GUIDELINES FOR REGULATORY IMPACT ANALYSIS

2016

Office of the Assistant Secretary for Planning and Evaluation
U.S. Department of Health and Human Services

ACKNOWLEDGEMENTS

These *Guidelines for Regulatory Impact Analysis* were prepared for the U.S. Department of Health and Human Services (HHS) Analytics Team, under the leadership of Amber Jessup (Office of the Assistant Secretary for Planning and Evaluation). The primary authors were Lisa A. Robinson and James K. Hammitt (Harvard University Center for Risk Analysis and Center for Health Decision Science) and Jennifer R. Baxter (Industrial Economics, Incorporated, IEc). The work was performed between 2013 and 2016 under subcontract to IEc and Mathematica Policy Research; Ms. Baxter was the IEc Project Leader. Dr. Hammitt's work was also supported by an HHS Intergovernmental Personnel Act agreement. The authors were assisted by IEc staff including Lindsay Ludwig, who helped develop the initial drafts of several sections; Margaret Black, who provided additional editorial support and helped draft the related primer; and Michael Welsh, who helped develop the index and glossary.

The draft *Guidelines* were independently peer reviewed by Joseph Aldy (Harvard Kennedy School) and David Weimer (La Follette School of Public Affairs, University of Wisconsin-Madison). HHS staff also provided substantial advice and comments, including Evell Barco, Laina Bush, Caroline Cochran, Daniel Converse, Walt Francis, Sherry Glied, Scott Grosse, Kevin Haninger, Amber Jessup, Daniel Lawver, Nellie Lew, Clark Nardinelli, John Rigg, Kakoli Roy, C'Reda Weeden, Daniel Wilmoth, Nancy Zhang, and David Zorn, as well as other Analytics Team members and Centers for Disease Control and Prevention staff.

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.

TABLE OF CONTENTS

Acronyms

ASPE	Assistant Secretary for Planning and Evaluation
BLS	U.S. Bureau of Labor Statistics
CBO	Congressional Budget Office
CDC	Centers for Disease Control and Prevention
CEA	cost-effectiveness analysis
Census	U.S. Census Bureau
CPI	Consumer Price Index
CPS	Current Population Survey
CRA	Congressional Review Act
DOT	U.S. Department of Transportation
ECEC	Employer Costs for Employee Compensation
ECI	Employer Cost Index
EQ-5D	EuroQol-5 Dimensions
FDA	Food and Drug Administration
FICA	Federal Insurance Contributions Act
FRFA	Final Regulatory Flexibility Analysis
G&A	general and administrative
GAO	Government Accountability Office
GDP	gross domestic product
GSA	U.S. General Services Administration
HHS	U.S. Department of Health and Human Services
HRQL	health-related quality of life
HUI	Health Utilities Index
ICR	Information Collection Request
IRFA	Initial Regulatory Flexibility Analysis
IRS	Internal Revenue Service
NCS	National Compensation Survey
NHTSA	National Traffic Highway Safety Administration
O&M	operations and maintenance
OES	Occupational Employment Statistics
OMB	U.S. Office of Management and Budget
PRA	Paperwork Reduction Act
QALY	quality-adjusted life year
QCEW	Quarterly Census of Employment and Wages
QWB	Quality of Well-Being
RFA	Regulatory Flexibility Act
RIA	regulatory impact analysis
SBA	Small Business Administration
SBREFA	Small Business Regulatory Enforcement Fairness Act
SOP	standard operating procedure
UMRA	Unfunded Mandates Reform Act

VSL	value per statistical life
VSLY	value per statistical life year
WTA	willingness to accept compensation
WTP	willingness to pay

Chapter 1
Introduction

Executive Orders 12866 and 13563 (Clinton 1993, Obama 2011) call for a regulatory system that protects "public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation." To achieve these goals, the Department of Health and Human Services (HHS) analyzes the benefits, costs, and other impacts of significant proposed and final rulemakings, consistent with the requirements of the executive orders.

In the HHS 2011 *Plan for Retrospective Review of Existing Rules*, the Assistant Secretary for Planning and Evaluation (ASPE) was asked to establish an agency-wide Analytics Team to provide recommendations for strengthening regulatory analysis, leveraging the existing expertise of economists and analysts from throughout the Department's operating divisions.[1] The Analytics Team investigated current challenges and determined that guidance was needed to address common difficulties and to ensure consistent treatment across agencies. To meet that need, the Department developed these *Guidelines for Regulatory Impact Analysis* to assist its agencies in conducting economic analyses that meet the goals of the executive orders. This chapter briefly introduces related requirements and the contents of these *Guidelines*.

1.1 WHAT IS REGULATORY IMPACT ANALYSIS?

A regulatory impact analysis (RIA) reflects a well-established and widely-used approach for collecting, organizing, and analyzing data on the impacts of policy options, to promote evidence-based decision-making. It provides an objective, unbiased assessment that is an essential component of policy development, considering both quantifiable and unquantifiable impacts. Along with information on legal requirements, general policy goals, the distribution of the impacts, and other concerns, it forms the basis of the ultimate policy decision.

The RIA describes the effects of the regulation rather than advocating a particular approach. The arguments supporting the agency's decision are provided separately in the preamble to the *Federal Register* notice for the proposed and final regulation. The core of the RIA is an assessment of the benefits and costs of regulatory and other policy options in comparison to a "without regulation" (or "no action") baseline. In addition, the RIA includes supplementary analyses that respond to various statutory and administrative requirements.

WHY PREPARE AN RIA?

RIAs provide objective information and analysis that is essential for evidence-based decision-making. They include a benefit-cost analysis as well as other analyses mandated by various statutes and executive orders.

The RIA framework is described in general terms in Executive Orders 12866 and 13563 (Clinton 1993, Obama 2011).[2] More specific guidance and oversight is provided by the Office of Information and Regulatory Affairs within the U.S. Office of Management and Budget (OMB), which is part of the Executive Office of the President. OMB reviews both the regulation and the supporting analysis prior to promulgation.[3] Its primary analytic

[1] We provide links to those documents that are freely available on the internet in the reference list. Where possible, we link to the webpage that features the document rather than to the document itself, so that readers can check for updates.

[2] These requirements apply only to the extent allowable by law.

[3] Under the Congressional Review Act (CRA), agencies must also submit final rules and supporting analyses to the Government Accountability Office (GAO) for congressional review prior to promulgation. This submission must indicate whether the rule is "major" as defined under the CRA (5 USC §804(2)): "'major rule' means any rule that the Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget finds 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. The term does not include any rule promulgated under the Telecommunications Act of 1996 and the amendments made by that Act." More information is available on the GAO website (http://www.gao.gov/legal/congressact/cra_faq.html).

guidance is provided in *Circular A-4* (2003); it summarizes related requirements in a checklist for agencies (2010), a compilation of frequently-asked questions (2011a), and a primer (2011b). The OMB checklist is replicated in Appendix A of this document. Examples of RIAs completed by HHS and other agencies can be found by searching regulations.gov; however, analysts should be aware that many of the HHS analyses were completed prior to issuance of these *Guidelines*.[4]

In addition to the assessment of the benefits and costs, the RIA may include supplementary analyses that address the following, as relevant.

- the distribution of the impacts;
- the Unfunded Mandates Reform Act;
- the Regulatory Flexibility Act and Small Business Regulatory Enforcement Fairness Act;
- Executive Order 13132, "Federalism;"
- Section 1102(b) of the Social Security Act, small rural hospitals; and,
- the Paperwork Reduction Act.

More information on these requirements, as well as on the conduct of the benefit-cost analysis, is provided in the subsequent chapters of this guidance.

1.2 WHAT ARE THE BENEFITS AND COSTS OF CONDUCTING AN RIA?

The most important goals of the RIA are (1) to indicate whether Federal regulation is necessary and justified, and, if so, (2) to identify the regulatory option that is most economically efficient, providing the largest net benefits to society. A well-conducted RIA has numerous additional benefits. It develops the evidence to support well-informed decision-making and supplies a record of the data, assumptions, and analyses considered – providing a reasonable basis for rulemaking as required by the Administrative Procedures Act.

The RIA plays several other useful roles. For example, it:

- encourages comprehensive consideration of impacts;
- provides information on important regulatory outcomes expressed in physical and behavioral terms;
- estimates the economic value of the outcomes, based on the preferences of those who are affected;
- anticipates potential side effects, beneficial and adverse;
- supports consideration of non-quantifiable effects and uncertainty; and,
- aids decision-makers and stakeholders in clarifying 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 the efficient use of these resources, the analysis should be carefully tailored to focus on providing the information that is most important for decision-making. Screening analysis, discussed in the following chapter, is a useful tool for targeting efforts.

1.3 WHEN IS AN RIA REQUIRED?

An RIA is required for significant and economically significant regulatory actions as defined under Executive Order 12866 (§3(d-f)) and Executive Order 13563. An economically significant regulatory action is one that:

- is likely to **impose costs, benefits, or transfers of $100 million or more** in any given year, 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, §3(f)(1)).

[4] Many agencies also post their RIAs on their websites. For example, analyses completed by the Food and Drug Administration (FDA) can be found at: http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.

If a regulation is economically significant, then the analysis discussed in OMB *Circular A-4* (and described in more detail in these *Guidelines*) must be completed (Clinton 1993, §6(a)(3)(C)).

In addition, many other regulations are considered "significant," defined as those that:

- "[c]reate a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
- [m]aterially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or
- [r]aise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive order" (Clinton 1993, §3(f)(2-4)).

For regulatory actions that are significant, but not economically significant, Executive Order 12866 requires:

- "a reasonably detailed description of the need for the regulatory action and an explanation of how the regulatory action will meet that need," and
- "[a]n assessment of the potential costs and benefits of the regulatory action" (Clinton 1993, §6(a)(3)(B)).

Agencies may wish 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.

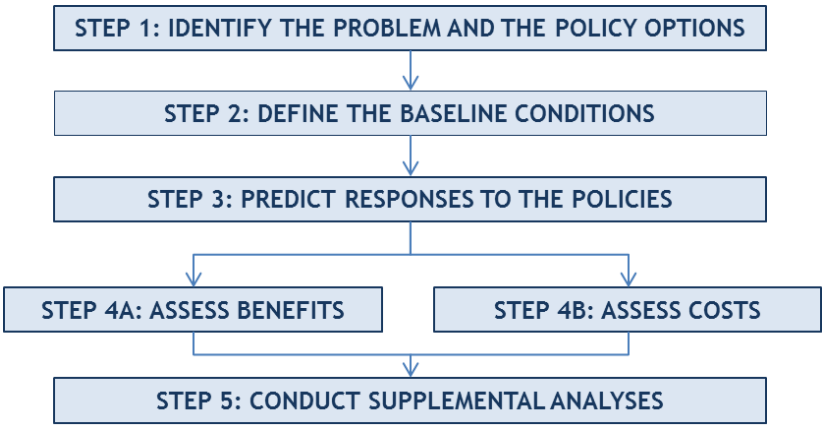
HOW DOES OMB INTERPRET THE $100 MILLION THRESHOLD?

An RIA is required for economically significant regulations. In defining "economically significant," OMB (2011a) states, "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: the categories are considered separately, not summed, so $100 million in any of the three categories -- annual benefits, or costs, or transfers -- is sufficient. For example, a regulation with $75 million in benefits, $60 million in costs, and $40 million in transfers is not economically significant. An RIA is also required for regulations deemed to be significant for other reasons and is an essential element of good regulatory practice.

1.4 WHAT ARE THE BASIC COMPONENTS?

The remaining chapters of this guidance are organized around the major components of an RIA, as illustrated in Figure 1.1.

FIGURE 1.1. MAJOR RIA COMPONENTS



- The first three steps are discussed in **Chapter 2: Frame the Analysis**.
- Steps 4A and 4B are described in detail in **Chapter 3: Assess Benefits** and **Chapter 4: Assess Costs**.
- Topics that affect the assessment of both benefits and costs are considered in **Chapter 5: Account for Timing** and **Chapter 6: Address Uncertainty and Nonquantifiable Effects**.
- The analyses under step 5 are discussed in **Chapter 7: Conduct Distributional and Other Supplementary Analyses.**
- The presentation of the results is considered in **Chapter 8: Communicate the Approach and Results.**
- The *Guidelines* conclude by turning from the discussion of *ex ante* (prospective) analysis to *ex post* analysis in **Chapter 9: Conduct Retrospective Analysis.**

Supplementary information is provided in the appendices.

Chapter 2

Frame the Analysis

Conducting an RIA involves first defining the problem to be addressed, identifying the policies to be assessed, exploring their potential consequences, and developing the approach for subsequent analytic work. This chapter describes these steps, focusing on the benefit-cost analysis that forms the core of the RIA. As introduced in Chapter 1 and discussed in more detail in Chapter 7, an RIA includes several supplementary analyses, to which the principles discussed in this chapter also apply. These analyses should be initiated in the early stages of the regulatory development process, to inform both internal agency deliberations and discussions with other stakeholders.

Benefit-cost analysis is a well-established systematic framework, based on economic welfare theory, for assessing and comparing the positive and negative impacts of policy options. It addresses the question of whether those affected by the policy, in the aggregate, value the benefits they receive more than the costs they incur. The distribution of the impacts (who receives the benefits and who bears the costs) is assessed separately (see Chapter 7).

The goal of the benefit-cost analysis is to indicate how limited resources can be best allocated to maximize net social welfare. Welfare is based on individual preferences, and money is used as a convenient and practical numeraire (or measuring rod) that describes the extent to which individuals are willing, as a society, to reduce their consumption of other goods and services to achieve the policy outcomes.

Conducting a benefit-cost analysis is often useful and informative even if the resulting summary measure – net benefits (benefits minus costs, which may be positive or negative) – is not used as a decision-making criterion or is only one of many factors considered.[5] The data and analysis provide a wealth of information on possible impacts, including many that often were not anticipated or predicted, and this information has important implications for regulatory design and implementation. The analysis should be descriptive, providing unbiased and objective information.

Framing the analysis involves defining what will be assessed and developing the general analytic approach. This chapter describes related activities, including explaining the need for the action and identifying the alternatives to be addressed, specifying the baseline, and determining the consequences of the regulation. It concludes by describing how screening analysis can be used to target analytic resources.

2.1 EXPLAIN THE NEED FOR ACTION AND IDENTIFY ALTERNATIVES

Consistent with OMB *Circular A-4*, agencies must first describe the market failure or other social purpose that leads to the need for regulatory action. They must also describe why action at the Federal level, rather than at the State or local level, is necessary or desirable. Agencies must indicate the significance of the regulation, based on the definitions in Executive Order 12866 that are replicated in the previous chapter.

[5] The normative basis for using benefit-cost analysis in decision-making begins with the Pareto principle, which states that a policy is desirable if it makes at least one person better off and no one worse off. While attractive in theory, few policies meet this criterion: most will harm (or impose costs on) at least a few people. To address this limitation, variations were developed by Nicholas Kaldor and John Hicks. These variations state that a policy is desirable if it makes the winners better off by an amount large enough to compensate the losers, and, alternatively, that it should be rejected if the losers could compensate the winners to not pursue the policy. These criteria do not demand that actual compensation take place. They imply that a policy for which costs exceed benefits should not be adopted and, if more than one policy provides positive net benefits, the one with the largest net benefits should be adopted. This principle is rarely applied strictly, as regulatory and other policy decisions are based on several considerations in addition to the results of the benefit-cost analysis.

Agencies must also consider a range of regulatory and non-regulatory alternatives, regardless of whether the statute or other authorities prescribe the option they can ultimately implement.[6] OMB *Circular A-4* lists the types of alternatives that should be considered, not all of which will be applicable to a particular regulation:

- different choices defined by statute;
- different compliance dates;
- different enforcement methods;
- different degrees of stringency;
- different requirements for different sized firms;
- different requirements for different geographic areas;
- performance standards rather than design standards;
- market-oriented approaches rather than direct controls; and,
- informational measures rather than regulation.[7]

HOW MANY ALTERNATIVES MUST BE ANALYZED?

Agencies must justify the need for regulatory action and consider a range of policy alternatives. These alternatives must, at minimum, include at least one that is more stringent and one that is less stringent than the preferred option; additional options should also be assessed.

Considering a wide-range of options both helps inform agency decision-making and encourages public comment. The versions of the analysis published to support the proposed and the final rule must include, at the very least, comprehensive analysis of one option that is more stringent and one that is less stringent than the preferred option; in total, more than three options should be assessed. These options should represent diverse approaches to meeting the policy goals and should be sufficiently distinct for the analysis to differentiate among them. In some cases, the statute or other legal constraints, or issues of technical feasibility, will limit the types of alternatives considered; this should be explicitly noted in the RIA. However, an option does not need to be legally permissible to be assessed.

Prior to promulgation, the analysis conducted to support the regulatory development process should consider a substantially broader array of options, which may be subject to varying degrees of assessment depending on their feasibility and likely impacts. These additional options also should be discussed in the RIA documentation to encourage public review and comment.

Selecting alternatives for assessment is an iterative process. As analysts gain a better understanding of the benefits and costs of the options, the alternatives to be included in the final RIA are likely to be altered and refined. Screening analysis, discussed later, can be used to eliminate many alternatives from detailed consideration. The rationale for excluding and including alternatives, and the alternatives excluded, should be explicitly discussed when documenting the analysis.

2.2 DEFINE THE "WITHOUT REGULATION" BASELINE

Each regulatory and non-regulatory alternative must be compared to a "no new regulatory action" baseline that reflects expected future conditions.[8] The analysis should, at minimum, compare conditions with and without the policy once the policy is fully implemented. This may occur several years from the present, given the time needed for notice and comment as well as implementation. In many cases, benefits and costs that accrue over the transition period may be significant and should be assessed. In some cases, there may be a significant time lag between when costs are incurred and when benefits accrue or vice-versa. In such cases, the analysis should cover the full time period between when the impacts first occur and when benefits and costs are expected to

[6] RIAs also aid the agency in identifying ways in which the statute can be improved. OMB *Circular A-4* notes: "You should also discuss the statutory requirements that affect the selection of regulatory approaches. If legal constraints prevent the selection of a regulatory action that best satisfies the philosophy and principles of Executive Order 12866, you should identify these constraints and estimate their opportunity cost." (OMB 2003, p. 17)

[7] Alternatives that provide information and disclosure are discussed in more detail in Sunstein (2010a).

[8] If the regulation is required by statute, the baseline should reflect the absence of the statutory requirement.

achieve equilibrium.[9] The RIA should generally consider benefits and costs that accrue over a 10 to 20 year time period, unless the program is expected to end sooner.

Analysts should explore likely trends rather than simply assuming that current conditions will continue. These projections should address future economic and health conditions as well as other factors that may affect the regulatory environment. Where future conditions are uncertain and changes in baseline assumptions significantly affect the analytic results, analysts should consider modeling more than one baseline or testing the sensitivity of their results to key assumptions.

WHAT IS THE APPROPRIATE TIMEFRAME FOR THE ANALYSIS?

In theory, the timeframe for the analysis should begin when regulated entities or others begin to change their behavior in response to the regulation (which may occur before or after the effective date of the regulation) and end when the impacts of the regulation cease. However, it is generally difficult to reasonably forecast effects far into the future. OMB suggests that if the proposed regulation has no predetermined sunset provision, the agency should use its best judgment about the foreseeable future. "For most agencies, a standard time period of analysis is 10 to 20 years, and rarely exceeds 50 years" (OMB 2011a).

Any difference between the baseline and a policy alternative may have both positive and negative consequences, and both should be considered. Conversely, neither the costs nor the benefits of changes predicted in the absence of the regulation should be attributed to the rule. For example, if a change in food handling procedures is expected under the baseline, the associated costs would not be counted as costs of the regulation. Similarly, the benefits of that change would have materialized in the baseline and cannot be attributed to the regulation.

When developing the baseline, analysts should also consider who has "standing;" i.e., whose benefits and costs should be counted. OMB *Circular A-4* (2003) indicates that the analysis should focus on U.S. residents and citizens. At times, determining standing raises difficult issues, such as how to address the preferences of those engaged in illegal activities. When such issues arise, the analysts should explicitly discuss their treatment in the RIA documentation.

If a regulation is likely to have impacts outside of the United States, these impacts should be assessed separately (see Chapter 7). A related issue is whether to assess only the immediate or direct impacts of the regulations, or to also account for second-order or indirect effects, which may affect different groups of people. Screening analysis is a useful tool for determining whether these less immediate effects are significant enough that they should be considered.

2.3 DESCRIBE THE CONSEQUENCES OF EACH POLICY ALTERNATIVE

One of the most difficult steps in conducting regulatory analysis is predicting responses to the policy options, given an evolving baseline, complex regulatory requirements, data gaps, and the diversity of the individuals and organizations affected. Regulatory requirements typically lead to a series of consequences (events and outcomes). It is important to distinguish between the initial requirement (e.g., hospitals must report certain adverse drug reactions); subsequent events (e.g., hospital staff change their prescribing behavior); the ultimate outcome (e.g., greater health improvements for some patients in comparison to the baseline); and its evaluation (e.g., the monetary value of the behavioral changes and the health improvements). Evidence must be used to establish the causal link between these events and outcomes. Analysts often find it useful to map these relationships as a decision tree (Raiffa 1968) or as a logic model (Centers for Disease Control and Prevention (CDC) 2007, Sundra et al. 2003, Wholey et al. 2010), which can be updated as more is learned about likely impacts.

