GUIDELINES FOR REGULATORY IMPACT ANALYSIS: A PRIMER

U.S. Department of Health and Human Services
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This document briefly answers key questions related to developing regulatory impact analyses (RIAs), as required by Executive Order 12866 and by Executive Order 13563 (Clinton 1993, Obama 2011), and consistent with implementing guidance provided by the U.S. Office of Management and Budget (OMB 2003). For more detailed discussion of these and related topics, please see the *Guidelines for Regulatory Impact Analysis* (2016a), hereafter referred to as "the Guidelines," prepared by the U.S. Department of Health and Human Services (HHS) agency-wide Analytics Team, as well as other key references cited below.

This guidance represents the current thinking of the Department of Health and Human Services (HHS) on the conduct of regulatory impact analysis. It does not establish any requirements for any person and is not binding on HHS, any HHS agencies or the public. You can use an alternative approach if it satisfies the requirements of the applicable Executive Orders and regulations. To discuss an alternative approach, contact the Office of the Assistant Secretary for Planning and Evaluation.

WHAT IS REGULATORY IMPACT ANALYSIS AND WHY IS IT USEFUL?

RIAs apply a well-established and widely-used framework for collecting, organizing, and evaluating data on the anticipated consequences of alternative policies. They help ensure that regulatory actions are justified and necessary to achieve social goals, and that these actions are implemented in the most efficient, least burdensome, and most cost-effective manner possible (OMB 2011a). To support these aims, RIAs include an assessment of the benefits and costs anticipated to result from a proposed regulatory action and from alternative policy options. They also address other impacts as required by law and executive order, to aid agencies and the general public in understanding the potential effects of regulatory decisions. To the extent possible, RIAs quantify and monetize the anticipated benefits and costs and assess the distribution of the impacts.

Preparing an RIA itself has both benefits and costs. The benefits include improving the quality of the resulting decisions and their ultimate effects on social welfare. A well-conducted RIA develops the evidence to support informed choices, supplying a record of the data, assumptions, and analyses considered. It provides objective information on important outcomes, including those that are difficult to quantify, as well as related uncertainties. It aids decision-makers and others in comprehensively identifying impacts, including those that may be otherwise unanticipated, and helps clarify areas of agreement and disagreement. The costs of conducting RIAs include the need to devote staff and funding to preparing these assessments rather than to other tasks. To ensure efficient use of these resources, the analysis should be carefully tailored to focus on providing the information that is most important and useful.

After the RIA is completed, to the extent permitted by law, agencies should proceed with the regulation only if they can reasonably determine that its benefits justify its costs, recognizing that some impacts cannot be quantified and taking into account distributive impacts and equity (Clinton 1993, OMB 2011a). If more than one regulatory alternative meets this criterion, agencies should select the alternative that maximizes net benefits, both quantitative and qualitative, unless a statute requires another approach.

WHEN IS A REGULATORY IMPACT ANALYSIS REQUIRED?

An RIA is required for significant and economically significant regulatory actions. Section 3(d)(f) of Executive Order 12866 and supporting materials provide guidance as to what constitutes an "economically significant" rulemaking, stating that such actions 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" (Clinton 1993).

OMB states that "the $100 million threshold applies to the impact of the proposed or final regulation in *any one year*, and it includes *benefits, costs or transfers*. (The word 'or' is important: $100 million in annual benefits, *or* costs, *or* transfers is sufficient…)" (OMB 2011b).

The required contents of an RIA, particularly the degree of quantification, vary for significant and economically significant rulemakings (see Executive Order 12866 sections 6(a)(3)(B) and (C)). Additionally, agencies are encouraged to complete RIAs for regulations that are not defined as significant to improve the foundation for decision-making and to demonstrate the rationale and basis for the action.

