking Process – Use of the Regulation Identifier Number (RIN)” (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.

²⁶ 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, at <https://www.reginfo.gov/public/do/eAgendaEO13771>.

²⁷ 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.

²⁸ 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

2. *Major Rules Issued by Historically Independent Agencies*

The Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA)²⁹ 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. 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, 2017, October 1, 2017, to September 30, 2018, or October 1, 2018, to September 30, 2019.³⁰ GAO reported that seven agencies issued a total of fifteen major rules during fiscal year 2017, eleven major rules during fiscal year 2018, and fifteen rules during fiscal year 2019. (Rules by independent agencies have not historically been subjected 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 provided some information on the benefits and costs of the regulation. Ten of the eleven FY 2018 rules provided some information on the benefits and costs of the regulation. 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, 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.

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.

²⁹ Pub. L. No. 104-121.

³⁰ In practice, a rule was considered “major” for the purposes of the report 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.

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 years, the following rules have imposed costs of more than \$100 million per year (1995\$) on State, local, and tribal governments and have been classified as public sector mandates under the Act:³¹

- *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.

³¹ 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 FY2013), for 2015 (issued FY2014), for 2016 (issued FY2015), for 2017 (issued FY2016)*: 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.³²

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.³³ Here, we focus on several recent contributions to this literature.³⁴

³² 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.

³³ 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.

³⁴ We request comment on whether readers prefer the consolidated approach featured in past Reports or this more succinct update 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 similar conclusion regarding the effect of regulation on employment; they examine the Federal Communication Commission's 2015 common carriage 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, 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 that abandoning such a policy leads 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.³⁵

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 (under section 553 of title 5, United States Code) and to allow interested parties an opportunity to comment. 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.³⁶ 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.

³⁵ <https://www.federalregister.gov/documents/2019/10/15/2019-22623/promoting-the-rule-of-law-through-improved-agency-guidance-documents>

³⁶ 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*³⁷

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, in shared bodies of water.

*United States-Canada Regulatory Cooperation Council RFI*³⁸

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

³⁷ <https://www.federalregister.gov/documents/2018/05/17/2018-10539/maritime-regulatory-reform>

³⁸ <https://www.federalregister.gov/documents/2018/10/09/2018-21765/request-for-information>

OMB may issue future RFIs, with the goal of aiding in the coordination of interagency 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.

Request for Comment

Consistent with the previously-discussed requests for information, are there other trading relationships, sectors, multi-agency regulatory programs, or cross-cutting regulatory issues that have not yet received a thorough opportunity for comment? Please identify these broad-based categories that would benefit from similar efforts as well as the relative value of such an effort (i.e. impacts on jobs, wages, competitiveness, sectors, or other).

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

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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 principles³⁹:

- 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 (a description of agency consultation activities will be included in the final version of this Report).

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, or from October 1, 2018, to September 30, 2019, which impose expenditures meeting the UMRA Title II threshold. 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.⁴⁰

³⁹ OMB, Memorandum for the Heads of Executive Departments and Agencies, M-95-09, "Guidance for Implementing Title II of S.1," 1995, available at <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/1995-1998/m95-09.pdf>.

⁴⁰ 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)." See OMB, Memorandum for the Heads of Executive Departments and Agencies, M-95-09, "Guidance for Implementing Title II of S.1," 1995, available at <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/1995-1998/m95-09.pdf>.

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.

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		

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APPENDIX A: ASSUMPTIONS INHERENT IN THE HEALTH BENEFITS ASSOCIATED WITH THE AMERICAN CLEAN ENERGY RULE

In FY2019, high estimated net benefits were associated with monetization of the ancillary health co-benefits of premature mortality associated with exposure to fine particulates (PM 2.5) in EPA's American Clean Energy (ACE) regulation. Projections of the health impact of reducing particulate matter 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. A 2002 study by the National Research Council/National Academy of Sciences entitled *Estimating the Public Health Benefits of Proposed Air Pollution Regulations* (2002) highlighted the uncertainty in the reduction of premature deaths associated with reduction in particulate matter and noted that EPA should describe uncertainty "as completely and realistically as possible...recognizing that regulatory action might be necessary in the presence of substantial uncertainty."

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 the very low concentrations experienced by most Americans on a daily basis. This assumption carries with it uncertainty that is currently not accounted for in the analysis presented in EPA's monetized benefits estimates.
2. The concentration-response function for fine particles and premature mortality is approximately linear, and thus benefits can be estimated using a linear no-threshold model. Such a model monetizes benefits for concentrations 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 occur above the annual mean PM_{2.5} NAAQS of 12 µg/m³. In the executive summary for the ACE final rule EPA stated:

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.⁴¹ 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

⁴¹ 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."

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.” (78 FR 3154, 15 January 2013).

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.⁴² However, some agencies and stakeholders have suggested that this research provides insight regarding potential differential toxicity among species of particulate matter. This assumption of equal toxicity contributes to the uncertainty associated with particulate matter benefits estimates 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. The forecasts for future emissions and associated air quality modeling accurately predict both the baseline (state of the world absent a rule) and the air quality impacts of the rule being analyzed. The models used are based on up-to-date assessment tools and scientific literature that has been peer-reviewed; however, as in all models the results may be significantly influenced by assumptions, incomplete data, and/or model parameter specification. Inherent uncertainties in the overall enterprise must be recognized, even if the results are critical to projecting the benefits of air quality regulations.
5. The value of mortality risk reduction, which is taken largely from studies of the willingness to accept risk in the labor market, is an accurate reflection of what the broader population would be willing to pay for incremental reductions in mortality risk from air pollution exposure. However, the labor market studies focus on working-aged males whereas air pollution affects non-working populations, including older and younger 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. 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

⁴² “[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.” U.S. Environmental Protection Agency (U.S. EPA). 2009. Integrated Science Assessment for Particulate Matter (Final Report). EPA-600-R-08-139F. National Center for Environmental Assessment—RTP Division. December. Available at <http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=216546>.

of the VSL. In light of these issues, agencies are encouraged to supplement the existing VSL approach with alternative measures of mortality valuation consistent with Circular A-4.

Some studies indicate that willingness to pay for reductions in risk may change with age.⁴³ 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.⁴⁴

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⁴³ See Krupnick (2007) for a survey of the literature.

⁴⁴ Regulatory Impact Analysis for the Final Revisions to the National Ambient Air Quality Standards for Particulate Matter, U.S. Environmental Protection Agency, 2012. [Pages 5-75 and 5-76, Chapter 5, Benefits]. <http://www.epa.gov/ttnecas1/regdata/RIAs/finalria.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).

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