[9] For meaningful comparison, benefits and costs should be measured over the same time period. If the nature of the impacts is such that assessing some over longer periods than others provides important information, the time period over which only some impacts are assessed should be reported separately when summarizing the analysis to avoid misleading comparisons.

Whether a particular consequence is classified as a benefit or cost does not affect the estimated net benefits, as long as the sign is correct (i.e., positive benefits and negative costs increase net benefits; negative benefits and positive costs decrease net benefits).[10] However, for clear communication, analysts should follow a consistent approach. Impacts categorized as benefits should relate to the intended outcome of the regulation (e.g., improved health); impacts categorized as costs should relate to the investment or inputs needed to achieve those outcomes (e.g., safety expenditures by industry). In this case, any negative effects that relate to the intended outcomes (e.g., through substitution of less safe drugs or less healthy foods for those that are regulated) would be combined with the benefit estimates, while any offsetting savings from regulatory compliance (e.g., increased efficiency from automation of previously manual tasks) would be combined with the cost estimates.

Understanding these consequences is an iterative process, as each step in the analysis often provides new insights. Initially, analysts should describe the possible outcomes ("fewer cases of cardiac and respiratory disease," "higher production costs") in as much detail as possible. What is ultimately assessed and quantified, and the level of detail, will depend on the results of the subsequent screening, as well as on what is learned in the course of the analysis.

WHEN SHOULD AN IMPACT BE CLASSIFIED AS A COST VERSUS A BENEFIT?

Costs are the inputs needed to implement the regulation (e.g., industry expenditures to improve safety); benefits are the intended outcomes (e.g., health improvements). Counterbalancing effects, such as cost-savings (e.g., lower operating costs if the regulation allows industry to replace older technology with more efficient equipment) or negative benefits (e.g., health risks of substituting less safe drugs or less healthy foods) should be assigned to the same category as the effect they offset; i.e., as costs and benefits respectively.

Analysts should comprehensively consider all potentially important consequences, including both those that are intended and unintended (positive or negative). They should also consider whether behavioral anomalies will lead to different outcomes than expected under the rational actor model typically assumed in economics. For example, individuals may respond to policies intended to increase safety by reducing their level of precaution, or such polices may lead to changes in social norms that lead to healthier behaviors. Another example is hyperbolic discounting (or present bias, sometimes described as self-control problems), which can lead individuals to engage in behavior (such as eating too much, exercising too little, or continuing to smoke) that is contrary to their own self-described preferences.[11]

Evaluating these consequences, through estimating their monetary value, is discussed in Chapters 3 and 4. These monetary values should be estimated as accurately and comprehensively possible, given analytic goals and time and resource constraints. Effects that cannot be quantified should be highlighted for consideration by decision-makers, as described in Chapter 6. That chapter also discusses methods for addressing uncertainty in the quantitative results.

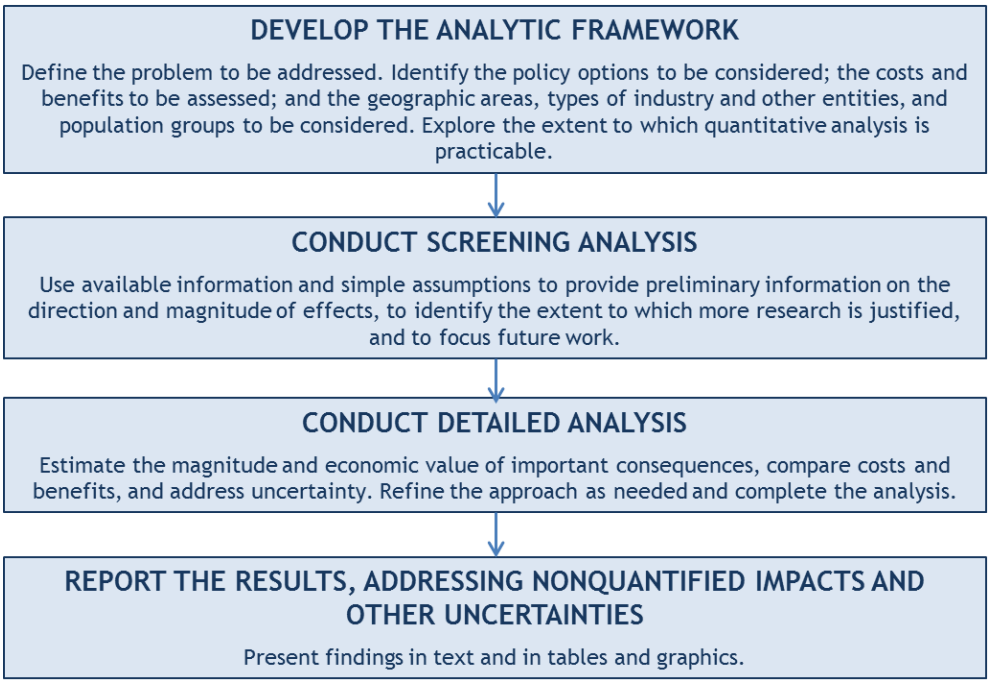
2.4 USE SCREENING TO FOCUS THE ANALYSIS

Once the initial framing of the analysis is completed, as discussed above, the subsequent steps involve determining how to best target future work, conducting the analysis, and reporting the results, as illustrated in Figure 2.1. Analysts will need to follow a similar process to determine the types of supplemental analyses to be conducted and the focus of that work. These processes are iterative; each step in the analysis will result in another round of decisions about whether to address certain impacts in more detail or focus attention elsewhere.

[10] Whether an impact is counted as a benefit or cost will affect the ratio of benefits to costs. As noted in OMB *Circular A-4*, benefit-cost ratios (and cost-benefit ratios) can be misleading (OMB 2003, p. 10) and generally should not be used as an indicator of economic efficiency. To avoid misunderstanding, such ratios should not be reported unless accompanied by information clarifying their appropriate interpretation.

[11] For more discussion of the valuation of the benefits of HHS policies that address habitual or addictive goods, see Cutler et al. (2015).

FIGURE 2.1. ANALYTIC STEPS



Screening analysis is a useful tool for targeting subsequent work. Such analysis is typically based on easily accessible data and simple assumptions; its goal is to provide preliminary information on the possible direction and magnitude of the effects and to inform decisions about future work. For example, high-end values can be used to determine whether various types of outcomes are likely to be significant even under extreme assumptions. Depending on the results, this screening may be followed by more detailed assessment that involves collecting additional data, refining the methods used, and possibly expanding the scope of the analysis as discussed in the following chapters. The analysis should discuss non-quantified impacts along with the quantitative results, and include assessment of uncertainties. The RIA should clearly document the results, as well as discuss the data sources and analytic steps and the implications of uncertainties.

Because analytic resources are limited, the ideal regulatory analysis will not assess all policy options, nor quantify all outcomes, with equal precision. In some cases, the cost of analyzing a particular policy option or quantifying a specific outcome will be greater than the likely benefit of assessing it, given its importance for decision-making.[12] In other words, the analysis may not sufficiently improve the basis for decision-making to pass an informal benefit-cost or value-of-information test. Conversely, options and outcomes that are important for decision-making should receive substantial attention. "Importance" may depend on the likely magnitude of the impacts; it may also depend on the need to respond to questions likely to be raised by decision-makers and others.

The content and level of detail, and the length of the RIA (which may be very short or very long), are likely to depend on the nature of the regulation, the characteristics of its benefits and costs, the populations affected, and the data and other analytic resources available. It is not possible to design a "one size fits all" approach; analysts need to exercise professional judgment in tailoring the analysis for an individual regulation. Generally, conducting screening analysis and following a phased approach will help ensure that the work is carefully focused and useful.

[12] Such decisions include those related to assessing whether statutory change may be desirable; as noted earlier, the analysis need not be limited to considering options allowed under current law.

Chapter 3

Assess Benefits

HHS regulations have many beneficial outcomes, including cost-savings as well as reduced health risks. As introduced in Chapter 2, the distinction between benefits and costs is not always clear. Generally, impacts categorized as benefits should relate to the intended outcomes of the regulation; i.e., the welfare improvements that comprise its goals. Impacts categorized as costs should relate to the investment or inputs needed to achieve those outcomes.

Methods for assessing both increases and decreases in costs are discussed in Chapter 4; this chapter addresses changes in health risks.[13] Such benefits are often the primary goal of HHS regulations and generally cannot be valued using market measures.[14] Calculating these benefits requires first estimating the change in risk associated with each regulatory and non-regulatory option (in comparison to the baseline) then estimating its monetary value. Below, we focus on valuation, first introducing basic concepts and methods, then describing specific approaches for application in HHS analyses.

3.1 BASIC CONCEPTS

The starting point for valuation is an estimate of the impact of each regulatory option on specific health effects, generally expressed as a change in the probability of illness or death for the average affected individual. The monetary value of the benefit to the average individual can be calculated as the change in probability of the illness or death multiplied by the value per statistical case, and summed across the affected population.

In practice, there is often little information on how the risk reduction or the value per statistical case varies across individuals. It is common practice to aggregate the changes in risk over the affected population to calculate the number of "statistical" cases averted by a regulation or other policy, and to multiply this by an average value per statistical case.[15] If, for example, a regulation would decrease the individual risk of a particular illness or death by 10/20,000 annually throughout a population of 200,000, then 100 statistical cases would be averted each year. The calculation is straightforward:

10/20,000 risk reduction x 200,000 individuals annually

= 100 statistical cases

Thus averting a statistical case or "saving" a statistical life is not the same as preventing an identifiable individual from becoming ill or dying; rather, it is a sum of probabilities.[16]

The question for the regulatory analyst is thus how to best estimate the value of these risk changes. Because we currently lack high quality, applicable studies that can be used to value the combined risk of illness and death, we generally estimate the number of averted statistical cases of premature mortality and of morbidity separately, then apply values to each and sum the results. The framework and methods for estimating these values is described below.

[13] Information on valuing other types of benefits, such as environmental improvements, is available in the U.S. Environmental Protection Agency's *Guidelines for Preparing Economic Analysis* (2014) and in Freeman et al. (2014).

[14] The goal of some regulations is to provide cost-savings rather than risk reductions. In such cases, these savings would be categorized as benefits and the methods described in the cost chapter would be used to value them. 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.

[15] This second approach yields the same result as the first, theoretically correct, approach if the risk reduction is the same across individuals, or the value per statistical case is the same across individuals, or the risk reduction and value per statistical case are uncorrelated in the population.

[16] In is typically impossible to identify *ex ante* whose illness or death will be prevented by a rule; in many cases, it is also impossible *ex post*.

3.1.1 ECONOMIC FOUNDATION

The approach for valuing mortality and morbidity risk reductions, as well as other policy impacts, is grounded in four basic assumptions that underlie the standard economic model. The first is that each individual is the best judge of his or her own welfare. This principle of consumer sovereignty means that benefit values should be based on the preferences of those affected by a policy. Such framing allows analysts to provide decision-makers with information on how those who would benefit are likely to value the improvement in their own health or longevity.

The second is that individuals can be modeled as deriving utility (well-being) from the goods and services they consume. If an individual chooses to buy a good or service, economists conventionally assume (consistent with consumer sovereignty) that he or she values the good or service more than the other goods or services he or she could have used that money to buy. Thus an individual's willingness to exchange money for different goods and services can be used to measure the utility he or she receives from their consumption. The monetary value of a risk reduction is appropriately measured by determining the change in wealth that has the same effect on utility as the risk reduction.

The third is that estimates of individual willingness to pay (WTP) provide a conceptually appropriate measure of value.[17] WTP is the maximum amount of money an individual would voluntarily exchange to obtain an improvement, given his or her budget constraints. It indicates the point at which the individual would be equally satisfied with having the good and less money, or with spending the money on other things. In addition to reflecting the trade-offs individuals make in everyday decisions related to spending on health and safety, this framing mimics the actual trade-offs implicit in regulation. If we as a nation choose to spend more, for example, on regulations that reduce food pathogen risks, we will have less to spend on other goods or services – including other risk-reducing measures.

The fourth key assumption is that benefit values are determined by the change in the amount by which aggregate WTP exceeds the market price, or "consumer surplus." When WTP exceeds price, the individual benefits from the fact that he or she can acquire the good or service for less than his or her willingness to pay. If price exceeds WTP, the individual would not purchase the good or service. The difference between WTP and price can be aggregated across individuals to determine the consumer surplus associated with different price levels. Consumers generally benefit from price decreases, because WTP then exceeds price by a larger amount, and vice-versa. More information on this concept is provided in Appendix B.[18]

WHAT IS THE BASIS FOR VALUATION?

Benefits are valued based on the maximum amount of money an individual would willingly exchange for the improvement, reducing his or her ability to purchase other things. This means that the value of mortality and morbidity risk reductions is determined by the affected individuals' willingness to pay for the change in their own risk.

3.1.2 VALUATION METHODS

For goods such as mortality and morbidity risk reductions, prices do not exist because they are not directly bought and sold in markets. Instead, we use the methods described below to estimate how much individuals would be willing to pay for the risk reductions. We can then compare aggregated WTP for these risk reductions (and other benefits) to the costs of a policy to determine the extent to which it is likely to yield net benefits.

[17] Estimates of willingness to accept compensation (WTA); i.e., of the least amount of money an individual would accept to forgo an improvement, are also consistent with this framework (see Robinson and Hammitt 2011, 2013). We refer to WTP throughout this discussion because it is more frequently studied. In addition, regulations generally involve spending for improvements from the status quo, rather than compensation to forego an improvement, in which case WTP is conceptually more appropriate.

[18] A similar concept applies to producers, who earn a surplus when they can supply units of a good for less than the market price, as discussed in Appendix B.

For nonmarket outcomes, economists typically rely on revealed or stated preference studies to estimate WTP.[19] Each has advantages and limitations: the choice of approach depends on the quality of the available research and the extent to which it measures an outcome similar to the policy outcome.

Revealed preference studies rely on observed market behavior to estimate the value of related nonmarket goods. For example, wage-risk (hedonic-wage) studies examine the compensation associated with jobs that involve differing risks of death or nonfatal injury, using statistical methods to separate the effects of these risks from the effects of other job and personal characteristics. While such methods have the advantage of relying on actual behavior with real consequences, it may be difficult to find a market good that can be used to estimate the value of a particular policy outcome.

Stated preference methods typically employ survey techniques to ask respondents about their WTP for the outcome of concern. Such surveys may directly elicit WTP for a particular scenario, or may present respondents with two or more scenarios involving different attributes and prices.[20] In the latter case, estimates of WTP are derived from the way in which respondents choose, rank, or rate alternatives. Stated preference methods are attractive because researchers can tailor them to directly value the outcomes of concern; for example, the survey can describe a particular type of illness from a particular type of exposure. A potential weakness is that respondents do not directly experience the consequences of their decisions and may have limited incentives to consider the questions carefully. Such surveys must be carefully designed and administered and satisfy various tests for coherence to be considered reliable for use in regulatory analysis.

Analysts often must rely on existing studies when estimating parameters values as well as their interrelationships, due to the substantial time and expense associated with conducting new primary research. When used to value benefits, this approach is typically referred to as "benefit transfer," and generally consists of the five steps described in Figure 3.1. It requires careful review of the literature to identify high-quality studies that are suitable for use in a particular context. "Quality" can be evaluated by considering the likely accuracy and reliability of the data and methods used, referencing guidance on best practices.[21] "Suitability" or "applicability" involves considering the similarity of the risks and the populations affected.

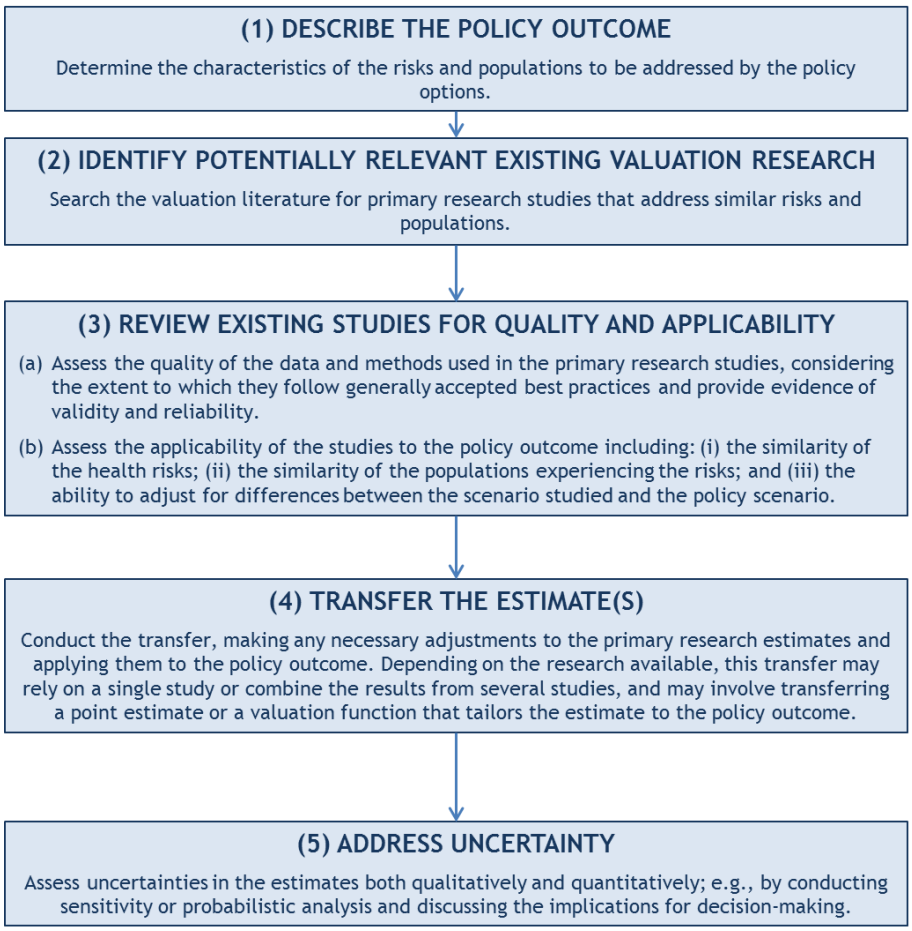
In the subsequent sections, we describe how this framework should be used by HHS regulatory analysts to value mortality and morbidity risk reductions. Numerous studies of the value of mortality risk reductions have been conducted; morbidity risk reductions have received substantially less attention. In the latter case, because fewer studies have been completed, analysts often rely on proxy measures.

[19] Experimental methods (see, for example, Shogren 2005) and structural models that combine theoretical expectations with data from various sources (see, for example, Smith et al. 2006) are less frequently applied but may be useful in some cases.

[20] Although the terminology is not always used consistently, the first type of study is usually referred to as a contingent valuation survey; the second as a choice experiment.

[21] Some guidelines for determining study quality are provided in OMB (2003) and EPA (2014) as well as in the sources cited in this guidance. Because these methods are continually evolving as additional research provides new insights, analysts should also consult recent articles and reports for updated guidance.

FIGURE 3.1. BENEFIT TRANSFER FRAMEWORK



3.2 VALUING MORTALITY RISK REDUCTIONS

The approach for valuing mortality risk reductions is generally based on estimates of the value per statistical life (VSL), from which a value per statistical life year (VSLY) is sometimes derived.[22] We first introduce both concepts then discuss recommendations for HHS analyses.

3.2.1 THE VALUE PER STATISTICAL LIFE AND THE VALUE PER STATISTICAL LIFE YEAR

As noted earlier, the starting point for valuation is typically an estimate of the individual risk change associated with each regulatory option. Valuation also starts at the individual level, estimating what an individual would be willing to pay for a defined change in his or her own risk, consistent with the principle of consumer sovereignty. Values for mortality risk reduction reflect the rate of tradeoff between money and small changes in mortality risk, referred to as the marginal rate of substitution between wealth and risk (Hammitt 2000). This value is conventionally reported in dollars per statistical life (the VSL), and often estimated by dividing the value of a small risk reduction by the size of the risk change.[23] For example, if an individual is willing to pay $900 for a 1 in 10,000 reduction in his or her risk of dying in the current year, his or her VSL is calculated as:

$900 WTP ÷ 1/10,000 risk change

= $9.0 million VSL

[22] Recommendations related to the use of the VSL or VSLY in HHS RIAs are discussed later in this chapter.

[23] For the U.S. population, the annual likelihood of dying at each year of age increases from about 10/10,000 to about 100/10,000 between age 20 and age 65, conditional on surviving to that age (Arias 2014).

The key parameter is the individual's WTP for the 1 in 10,000 risk reduction (i.e., the $900); it is expressed as the VSL (i.e., the $9.0 million) largely for convenience.[24] The value of a *statistical* life is not the value of saving an individual's life with certainty.

In principle, WTP should change nearly in proportion to the change in risk, as long as the risk change is small enough that WTP does not substantially limit other spending. Thus a single VSL can be used to value a range of small risk changes.[25] In other words, if we decrease the risk change in the above equation by a factor of 10, to 1/100,000, we assume that WTP will also decrease by a factor of 10, so the VSL will still be $9.0 million (= $90 WTP ÷ 1/100,000 risk change).