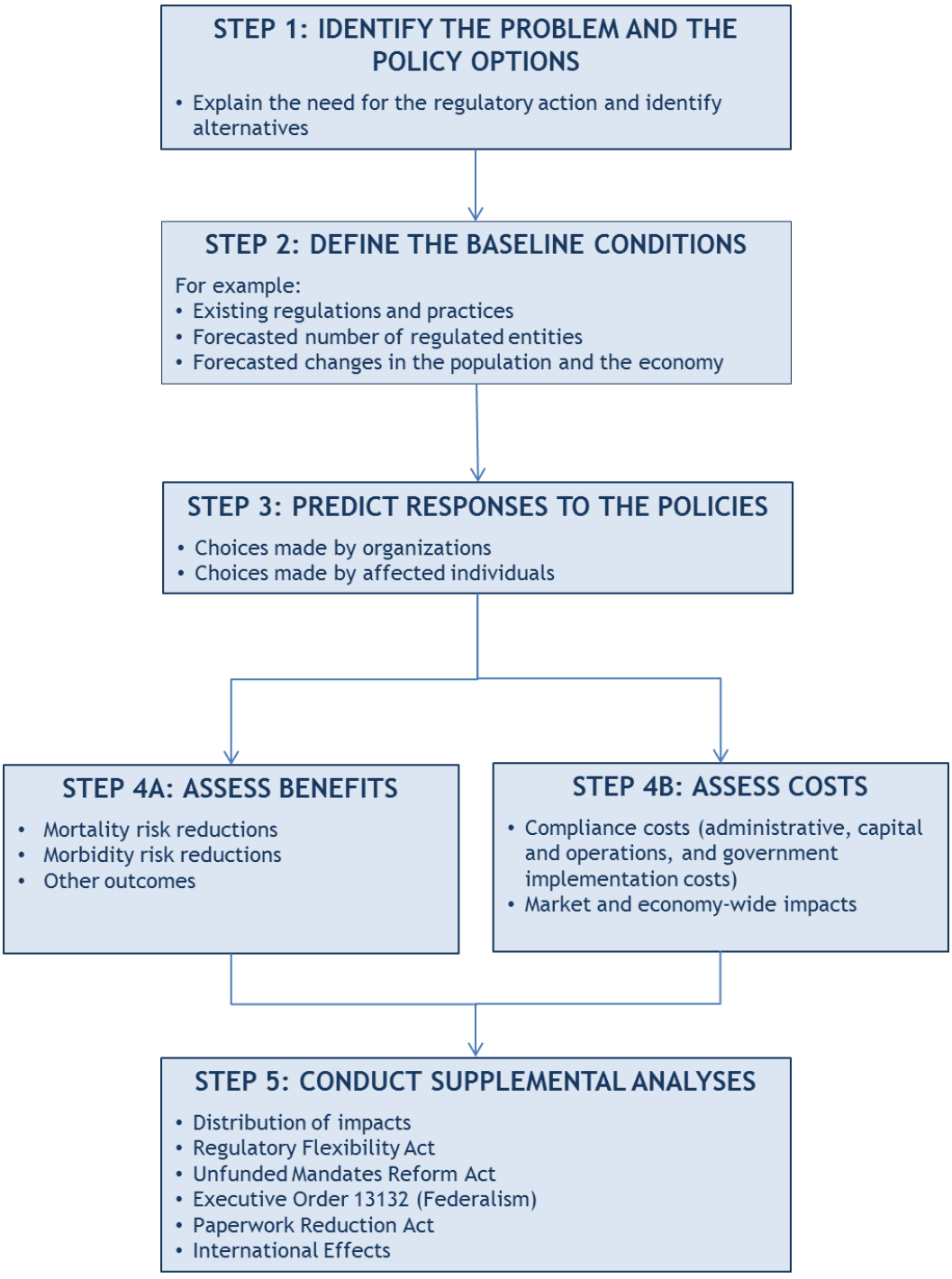
WHAT ARE THE STEPS IN A REGULATORY IMPACT ANALYSIS?

Figure 1 presents the general framework for conducting an RIA, which includes five steps that are described in more detail in the referenced sections of the Guidelines. This analysis should be initiated early in the regulatory development process, to inform internal agency deliberations and discussions with stakeholders. Typically, these steps are iterative, as each phase of the analysis provides new information that may lead to revision of previous work. Screening analysis is an important tool for determining how to best focus these efforts, to ensure that analytic resources are targeted on those issues that are most important for decision-making. In addition, the analysis must assess related uncertainties.

- In **Step 1**, the agency defines the framework for the analysis, explaining the need for the regulatory action and identifying the regulatory and non-regulatory options that will be considered. RIAs published to support proposed and final rules must include, at minimum, comprehensive analysis of one alternative that is more stringent than the preferred option and one that is less stringent; in total, more than three options should be assessed. A broader array of options should be considered during the regulatory development process and discussed in the RIA documentation. (Guidelines Sections 2.1)
- In **Step 2**, the agency defines the "no action" baseline, predicting expected future conditions without the regulation over the time period addressed.[1] (Guidelines Section 2.2)

[1] The standard time period covered by an RIA is generally 10 to 20 years (OMB 2011a), starting when the proposed regulation takes effect or when regulated entities or others begin to change their behavior in response to the regulation. However, other time periods may be selected depending on the regulation's characteristics.

FIGURE 1. THE FRAMEWORK OF A REGULATORY IMPACT ASSESSMENT



- In **Step 3**, the agency compares the baseline conditions to those expected once each policy option is implemented, to identify the incremental effects (those consequences that would not occur "but for" the policy), and categorizes these effects as benefits or costs. *Benefits* are the intended outcomes of the policy, and *costs* are the inputs needed to implement the policy. Offsetting effects, such as negative benefits (e.g., health risks from substitution of less safe drugs for a regulated product) or cost-savings (e.g., increased efficiency if the policy encourages transition from manual to automated systems), should be assigned to the same category as the effect they offset; i.e., as benefits and costs respectively. (Guidelines Section 2.3)
- In **Step 4**, the agency assesses the benefits and costs of the proposed regulatory action and the alternatives, quantifying them to the greatest extent possible and estimating their monetary value. *Benefits* typically include the resulting mortality and morbidity risk reductions as well as other impacts related to the regulation's goals (Guidelines Chapter 3). *Costs* include the reallocation of resources necessitated by the regulation, including compliance costs incurred by regulated entities as well as government implementation and enforcement costs (Guidelines Chapter 4). [2]
- In **Step 5**, the agency addresses other analytic requirements. These include considering the distribution of benefits and costs across demographic or other population groups as well as complying with the analytic requirements of several executive orders and statutes. In addition, analysis of significant impacts outside the United States is required. Much of the information needed to address these requirements is derived from the primary analysis of benefits and costs (Guidelines Chapter 7).

HOW SHOULD HEALTH BENEFITS BE VALUED?

The value of an improvement, such as a reduction in health risk, is determined by how much money the affected individuals would exchange for that improvement, given their budget constraints and preferences for spending on other goods and services. This means that the value of mortality and morbidity risk reductions is determined by individuals' willingness to pay (WTP) for changes in their own risks (Guidelines Section 3.1). Due to gaps in the available research, mortality and morbidity risk reductions are usually valued separately then summed, taking care to avoid double-counting. Costs incurred by third parties, such as insured medical costs and caretaker time, may be added to these estimates, as long as they are not included in the underlying WTP studies.

Valuing Mortality Risk Reductions

The approach for valuing mortality risk reductions is based on WTP estimates conventionally expressed as the value per statistical life (VSL). The VSL reflects individuals' WTP for changes in their own risk within a defined time period, and is typically calculated by dividing individual WTP for a small risk change (e.g., 1/10,000 annually) by the size of the risk change. For analyses conducted in 2014 dollars, risk reductions that occur in 2016 should be valued using a central VSL estimate of $9.6 million, and analysts should test the sensitivity of their results to values of $4.5 million and $14.6 million. See the Guidelines for information on how to adjust these values for other years (Guidelines Section 3.2).

The VSL is not the value of a person's life and should not be described as such. It is the rate at which an individual is willing to trade money for small changes in his or her own mortality risk.

[2] Guidelines Chapters 3 and 4 discuss the appropriate categorization of changes in medical costs, which may be included in the cost or benefit calculations depending on the regulation's characteristics. At times, whether to include an impact as a benefit or cost will be unclear, and analysts will need to document this uncertainty in describing how the impact is categorized in the RIA.

Valuing Morbidity Risk Reductions

The approach for valuing morbidity risk reductions is also based on WTP estimates, conventionally expressed as the value per statistical case. Analysts should first review the literature to determine whether WTP estimates of sufficient quality are available to value each health outcome of concern. If such values are not available, analysts should apply a proxy measure based on estimates of the monetary value of the quality-adjusted life years (QALYs) gained. QALYs are derived by multiplying the amount of time an individual spends in a health state by a measure of the health-related quality of life associated with that state.