The VSLY is a related concept. In contrast to the VSL, which is the rate at which the individual substitutes money for reductions in current mortality risk (within the current year or other short time period), the VSLY is the rate at which he or she substitutes money for gains in life expectancy. A reduction in current mortality risk implies a corresponding increase in life expectancy and hence a corresponding gain in life years.[26]

Under the VSLY approach, a reduction in mortality risk is typically valued by calculating the corresponding gain in life expectancy and multiplying it by a VSLY. (Generally, future life years are first discounted to account for time preferences; discounting is discussed in more detail in Chapter 5.) As does WTP more generally, both the VSLY and the VSL vary depending on the characteristics of the individual and of the risk, and may increase, decrease, or remain the same depending on the age (and remaining life expectancy) of the affected individual. However, few primary research studies directly estimate the VSLY; it is typically instead derived from a VSL estimate using simple assumptions.

3.2.2 LITERATURE REVIEW

HHS commissioned a review of the VSL literature to identify values that are suitable for use in its regulatory analyses (Robinson and Hammitt 2016). The review had two goals: (1) to identify studies that meet evolving criteria for "best practices" for VSL research; and (2) to tailor the estimates used by HHS to the types of risks it regulates.

The criteria for that review were derived from several reports and articles that describe best practices for valuing mortality risk reductions in regulatory analyses (OMB 2003, EPA 2010, Kling et al. 2011, Cropper, Hammitt, and Robinson 2011, and U.S. Department of Transportation (DOT) 2015a). The criteria are listed in Figure 3.2 and discussed in more detail by Robinson and Hammitt (2016) as well as in these source documents.

[24] The VSL is at times described as aggregating individual WTP across a population; i.e., if each individual is willing to pay $900 for a 1 in 10,000 risk, and the population included 10,000 such individuals, then the value per statistical case would be $9 million ($900 * 10,000 individuals). This definition can be misleading, however, because WTP for a similar risk reduction is likely to vary across individuals.

[25] Many VSL studies consider risks in the range of 1/10,000 or 1/100,000. While applying the resulting VSL to smaller risk changes is appropriate, care must be taken in cases where the risk change is substantially larger. As the risk change increases, WTP will be increasingly limited by income, reducing the VSL (see Alolayan et al. 2015 for more discussion).

[26] Because death can be postponed but not prevented, reducing the risk of dying at one time necessarily increases the risk of dying at some later time. Similarly, reducing the chance of dying from one cause necessarily increases the risk of dying from some other cause. For example, if a policy were to reduce the chance of dying this year from 5 percent to 2 percent, then the chance of dying in a future year would increase from 95 percent to 98 percent. In general, a regulation may reduce individuals' hazard function (the chance of dying at specific dates or ages conditional on being alive). This shift in the hazard can be expressed as a reduction in the expected number of deaths in a specified time period (less than one for an individual) or as an increase in the expected number of years lived; the individual's WTP for the shift in the hazard can be expressed as a VSL or a VSLY by dividing WTP by the expected change in deaths or years lived (see Hammitt 2007).

FIGURE 3.2. SELECTION CRITERIA FOR VSL STUDIES

General Criteria

1. Be publicly available.
2. Be written in English.
3. Provide estimates for the general U.S. population.

Criteria for Revealed Preference Studies

4. Use hedonic methods that address the trade-off between wages and job-related risks.
5. Control for potentially confounding factors, such as nonfatal injury risk as well as both industry and occupation.
6. Rely on high quality risk data, equal or superior to the Census of Fatal Occupational Injuries.

Criteria for Stated Preference Studies

7. Elicit values for private risk reductions that accrue to the respondent.
8. Express the risk change as a probability.
9. Estimate willingness to pay, not willingness to accept compensation.
10. Provide evidence of validity, including sensitivity of willingness to pay to changes in risk magnitude.

The review yielded six revealed preference studies that meet the selection criteria, all of which consider the trade-off between wages and occupational risks, as well as one meta-analysis of these studies.[27] Of the stated preference studies, three met the selection criteria.[28] These latter studies consider fatal risks associated with motor vehicle accidents, ingesting pesticide residues on food, and unspecified causes. One considers only fatal injuries, the other two also address illness-related fatalities.

When adjusted for inflation and real income growth, the VSLs highlighted in these studies range from $4.4 million to $14.2 million, with a mid-point of $9.3 million (2014 dollars and income levels).[29] Applying these results in HHS analyses requires additional adjustments, as described below.

3.2.3 RECOMMENDED VALUES

The range of VSL estimates that result from this review form the basis for HHS' approach for valuing mortality risk reductions; HHS anticipates periodically updating these estimates to reflect the results from new research. This section discusses issues related to adapting these values for application in different regulatory contexts and in different years. The approach it discusses should be applied in all HHS RIAs to provide a common reference case that is comparable across analyses. However, analysts may also report results using alternative estimates or assumptions, if well-justified given the characteristics of the policy and the available research.[30]

WHAT VSL SHOULD BE APPLIED IN HHS ANALYSES?

For analyses conducted in 2014 dollars, risk reductions that occur in 2016 should be valued using a central VSL estimate of $9.6 million. Analysts should test the sensitivity of their results to values of $4.5 million and $14.6 million. The text describes how to adjust these values for other years.

We expect the VSL to vary depending on individual characteristics such as age and health status, and on risk characteristics such as whether death occurs immediately or after an extended illness. However, the effects of many of these characteristics have not been well-studied, and the results of the available research are often inconsistent. Thus the same population-average VSL should be applied in all RIAs, accompanied by discussion of

[27] The six wage-risk studies are: Viscusi (2004), Kniesner and Viscusi (2005), Hersch and Viscusi (2010), Lee and Taylor (2013), Scotton (2013), and Viscusi (2013). The meta-analysis of wage-risk studies is Viscusi (2015).

[28] The three stated preference studies are Corso, Hammitt, and Graham (2001), Hammitt and Haninger (2010), and Cameron and DeShazo (2013).

[29] The estimates reported in Robinson and Hammitt (2016) ranged from $4.2 million to $13.7 million, with a mid-point of $9.0 million (2013 dollars and income levels). They have been updated to 2014 dollars and income levels in these *Guidelines*, using the approach described below.

[30] See Chapter 6 for more discussion of the analysis of uncertainties.

uncertainties.[31] The values cited above should be adjusted for inflation and real income growth as well as for latency or cessation lag if relevant.[32] Sensitivity analysis also should be conducted in cases where the individuals affected are predominantly very young or very old. Each of these adjustments is discussed below.

The first set of adjustments is needed to reflect the time that has elapsed since the VSL studies were conducted, and involve addressing both inflation and changes in real income. The process for inflating values to reflect economy-wide price levels as of a common dollar year is discussed in Chapter 5.[33] Adjusting for real income growth is a separate step that requires two inputs: an estimate of the change in population-wide real income per person, and an estimate of the extent to which WTP is expected to change in response to the income change. The latter is generally expressed as the percentage change in the VSL associated with a one percent change in real income; i.e., the income elasticity.

Although both economic theory and numerous empirical studies suggest that the VSL increases as real income increases, the rate of increase is uncertain (Hammitt and Robinson 2011, DOT 2015a). Some research suggests that a one percent change in income leads to less than a one percent change in the VSL (e.g., Viscusi and Aldy 2003), and other research suggests that it leads to more than a one percent change (e.g., Kniesner, Viscusi and Ziliak 2010, Viscusi 2015). Given this uncertainty, HHS analysts should apply an income elasticity of 1.0 in their analyses.[34]

Once the VSL has been inflated to the common dollar year used in the analysis, the formula for adjusting for real income growth (assuming a constant rate of income growth and a constant income elasticity) is:

$$VSL(\text{year } y) = VSL(\text{year } x) * (1+\text{real income growth rate})^{\text{elasticity} * (y-x)}$$

Because no single source provides data on both actual and projected changes in real income, analysts will need to use different sources depending on the time period. More specifically, analysts should use Current Population Survey (CPS) data to adjust for past income growth, and Congressional Budget Office (CBO) data to adjust for future income growth; both focus on earnings, consistent with the measures generally used in the VSL studies.[35] The most recent CBO report (2015, p. 112) projects real earnings growth at 1.4 percent per year for 2015 through 2040.

Table 3.1 provides an example of the adjustments to these values over a 10-year period using the data sources identified above, including a VSL income elasticity of 1.0 and real income growth of 1.4 percent per year. (Note that while values should be inflated only to the common dollar year used in the analysis (2014 in this example), the adjustment for real income growth is needed for each subsequent year that the analysis covers.) As indicated by the table, if the analysis is conducted in 2014 dollars, mortality risk reductions that accrue in 2016 would be valued using a central VSL estimate of $9.6 million. At minimum, analysts should test the sensitivity of their results to the values at the low and high ends of the range; i.e., $4.5 million and $14.6 million.

[31] This implies there should be no adjustment for morbidity prior to death for fatal cases. If regulation of a hazard (such as a foodborne pathogen) can prevent both fatal and nonfatal illness, the expected reduction in fatal cases should be valued using the VSL and the expected reduction in nonfatal cases should be valued using appropriate estimates of WTP or monetized QALYs as discussed in Section 3.3.

[32] Latency is the time between when an individual is exposed to a hazard and when the adverse effect results; cessation lag is the time between when an individual's exposure to a hazard ends (or is reduced) and when his or her risk of adverse effect declines. These time periods are not necessarily equal.

[33] The calculations in the text use the Consumer Price Index (CPI, available at http://www.bls.gov/cpi/) to adjust for inflation. As discussed in Chapter 5, analysts may use the Gross Domestic Product implicit price deflator instead of the CPI.

[34] If changing the income elasticity estimate is likely to substantially change the analytic results, analysts should explore the effects of applying alternative elasticities.

[35] More specifically, for income growth in prior years, analysts should use CPS data on the annual median usual weekly earnings of employed wage and salary workers, for fulltime workers (usual working hours over 35), reported on an average per capita basis in constant dollars, which are available at http://www.bls.gov/cps/earnings.htm. For income growth in future years, analysts should use the estimates in the CBO Long-Term Budget Outlook. The 2015 CBO report is available at https://www.cbo.gov/publication/50250. See Chapter 4 of these *Guidelines* for more discussion of the use of median versus mean values.

TABLE 3.1. VSL ESTIMATES BY YEAR (2014 DOLLARS)

YEAR	LOW VSL ESTIMATE	CENTRAL VSL ESTIMATE	HIGH VSL ESTIMATE
2014	$4.4 million	$9.3 million	$14.2 million
2015	$4.4 million	$9.5 million	$14.4 million
2016	$4.5 million	$9.6 million	$14.6 million
2017	$4.5 million	$9.7 million	$14.8 million
2018	$4.6 million	$9.9 million	$15.0 million
2019	$4.7 million	$10.0 million	$15.2 million
2020	$4.7 million	$10.1 million	$15.4 million
2021	$4.8 million	$10.3 million	$15.6 million
2022	$4.9 million	$10.4 million	$15.9 million
2023	$4.9 million	$10.6 million	$16.1 million
Note: See text for discussion of assumptions and calculations.			

Thus if a regulation reduced the number of statistical cases of premature mortality by 75 in 2016, applying the central VSL estimate would result in benefits of $720.0 million (75*$9.6 million), with a low of $337.5 million (75*$4.5 million) and a high of $1,095.0 million (75*$14.6 million).

In some cases, analysts may also need to adjust the VSL estimates to reflect a lag or delay between when exposure to a hazard is reduced and when the risk change occurs. If the risk reduction is expected to occur in the same year that the regulatory costs are incurred, then the VSL for that year should be applied. If the risk change occurs later, then the VSL should be applied at the time when the risk change occurs, rather than in the year in which the associated regulatory costs are incurred.[36] In other words, using the values above, if both the costs and the risk reductions occur in 2016, than $9.6 million would be used as the central VSL estimate. If instead the costs are incurred in 2016 but the risk reduction does not occur until 2018, then the central estimate would be $9.9 million, which would be discounted back to 2016 for comparison with the costs incurred in that year, using the same discount rate as applied elsewhere in the analysis. Recommended rates, as well as the mechanics of discounting, are discussed in Chapter 5.

Finally, some regulations may predominantly affect the very young or very old, rather than those of all ages. In these cases, the age distribution of those affected is likely to differ significantly from the age of those included in the VSL studies that underlie the approach discussed above, which often address individuals between the ages of 18 and 65 (with some exceptions). There is substantial uncertainty regarding how VSL varies with age (see, for example, Aldy and Viscusi 2007, Krupnick 2007, and Hammitt 2007; Robinson and Hammitt 2016 discuss related theory and empirical research in more detail).

If a regulation largely affects the very young or the very old, analysts should at minimum provide a supplemental sensitivity analysis based on estimates of the expected value of future quality-adjusted life years (QALYs).[37] In other words, regulations that primarily affect young children or the elderly should include two calculations: a primary benefit estimate based on the VSL recommendations in this section, and a sensitivity analysis based on monetized QALY estimates, which are discussed in detail in the next section. In this sensitivity analysis, the value per QALY is multiplied by the present value of the expected life year gain.[38]

In addition to the uncertainties represented by the ranges of values and adjustments discussed above, analysts should provide a qualitative discussion of the other limitations of this approach. The major limitations include differences in the types of risks addressed in the underlying studies and those addressed by the particular policy,

[36] As noted earlier, this delay is described as the "cessation lag" when it refers to risk reductions rather than risk increases.

[37] Analysts may also explore the effects of alternative assumptions regarding the relationship between the VSL and age or life expectancy, if clearly explained and well-justified. Many analyses have used a VSLY estimate rather than an estimated value per QALY to explore these effects.

[38] Such sensitivity analysis would not noticeably change the results if the age distribution of those affected by the regulation is similar to the U.S. age distribution, as long as the value per QALY (or VSLY) is calculated from a population-average VSL.

as well as in the population affected. Thus this approach may over- or understate the value of mortality risk reductions. Where the analytic conclusions are particularly sensitive to the approach used to value mortality risks, analysts may also wish to conduct breakeven analysis to identify the VSL at which the costs would be equal to the benefits, as discussed in Chapter 6.

3.3 VALUING MORBIDITY RISK REDUCTIONS

Valuing morbidity risk reductions is more complicated than valuing mortality risk reductions for two reasons. First, morbidity risks are more diverse, differing in duration and severity as well as in the attributes of health that are affected (e.g., physical or cognitive functioning). Second, high quality WTP estimates are not available for many morbidity risks, requiring the use of proxy measures. Thus, as discussed below, HHS analysts should first review the literature to determine whether WTP estimates of reasonable quality are available for risks similar to those addressed by the regulation, applying the benefit transfer framework described previously.[39]

HOW SHOULD MORBIDITY RISK REDUCTIONS BE VALUED?

Analysts should first review the literature to determine whether suitable WTP estimates of reasonable quality are available. If not, they should use monetized QALYs as a proxy, following the approach described in this section.

If such estimates are not available, analysts should instead apply values that combine estimates of the resulting QALY gain with estimates of the monetary value per QALY. Cost-savings that are not reflected in the QALY measure may be added to these values, including those that accrue to third parties (such as savings in insured medical costs). Because of the diversity of the health effects and the gaps in the research literature, the discussion that follows focuses on the approach analysts should follow to develop estimates, rather than recommending values for particular health conditions.

3.3.1 QUALITY-ADJUSTED LIFE YEARS

The QALY is a nonmonetary measure that integrates the duration and severity of illness. QALYs are widely used to rank and prioritize public health programs, analyze the cost-effectiveness of health policy and medical treatment decisions, and compare health status across individuals or population groups. In these contexts, QALYs are generally not assigned a monetary value, but monetization is needed to apply these estimates in regulatory analysis.[40]

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 (HRQL) associated with that state. HRQL is estimated using a scale anchored at zero and one, where one corresponds to full health and zero corresponds to a state that is as bad as dead (values cannot be greater than one but may be less than zero for states that are judged to be worse than dead). In principle, the HRQL associated with a health state may vary among individuals, but in practice a common value is used for each health state. Expected QALYs are then calculated by weighting the HRQL experienced in each future year of life by the probability of living in that year (i.e., by the survival curve).[41] In addition, future QALYs are usually discounted using the same rates as applied to monetary values. Appendix C provides more information on the estimation of QALYs.

Once HRQL is determined for a particular health state and multiplied by the duration of that state, the resulting QALYs can be summed across the health states (e.g., acute and chronic phases) associated with a particular illness, and across the illnesses associated with a particular hazard. For example, for foodborne illness, QALYs

[39] Due to the lack of a reasonably recent and comprehensive review of this research, analysts will need to search bibliographic databases, such as EconLit (http://www.aeaweb.org/econlit/index.php) and EVRI (https://www.evri.ca/Global/HomeAnonymous.aspx), to identify potentially applicable studies and conduct a criteria-driven review that follows the benefit transfer framework introduced above.

[40] In cost-effectiveness analysis, valuation is implicit, because monetary thresholds are needed for comparison to the cost-effectiveness ratio to determine whether an intervention is worth implementing. In addition, valuation is implicit in any policy decision that results, which involves choosing to fund a particular invention rather than using the money for other goods or services.

[41] For the U.S. population, survival curves are updated annually by the CDC; see http://www.cdc.gov/nchs/products/life_tables.htm.

can be summed across cases of acute gastrointestinal illness, including those that do and do not require hospitalization, as well as more severe effects. For regulatory analysis, health status with the regulation or other policy must be compared to health status in the absence of the regulation, which is likely to be less than full health. In particular, health status generally deteriorates with age, so that average HRQL for older individuals is generally less than 1.0 (see Hamner et al. 2006). Some regulations may also target individuals with pre-existing conditions or lifestyle characteristics that will not be ameliorated by the regulation.

An example of these calculations is provided in Figure 3.3. For simplicity, in this example we do not discount future impacts; however, as discussed in Chapter 5, discounting should be used to reflect time preferences when similar calculations are performed in regulatory analyses.

FIGURE 3.3. EXAMPLE OF QALY CALCULATIONS

- Assume that, in the absence of the policy, the average individual affected will experience health-related quality of life of 0.7 throughout their estimated remaining life span of 20 years.
- With the policy, assume that the average individual affected will instead experience health-related quality of life of 0.9 over the same time period
- The QALY gain attributable to the policy is the difference between 20 years with a health status of 0.9 (18 QALYs) and 20 years with a health status of 0.7 (14 QALYs), which equals 4.0 QALYs, prior to discounting.

The research base for estimating QALYs is extensive, including numerous primary research studies as well as population databases that collect HRQL data for a wide range of conditions. Thus regulatory analysts can generally rely on existing research to estimate the QALY gains associated with reducing the risks of various types of morbidity.[42] Estimates from many previously completed studies can be found in the Tufts Cost Effectiveness Analysis (CEA) Registry (described in Thorat et al. 2012), using the benefit transfer process discussed earlier to assess their quality and applicability. However, this database does not include studies that estimate QALYs or HRQL without comparison to costs, so analysts should search the research literature to identify other potentially applicable studies.

Another option is to rely on population-wide surveys. Some large national surveys (such as the U.S. Medical Expenditure Panel Survey or MEPS) have at times included one or more of the generic HRQL indices, such as the EQ-5D which is described in more detail in Appendix C. These HRQL estimates can then be multiplied by duration estimates from research on the health state of concern. Relying on such surveys can be particularly useful for regulatory analysis, because they provide consistently-derived estimates across a wide range of outcomes and enable analysts to control statistically for the effects of other factors (such as age and co-morbidities) on HRQL.[43] For some health effects, however, these surveys may not include enough cases to reliably estimate HRQL.

A 2006 Institute of Medicine report provides more detailed discussion of these measures and their application in regulatory analysis, recommending factors that should be considered in selecting among the available sources of HRQL and QALY estimates. In particular, to the extent possible, QALY estimates should satisfy the criteria listed in Figure 3.4.

[42] In those rare cases where suitable estimates are unavailable, analysts may need to rely on expert judgment to estimate the QALY gains associated with the regulation. Analysts should apply the EQ-5D index with U.S. weights when implementing this approach.

[43] For example, EQ-5D scores for a large number of health conditions based on MEPS are provided in Sullivan and Ghushchyan (2006). This article, and a calculator that allows users to retrieve EQ-5D scores by International Classification of Disease code and demographic characteristics, is available online at http://www.ohsu.edu/epc/mdm/webResources.cfm.

FIGURE 3.4. SELECTION CRITERIA FOR QALY ESTIMATES

1) QALY estimates should be based on research that addresses the risks and populations affected by the regulation.
2) The description of the effects of the health state on quality of life should be based on information from those who have experienced the condition (such as patients).
3) The preference weights placed on the health states should be based on a survey representative of the general U.S. population.
4) The "without new regulation" baseline (with the condition) should be compared to a realistic estimate of "with-regulation" health status, which takes into account factors (such as age and co-morbidities unrelated to the regulated hazard) that may lead those affected to be in less than perfect health once the regulation is implemented.[44]
5) The implications of related uncertainties should be discussed and addressed quantitatively if significant.