Implementing this proxy approach involves two steps. First, analysts should review the literature to identify suitable, high-quality estimates of the change in QALYs attributable to the expected morbidity risk reductions, applying the criteria described in Guidelines Section 3.3.1. To value this change, analysts should multiply the QALY gain by estimates of the value per QALY derived from the range of VSL estimates described above, as also discussed in Guidelines Section 3.3.1. Table 1 provides the resulting values for 2016, in 2014 dollars, based on U.S. estimates of health-related quality of life and survival probabilities for each year of age (Guidelines Section 3.3).

TABLE 1. VALUE PER QALY IN 2016 (2014 DOLLARS)

VSL	VALUE PER QALY	
	3% DISCOUNT RATE	7% DISCOUNT RATE
$4.5 million	$230,000	$380,000
$9.6 million	$490,000	$820,000
$14.6 million	$750,000	$1,200,000

HOW SHOULD COMPLIANCE COSTS BE ESTIMATED?

Two fundamental economic concepts are of particular importance in assessing costs (Guidelines Section 4.1).

Opportunity Cost

Economists measure costs by the value of forgone opportunities, consistent with the concept of WTP introduced above. Costs are incurred when resources are used for one purpose and hence cannot be used for another purpose (e.g., employees who spend their time on compliance-related tasks cannot devote that time to other tasks). The opportunity cost is the value of the benefit that could have been provided by devoting the resources to their best alternative use.[3]

Transfers

Transfers are payments between persons or groups that do not affect the total resources available to society. They are a benefit to recipients and a cost to payers, with zero net effects. Although a transfer is not itself a resource cost, imposition of transfer payments may affect behavior and impose resource costs.[4]

[3] Opportunity costs are easy to confuse with accounting costs. Some may argue that a proposed regulation will not have any costs because regulated entities will simply re-allocate existing resources to comply with the regulation; no new expenditures are incurred. However, if resources are shifted for compliance purposes, other uses of those resources are forgone.

[4] For example, reductions in government payments to hospitals would generally be viewed as a transfer. However, the affected hospitals may change their behavior by accepting fewer patients or using less expensive treatments, in turn affecting health outcomes. The resulting change in health is an impact of the regulation that should be considered in the analysis if significant.

Typical categories of compliance costs and approaches to valuing them in an RIA are as follows.

➢ Administrative Costs

Administrative activities resulting from a regulation or alternative policy may include, for example, reviewing the regulatory requirements, developing protocols for compliance, collecting and reporting data, and training staff on implementation. Costs are valued based on the time and materials devoted to these new activities, taking care to include only the incremental effect of these activities in comparison to what would be undertaken in the baseline. For example, if new reporting requirements replace old requirements, the cost of the regulation is the difference between the two efforts (Guidelines Section 4.2.1).

Administrative costs should be valued using the following approach.

1. *Identify who will be undertaking the administrative tasks and estimate the amount of time required to complete them.* See Table 4.1 of the Guidelines for suggestions on quantifying the amount of time spent on typical administrative tasks.
2. *Multiply the hours by a per-hour value of time.* If the activities are undertaken by paid employees, the hours may be valued based on the marginal value of the product they would otherwise have produced. This value should be estimated as the combined total of wages, benefits, and overhead costs. If the activities are undertaken by individuals outside of work (e.g., filling out additional paperwork for health care reimbursement), this value should be estimated as the post-tax wage rate. Table 2 (below) summarizes the construction of these estimates. See Figures 4.1 and 4.2 of the Guidelines and associated text for example calculations.[5]
3. *Value any required sampling or testing.* If a regulation requires sampling or testing of materials, analysts may obtain cost estimates from third party vendors or other experts. Such costs should include both materials and labor.
4. *Value any materials used to complete administrative activities using readily-available prices from vendors and other experts.* For example, if the regulation generates the need for records storage, analysts should consider costs of electronic file storage or backup, rent for additional storage space, and/or the cost of filing cabinets or boxes.
5. *Value the cost of any travel required for administrative activities*. Particularly where the regulation creates the need for additional meetings or training activities, analysts should consider travel costs. The U.S. General Services Administration (GSA) provides per diem travel rates for lodging and meals, and air and car travel costs can be estimated using internet search engines and Internal Revenue Service (IRS) reimbursement rates for mileage, respectively.

[5] HHS is now undertaking a project to further refine the approach for valuing time; in the interim, analysts should follow the approach described in the Guidelines.

TABLE 2. CONSTRUCTING ESTIMATES OF THE VALUE OF ADMINISTRATIVE TIME

CONTEXT	COST CATEGORIES INCLUDED IN HOURLY VALUE	DATA SOURCES
Employees undertaking administrative tasks while working	• Pre-tax wages	• OES or NCS ECEC data on wages
	• Benefits: - Paid time off - Health benefits - Retirement benefits - Other legally required benefits - Payroll taxes • Other overhead costs: - General and administrative (G&A) - Fixed overhead - Insurance - Accounting profit	• Industry-specific data as available, or assume benefits plus other overhead costs equal 100 percent of pre-tax wages (i.e., for a fully-loaded wage rate, multiply pre-tax wages by a factor of two)
Individuals undertaking administrative tasks on their own time	• Post-tax wages	• OES or NCS ECEC data on wages • Adjust wage estimates using data on household income before and after taxes collected in the CPS

Acronyms:
CPS – Current Population Survey (http://www.census.gov/cps/data/cpstablecreator.html) (U.S. Census Bureau)
ECEC – Employer Costs for Employee Compensation (http://www.bls.gov/ncs/ect/) (U.S. Bureau of Labor Statistics)
NCS – National Compensation Survey (http://www.bls.gov/ncs/) (U.S. Bureau of Labor Statistics)
OES – Occupational Employment Statistics (http://www.bls.gov/oes/home.htm) (U.S. Bureau of Labor Statistics)

➢ Capital and Operations and Maintenance Costs

Regulated entities may need new equipment to comply with regulatory requirements. Capital costs refer to the resources needed to purchase the equipment (e.g., computers, software, or machinery) not immediately consumed in the production process. Operations and maintenance (O&M) costs include the labor, utilities, raw materials, and other resources consumed in production, including service provision and operation and maintenance of capital equipment. In both cases, analysts must be careful to isolate incremental costs relative to the baseline. For example, if a firm needs to purchase new and improved equipment to replace current machinery, the incremental costs of the regulation include only the costs above and beyond those associated with the equipment the firm would have otherwise purchased or maintained.

Capital and O&M costs should be valued using the following approach (Guidelines Section 4.2.2):

1. *Use market data to estimate the price of purchasing and installing equipment required by the regulation.* In some cases, the cost of the equipment may include installation costs; in other instances, these costs must be estimated separately. Information describing the useful life of the equipment is also necessary to determine whether the equipment must be replaced during the time period covered by the analysis.

2. *Use market data to value the annual costs of labor, utilities, and other resources required for production, service provision, and the operation and maintenance of capital equipment.* Methods for valuing labor costs are similar to those described previously for valuing time spent completing "on-the-job" administrative tasks.

Medical Costs

When a regulation imposes costs on the health care sector, for example by establishing or changing requirements for treatment, then medical costs may be included in the cost analysis.[6] The appropriate methodology for estimating medical costs will depend on the context. Analysts should review the literature for recent studies of the specific health effects and types of costs needed for the RIA. Analysts should consider contacting relevant health care cost researchers who focus on the outcomes of interest, such as technical experts at the Centers for Disease Control and Prevention, academic institutions, or nonprofit research organizations (Guidelines Section 4.2.3).

Government Implementation Costs

Government entities, including HHS agencies, may also incur costs, either as a regulated or implementing entity. For example, a regulation may impose new review, reporting, and record keeping requirements on government entities. Analysts should use the methods described above to estimate these costs (Guidelines Section 4.2.4).

WHAT APPROACH SHOULD BE USED TO ACCOUNT FOR TIMING?

Two aspects of timing should be taken into account in the regulatory analysis: (1) the effects of inflation; and (2) the effects of time preferences. Inflation affects general (nominal) price levels and hence the money value (but not the real value) of goods and services. In other words, it affects the price but not the rate at which one good can be exchanged for another. To avoid confusion between nominal and real prices, regulatory analyses should be conducted in constant (real) dollars. Generally, a dollar year is selected that is reasonably close to the current year. For example, a regulatory analysis conducted in 2016 may be conducted in constant 2015 dollars.

Second, individuals generally prefer to hasten benefits and defer costs, in part because money received today can be invested for future returns. This means that there is an opportunity cost associated with the timing of when benefits and costs accrue. Analysts account for this opportunity cost by discounting future impacts to the base year of the analysis using a real discount rate.