Developing approaches for measuring QALYs and testing their implementation is an active area of research. There continue to be diverse opinions on many technical issues such as the dimensions of health that should be considered, the types of survey questions that should be used to explore these dimensions, the elicitation of preferences, and the statistical analysis of the results (Lipscomb et al. 2009). Thus the approaches described above continue to evolve, and new options are under development.

3.3.2 THE VALUE OF A QALY

To use QALY estimates to value morbidity risk reductions in regulatory analysis, they must be assigned a monetary value. One approach would be to rely on emerging research that explicitly considers individual WTP per QALY (e.g., Haninger and Hammitt 2011); HHS is currently exploring this research to determine whether it is possible to develop a function that reflects how the value varies depending on factors such as the severity and duration of the effect.

In the absence of such a function, analysts often assume that the value per QALY is a constant, frequently applying a VSLY estimate, calculated by dividing the VSL by the discounted expected number of life years remaining. A preferable approach is to calculate a constant value based on expected QALYs rather than expected life years. Future QALYs are generally less than future life years because health tends to deteriorate with age. Dividing the VSL by future QALYs yields an average value per QALY larger than the VSLY (see Hirth et al. 2000).

For analyses conducted in 2014 dollars, HHS analysts should estimate the value of a QALY based on the VSLs reported in Table 3.1. For analyses that use a different dollar year, the VSL estimates will first need to be adjusted to reflect inflation and real income growth, as discussed earlier.

Based on data reported in the underlying VSL studies, analysts should assume that the average individual in these studies is 40 years of age. Table 3.2 reports the value of a QALY that results when health-related quality of life in each subsequent year is estimated using the U.S. EQ-5D results reported in Hamner et al. (2006) and the conditional likelihood of survival for each year of age is based on the population-averages in Arias (2014).[45] The value of future years should be discounted at the same rates as used elsewhere in the analysis. The table provides the results of these calculations for risk reductions that occur in 2016, in 2014 dollars.[46]

[44] This point is of particular importance in regulatory analysis, which is intended to realistically reflect the health of the affected population without and with the policy. In the absence of regulation, this population may suffer from a variety of health conditions, some of which will not be affected by the policy change. For example, a food safety regulation that targets the risk of gastrointestinal illness is not likely to affect air pollution-related respiratory effects. In addition, health status generally declines with age. Thus the average health of the affected population is likely to be less than perfect health (i.e., less than HRQL = 1.0) even after the regulation becomes effective.

[45] Arias (2014) provides life tables for 2009. Updated values may be used when available; see: http://www.cdc.gov/nchs/products/life_tables.htm.

[46] Many previous analyses value QALYs using a constant VSLY rather than the value per QALY presented here. As noted earlier, both are calculated from a VSL based on the average life expectancy of the individuals studied. The difference is that the resulting VSLY estimate implicitly averages over future health, while the value per QALY estimate takes into account the expected decline in health status associated with aging.

TABLE 3.2. 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

For example, if a regulation leads to a 0.2 QALY gain per affected individual on average in 2016, then applying the central VSL estimate (using a 3 percent discount rate) from Table 3.2, the value of that gain would be $98,000 (0.2*$490,000). If the gain accrues to 75 members of the population, than the total value of the risk reduction would be $7,350,000 (75*$98,000).

Estimates of the averted costs of illness may be added to estimates of WTP or monetized QALYs, as long as the same cost-savings are not counted elsewhere in the analysis (see Chapter 4 for more discussion of medical costs).[47] These cost estimates should always be reported as a separate line item in the RIA, so that their treatment is clear. If a WTP study is used for valuation, the analysts should review the study to ensure that the costs are not already captured in the WTP estimates. Typically, WTP studies may capture out-of-pocket costs and lost earnings, and possibly informal care provided by household members, but do not include costs paid by third parties, such as medical expenses paid by insurance. If a regulation reduces these costs, the savings can be added to the WTP estimate. Any cost-savings included in the analysis of regulatory costs should not also be added to the benefit estimates.

If monetized QALYs are used for valuation, the extent to which costs are included is highly uncertain given that the measure does not directly reflect monetary consequences. Occasionally, studies that estimate HRQL instruct respondents to assume their medical costs and lost income will be offset by insurance. In the absence of more specific information, analysts may add medical costs paid by third parties to the monetized QALYs, but should not add estimates of lost productivity or income to avoid potential double-counting.

Estimates based on QALYs monetized using a constant value are likely to be less accurate than approaches based on direct estimation of WTP, but may provide a reasonable proxy when WTP estimates are unavailable. The limitations of this approach relate in part to the characteristics of the QALY measure and in part to the approach used for valuation, and should be discussed when documenting the analysis.

The construction of the QALY assumes that how individuals value health states is independent of the duration of the state, the age at which it is experienced, the individual's remaining life expectancy, and his or her wealth and income (Hammitt 2002, 2013, Institute of Medicine 2006). Moreover, QALYs do not explicitly account for the changes in wealth or income that result from changes in health, nor for how individuals are willing to trade off spending on particular risk reductions versus spending on other goods and services.

[47] For some rules, whether medical costs should be counted as a "cost" or "benefit" will be uncertain, and analysts will need to be clear about how these costs are treated when documenting the analysis. Generally, if changes in medical costs are part of the implementation of the requirements (i.e., a policy input), then they should be counted on the cost-side of the equation. If they are one of the policy outcomes, then they should be included in the benefit calculation.

In addition, relying on a constant value per QALY does not reflect the likely variation in value due to factors such as duration and severity.[48] More research is needed to develop a valuation function for QALYs that better approximates individual WTP for risk reductions.

Given the above discussion, HHS analysts should first consult the WTP research to determine whether suitable estimates are available for the morbidity risk reductions of concern. If not, they may use monetized QALYs as a proxy, recognizing that we are uncertain whether the resulting values under- or overstate individual WTP for the risk reduction. Regardless of whether WTP or monetized QALY estimates are applied, analysts should document any concerns about the quality or applicability of the selected studies.

[48] Given these concerns, an expert panel recommended against assigning monetary values to QALYs in regulatory analysis (Institute of Medicine, 2006); however, OMB has not amended *Circular A-4* to adopt this recommendation. It continues to suggest that the use of monetized QALYs is acceptable as long as analysts acknowledge the limitations of the approach.

Chapter 4

Assess Costs

HHS regulations may impose costs on individuals, industries, other organizations (both for-profit and nonprofit), and government entities. In some cases, costs may be offset by savings; for example if a regulation reduces or streamlines existing requirements by replacing paper with electronic recordkeeping and reporting.[49] This chapter begins by describing some basic concepts that are particularly important when estimating costs. It then describes approaches for estimating the most common types of costs in more detail.

4.1 BASIC CONCEPTS AND APPROACH

Below, we describe economic concepts that are of particular importance when estimating costs: opportunity costs, transfers, and producer surplus. A discussion of the general approach to the cost analysis follows.

4.1.1 ECONOMIC FOUNDATION

Three fundamental notions from economic theory are of particular importance in assessing costs. The first is that economists measure costs by the value of forgone opportunities. In other words, costs are incurred when resources are used for one purpose and hence cannot be used for another purpose. The opportunity costs are the value of the benefits that could have been provided by devoting the resources to their best alternative use. This interpretation differs from the concept of accounting costs (i.e., actual expenses plus depreciation of capital equipment). It is consistent with the concept of WTP, as discussed in Chapter 3.

The second is the distinction between resource costs and transfers. Transfers are monetary payments between persons or groups that do not affect the total resources available to society.[50] They are a benefit to recipients and a cost to payers, with zero net effect. For example, some types of taxes, fees, and surcharges can be categorized as transfer payments. Such transfers often can be ignored in benefit-cost analysis, as long as they do not lead to behavioral changes that significantly affect the calculation of net benefits. However, transfers should be included in the distributional analysis, as discussed in Chapter 7.

OPPORTUNITY COST VERSUS ACCOUNTING COST

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 productive uses of those resources are forgone. If labor is shifted to compliance from production, for example, the opportunity cost is the value of forgone production.

Where the imposition of transfer payments affects behavior, associated impacts should be taken into account in the benefit-cost analysis. For example, reductions in government payments to hospitals would often be viewed as a transfer. However, the affected hospitals may accept fewer patients or use less expensive treatments, in turn affecting health outcomes. This change in health should be addressed in the benefit-cost analysis, if significant. Similarly, taxes can also change behavior; for example, taxes on wages provide a disincentive for working and higher taxes may lead more people to stay out of the labor force.[51] In addition, transfers involve transaction costs that may be significant in some cases. When identifying the costs to be

[49] As discussed in Chapter 2, analysts should decide whether to report offsetting cost savings as negative costs or positive benefits depending on whether these savings relate to the inputs needed to achieve regulatory goals, or the outcomes associated with those goals.

[50] Because RIAs focus on the effects on the U.S. population, transfers from the United States to other nations, and from other nations to the United States, should be included in the benefit-cost analysis.

[51] HHS regulations rarely, if ever, affect tax rates. If such rates are affected, analysts may wish to consult Boardman et al. (2011) and other resources on estimating the associated deadweight loss, typically referenced as the marginal excess tax burden.

quantified, analysts should consider the potential for significant net losses or gains nationally resulting from the imposition of transfer payments.[52]

The third fundamental notion is the difference between compliance costs and changes in producer and consumer surplus. As introduced in Chapter 3 and discussed in Appendix B, consumer surplus is the benefit that consumers receive when they are able to purchase products for less than they are willing to pay; producer surplus is the difference between the revenue producers receive and their cost of production. When a regulation increases production costs, the market price is likely to increase, inducing consumers to reduce their consumption and producers to reduce production. The cost of the regulation includes both the direct compliance costs and the "deadweight loss" associated with the reduction in output. However, regulation often has negligible impact on prices, in which case the deadweight loss will be quite small and compliance costs will be a reasonable approximation of total costs. We return to this issue later in this chapter, when discussing the use of partial and general equilibrium models.

4.1.2 GENERAL APPROACH

Social cost is the sum of the resource costs incurred as a result of implementing the regulation. These costs may include costs incurred by regulated entities in the form of resources (labor, material, equipment) used to comply with the regulation, valued by their opportunity costs. Social cost may also include costs incurred by governments to implement and enforce the regulation. Other effects, such as consumer decisions to replace the regulated product with a substitute, may also occur in response to the compliance costs.

In principle, analysts could develop a model that includes all the interactions between regulated entities, consumers, and related markets to capture the total social cost of a regulation. However, such analysis is usually impractical given data, time, and resource constraints. Furthermore, most regulations are likely to have negligible impacts on price, in which case such complex modeling is not necessary to understand key impacts. During the framing and screening process (see Chapter 2), analysts should determine the cost categories of interest and the modeling techniques to be applied, recognizing that this is an iterative process. Changes in the approach may be needed as more is learned about the potential impact of the policy options. Nonquantified costs, as well as the reason for not quantifying them, should be reported as well (see Chapter 6).

In most cases, the analysis focuses on estimating the incremental compliance costs incurred by the regulated entities, assuming full compliance with the regulation, and government costs.[53] Compliance costs include the resources used by the regulated entities to comply with the regulation. These costs often account for the largest proportion of social costs and are an important input into the supplemental analyses discussed in Chapter 7. The analysis should also include costs incurred by the government. Such costs generally involve guiding and monitoring implementation of the regulation, as well as providing information and training as needed. In some cases, the government may have an ongoing operational role; for example, it may provide services in addition to those provided by the regulated community. Government costs also include enforcing the regulation through activities such as inspections and reporting requirements. When significant, these government costs should be quantified.

If compliance costs are significant on a per entity or industry basis, they may result in other impacts. If these additional effects are sufficiently large, they should be quantified. For example:

- Compliance costs may result in substituting behaviors. If industry or consumers shift to alternative products, or if industry develops new products to replace the regulated products, analysts should consider the net effect on society.

[52] As noted in Chapter 1, an RIA is required for regulations resulting in significant transfers, because of the additional costs or benefits that may result.

[53] Analysts should consider the uncertainty associated with an assumption of full compliance and provide analysis of alternative assumptions, as appropriate.

- Compliance costs may result in changes in available services, which could result in additional, and possibly non-pecuniary, costs (e.g., time losses associated with needing to find new doctors or traveling farther for treatment). Such costs should also be taken into account.[54]

Finally, care should be taken to identify transfer payments as discussed earlier. For example, proposed regulations may require the payment of fees to HHS agencies for processing paperwork or adjudicating claims. The fees may be set to recover the HHS labor and other costs associated with administering the program. If the opportunity cost to HHS of administering the requirement is already captured in the analysis, the fees represent a transfer payment that should not be counted. However, if the HHS opportunity costs are not separately calculated, then the fees paid by regulated entities might be a reasonable proxy for these opportunity costs and should be included as a social cost.

4.2 ASSESSING COMPLIANCE AND GOVERNMENT IMPLEMENTATION COSTS

Chapter 2 discusses the screening process used to identify key cost categories. Typical categories include administrative costs (including time, materials, and travel), capital and operations costs, and medical costs. As discussed above, government implementation costs should also be considered.

4.2.1 ADMINISTRATIVE COSTS

Most regulations impose administrative costs on regulated entities or the implementing government agency. Related activities may include, for example, reviewing the new regulations, developing protocols for compliance, collecting and reporting data, and training staff on implementation. The following sections describe how to quantify and monetize the components of these costs, including estimating the amount of time required for administrative tasks, valuing this time in monetary terms, and locating data on administrative expenditures.

Amount of time required: Estimating the amount of time needed to comply with administrative requirements is relatively straightforward.[55] Usually, time should be measured in terms of "hours" so that the quantity can be easily combined with information on the value of time, which is generally measured in terms of hourly compensation (see below).[56] Analysts may obtain estimates of the number of hours needed to review the requirements, fill out forms, transmit data, or complete other similar tasks using surveys, information interviews, past analysis, or Information Collection Requests (see Chapter 7). Who is undertaking these activities is also important, as it affects the monetary value of time. Finally, care must be taken to ensure that the hours estimates reflect the net effect of the regulation. For example, the regulation may require that workers discontinue some activities (e.g., completing paper forms) and replace them with others (e.g., maintaining records electronically). The time saved by discontinuing activities will offset time spent on the new activities to some extent.

Table 4.1 lists the types of administrative tasks that may result from new regulations and provides suggestions for quantifying the amount of time associated with each task, noting associated costs (such as travel or materials) that should also be addressed. Time spent complying with a regulation may vary by establishment type or size. Thus, analysts should explore differences across key groups. In addition to providing more accurate cost estimates, this information is used in the supporting analyses that address impacts on entities of differing sizes and types (see Chapter 7).

[54] For a detailed discussion of the identification and assessment of secondary effects, see Chapter 5 of Boardman et al. (2011).

[55] The same general approach can be used when regulations affect other types of time use.

[56] For rules requiring substantial amounts of labor, such as the hiring of additional, full-time employees, analysts might instead estimate the number of new employees needed and annual salaries using the data sources identified in the next section.

TABLE 4.1. TYPICAL ADMINISTRATIVE TASKS

ADMINISTRATIVE TASK	EXAMPLES OF SOURCES OR METHODS USED FOR QUANTIFICATION
Regulation and Guidance Review: All regulated entities, including those who incur no other compliance costs, will require time to read and interpret the regulation.	• Interview representatives of the affected community to obtain estimates of the amount of time required to review regulations, including time spent by legal or technical experts. • Review prior agency analyses for relevant data or conduct other literature reviews. • Assume reviewers read at the average adult reading speed (approximately 200 to 250 words per minute) and allow time for both review and interpretation.
Development or Revision of Standard Operating Procedures (SOPs): The affected entities may need to devise a compliance plan that may require them to change their SOPs. SOPs are "detailed, written instructions to achieve uniformity of the performance of a specific function" (International Conference on Harmonization).	• Interview the affected community to obtain estimates of the amount of time required to review and revise SOPs. • Review prior agency analyses for relevant data or conduct other literature reviews.
Training: Once new SOPs are established, entities will spend time training staff on how to implement the regulation.	• Interview the affected community to obtain estimates of the amount of time required for training. • Review prior agency analyses for relevant data or conduct other literature reviews. • Note that training may also require travel costs.
Sampling and Testing: A regulation may require entities to sample or test materials.	• Contact third party vendors to obtain estimates of sampling or testing costs. In such cases, the cost per test likely includes both labor and materials. • Some entities may be able to conduct the testing more cheaply using in-house staff. Interviews with the affected community may provide data on the amount of time required. In these cases, material costs should be added.
Record Keeping and Reporting: Some rules require entities to perform additional record keeping to track training, inspections, and infractions. In addition, entities may be required to submit recurring reports to the regulating agency.	• Interview the affected community to obtain estimates of the amount of time required for record keeping and reporting. • Review prior agency analyses for relevant data or conduct other literature reviews. • Note that record keeping may also result in substantial storage costs.

Valuing time: Once the amount of time needed has been calculated, analysts multiply these hours by a per hour value of time. This value will vary depending on the characteristics of the activities, the preferences of those affected, the duration of the activities, and other factors. As in other components of the analysis, the approach to valuation requires comparing the value of time use with and without the regulation, to calculate the opportunity costs the regulation imposes.

In RIAs, as in other types of analysis, time use is often valued based on simplifying assumptions that allow analysts to use readily accessible data on compensation. We introduce the default assumptions for HHS analyses below, then discuss their implications in more detail. If the characteristics of the regulation and the available data justify a different approach, the rationale for the approach should be included in the RIA along with the detailed calculations.

The value of time is an active area of research, and HHS is now working on a project that will further explore these values.[57] This new work will investigate the extent to which the default values discussed in this section appropriately measure different types of time use, including the suitable treatment of overhead costs. In the interim, analysts should apply the default values described below. Regardless of the approach used, the assumptions and related uncertainties should be addressed as discussed in Chapter 6.

[57] See Boardman (2011) and DOT (2015b) for more discussion of the related literature.

The starting point for valuing changes in time use involves distinguishing between paid and unpaid time; i.e., between market production and nonmarket activities including leisure, household tasks, and volunteer work. The first default assumption is that regulatory activities undertaken by paid employees will displace other paid work tasks, while activities undertaken during non-work time will replace other unpaid activities. In other words, the work-related administrative requirements likely to be imposed by HHS regulations (e.g., completing additional reports) would not require that the affected individuals spend more time at work and less time on leisure activities; instead they would spend less time on other tasks associated with their current occupation and the employer might rearrange work assignments. If new employees are hired, this approach assumes that the activities required for regulatory compliance would replace the activities they pursued in their previous job; those hired would be transitioning between similar jobs rather than moving from unemployment to employment.

The second default assumption is that average or median estimates appropriately measure the value of a marginal unit of time. In reality, this marginal value will likely vary based on a variety of factors, such as the amount of time (e.g., a few hours versus days or months) or the types of time use affected. However, marginal estimates generally are not readily available; most easily accessible data sources provide averages or medians.

The third default assumption is that the value of activities conducted during paid work time can be best approximated by the cost of labor to the employer. The standard economic model assumes that employers are willing to incur labor costs equal to the value of workers' marginal product. Conceptually, this amount represents the value of what the employee would have otherwise produced in the absence of the regulation. Thus the opportunity cost of paid work time can be approximated based on the employer costs, including pay, benefits, taxes, and associated overhead.

The fourth default assumption is that the opportunity cost of unpaid time can be best approximated by post-tax wages. Consistent with the standard economic model, this approach assumes that individuals decide whether to engage in paid work depending on whether the incremental income exceeds the value they place on unpaid time, a decision generally described as the labor-leisure trade-off. Taxes and benefits are usually excluded from this calculation, assuming that individuals focus on their take-home pay in making related decisions. In other words, an additional hour of paid work is valued differently by the employee than the employer, because many costs to the employer are not received by employees (e.g., income and payroll taxes) or may not be visible to the employees (e.g., benefits) and hence are unlikely to be taken into account in their decision-making. As is the case throughout the analysis, particularly if the value placed on time use significantly influences the analytic conclusions, then the approaches discussed in Chapter 6 should be used to assess the implications of related uncertainties.[58]

Table 4.2 summarizes the assumptions used to develop default estimates of the value per hour of time. Below, we discuss these assumptions in greater detail.

[58] Estimating the value of time for individuals who are not active in the labor market, such as children or seniors, is particularly challenging. As discussed later in this chapter, analysts should apply the same approach for valuing non-work time to all individuals.

TABLE 4.2. CONSTRUCTING DEFAULT ESTIMATES OF THE VALUE OF TIME

CONTEXT	COSTS INCLUDED IN HOURLY VALUE	DATA SOURCES AND KEY ASSUMPTIONS
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 "2")
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, available at http://www.census.gov/cps/data/cpstablecreator.html (U.S. Census Bureau) ECEC – Employer Costs for Employee Compensation, available at http://www.bls.gov/ncs/ect/ (U.S. Bureau of Labor Statistics) NCS – National Compensation Survey, available at http://www.bls.gov/ncs/ (U.S. Bureau of Labor Statistics) OES – Occupational Employment Statistics, available at http://www.bls.gov/oes/home.htm (U.S. Bureau of Labor Statistics)		

On-the-job activities: For paid work-related activities, the opportunity cost, or value, of a unit of time devoted to regulatory compliance equals the marginal value of the product that would have otherwise been produced in the absence of the regulation. Another way to frame this concept is to ask, what benefit to the economy would the employee have produced with an additional hour of time?[59] Data on this value are not readily available; however, market data on employee compensation provide a reasonable proxy.