Thus analysts must estimate the "present value" of the stream of future benefits and costs, as follows (Guidelines Chapter 5).

1. *Estimate unit benefits and costs in constant dollar terms.* All monetized values should be adjusted to a constant dollar year (e.g., 2015) using an appropriate inflation index, generally either the Consumer Price Index (CPI) or the Gross Domestic Product (GDP) implicit price deflator.
2. *Assign benefits and costs to the future year in which they occur.* The benefit and cost models should be set up to allow analysts to enter benefits and costs, in constant dollars, in separate cells for each year they occur (e.g., Year 0, Year 1, Year 2, etc.). Analysts must present this undiscounted stream of benefits and costs, in constant dollars, in the RIA, along with the discounted results (OMB 2003).
3. *Select the appropriate discount rate.* OMB directs Federal agencies to estimate costs, benefits, and net benefits under two real discount rates, three and seven percent per annum (OMB 2003).

[6] As noted earlier, medical costs may be relevant to either the benefit or cost calculations depending on the characteristics of the regulation. For further discussion, see Guidelines Section 4.2.3. HHS is now undertaking a project to further refine the approach for estimating medical costs in RIAs.

4. *Discount the future effects to estimate their present value.* In each year of the analysis, calculate the present value of incurred benefits and costs by multiplying each effect by the formula $1/(1+d)^t$, where "d" is the discount rate and "t" measures the number of years in the future that the impact occurs. Separately sum the streams of discounted benefits and discounted costs and calculate the present value of the net benefits (benefits minus costs).[7]

5. *Calculate annualized values:* OMB directs agencies to also report impacts on an annualized basis. The annualized value is the constant annual amount that, if accrued over the same time period, has the same present value as the original stream.[8]

HOW SHOULD UNCERTAINTY AND NONQUANTIFIABLE EFFECTS BE ADDRESSED?

Analysts must ensure that decision-makers and other stakeholders understand the extent to which key uncertainties – in the data, models, and assumptions – affect the analytic conclusions. Approaches used to address uncertainty may be quantitative or qualitative, depending on available data and the importance of the affected quantity. Over time, analysts should work to reduce these uncertainties, and minimize the types of effects that cannot be quantified, by anticipating future analytic needs and investing in research that will be useful across a variety of regulatory and other analyses.

Table 3 presents approaches for addressing uncertainty in an RIA (Guidelines Chapter 6).

TABLE 3. APPROACHES FOR ADDRESSING UNCERTAINTY IN QUANTIFIED EFFECTS

APPROACH	APPLICABILITY	CONDUCT
Qualitative Discussion	• For all analyses. • May suffice if: – the rule involves annual economic effects less than $1 billion; – the analyst is able to demonstrate that the results are robust to uncertainties; and, – the consequences of the rule are modest.	Disclose key assumptions and uncertainties and include information on the implications for decision-making.
Numerical Sensitivity Analysis	• For rules involving annual economic effects less than $1 billion, where: – the qualitative discussion raises questions about the robustness of the results; or, – the consequences of the rule are large.	Vary one or many parameters to calculate distinct sets of results for comparison.
Probabilistic Analysis	• For rules involving annual economic effects of $1 billion or more (required). • For rules with smaller impacts where numerical sensitivity analysis raises questions about the robustness of the results.	Develop distributions for the uncertain parameters and conduct Monte Carlo analysis to determine the distribution of the results.

[7] Alternatively, analysts can use the present value function (PV) on a calculator or in spreadsheet software for this calculation.
[8] Annualized impacts can be calculated using the payment function (PMT) on a calculator or in spreadsheet software; OMB (2011b) provides step-by-step instructions.

Analysts should quantify impacts to the greatest degree possible, using tools such as sensitivity and probabilistic analysis to evaluate the effects of uncertainty. OMB (2003) requires probabilistic analysis for regulations with annual impacts greater than $1 billion; such analysis may also be useful for regulations with smaller impacts.

For outcomes that cannot be quantified but may have important implications for decision-making, analysts should clearly describe the effects and discuss their significance in comparison to each other and to the quantified impacts. Options to illustrate the potential implications of nonquantified impacts include break-even, cost-effectiveness, and bounding analysis, as well as presentation in tables and text.

WHAT SUPPLEMENTARY ANALYSES ARE REQUIRED?

Table 4 describes the supplementary analyses that may be required in an RIA in addition to the benefit-cost analysis (Guidelines Chapter 7).

TABLE 4. SUPPLEMENTARY ANALYSES

REQUIREMENT	APPLICABILITY	GUIDANCE DOCUMENTS
Regulatory Flexibility Act: Requires agencies to consider the impact of regulatory actions on small entities, analyze effective alternatives that minimize small entity impacts, and make their analyses available for public comment.	All regulations subject to notice and comment under section 553(b) of the Administrative Procedures Act. Note: a full regulatory flexibility analysis is not required if the agency can certify that the proposed rule will not "have a significant economic impact on a substantial number of small entities" (5 U.S.C. §605(b)). HHS provides guidance defining a "substantial number" and "significant effect" (see HHS 2003).	• *A Guide for Government Agencies: How to Comply with the Regulatory Flexibility Act* (SBA 2012) • *Guidance on Proper Consideration of Small Entities in Rulemakings of the U.S. Department of Health and Human Services* (HHS 2003)
Unfunded Mandates Reform Act: Requires agencies to assess the effects of regulatory actions on State, local, and tribal governments, and the private sector.	All "significant" rulemakings – defined as those likely to result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year in 1995 dollars, adjusted for inflation.	• "Guidance for Implementing Title II of S.1" (OMB 1995) • Annual memorandum from HHS updating "significant rulemaking" threshold value (e.g., HHS 2014)
Executive Order 13132 ("Federalism"): Requires agencies to develop a process to ensure meaningful and timely input by State and local officials.	All policies that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."	None.
Paperwork Reduction Act: Requires agencies to estimate the information collection (reporting, recordkeeping, and third-party disclosure) burden associated with their actions.	All policies that require generation, maintenance, or provision of information to or for a Federal agency. Agencies must obtain approval from OMB prior to requesting the same information from 10 or more individuals.	• Paperwork Reduction Act Primer (Sunstein 2010) • OMB's website Federal Collection of Information (OMB 2016) • HHS's website Frequently Asked Questions about PRA/Information Collection (HHS 2016b) • Agency's designated Paperwork Reduction Act team
OMB Guidance on International Effects: Requires agencies to consider the effects of regulations addressing trade barriers or other market failures on both the U.S. and its trading partners.	If a regulation has impacts outside of the U.S., these effects should be addressed in a supplementary analysis.	None.

HOW SHOULD THE APPROACH AND RESULTS BE COMMUNICATED?

RIAs are intended to inform decision-makers and other stakeholders about the consequences of different policy choices. Thus, it is essential that the analysis and the results be described in terms that can be easily understood by a lay audience. In general, the RIA should include the following sections:

1. Executive Summary
2. Statement of need for the regulation
3. Characterization of the without-regulation baseline
4. Description of the regulatory and non-regulatory alternatives
5. Benefits of the alternatives
6. Costs of the alternatives
7. Comparison of benefits and costs
8. Supplementary analyses

The RIA should include tables and figures that clearly convey the results of the analysis. Key information to be summarized includes:

- Annual benefits and costs (undiscounted);
- Annualized and present value benefits;
- Annualized and present value costs;
- Net benefits (i.e., benefits minus costs) presented on an annualized basis and in present value terms.

These quantified results should be accompanied by information on important nonquantified impacts.

In addition to "central" or "best" estimates, information on uncertainty must also be presented. When presenting annualized or present value impacts, analysts must report the time period over which impacts are estimated as well as the discount rate used.[9]

For economically significant rules, agencies are required to provide OMB with an accounting statement that reports estimates of benefits, costs, and other impacts. Figure 8.1 in Section 8.2 of the Guidelines provides a template for this accounting statement.

WHAT IS RETROSPECTIVE ANALYSIS AND WHEN IS IT REQUIRED?

Retrospective (*ex post*) analysis of the benefits and costs of regulatory actions provides useful information about the effectiveness of regulations after they have been implemented, as well as about the accuracy of the accompanying RIAs. In general, HHS analysts should conduct retrospective analysis for those economically significant regulations identified in the HHS *Plan for Retrospective Review* where the need for regulatory reform is not obvious for other reasons (such as where the regulation requires obsolete technology) (Guidelines Chapter 9).

[9] For meaningful comparison, benefits and cost must be measured over the same time period.

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