From an employer's perspective, when making a decision about whether to hire more help, the company will think about the entire cost of the new employee, including wages, fringe benefits, and other overhead costs needed to support the employee in accomplishing the work. Thus, to estimate the value of an hour of time, analysts should sum the costs of these items. Wages (pre-tax) generally include base pay, cost-of-living allowances, guaranteed pay, hazardous-duty pay, incentive pay (commissions, bonuses), and tips.[60] Fringe benefits generally include paid time off, health benefits, retirement benefits, other legally required benefits (e.g., worker's compensation) and payroll taxes.[61] The combination of wages and fringe benefits is often referred to as the employer costs of compensation.

In addition, employers incur other costs that support labor and are not directly relatable to the production of goods and services. These costs are generally referred to as "overhead costs," and may include the following categories:

[59] Analysts should generally assume that time losses associated with HHS regulations only affect the quantity of hours worked, not the price of goods and services produced with that time. Thus, the analysis focuses on the marginal value of production associated with an hour of time. If a proposed regulation will result in time reallocations that are sufficiently large to affect the price of goods and services produced, more complex analysis may be required.

[60] Throughout the remainder of this chapter, the term "wages" is used generally to refer collectively to all of these categories.

[61] Conceptually, payroll taxes are included in this calculation because analysts need a full accounting of the total cost paid by employers for their employees' time. As explained above, this cost is used as a proxy for the value of the employees' production.

- General and administrative (G&A) costs, such as human resources, payroll, accounting, sales personnel, executive salaries, legal fees, office supplies, equipment, communications, administrative buildings, office space, travel, subscriptions, and other items related to administrative activities that support operating (production) labor;
- Fixed costs, such as building services (safety, general engineering, general plant maintenance, janitorial, cafeteria);
- Insurance costs, such as liability, property, and travel; and
- Accounting profit, which reflects the opportunity cost of equity capital.[62]

Thus combining data on wages, benefits, and other overhead costs approximates the value of time from the employer's perspective.[63]

Two data sources published by the U.S. Bureau of Labor Statistics (BLS) provide national information on hourly wages by industry sector (see bottom of Table 4.2 for hyperlinks to data sources).[64] The Occupational Employment Statistics (OES) are generated from a semiannual mail survey that covers a broad number of establishments across the United States.[65] The National Compensation Survey (NCS) is an in-person survey of a subset of establishments and provides information on quarterly changes in employer costs (the Employer Cost Index, or ECI) and cost levels (Employer Costs for Employee Compensation, or ECEC).[66,67]

Both surveys use statistical methods to collect nationally representative samples. The OES survey is larger, covering a greater range of occupations and geographic areas, and provides estimates of median, as well as mean, wages.[68] In contrast, the NCS program samples fewer establishments, but conducts the survey in-person and collects more detailed information on occupations within an establishment. In addition to reporting wage and salary information (pre-tax, average only), the NCS provides data on other compensation, including benefits (paid leave, insurance, retirement). Generally, OES is the preferred source for national estimates of hourly wages given its broader geographic coverage. The ECEC is useful for identifying compensation rates for specific categories of employees (e.g., managers).

USING MEDIAN VS MEAN WAGE DATA

Whether the median or mean (i.e., average) is the best central tendency estimate of compensation depends on the extent to which the distribution is highly skewed for workers in the occupations of concern. When considering the overall population, the average is significantly greater than the median because of the small number of people who are very highly compensated. Thus, if only a fraction of the U.S population is affected by a regulation, the best estimate may be the median (which is the center of the income distribution), rather than the mean (which is closer to the upper tail of the distribution). However, if the entire population is affected, applying the mean may be appropriate. Analysts should consider the specific characteristics of the rule when selecting the most appropriate measure.

[62] "Accounting profit" is a different concept from "economic profit." Firms require the investment of capital to operate and must provide a reasonable return on that investment, or the capital would be put to other uses. Accounting profit is a measure of the return on this capital investment. Economic profit, in contrast, equals sales revenue minus all costs, including the cost of equity capital. Under perfect competition, long-run economic profits are zero. See U.S. Environmental Protection Agency's Science Advisory Board (2007) for more discussion.

[63] Publicly-available estimates of overhead costs may include fringe benefits; thus whether to separately include benefits will depend on the data sources used in the analysis. The overhead rate discussed in this section is intended to be inclusive of fringe benefits; therefore it is applied to an estimate of wages that does not include benefits.

[64] We focus on data sources providing hourly wage data, as opposed to weekly, annual, or household estimates, to avoid the need for additional assumptions about the number of hours worked and/or the number of employed workers in a household. If data on annual salaries is required, additional sources, such as the U.S. Bureau of Labor Statistics' Quarterly Census of Employment and Wages (QCEW, available at http://www.bls.gov/cew/), may also be used.

[65] OES excludes farm establishments and self-employed persons.

[66] See http://www.bls.gov/oes/ pages on "OES Frequently Asked Questions" for a comparison of the OES and NRC.

[67] NCS excludes federal government employees.

[68] Ideally, analysts would use estimates of the marginal wage rate (i.e., the increment paid for the last hour worked) rather than the average cost across all hours worked. However, average or median values are generally used due to the lack of data on marginal rates.

Obtaining data on other overhead costs is challenging. Overhead costs vary greatly across industries and firm sizes. In addition, the precise cost elements assigned as "indirect" or "overhead" costs, as opposed to direct costs or employee wages, are subject to some interpretation at the firm level.

No readily available, national data exist on overhead rates by industry or sector. Data available in the ECEC suggest that benefits average 46 percent of wages and salaries.[69] Because this figure excludes overhead costs other than benefits, it represents a likely lower bound on the overhead rate. In the private sector, analysts often use a "rule of thumb" assumption that total overhead costs (benefits plus other overhead) equal 150 percent of wages. As a an interim default, while HHS conducts more research, analysts should assume overhead costs (including benefits) are equal to 100 percent of pre-tax wages (roughly the midpoint between 46 and 150 percent), and they should test the sensitivity of their results to alternative assumptions. Figure 4.1 provides an example of this calculation.

FIGURE 4.1. SAMPLE CALCULATION OF THE VALUE OF TIME SPENT ON A PAID ADMINISTRATIVE TASK

Assume a proposed rule will result in five additional hours each year of administrative work for occupational therapy assistants (OES Occupation Code 31-2011). The opportunity cost of the time spent undertaking these activities would be calculated as follows:

Mean wages for occupational therapy assistants (national estimate) (OES, May 2014):	$27.53 per hour[(a)]
Overhead cost per direct labor hour:	100 percent
Hours spent per employer:	5 hours
Opportunity Cost Per Employee:	$27.53 * 2 * 5 = $275.30

[(a)] Because all occupational therapy assistants employed throughout the United States will assume additional administrative tasks in response to the regulation, use of the mean is appropriate in this example.

Unpaid activities: HHS regulations may also impose administrative burdens on individuals (e.g., filling out additional paperwork for health care reimbursements) unassociated with their job. Unlike individuals employed in the labor market, those engaged in nonmarket labor activities are not compensated. As a result, the rationale for selecting a rate for valuing time spent performing such activities is less straightforward than for market labor.

As discussed earlier, economists often assume that the marginal value of an hour of uncompensated activity is equal to marginal compensation received. In other words, the opportunity costs of not working equal the value of the compensation the individual would have received if he or she chose to work. This value is generally estimated based on the post-tax wage an individual would have received for market work. This interpretation applies both to people employed in the labor force, who (in principle) could adjust their working hours and compensation, as well as to those out of the labor force, who presumably have chosen not to work because they value their time more highly than the rate at which they would be compensated.[70]

To estimate the hourly value of unpaid administrative tasks, analysts should apply the post-tax wage rate. This rate can be obtained by adjusting the pre-tax wage rates reported in the OES or NCS to remove taxes, which vary as a percentage of wages over time and across locations.[71]

[69] See http://www.bls.gov/news.release/ecec.t01.htm, Table 1. Civilian workers, by major occupational and industry group (September 2015). Total benefits account for 31.4 percent of total compensation (wages and salaries plus benefits). To calculate the size of total benefits relative to wages and salaries, apply the following equation: 31.4/(100 – 31.4) = 45.8 percent.

[70] Analysts should also apply this approach when valuing time costs incurred by children or seniors (e.g., time spent at additional medical appointments), noting related uncertainties.

[71] National estimates of the Federal and State income taxes paid as a percentage of pre-tax income are difficult to obtain. The Internal Revenue Service (IRS) provides detailed reports of total Federal income tax collected relative to adjusted gross income; however, these data exclude State taxes (see, for example, "Individual Income Tax Rates and Tax Shares" at https://www.irs.gov/uac/SOI-Tax-Stats-Individual-Income-Tax-Rates-and-Tax-Shares).

To estimate the tax rate, including both Federal and state taxes, analysts should use data on household income before and after taxes collected in the CPS, a joint effort by the U.S. Census Bureau (Census) and BLS. The CPS collects data from a nationally-representative sample of 60,000 households on a monthly basis.[72] The Census maintains a tool called the "CPS Table Creator," which allows analysts to create customized data tables.[73] It provides both mean and median income; as with wage rates, which central tendency estimate analysts should use will depend on the specific characteristics of the rule.[74] Figure 4.2 provides an example calculation of the value of time spent on unpaid administrative tasks.

For both paid and unpaid work time, the representativeness of the wage and tax rate estimates is likely to be uncertain. Where plausible alternative estimates exist, analysts should test the sensitivity of their results to these assumptions (see Chapter 6), particularly if the alternative estimates significantly affect the analytic conclusions.

Materials: Materials used to complete administrative activities may include office supplies or other items. Generally, analysts should obtain cost estimates from readily-available office supply catalogs or websites and courier services (e.g., the U.S. Postal Service, Federal Express, United Parcel Service, DHL). In addition, the rule may generate a need for records storage, either electronically or on paper. If a substantial amount of data must be stored, analysts should consider the costs of electronic file storage and backup, rent for additional storage space, or the cost of filing cabinets or boxes.

Travel: Administrative costs may include travel, particularly where the new rule creates a need for meetings or training activities. The U.S. General Services Administration (GSA) provides per diem travel rates for lodging and meals.[75] For air travel, plane fares can be obtained using internet travel search engines. For travel by car, the Internal Revenue Service (IRS) publishes reimbursement rates for mileage.[76] The mileage rate can be applied to estimates of miles traveled obtained from internet websites providing travel directions. Analysts should also include travel time, as discussed earlier.[77]

[72] Household tax rates are appropriate because ideally individuals should make decisions based on the tax rates they actually pay.

[73] To estimate mean or median household income before taxes, under "Data Options" select the relevant calendar year and get a count of "Persons-All." Next, "Define Your Table" by selecting "Household Income – Alternative" as a row variable. Under the "Statistics" section, in the subsection called "Additional numeric variable statistics" choose "Household Income-Alternative" and "Mean" or "Median." In the "Income Definition" section, select "Customize your own income definition" and then select "1. Earnings (wages, salaries, and self-employment income)" and "19. Federal Earned Income Credit." For household income after taxes, follow the same steps and add the following additional selections in the customized income definition: "20. Federal Income Taxes after refundable credits except EIC," "21. State income taxes after all refundable credits," and "22. Payroll taxes (FICA and other mandatory deductions)." For 2014 (select 2015 as the most recent year of data), median pre-tax household income ($53,000) minus post-tax income ($44,599) and divided by median pre-tax income results in a median tax rate of 16 percent. (To access the CPS Table Creator, see http://www.census.gov/cps/data/cpstablecreator.html).

[74] As with wage rates, ideally, analysts would use estimates of the marginal tax rate (i.e., the tax rate applied to the last dollar of income earned) to make this adjustment, rather than the average tax rate paid for all income. While data on the distribution of marginal tax rates paid by the U.S. tax filers are available from the IRS, they only include Federal taxes; excluding State or other taxes. Thus, analysts should use the CPS data, even though it provides mean or median, rather than marginal rates, because it includes both Federal and State taxes.

[75] See GSA's website "Per Diem Rates Look-up" at http://www.gsa.gov/portal/category/100120.

[76] See IRS's website "Standard Mileage Rates" at http://www.irs.gov/Tax-Professionals/Standard-Mileage-Rates.

[77] See DOT (2015b) for recommended adjustment factors for the hourly estimates of value of time spent traveling, for different types of travel (available at: http://www.dot.gov/office-policy/transportation-policy/guidance-value-time). That document provides a detailed discussion of the theoretical and empirical basis for these adjustment factors.

FIGURE 4.2. SAMPLE CALCULATION OF THE VALUE OF TIME SPENT ON AN UNPAID ADMINISTRATIVE TASK

Assume a proposed rule will result in five additional hours each year of administrative work for a subset of affected individuals (working and non-working adults, children, and seniors) in the United States. The opportunity cost of the time spent undertaking these activities would be calculated as follows:

Median wages, all occupations (OES, May 2014)	= $17.09 per hour[(a)]
Median household tax rate (CPS, 2014 data)	= 16 percent[(a)]
Hours spent per individual	= 5 hours
Opportunity cost per individual	= $17.09 * [1-0.16] * 5 = $71.78

[(a)] In this instance, the distribution of income among the subset of the population subject to the regulation may not be representative of the U.S. income distribution. Therefore, the median may represent the best central tendency estimate of wage and household tax rates for affected individuals.

4.2.2 CAPITAL AND OPERATIONS AND MAINTENANCE COSTS

Regulated entities may also need to purchase and operate new equipment to comply with regulatory requirements. For example, they may need to purchase new computers and software, change equipment or maintenance schedules at a production facility, or adopt other new technology. In this section, we describe methods for estimating such costs.

Equipment and other capital components: Capital costs generally refer to the reallocation of resources needed to purchase and operate additional equipment or other inputs that are not immediately consumed in the production process.[78] Typical capital costs may include, for example: purchasing computers and software to support administrative tasks; or installing or retrofitting new equipment associated with the production of food, drugs, or other goods. Some regulations may lead to capital expenditures to acquire buildings or land.

Generally, analysts use market data to estimate the price of purchasing and installing such equipment. These data may be obtained through interviews, literature reviews, review of online merchandise catalogues, or other sources. In some cases, the cost of the equipment may include installation costs and it will not be necessary to separately estimate the costs of associated labor. Otherwise, labor costs should be estimated in terms of the fees paid to licensed installers or, if the work is completed in-house, using the approach for valuing paid time described above. Information describing the useful life of the equipment is also necessary to determine whether the equipment must be replaced during the time period of the analysis. Finally, a side cost often associated with installation is the temporary shutdown of operations (i.e., forgone revenues net of avoided variable operations and maintenance (O&M) costs). In many cases these costs are minimized by installing or retrofitting equipment during regular downtimes (e.g., for maintenance).

Operations and maintenance costs: O&M costs include the annual costs of labor, utilities, and other resources required to operate and maintain capital equipment, as well as other expenditures that do not involve the purchase of a capital asset. Typical O&M costs include labor costs (discussed earlier); electricity and other utilities; replacement parts; raw materials and other inputs to production. O&M costs may be variable, in that

[78] Note that capital costs described in this section should not be confused with the fixed overhead component of the overhead rate used to estimate the value of time (see Table 4.2). In the latter case, overhead costs are used as a proxy to estimate the value of time. This section, in contrast, describes the valuation of additional equipment or other goods that may be necessary to implement a proposed regulation. Where an entity purchases new equipment (e.g., hard drives) to store compliance information and shifts staff resources (without hiring additional staff) to undertake administrative tasks, time cost and capital cost should be summed (they are not duplicative).

they fluctuate with production levels, or fixed, where the costs are not tied to production levels.[79] Again, analysts generally use market data to estimate such costs.

For both capital and O&M costs, analysts must be careful to estimate incremental costs. For example, if a firm needs to purchase new and improved equipment to replace current machinery (or the machinery they would purchase during their next scheduled turnover), the incremental costs of the rule include only the costs above and beyond those associated with the equipment the firm would have otherwise purchased. Therefore, data are required on the cost and useful life of both the existing equipment and the newer technology needed to comply with the regulation.[80]

4.2.3 MEDICAL COSTS

Medical costs may be relevant to either the benefit or cost calculations depending on the characteristics of the regulation. As noted in Chapter 2, costs are generally the inputs and benefits are the outputs or outcomes of a policy. Thus if increases or decreases in medical costs are part of the implementation of the requirements (i.e., an input), they should be counted on the cost-side of the equation. If they are part of the intended outcome, then they should be included in the benefit calculation, taking care to avoid double-counting with other benefit measures. For some rules, whether medical costs or savings should be counted as a "cost" or "benefit" will be uncertain, and analysts will need to discuss where they are counted in documenting the analysis. Medical costs generally should be presented as a separate line item in the calculations so their treatment is clear.

The appropriate calculation of medical costs in benefit-cost analysis is an area where more work is needed, because of the substantial distortions introduced by regulation of the health care sector and the effects of government and private insurance reimbursement policies. These distortions drive a wedge between market prices and opportunity costs, which make estimation difficult. Comparison across studies suggests that different approaches can lead to noticeably different results (e.g., Bloom et al. 2001; Akobundu et al. 2006; Larg and Moss 2011), but there is no established set of recommended best practices. In addition, much of the available data were developed to support reimbursement decisions and are not necessarily appropriate for estimating opportunity costs. HHS is now undertaking a project to further explore this issue; in the interim analysts should follow the general approach described below and discuss associated uncertainties.

When benefits consist of mortality and morbidity risk reductions, as discussed in Chapter 3, only some types of costs should be added to the estimates of individual WTP used for valuation. More specifically, the value per statistical life (VSL) estimates used to value mortality risk reductions, and the WTP estimates used to value morbidity risk reductions (including the estimates of monetized QALYs) used as proxies when suitable WTP estimates are not available), may include costs borne by the affected individuals. They presumably reflect the effect of the risk reductions on the activities the individual undertakes (including the allocation of both work and non-work time), and may also reflect out-of-pocket costs. Hence to avoid double-counting, savings in medical costs are generally not added to these benefit values. The one exception is when the costs in the absence of the regulation would be borne by third parties, in which case any savings in resource costs (excluding transfers) may added.

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. As a simple illustration, assume that a regulation requires monitoring the health of all workers exposed to contaminants while cleaning up after a natural disaster. The costs of the regulation would include the incremental cost of the medical

[79] For example, variable costs, such as raw materials used as inputs to production, will rise or fall with production levels. Fixed costs, such as rent or utilities, do not vary with production levels in the near-term.

[80] Analysts should consider whether compliance costs may decrease over time as regulated entities gain experience with the new regulation. A significant body of literature related to the operation and management of industrial processes suggests that the per-unit cost of producing or using a given technology declines as experience with that technology increases over time (see Baloff 1971, Dutton and Thomas 1984, and Epple et al. 1991). For a review of the literature measuring the "learning rate" for different industries and technologies, see Auerswald et al. (2000).

monitoring. The health benefits that result from earlier detection and treatment (than in the absence of such monitoring) would be valued using the approaches discussed in Chapter 3.

Analysts must also consider whether the cost assessment requires prevalence-based or incidence-based per case estimates. The former typically reflect the average costs of all cases in a given year, and may be appropriate for short-lived effects, such as acute health conditions or time-limited monitoring and treatment programs (e.g., in the immediate wake of a natural disaster). Incidence-based estimates instead track or model the lifetime costs per case, and are desirable when the regulation affects the incidence of chronic conditions or longer-term monitoring and treatment programs. In these cases, costs are likely to fluctuate over time, and extrapolating lifetime costs from prevalence-based estimates may understate or overstate actual costs. Incidence-based estimates that consider the entire, multi-year progression of the disease may be preferable. The appropriate measure will depend on the data available as well as the nature of the health effect.

Analysts will need to review the existing literature for recent studies of the specific health effects and types of costs needed for a particular regulatory analysis. Akobundu et al. (2006) and Larg and Moss (2011) provide useful overviews of the characteristics and limitations of different measurement approaches applied by researchers. Lund et al. (2009) provide a comprehensive inventory of relevant data sources. In addition, analysts should consider contacting health economists who focus on the conditions of interest, such as technical experts at the Centers for Disease Control and Prevention, academic institutions, or nonprofit research organizations. The series of articles included in Yabroff et al. (2009) also provide useful information.

In summary, estimating medical costs requires substantial professional judgment; the appropriate approach will depend on the characteristics of the practices affected by the regulation as well as the available data. Analysts are encouraged to work with subject matter experts if they are unfamiliar with methods used to estimate medical costs or with the particular health effect of interest.

4.2.4 GOVERNMENT IMPLEMENTATION COSTS

Government entities may also incur costs, either as an implementing or regulated entity. For example, a regulation may impose new review, reporting, and record keeping requirements on State or local government entities responsible for recording vital statistics, such as births and deaths. In this example, the HHS may incur implementation costs related to developing guidance, conducting training, and increasing enforcement. Likewise, State and local governments may incur compliance costs to train staff, adjust their electronic databases and reporting systems, and alter how they store information.

If the government is involved in implementing the regulation, the costs to the agency represent an opportunity cost of the regulation, as do similar costs imposed on industry, even if no new staff are hired. The effort undertaken to implement the regulation would otherwise be spent on other productive tasks. Thus, these costs should be counted in the analysis, using the methods discussed above. Information included in internal budget estimates, such as full-time equivalent labor needed for the program or requests for capital expenditures, are useful sources of data for these cost estimates.

If the government is the subject of the regulation, estimating related costs also follows the same approaches described elsewhere in this chapter. If grants or other funding are provided by HHS to support implementation of the regulation by industry or others, these funds are transfers and should not be included as costs, assuming they have no behavioral impacts that could affect the estimates of national net benefits. However, the amount of the funding may serve as a proxy estimate of the compliance costs imposed by the rule, to the extent that related costs are fully covered.

4.3 ESTIMATING MARKET-LEVEL IMPACTS

The preceding sections assume that the proposed regulation will not significantly affect the quantity of goods produced (e.g., a new regulation resulting in increased costs to electronically store and transmit data related to certain medical procedures will not affect the quantity of procedures performed). When the regulation is anticipated to affect the quantity of goods produced, a more precise estimate of social costs would involve estimating changes in consumer and producer surplus (see Appendix B) using partial or general equilibrium models.

Where a single market or a small number of unconnected markets are affected, partial equilibrium analysis provides a useful tool for estimating welfare changes. Analysts use information about the quantity and price of goods produced without the regulation, compliance costs, and elasticities of supply and demand to estimate the equilibrium output with the regulation and net changes in consumer and producer surplus (see Appendix B and Boardman et al. 2011).[81] In addition to providing a more precise estimate of welfare changes, a partial equilibrium model also provides insight into who bears the cost of the regulation. Such information may be important if analysts anticipate the regulation will have significant distributional impacts (see Chapter 7).[82]

WHEN SHOULD ANALYSTS USE PARTIAL OR GENERAL EQUILIBRIUM MODELS?

Analysts should consider employing partial or general equilibrium models when changes in consumer and producer surplus are likely to significantly affect the analytic conclusions. For example, such effects might be important if large sectors of the U.S. economy are affected or if impacts are likely to be measurable at a national scale (e.g., relative to U.S. gross domestic product, GDP). In most cases, estimating compliance costs is a sufficient proxy for changes in surplus.

Where multiple, interconnected markets are affected, or substantial international effects are anticipated, analysts might consider using computable general equilibrium analysis to estimate impacts. Such modeling may also be useful when a regulation is part of a larger suite of regulations that may have economy-wide, interactive effects. These models measure shifts in production and consumption resulting from compliance costs. In addition, they estimate how shifts in quantity or price in one market affect related markets. General equilibrium models are complex and generally require a significant amount of data to capture the effects of a regulation (see Berck and Hoffman 2002 and Lofgren et al. 2002). Such analysis requires working with a pre-existing model developed by one of several academic, government, or other institutions.[83]

[81] Because compliance costs serve as the basis for changes in the supply curve, analysts should not combine separate estimates of total compliance costs with estimates of changes in surplus. Adding these cost estimates together would result in double-counting.

[82] For example, for products where consumer demand is relatively inelastic, producers may have greater ability to pass compliance costs on to consumers in the form of higher prices.

[83] Examples of computable general equilibrium models used by Federal agencies to estimate impacts to the U.S. economy include the Global Trade Analysis Project (GTAP) model, the USAGE model, the Intertemporal General Equilibrium Model, and EMPAX-CGE.

Chapter 5

Account for Timing

The costs, benefits, and other impacts of regulations often accrue over several years, requiring that analysts take into account how affected individuals value impacts that occur in different time periods. In addition, RIAs generally involve applying data that reflects past rather than current price levels. Thus analysts must both inflate prices from prior years to the same dollar year, and discount future impacts back to the base year in which the regulation is first implemented.[84] Carrying out these steps involves distinguishing between inflation and real changes in value, and understanding how to appropriately account for time preferences. Below, we first discuss the underlying concepts and basic approach, then describe how to adjust for inflation, calculate discounted present values, and determine impacts on an annualized basis.

5.1 BASIC CONCEPTS AND APPROACH

Consider the four streams of payments in Table 5.1. If they represent the net benefits of different policy options in each year, how might we choose among them? Options A, B, and C sum to the same total over the 10 year period, but the net benefits vary across years. Under Option A, costs substantially exceed benefits for two years after which benefits exceed costs; under Option B, costs also initially exceed benefits but by lesser amounts and for a longer period; under Option C, benefits exceed costs by the same amount in all years. Option D sums to a smaller total with net benefits that decline over time. Comparing such streams of payments, regardless of whether they represent costs, benefits, or net benefits, requires (1) understanding whether they include the effects of inflation and (2) addressing time preferences through discounting. In combination, considering these issues allows us to determine which option is preferable.

TABLE 5.1. COMPARING UNDISCOUNTED ANNUAL NET BENEFITS

YEAR	0	1	2	3	4	5	6	7	8	9	TOTAL
Option A	**($2,000)**	**($1,000)**	$200	$300	$400	$500	$600	$600	$700	$700	$1,000
Option B	**($600)**	**($500)**	**($400)**	**($300)**	$100	$200	$300	$600	$700	$900	$1,000
Option C	$100	$100	$100	$100	$100	$100	$100	$100	$100	$100	$1,000
Option D	$200	$200	$200	$50	$50	$50	$50	$50	$50	$0	$900

The first question is whether values are measured in real or nominal dollars. Observed prices are measured in nominal (current-year) dollars. Because these prices may be affected by economy-wide inflation, values in different years are not necessarily comparable. If there is inflation, the quantity of goods one can buy for $1.00 decreases over time. Real (constant or inflation-adjusted) dollars net-out the effect of inflation so that dollars have equal purchasing power over time and are comparable across different periods.

To avoid misleading comparisons, regulatory analyses should always be conducted in constant (real, inflation-adjusted) dollars.[85] This approach has the advantage of allowing analysts to avoid the difficult task of attempting to project future inflation rates. As discussed in more detail in section 5.2, all values should be first converted to the same year dollars, then the analysis should be conducted in real dollars from that point forward. For example, a regulatory analysis prepared in 2015, which projects benefits and costs over the next 10 or 20 years,

[84] As discussed in more detail later, the dollar year is likely to differ from the base year used for discounting.

[85] For the remainder of this discussion, we assume that the values in Table 5.1 are undiscounted and expressed in real terms.

may be conducted in constant 2014 dollars. Generally, a dollar year should be selected that is reasonably close to the current year.[86]

The second question is how to weight real benefits and costs that accrue in different time periods. There are two interrelated reasons why values are not likely to be weighted equally over time. One is individual time preferences; people generally prefer to receive benefits as soon as possible and to defer costs. The other is opportunity costs; resources received today can be invested to yield a positive return while resources expended are no longer available for investment.[87]

Analysts account for the effects of timing by discounting future impacts to the *base* year of the analysis. This base year commonly reflects the first year in which the regulation is implemented, and is likely to differ from the *dollar* year selected for the analysis. For example, an analysis conducted in 2015 may express all values in 2014 dollars. However, if the rule will not be implemented until 2017, the analysts may use 2017 as the base year for discounting. The dollar year and the base year must be clearly identified throughout the analysis.

HOW SHOULD ANALYSTS ACCOUNT FOR THE EFFECTS OF TIMING?

Analysts should first select a common *dollar* year, and inflate all unit values to that year. They should then calculate the benefits, costs, and net benefits expected to accrue in each future year of the analysis, report the undiscounted stream of benefits and costs, and report their present value applying discount rates of 3 and 7 percent. Analysts should also report annualized values (calculated using each discount rate). The *base* year used when calculating present values should be the year in which the regulation is initially implemented, and may differ from the dollar year.

Although there are conceptual differences between a discount rate and an interest rate, they are closely related. An interest rate is the market rate at which money can be borrowed or loaned, and results from the interaction between market participants' willingness to save and demand for borrowing. The discount rate reflects preferences for receiving benefits or bearing costs at different dates, which may be influenced by the opportunity costs imposed by regulations or by similar actions that divert resources from other investments or consumption. In practice, discount rates are often based on market interest rates.

As in the case of prices, care must be taken to distinguish between nominal and real discount rates. Because regulatory analyses are conducted in real dollars, a real discount rate must be applied. Below, we first discuss how to adjust for inflation. Section 5.3 then discusses discounting in more detail, and Section 5.4 describes how to convert discounted amounts to annualized dollars.

5.2 ADJUSTING FOR INFLATION

In regulatory analysis, analysts often work with data from many different time periods; an analysis conducted this year is likely to rely on unit cost and benefit data collected in several previous years. Adjusting for inflation involves using an index to convert all dollar values to the same year dollars. Indices commonly used to reflect economy-wide trends are the Consumer Price Index (CPI), and the gross domestic product (GDP) implicit price deflator. Because the CPI is more easily accessible, it is more frequently applied.[88] In general, the two approaches yield similar estimates of the inflation rate.

[86] A year prior to the current year is generally used as the dollar year because the rate of inflation for the current year is not yet known.

[87] The two reasons are related. When real interest rates are positive, individuals can purchase more goods and services if they postpone those purchases by saving more or borrowing less. To maximize utility (well-being), they should allocate their spending over time such that their preference for incremental current over future spending equals the interest rate. Real interest rates are typically positive because individuals require compensation for deferring consumption.

[88] As discussed in Chapter 8, the GDP deflator must be used in preparing the accounting statement required under OMB *Circular A-4*. It is also used to determine the threshold for conducting analyses under the Unfunded Mandates Reform Act as discussed in Chapter 7 (see, for example, HHS 2015). However, within the analysis itself, the CPI (or more specialized indices) may be used instead of the GDP deflator to adjust benefits and costs to the same year dollars.

Other, more specialized indices are also available that reflect price trends in particular market segments (such as producer prices or medical services) or in particular geographic areas. In this section, we focus on the CPI and GDP deflator, since these are the indices most commonly used in regulatory analysis. However, in some cases analysts may instead apply more specialized indices. The inflation index or indices used, and the rationale for applying them, must be clearly documented in the RIA.

The CPI is developed by the Bureau of Labor Statistics within the U.S. Department of Labor. It measures the average change over time in the prices paid by urban consumers for a market basket of goods and services. (According to the Bureau of Labor Statistics, these urban consumers represent about 87 percent of the U.S. population.[89]) The CPI is based on detailed information on actual expenditures by a statistically-representative sample of individuals and families, including all consumption goods and services.

The CPI website includes an inflation calculator (http://www.bls.gov/data/inflation_calculator.htm) that can be easily used to convert values to the same year dollars, based on purchases of all goods and services nationally. If an analyst prefers to directly apply the index values from the CPI tables (for example, including these values in a spreadsheet used to calculate benefits and costs), the index values must be converted to reflect the rate of change, expressed as a proportion or percentage. For example, if the analyst wishes to inflate a value from dollar year "a," in which the index was 120, to a dollar year "b," in which the index was 140 (a 20 point difference), the increase would be (20/120) * 100 = 17 percent.[90] Thus a unit cost of $100 in year "a" dollars would become $117 if expressed as year "b" dollars.

More generally, to inflate a value from year "a" to year "b," the percentage change is calculated as:

$$\textit{Percent inflation (CPI)} =$$

$$((CPI_{year\ b} - CPI_{year\ a}) / CPI_{year\ a}) * 100$$

The GDP deflator is instead based on the value of all goods and services produced within the U.S. economy; it also can be calculated for subsectors of the economy. It is developed by the Bureau of Economic Analysis in the U.S. Department of Commerce, and includes personal consumption, domestic investment, net exports, and government consumption and investment.[91] It is not derived from a market basket of goods; rather it changes depending on investment and consumption patterns.

The GDP deflator is provided in Table 1.1.9 of the National Income and Product Accounts, which can be accessed through the Bureau of Economic Analysis website.[92] Again, as in the case of the CPI, the index values need to be converted to a proportional or percentage change to be applied in the analysis. This conversion follows the same formula as provided above for the CPI.

5.3 DETERMINING PRESENT VALUES

Once all unit benefits and costs are converted to the same dollar year (i.e., to constant dollars) and the year in which they occur is identified, the next step is to calculate their discounted present value. This value indicates how much dollars paid or received at a later time are worth in the base year (i.e., the year in which the regulation is first implemented), given time preferences and opportunity costs as discussed earlier.[93] For

[89] This and other basic information on the CPI is available at http://www.bls.gov/cpi/cpifaq.htm.

[90] The change can also be expressed as a multiplier, applying the formula $CPI_{year\ b} / CPI_{year\ a}$ (140/120 = 1.17 percent in the example). In spreadsheet analysis, converting the proportion into a percentage is not necessary; the analyst may simply enter the proportion and multiply the year "a" value by the result.

[91] A glossary of related terms is available at: http://www.bea.gov/glossary/glossary.cfm; more information on the underlying concepts and methodology is available at: http://www.bea.gov/methodologies/.

[92] To access this table: (1) click on the "Interactive Data" tab at the top of http://www.bea.gov/; (2) select "GDP & Personal Income" under "National Data;" (3) click on "Begin Using the Data;" (4) under "National Income and Product Account Tables," click on Section 1, and select Table 1.1.9, "Implicit Price Deflators;" (5) click on the "Options" icon to choose the desired time period and to indicate annual as the frequency, then select "Update" to regenerate the table.

[93] In some cases, regulated entities may begin to respond to the regulation before it becomes effective, and related costs, benefits, and net benefits will need to be carried forward to the base year rather than discounted. In this case, their value will increase rather than decrease between the time when they are incurred and the base year.

regulatory analysis, the OMB guidance in *Circular A-4* (2003) requires agencies to report the results of their analyses applying discount rates of three and seven percent per year.[94] The use of two rates reflects uncertainty about whether regulation is likely to displace investment or consumption.[95] In a simple theoretical model, investment- and consumption-based discount rates would be equal, but in reality distortions such as taxes lead to differences.

The seven percent rate is intended to reflect the opportunity costs associated with displacing private investment, and was based on the estimated average before-tax rate of return to private capital in the U.S. economy at the time when the OMB guidance was developed. The three percent rate is intended to reflect the opportunity costs associated with displacing consumption (often referred to as the marginal "social rate of time preference"), and was based on the before-tax rate of return on long-term government debt to approximate the interest paid on savings. This approach assumes that the savings rate represents the average by which consumers discount future consumption. Both are real rates, consistent with the use of real dollars when estimating benefits and costs.

The formulae for calculating present values are provided in Figure 5.1.

FIGURE 5.1. CALCULATING PRESENT VALUES

If:

- PV = present value as of the base year
- FV_t = future value in the year (t) when the benefit or cost accrues
- NPV = net present value of benefits and costs combined across all time periods
- r = the discount rate
- t = the number of years in the future (measured from the base year) when the cost or benefit accrues
- n = the number of years included in the analysis

Then the discount factor for costs or benefits that accrue at the end of year t is:

$$1/(1+r)^t$$

The present value of a future cost or benefit that accrues in year t is:

$$PV = FV_t\,(1/(1+r)^t)$$

The net present value for a stream of future benefits and costs is:

$$NPV = V_{t=0} + (FV_{t=1}/(1+r)) + (FV_{t=2}/(1+r)^2) + (FV_{t=3}/(1+r)^3)...(FV_{t=n}/(1+r)^n)$$

Most spreadsheet programs automate these calculations, as do many calculators. In Excel, the function is NPV(r, [range or list of cells with flows ordered from "now" to the last period]).[96] Financial calculators typically have an NPV function into which you can enter a stream of costs, benefits, or net benefits as well as a discount (interest) rate. While in Excel r should be entered as a decimal (e.g., 0.03 if the discount rate is three percent), in many calculators r instead must be entered as a percentage (e.g., 3). The Excel function also has some optional arguments, such as whether the payments occur at the start or end of each period. While the end of the period

[94] While OMB allows agencies to apply other rates if justified, in practice agencies usually apply only the three and seven percent rates for intra-generational impacts. Discounting inter-generational impacts (for policies such as those addressing climate change or radioactive waste storage) raises several difficult issues related to forecasting future preferences and opportunity costs as well as inter-generational equity. HHS analysts rarely need to address these concerns because most HHS analyses cover shorter time periods; i.e., 10 to 20 years as noted earlier in this this guidance. OMB *Circular A-4* (2003) provides more discussion of these issues.

[95] On occasion, it may be informative to estimate the internal rate of return, which is the discount rate at which benefits equal costs (i.e., the net present value is zero). Calculating the internal rate of return is generally not useful for selecting among regulatory alternatives, however. A policy may have more than one internal rate of return if net benefits change from positive to negative (or vice-versa) more than once over the time period addressed. In addition, as is the case for both benefit-cost and cost-effectiveness ratios, the internal rate of return is not sensitive to scale. It does not indicate the amount by which benefits exceed costs, and hence does not provide information on which policy maximizes net benefits when policies differ in size.

[96] Excel also provides a present value function [PV(r, n, payment per period)] that is useful when the values are the same in each period.

is the Excel default, analysts often instead assume that payments occur at the beginning of each period, which means that the impacts in the base year (year "0" in the examples) are not discounted. In this case, a value of "1" must be entered into the Excel formula under "type," to change the default from the end to the beginning of each period.[97]

As discussed in Chapter 2, benefits and costs generally should be assessed over a 10-to-20 year period, consistent with the OMB guidance, unless the policy terminates sooner. Analysts should select a period that is adequate to encompass the time needed for the regulation to become fully effective, without requiring extrapolation so far into the future that predicting impacts become highly speculative given changes in the population, economy, technology, and other factors. Impacts further in the future often add relatively little to the present value of benefits and costs, given the effects of discounting, and are unlikely to alter the policy implications of the analysis. However, longer time periods may be considered if clearly justified.

We can use the streams of undiscounted net benefits in Table 5.1 to provide an example of this process. First, consistent with the OMB guidance in *Circular A-4*, analysts should present the stream of undiscounted costs, benefits, and net benefits (as illustrated for net benefits in Table 5.1), to aid decision-makers in understanding the timing. Presenting these graphically is often useful, as illustrated in Figure 5.2 for Option A from Table 5.1.

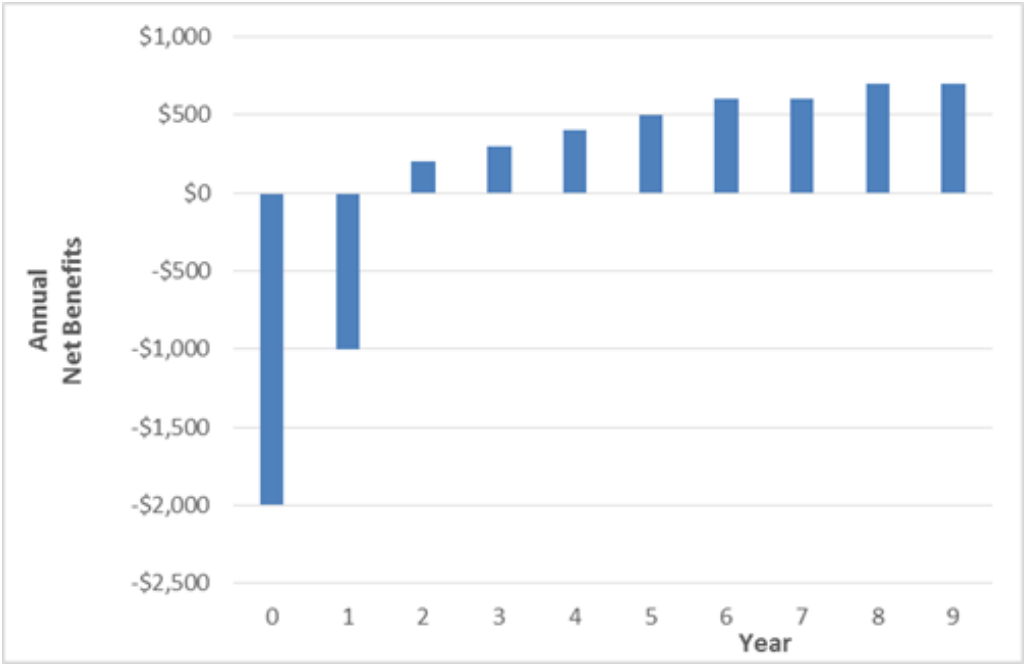


FIGURE 5.2. EXAMPLE PRESENTATION OF UNDISCOUNTED NET BENEFITS

Second, OMB requires that the results be presented using different discount rates, as illustrated in Table 5.2. This table presents the same four streams of net benefits as Table 5.1, undiscounted as well as discounted applying rates of the three and seven percent. Calculating present values makes it clear that the preferred option depends on the discount rate. Without discounting, Options A, B, and C all appear preferable to Option D. Discounted at a three percent rate, Option C is the best option. If the discount rate is seven percent, then Option D becomes best. At a seven percent rate, the net benefits of Option A also become negative. Thus at this rate, Option A would not be preferred to the "no action" baseline even if it were the only option being considered, since its costs exceed its benefits.

[97] While typically impacts incurred in the base year are not discounted, assuming payments occur at the beginning of each period, for some regulations analysts may find that it is more appropriate to assume end-of-period payments. In that case, base year impacts should be discounted and the Excel default assumption is appropriate. In the RIA, analysts should report the timing assumption used and the same assumption should be applied throughout the analysis.

TABLE 5.2. COMPARING DISCOUNTED NET BENEFITS

YEAR	0	1	2	3	4	5	6	7	8	9	NPV
Undiscounted											
Option A	**($2,000)**	**($1,000)**	$200	$300	$400	$500	$600	$600	$700	$700	$1,000
Option B	**($600)**	**($500)**	**($400)**	**($300)**	$100	$200	$300	$600	$700	$900	$1,000
Option C	$100	$100	$100	$100	$100	$100	$100	$100	$100	$100	$1,000
Option D	$200	$200	$200	$50	$50	$50	$50	$50	$50	$0	$900
Discounted to Year "0" at 3 Percent											
Option A	**($2,000)**	**($971)**	$189	$275	$355	$431	$502	$488	$553	$536	$358
Option B	**($600)**	**($485)**	**($377)**	**($275)**	$89	$173	$251	$488	$553	$690	$506
Option C	$100	$97	$94	$92	$89	$86	$84	$81	$79	$77	$879
Option D	$200	$194	$189	$46	$44	$43	$42	$41	$39	$0	$838
Discounted to Year "0" at 7 Percent											
Option A	**($2,000)**	**($935)**	$175	$245	$305	$356	$400	$374	$407	$381	**($292)**
Option B	**($600)**	**($467)**	**($349)**	**($245)**	$76	$143	$200	$374	$407	$490	$28
Option C	$100	$93	$87	$82	$76	$71	$67	$62	$58	$54	$752
Option D	$200	$187	$175	$41	$38	$36	$33	$31	$29	$0	$770

As demonstrated by Table 5.2, the choice of a discount rate can have a significant effect on the estimated net benefits. Whether the discount rate will affect the conclusions of the analysis will depend on the pattern of benefits and costs over time for each alternative considered. The option that provides the largest net benefits will depend on the magnitude of the impacts and their timing, as well as on the discount rate. Generally, the decision rule is that if only one policy is considered, then the policy should be implemented if the present value of net benefits is greater than zero. For regulatory analyses, which should consider multiple options (as discussed in Chapter 2 of this guidance), the option that is preferable in terms of economic efficiency will be the option with the largest net benefits, as long as the net present value is greater than zero.

5.4 ANNUALIZING IMPACTS

For regulatory analyses, OMB *Circular A-4* (2003) also requires that analysts present benefits, costs, and net benefits on an annualized basis to facilitate comparisons across analyses that cover different time periods. The annualized value of a stream of benefits, costs, or net benefits is the constant annual amount that, if maintained for the same number of years as the initial stream, has the same present value. In other words, annualization spreads the costs, benefits, or net benefits equally over the time period assessed, taking the discount rate into account. The concept is similar to amortization of a loan, in which the principal and interest are paid through a series of constant payments.

The formula for annualization is provided in Figure 5.3; the expression in brackets transforms a value into an annuity of n years at a discount rate r. Note that applying this formula requires first estimating the present value, following the formulae in Figure 5.1 as discussed in the preceding section.

FIGURE 5.3. CALCULATING ANNUALIZED VALUES

If:

- PV = net present value of costs, benefits, or net benefits
- r = the discount rate
- n = the number of years included in the analysis
- AV = annualized value

The annualized value is:

$$AV = PV * [(r * (1 + r)^{n}) / ((1 + r)^{n} - 1)]$$

Once a present value is calculated, it can be easily converted to an annualized value using spreadsheet software or a financial calculator. In Excel, the function is PMT (r, nper [number of periods], and PV). Because the PMT function is designed to calculate loan payments, it will provide a value with the opposite sign of the present value; simply reversing the sign will provide the correct amount for the purpose of regulatory analysis. OMB's 2011 Regulatory Impact Analysis: Frequently Asked Questions provides more detailed, step-by-step guidance on these calculations.

The annualized value is an alternative method for expressing the net benefits; the ranking of policies by annualized value will be the same as the ranking by present value net benefits when estimated over the same time period. To illustrate, in Table 5.3 we provide the results for the same streams of net benefits as assessed in Table 5.2. The conclusions are the same: Option C has the largest annualized value under a three percent rate; while Option D has the largest annualized value under a seven percent rate. If, however, these options were implemented over different time periods, the results could vary.

TABLE 5.3. COMPARING ANNUALIZED NET BENEFITS

OPTION	ANNUALIZED
Undiscounted	
Option A	$100
Option B	$100
Option C	$100
Option D	$90
Discounted at 3 Percent	
Option A	$41
Option B	$58
Option C	$100
Option D	$95
Discounted at 7 Percent	
Option A	**($39)**
Option B	$4
Option C	$100
Option D	$102

Because annualization provides a different perspective than the estimate of net present values, both annualized and present values should be reported in the RIA along with information on the time period over which these measures are calculated. The annualized value measures the average flow over the years included; the net present value measures the total. Annualized estimates are also needed to complete the accounting statement that must be submitted to OMB along with the RIA, as discussed in more detail in Chapter 8.

Chapter 6

Address Uncertainty and Nonquantifiable Effects

Any analysis involves uncertainties, including difficulties related to quantifying some potentially important effects. The challenge for the analyst is to determine how to best assess or quantify these uncertainties to support decision-making. The goal is to ensure that decision-makers and other stakeholders understand the extent to which key uncertainties – in the data, models, and assumptions – affect the main analytic conclusions.

For example, if the agency's best estimates suggest that benefits exceed costs for a particular regulatory option, how likely is it that this conclusion would be reversed given uncertainty about the magnitudes of the quantified effects and the potential impact of nonquantified effects? Might these uncertainties affect the relative rankings of the policy options? Answering these questions requires quantifying impacts to the greatest extent possible, and identifying key uncertainties and exploring them in both quantitative and qualitative terms. 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 analyses.

This chapter discusses strategies for characterizing the uncertainty in quantified effects as well as the potential impacts of nonquantified effects. It focuses on the benefit-cost analysis, as discussed in the prior chapters, but the approaches it describes are applicable to the supplemental analyses discussed later in this guidance as well. As with other analytic components, the uncertainty analysis is often iterative; the initial analysis may lead to decisions to conduct more research or to change the assumptions used, and perhaps to explore other policy options.

Although the assessment of uncertainty (including nonquantified effects) may be described along with the analytic methods when documenting the RIA (see Chapter 8), it is often helpful to summarize key uncertainties in a separate section. For example, the chapter describing the benefits analysis could first describe the analytic approach, then present the results, and conclude by discussing uncertainty and its implications. The executive summary, and the chapter that compares costs to benefits, could consolidate the most important findings from the individual chapters and describe how the uncertainties affect the overall conclusions.

6.1 CHARACTERIZING UNCERTAINTY IN QUANTIFIED EFFECTS

The data and models used to estimate costs, benefits, and other impacts inevitably involve limitations. These may relate to the quality of the methods used to collect the data, the extent to which the data address the same population, industries, or geographic area as the regulatory impacts, and the degree to which conditions may change between when the data were collected and when the regulation is implemented. In addition, the models used in the analysis, which may range from simple formulae to complex computer simulations, involve making assumptions about the relationships between various factors. All analyses require predicting how those affected will respond to the regulation, which adds to the uncertainty. The challenge for the analyst is to clearly describe (in qualitative and quantitative terms) the uncertainties related to the data, models, and assumptions in a way that aids decision-makers in understanding the confidence they should have in the results and the likely direction and magnitude of any bias.

6.1.1 BASIC CONCEPTS

Conceptually, one should distinguish uncertainty and variability. Variability refers to heterogeneity; for example, differences in the ages of those affected by a regulation. While variability can be described by statistical measures such as the standard deviation, it may be difficult to characterize precisely given that data may be

available for only a small (and perhaps non-representative) sample of those affected or for a limited geographic area or time period. The usual measure of uncertainty about a parameter when estimated from a sample of the population ("sampling variability") will be larger when there is more variability in the population (if there were no variability, even a small sample would yield an exact estimate of the parameter).[98]

In contrast, uncertainty describes lack of knowledge. For example, data on the relationship between exposure to a pathogen and the risk of mortality may be available for only a particular age group, and the agency may be uncertain whether individuals of different ages would respond similarly to the exposure. Variability is a characteristic of the real world that cannot be reduced by research (although research can lead to a better understanding of variability). In contrast, uncertainty concerns lack of knowledge and can be reduced by research.

Regulatory analysts often lack the time and resources needed to engage in substantial new primary research, and must determine how to best target their efforts. Such targeting requires using screening analysis (see Chapter 2) to identify areas where more work will have the most important implications for decision-making. Analysts must then determine how to best combine the available data with reasonable models and assumptions to characterize regulatory impacts. The limitations and uncertainties in these data, models, and assumptions must be clearly disclosed in the RIA.

The requirements in OMB *Circular A-4* (2003) encompass both variability and lack of knowledge when discussing treatment of uncertainty. OMB urges analysts to fully disclose any uncertainties inherent in the analysis and to evaluate and justify their analytical choices. OMB cautions that, at times, uncertainties may be significant enough to warrant delaying a decision until more information can be collected and assessed. This is especially true in situations where uncertainties have a significant effect on which regulatory decision appears to be best. When considering whether to recommend a delay, analysts must take into account both costs (e.g., of further data gathering efforts) and benefits (e.g., of the knowledge likely to be obtained from the new data). Delay may also have consequences for social welfare (for instance if it allows dangerous practices to continue), which must also be considered along with the impacts of any interim protective measures. If the timing of the regulation is determined by statute or court order, delay may not be possible.

6.1.2 GENERAL APPROACH

There are many options for addressing uncertainty in quantified effects. In *Circular A-4*, OMB outlines three approaches with increasing levels of complexity: qualitative discussion, numerical sensitivity analysis, and probabilistic analysis. These three methods are summarized in Table 6.1 and described in more detail below. Additional information on these approaches is provided in Morgan and Henrion (1990), Boardman et al. (2011), and other texts.

[98] Statistical or sampling variability is the variability in a statistical estimate that results when the estimate is calculated from a sample, not the full population. For example, the average height in the sample may not equal the average height in the population because a disproportionate number of tall people were sampled by chance.

TABLE 6.1. 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.

Qualitative discussion of uncertainties: Qualitative discussion is the least rigorous approach, but is of significant importance. It should always be included in the RIA. This approach involves disclosing key assumptions and uncertainties and including information on the implications. To the greatest extent possible, the qualitative discussion should include both the likely direction of the potential bias (i.e., whether the assumption may lead to an under- or over-estimate of the impacts) and the likely magnitude of the effect (e.g., whether it is major or minor). Such information will help decision-makers and others better understand the implications of the analysis.

Numerical sensitivity analysis: Numerical sensitivity analysis allows the analyst to explore the effects of varying the values of key parameters and is often useful to determine whether uncertainty about particular components or assumptions may substantially affect the analytic result, as well as when data limitations or constrained resources prevent full probabilistic analysis. Sensitivity analysis can be conducted by: (1) by changing one variable or assumption at a time and calculating a new set of estimates (sometimes referred to as "partial sensitivity analysis"); or (2) by varying several variables simultaneously to learn more about the robustness of the results to widespread changes.

When conducting partial sensitivity analysis, it is generally infeasible to test all assumptions. Attention should be devoted to analyzing those assumptions or variables that are most important (in that they may have the greatest effect on the result) or are most uncertain. The analyst should vary key parameters one at a time using plausible alternative values while holding all other parameters constant. Partial sensitivity analysis can be conducted as a breakeven, or threshold, analysis; for example, where the analyst seeks to find the value of one key parameter at which quantified benefits equal costs (i.e., net benefits equal zero), as discussed later in this chapter.

Varying a combination of parameters simultaneously may obscure the effect that a single variable or assumption has on the estimates, but can be particularly useful when a group of parameters are closely related (e.g., changing demographics and participation in the labor market) or when conducting a bounding analysis. In a bounding analysis, the most- or least-favorable assumptions are selected to calculate best- or worst-case results. These two sets of results represent high-end and low-end estimates that bound the primary results of the analysis. However, care should be taken in conducting and interpreting this type of analysis, because it is

extremely unlikely that all of the parameters will simultaneously be at their highest or lowest values. Thus the outcome of an analysis that uses lower (or upper) bound estimates for all parameters is very improbable.

If the sign of the net benefits or the relative ranking of the regulatory alternatives does not change in response to sensitivity tests, analysts and decision-makers can conclude that the results are relatively robust and have greater confidence in them. Otherwise, the analyst should (1) further investigate whether it is likely that the alternative assumptions are more appropriate than the assumptions used in the original analysis; and (2) conduct more rigorous probabilistic analysis if possible.

Probabilistic analysis: Probabilistic analysis is generally most informative because it quantifies the likelihood that different results will occur. However, in some cases such analysis may not be warranted or feasible given data limitations and constrained time and resources. OMB *Circular A-4* indicates that probabilistic analysis "is appropriate for complex rules where there are large, multiple uncertainties whose analysis raises technical challenges, or where the effects cascade; it is required for rules that exceed the $1 billion annual threshold" (OMB 2003, p. 41).

Probabilistic analysis often involves the use of simulation models to quantify the probability distributions of the effects. It provides decision-makers with information about the variance, or spread, of the statistical distribution of the impacts. This information may be particularly useful when the expected value of the net benefits is close to zero or similar across multiple policy alternatives. In such cases, decision-makers may feel more confident about the results if they have a smaller variance, because the realized results are more likely to be near the expected value.

To conduct a formal probabilistic analysis, analysts must determine the joint distribution of the uncertain parameters; i.e., the distribution of each parameter together with any dependencies among them. For some parameters, such as the average body mass index (BMI) of the population when BMI has been measured for a large representative sample, the distribution can be well estimated from the sample distribution. In other cases, the probability distribution may be estimated from other data (e.g., by regression analysis), or it may be necessary to assume a distribution (e.g., uniform or triangular between upper and lower bounds) and to test whether the results are very sensitive to the assumed distribution.

Even when data are limited, distributions can be developed through formal, structured expert elicitation. Such elicitation is designed to avoid well-known heuristics and biases that can lead to poor judgment, and may be worthwhile if (1) assumptions about the distribution are likely to significantly affect the analytic results; (2) additional primary data collection is not feasible or cost-effective; and (3) sufficient time and resources are available.

Conducting structured expert elicitation requires substantial effort. Researchers first develop a well-defined question to be addressed, as well as an extensive elicitation protocol designed to ensure that the experts each interpret the questions similarly and explain the bases for their responses. Experts are identified through a formal process intended to provide a range of perspectives. The elicitation often includes supplying the experts with background materials and holding a pre-elicitation workshop to share and critique information. The elicitation is then conducted with each expert individually, frequently through a lengthy interview following a pre-determined protocol. More information on this process can be found in the expert elicitation literature (e.g., Morgan and Henrion 1990, Cooke 1991, and O'Hagan et al. 2006).

Once the joint distribution of the key parameters is estimated, Monte Carlo simulation techniques are applied to derive a probability distribution of the outcome measure, which may be total costs, total benefits, net benefits, or another impact of concern. Monte Carlo analysis involves taking a random draw from the joint distribution of the uncertain parameters (or from the distributions for each parameter if they are independent) to produce a value for each parameter; these values are then used to calculate the outcome measure. This process is

repeated many times to produce a distribution of the outcome measure, the average of which provides an estimate of its expected value.

An advantage of Monte Carlo analysis is that it provides information on the full distribution of effects, from which one can determine how likely it is that the effect exceeds any particular threshold (e.g., zero). A limitation is that the results can be sensitive to the probability distributions that are used for the input parameters, and these are often not known with much accuracy.

In sum, HHS analysts should quantify the impacts of the regulatory alternatives to the greatest extent practical.[99] The analysis should be accompanied by clear discussion of the evidence of causality as well as the quality of the studies and the statistical rigor of the methods used. However, even if the available data are of low quality or inconsistent, the impact should be quantified and accompanied by an appropriate assessment of uncertainty that clearly communicates the limitations of the analysis.[100] When time and resource constraints restrict the extent to which less significant impacts can be quantified, the evidence used to support the analytic decision should be reported. Potentially significant effects should be left unquantified only when there is no feasible approach for quantifying them.

Regardless of which approach is used to assess uncertainty, analysts should take care to avoid the appearance of false precision. Calculations should be performed without any intermediate rounding, but the results should generally be rounded for presentation in the RIA. While a variety of conventions are used in different disciplines to determine the number of significant figures to present, generally the results should be rounded to reflect the number of significant digits in the input data. For example, total costs should not be reported to the penny if the unit costs used as an input are reported in tens or hundreds of dollars.

6.2 CHARACTERIZING NONQUANTIFIED EFFECTS

Another challenge is addressing outcomes that cannot be quantified but may have important implications for decision-making. For example, available data may suggest that a regulated hazard affects the risk of both mortality and morbidity, but may not be adequate to estimate the change in some types of morbidity risks associated with each regulatory option. Without quantification, it is difficult to appropriately balance the risk reductions associated with each option against its costs, or to determine the relative importance of these different types of benefits.[101]

Quantification with appropriate treatment of uncertainty is desired (as discussed above) because it provides a clearer indication of the likely direction and magnitude of the impacts. If quantification is not possible, analysts must determine how to best provide related information. Ignoring potentially important nonquantified effects may lead to poor decisions, but there is also a danger of overemphasizing them. In the absence of information, decision-makers and others may weight nonquantified effects in a manner consistent with their own (unarticulated and perhaps unconscious) beliefs, without sufficiently probing the rationale or the weighting. Clear presentation of the available evidence is needed to counterbalance this tendency.[102]

Thus analysts should first quantify regulatory impacts to the greatest degree possible, using tools such as sensitivity and probabilistic analysis to evaluate the effects of uncertainty as discussed previously. They then should determine how to best describe those effects that remain unquantifiable, to provide insights into their significance in comparison to each other and to the quantified impacts, as discussed below.

---

[99] OMB *Circular A-4* states: "[t]o the extent feasible, you should quantify all potential incremental benefits and costs" (OMB 2003, p. 45).

[100] Determining how to best apply the available research requires careful review of the evidence and substantial professional judgment. A number of approaches, such as criteria-driven systematic review, meta-analysis, and structured expert elicitation, can be used to develop estimates in cases where the research varies in quality and provides inconsistent results. The benefit transfer framework, discussed in Chapter 3, also can be applied to other types of quantities to develop estimates from data on somewhat dissimilar effects.

[101] We use the term "quantification" to refer to the consequences of the regulation (generally measured in physical units, such as cases averted), and monetization to refer to the dollar value of those consequences.

[102] OMB *Circular A-4* (2003) indicates that nonquantified effects should be included in the summary table discussed in Chapter 8.

6.2.1 BASIC CONCEPTS

Analysts may be unable to estimate some potentially important regulatory impacts due to gaps in the available data, the nature of the impacts themselves, or the need to focus on assessing more significant effects due to time and resource constraints. For example, analysts may not have the data needed to estimate the effect of the regulation on disease incidence, even though the available research suggests that the disease is associated with the regulated hazard. In the case of costs, analysts may have evidence that the regulation will lead to significant innovation, but may not be able to predict or describe the likely innovations adequately to estimate the impacts in monetary terms.

Another example is information provision. Some regulations increase the type or quality of information available and its dissemination, but research may be lacking on how recipients are likely to respond. Thus while an intermediate measure may be available, such as the number of patients who receive information on potentially beneficial lifestyle changes, it may not be possible to translate this measure into a quantity that can be monetized to estimate benefits. The latter requires an estimate of the change in behavior that results and of how the behavioral change affects individual welfare; e.g., of the degree to which the risk of illness or death is reduced. While these types of deficiencies ideally would be remedied through additional primary research, such research may require more time and resources than immediately available. HHS agencies should, however, try to anticipate future analytic needs and invest in research that will be useful across several regulatory analyses.

In other cases, the lack of quantification may result because the effects are less tangible and more subject to normative judgment. They may involve important human values, such as dignity, equity, and privacy. While it may be difficult to quantify the change in these values attributable to a particular regulation, it may be possible to count the number of people affected or report other intermediate measures.

Any intermediate measures, such as these counts, should be presented in the analysis as indicators of potential costs or benefits. For example, if analysts have information on the number of organizations subject to a regulatory provision, but lack the information needed to estimate related costs, or they have information on the number of individuals affected, but lack the data needed to estimate a particular benefit, these counts should be reported. Such intermediate measures should also be reported when the resulting benefits and costs are fully quantified, to promote better understanding of the analytic results.

6.2.2 GENERAL APPROACH

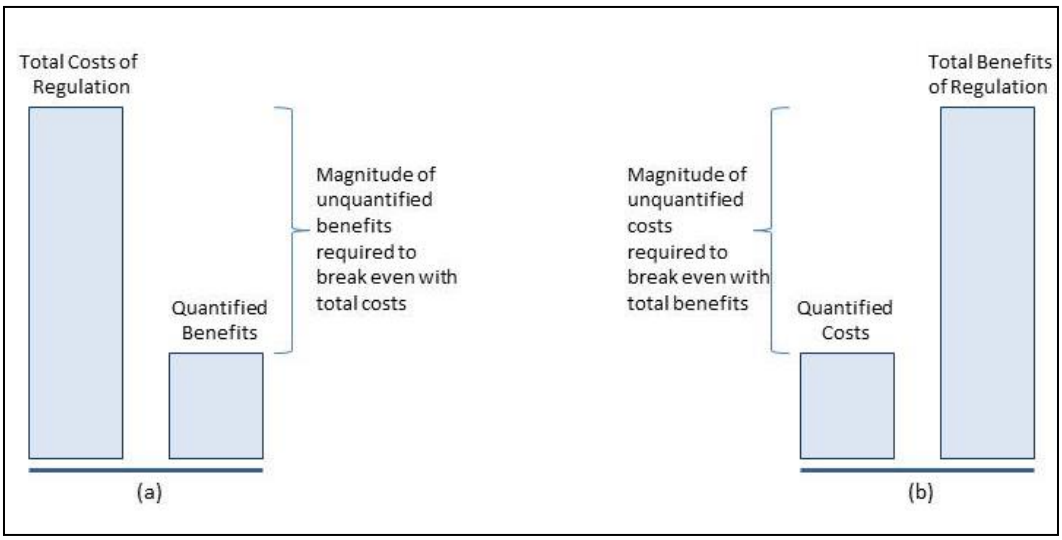
Options for incorporating nonquantified effects into the regulatory analysis depend on the available data and include both quantitative and qualitative approaches. Approaches that involve some calculation (and may be particularly useful when comparing benefits and costs) include breakeven, cost-effectiveness, and bounding analysis, but care must be taken to avoid misinterpretation of the results. More qualitative approaches include the use of tables and graphics as well as text discussions.

HOW SHOULD NONQUANTIFIABLE EFFECTS BE ADDRESSED?

If it is not possible to quantify an impact, analysts should consider using breakeven, cost-effectiveness, or bounding analysis, as well as tables and text, to illustrate the potential implications.

Breakeven analysis: Breakeven analysis, sometimes referred to as threshold analysis, asks the question "how large would the nonquantified effect(s) have to be, to bridge the gap between quantified benefits and costs?" Figure 6.1 provides an example of this concept. Part (a) shows the case where only some of the benefits can be quantified; part (b) illustrates the case where only some of the costs can be quantified.

FIGURE 6.1. BREAKEVEN ANALYSIS



Generally, breakeven analysis can only be conducted for a single quantity. Thus breakeven analysis is useful when analysts are particularly uncertain about one key parameter. For example, analysts may have information on the value of the effect (e.g., the VSL in the case of mortality risk reductions) but not the physical effects (e.g., the number of statistical cases averted). In this case, the breakeven analysis would be used to estimate the number of averted cases needed for benefits to exceed costs, given the VSL. Similarly, for costs, it may be possible to estimate the number of firms affected by a particular provision, but not the cost per firm. Breakeven analysis can be used to provide insight into how large the cost per firm would need to be for the costs to exceed the benefits of that provision. It can also be used to identify the breakeven probability of occurrence that would equalize costs and benefits.

Once the analysis is conducted, decision-makers and stakeholders can inspect the results to judge whether it is likely that the nonquantified effects are large enough to fill the gap. Breakeven analysis is most useful when some information is available on the potential magnitude of the impact, to provide a basis for judging whether the nonquantified effects can plausibly exceed the breakeven amount. It also may be informative when data are available but not public. For example, confidential information on the likelihood and consequences of terrorist attacks may be available to decision-makers but not to regulatory analysts or the general public. This information could provide context for decision-makers' review of the breakeven results for a regulation that addresses homeland security.

Cost-effectiveness analysis: Cost-effectiveness analysis is another approach that can provide insights when an impact can be quantified but cannot be assigned a monetary value (see Institute of Medicine 2006, Drummond et al. 2015). Under this approach, a monetary estimate of the costs (net of any monetized benefits) is divided by an effects measure to determine the cost per unit of effect. The effect could be the number of deaths averted, QALYs gained (see Chapter 3 and Appendix C), individuals treated, or another measure. Care must be taken, however, in interpreting the results. Cost-effectiveness ratios do not indicate whether an intervention is worth undertaking (i.e., whether the value of the benefits exceeds the costs), nor which option is likely to yield the largest net benefits.

Bounding or "what-if" analysis: Bounding analysis considers the extent to which benefits are likely to exceed costs based on lower- or upper-bound estimates of the magnitude of the nonquantified effects. For example, if the available data are sufficient to estimate that the mortality risk reductions associated with the regulation are unlikely to be greater than 1,000 statistical cases or fewer than 10 statistical cases, then the results could be presented using both estimates. "What if" analysis is similar, and involves investigating the impact of various hypothetical, but plausible, scenarios on the results. For example, the analyst could compare benefits and costs

for mortality risk reductions ranging from 10 to 1,000 statistical cases, if he or she believes that outcomes within this range are possible, and report the extent to which benefits exceed costs under each scenario.

The dividing line between these approaches and standard sensitivity analysis (discussed above) is somewhat vague. In concept, bounding or "what-if" analysis in this case would involve very wide ranges based on relatively little data or supporting evidence, and would be presented separately from the primary estimates of benefits and costs due to the high degree of speculation involved.

Tables and graphics: Tables and graphics are often useful for highlighting nonquantified effects, to ensure that they are not overlooked by decision-makers and others. One option is to simply list the effects in a table; however, the list is likely to be more useful if the effects can be categorized in a way that indicates the implications for decision-making. This categorization could include whether the effects are likely to be large or small, and to lead to over- or underestimates. Separate categories or exhibits could be used to report the strength of the evidence that links the effect to the regulation, the likelihood of its occurrence (e.g., high or low), or the extent to which it is reversible, as well as other attributes that will be salient for decision-making.

Table 6.2 below provides an example that uses symbols to highlight the potential magnitude of the impacts.[103] Alternatively or in addition, analysts could insert text into the table to provide more information than can be conveyed by a symbol. Such tables can also be used to separately indicate the effects on benefits and costs, rather than solely focusing on net benefits as in the example.

TABLE 6.2. EXAMPLE OF SUMMARY OF NONQUANTIFIED EFFECTS

EFFECT OF NONQUANTIFIED IMPACTS ON NET BENEFITS	POTENTIAL MAGNITUDE*
Analysis may overstate net benefits	
• impact "a"	
• impact "b"	
• etc.	
Analysis may understate net benefits	
• impact "c"	
• impact "d"	
• etc.	
Analysis may under- or overstate net benefits	
• impact "e"	
• impact "f"	
• etc.	
*Dashed vertical line indicates quantified net benefits.	

Text discussion: All of the approaches described above must be accompanied by text that clearly defines the nonquantified effects, explores the causal evidence that links them to the regulatory action, summarizes available information on their direction and magnitude, and discusses the conduct and interpretation of related analysis, including both the results and related uncertainties.

[103] Microsoft Excel and similar programs allow the user to represent quantities graphically; for example, to automatically size an arrow that represents the quantity "10" so that it is twice the size of an arrow that represents the quantity "5." While such features may be useful when analysts have some information on relative magnitudes, care should be taken to not mislead readers about the extent to which the size of the symbols represents evidence on the expected size of the effect.

In sum, the treatment of nonquantified impacts should be tailored to the characteristics of the effect (such as whether it involves intangibles or normative values), the extent to which relevant data are available, and the importance of the effect for decision-making. These impacts should be clearly defined and distinguished from the quantified impacts, to avoid the potential for double-counting.

At minimum, analysts should list significant nonquantified effects in a table and discuss them qualitatively. To the extent possible, the effects should be categorized or ranked in terms of their importance and implications for choosing among the regulatory alternatives (including the option of no action). Where some data exist, but are not sufficient to reasonably quantify the effect, analysts should consider whether breakeven, cost-effectiveness, or bounding analysis will provide useful insights. Intermediate measures, such as the number of individuals affected, should be reported where available. Where impacts can be monetized but not quantified, the monetary value per unit of impact (e.g., the value per averted statistical case in the case of health impacts) should be reported.

Chapter 7

Conduct Distributional and Other Supplementary Analyses

The previous chapters focus largely on the benefit-cost analysis that is the core of the RIA. However, agencies must also comply with a number of other analytic requirements. These include considering the distribution of benefits and costs across demographic or other population subgroups as well as complying with several other executive orders and statutes. In addition, for those regulations with impacts outside of the U.S., analysis of international impacts is required. These analyses should be reported in clearly labeled, separate sections of the regulatory analysis (see Chapter 8), which discuss the available evidence and related uncertainties as well as the implications for decision-making.

7.1 ASSESS DISTRIBUTION ACROSS DEMOGRAPHIC GROUPS

In addition to estimating the national net benefits of the policy options, HHS and other regulatory agencies are required to separately address how the benefits and costs of their economically significant regulations are distributed. The benefit-cost analysis discussed previously focuses on the net impact of the regulation on social welfare, while the distributional analysis focuses on the incidence of the benefits and costs.

In this section, we discuss the distribution of impacts across individuals with differing demographic or other characteristics. Such analysis is encouraged under Executive Orders 12866 and 13563 (Clinton 1993, Obama 2011), as well as by OMB *Circular A-4* (2003), and includes analyses required by Executive Order 13045, "Protection of Children from Environmental Health Risks and Safety Risks" (Clinton 1997), and Executive Order 12898, "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (Clinton 1994), where applicable.[104]

This analysis is intended to provide descriptive information for consideration by decision-makers and stakeholders; it should not assign values to reflect distributional preferences or make normative judgments related to the fairness or equity of the impacts. In many cases this analysis will be primarily qualitative or rely largely on simple screening; in those cases where distributional concerns are more significant, it will be more extensive and detailed.

7.1.1 BASIC CONCEPTS

The goal of distributional analysis is to provide information on how benefits and costs affect different groups, so as to make trade-offs between economic efficiency and distributional concerns more explicit. Decision-makers may choose the economically-efficient regulatory option that maximizes net benefits, or may choose a less efficient option to ameliorate distributional impacts or achieve other policy goals.

Generally, the distribution of both benefits and costs should be considered, so that decision-makers and others can consider the extent to which the impacts are counterbalancing for each group as well as the overall distribution of net benefits across groups. In addition to understanding the incremental effects of the regulation, analysts may wish to provide information on the distribution under the "without new regulation" baseline as well as on the distribution that results under each policy alternative.

The starting point for distributional analysis is the national assessment of social benefits and costs, discussed in Chapters 3 and 4. However, as noted in Chapter 4, transfer payments are generally not included in the benefit-cost analysis, but must be considered in the distributional analysis.

[104] See the National Archives website for a complete set of executive orders (http://www.archives.gov/federal-register/executive-orders/disposition.html).

A key step in the analysis involves identifying which population groups should be considered.[105] In some cases, groups of concern may be defined by statute. In addition, Executive Order 12898, "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (Clinton 1994), requires agencies to identify and address "disproportionately high and adverse human health or environmental effects" on these groups. Executive Order 13045, "Protection of Children from Environmental Health Risks and Safety Risks" (Clinton 1997), requires agencies to identify and address risks that may disproportionately affect children. Other groups of concern may emerge in the course of the analysis. For example, analysts may find that the effects of the regulations are likely to be concentrated in certain geographic areas or among groups with particular characteristics, such as the homeless, the HIV-infected, or those with specific dietary habits.

It is often tempting to focus solely on adverse effects on disadvantaged groups. However, such focus is problematic because it leads analysts to ignore potential beneficial effects that may be of equal or greater importance. Any distributional effect involves both "from" and "to" sides of the equation; who gains may be as important as who loses. The benefits and costs of the regulation may be counterbalancing, or may differentially affect the advantaged and the disadvantaged.

When describing these effects, one option is to provide a table or graph that reports the percentage and value of the costs, benefits, and net benefits that accrue to individuals or households at different points in the distribution; e.g., to income quintiles. Other measures for describing inequality are available; their advantages and disadvantages are discussed in detail in several sources.[106]

7.1.2 GENERAL APPROACH

Assessing the distribution of regulatory benefits and costs, as well as net benefits, can be challenging. As noted earlier, the conduct of such analysis is likely to vary significantly depending on the nature of the regulation, the characteristics of its benefits and costs, the population groups of interest, and the data and other analytic resources available. Screening analysis (see Chapter 2) can be useful in determining how to best focus this effort. Below, we discuss some of the challenges related to assessing the distribution of regulatory costs and health-related benefits, which affect analysts' ability to address each independently as well as their net effect.

WHAT ARE THE REQUIREMENTS FOR DISTRIBUTIONAL ANALYSIS?

At minimum, analysts should include a short description of the likely distribution of benefits and costs across individuals or households in different population groups, including low income and minority groups and children as discussed in Executive Orders 12898 and 13045. Requirements for other types of distributional analysis are discussed in the next section.

Distribution of regulatory costs: In the case of regulatory costs (and off-setting savings), we are typically interested in the monetary expenditures needed to comply with the regulatory requirements (including transfers), measured in dollar terms, and the ultimate effect on the disposable income of the groups of concern. Where regulatory costs are borne directly by individuals and households, the main challenge is determining how the costs are distributed across those who belong to different groups, which may be identified, for example, by income quintile, minority status, or degree of health impairment.[107] Where the costs are borne initially by firms, assessing the effects on individuals and households in different groups requires additional steps.[108] We first need to know how regulatory costs imposed on these entities translate into changes in unit prices paid by

[105] OMB *Circular A-4* (2003) defines distributional effects broadly as including, for example, how regulatory impacts are divided across "income groups, race, sex, industrial sector, geography" as well as over time.

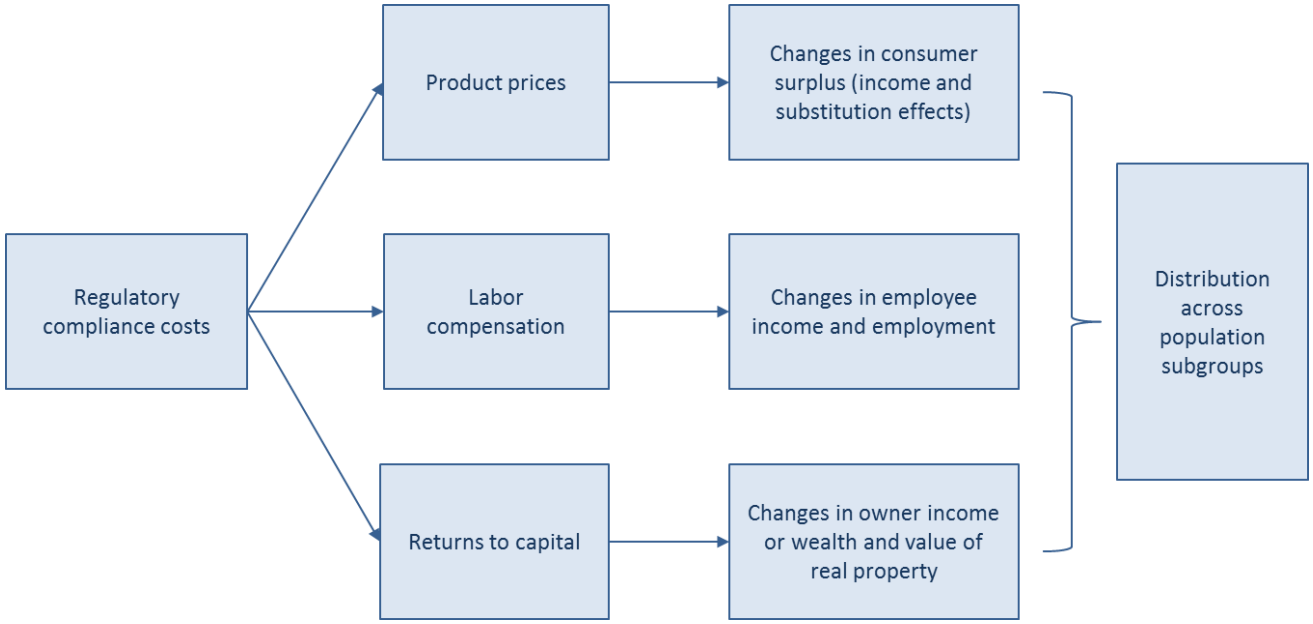
[106] For a general overview of options for addressing distributional concerns in policy analysis, see Weimer and Vining (2011), Chapter 7. For further discussion, see Boardman et al. (2011).

[107] Consumer behavior will also affect the distribution of these costs. For example, if the price of a food is increased, some may substitute an alternative food. This substitution may affect both the costs and the benefits incurred, and such behavioral responses may vary across population groups.

[108] If the organizations are not-for-profit, similar principles apply although the nature of the impacts may differ. If the costs are initially incurred by a government unit, then the analysis would address how that unit is funded; i.e., the distribution of taxes, users fees, or other revenue sources.

consumers (including both income and substitution effects), in wages paid to employees, and in returns to capital that accrue to owners, as illustrated in Figure 7.1.

FIGURE 7.1. DISTRIBUTION OF INDUSTRY COSTS ACROSS INDIVIDUALS AND HOUSEHOLDS



As in the benefit-cost analysis, the distributional analysis must clearly differentiate the impacts of the new policy from the impacts of other factors that should be reflected in the "no new regulation" baseline projections. At times, retrospective analysis may be available that addresses similar regulations and uses statistical tools to distinguish the effects of regulatory costs.[109] Interviews with members of the affected industry may also be useful. Otherwise, the extent to which each of the pathways in Figure 7.1 can be assessed will depend largely on the data available from the benefit-cost analysis. If only direct compliance costs are estimated, then it may be difficult to estimate how the costs are allocated across consumers and producers. If partial equilibrium modeling is included (which estimates changes in consumer and producer surplus), more sophisticated distributional analysis is possible. In a few cases, where regulations are expected to have significant impacts throughout the economy, results for model households from general equilibrium modeling may also be available. In all cases, the analysis of total social costs will exclude transfers, which will need to be estimated to assess the distribution of the impacts.

The allocation of costs across producers and consumers will also depend on the timeframe considered. Some costs that are fixed in the short run will be variable in the long run. For example, in the near term firms may not be able to make major changes in their physical plant (and some may close due to the costs of complying with the regulation), but such changes become more possible in the future, affecting how the costs are distributed.

Distribution of health benefits: In the case of benefits, some regulations may primarily provide savings in monetary costs, in which case the distributional analysis would proceed along the same lines as described above although the effects are likely to be in the opposite direction – savings potentially decrease prices, increase wages, and increase returns to capital. When the benefits involve reduced mortality and morbidity risks, there are several options for measuring the effects on each group. We can count the number of statistical cases averted (by multiplying the expected individual risk reduction by the number of people affected); we can use integrated measures (such as quality-adjusted life years, QALYs) to estimate the net effect on health-related

[109] For employment impacts, see Morgenstern (2013) for a comprehensive review.

quality of life and longevity; and we can use monetary measures that indicate the amount those affected would be willing to pay for the risk reductions (see Chapter 3).

In general, the distribution of health effect incidence is easier to calculate than the distribution of costs. The benefit analysis is likely to provide estimates of the number of people affected; the challenge is then to identify how the effects are allocated across the groups of concern.[110] In some cases, the characteristics of the regulation may aid in estimating this distribution. For example, if a food safety regulation affects the risks associated with drinking juice, and the distribution of juice drinking across groups (categorized by income, age, or other demographic attributes) is known, the analysis may be relatively straightforward. The risk assessment that supports the regulation will often provide related information. It typically summarizes or references available data on populations that may be particularly sensitive or vulnerable to the effects of the regulated hazard, including those who may be disproportionately affected due to health conditions, age, or socioeconomic status. In addition, HHS maintains several population databases that provide information on the characteristics of those who experience various types of health effects. Examples include the National Health Interview Survey and the Medical Expenditure Panel Survey.

In sum, the discussion above suggests that distributional analysis may be quite complex, and requires thinking carefully about what types of information will be most useful to decision-makers given the characteristics of the regulation and of those it is likely to affect. In some cases, the analysis may be primarily qualitative; in others more detailed quantitative assessment will be warranted. Analysts should follow a phased approach to ensure that the assessment is well-focused and useful for decision-making, using screening analysis as discussed in Chapter 2. Both gains and losses among advantaged and disadvantaged groups should be considered, to ensure that any counterbalancing or exacerbating impacts are taken into account.

7.2 CONDUCT SUPPLEMENTARY ANALYSES

Several other types of analysis are required by various statutes and executive orders. In general, all of these requirements should be addressed; however, the extent to which detailed analysis is required will depend on the characteristics of the specific rule. Table 7.1 summarizes these requirements and directs the analyst to additional guidance documents. The basic requirements are discussed in more detail below.

[110] As noted earlier, to the extent that people may alter their behavior in response to the regulation (e.g., taking less precaution in handling food when packaging is improved), any difference in this response can affect the distribution of benefits.

TABLE 7.1. REQUIREMENTS FOR 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 2010b) • OMB's website Federal Collection of Information • HHS's website Frequently Asked Questions about PRA/Information Collection • Agency's designated PRA team

7.2.1 REGULATORY FLEXIBILITY ACT

The Regulatory Flexibility Act of 1980 (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) (5 U.S.C. 601, *et seq.*), "requires agencies to consider the impact of their regulatory proposals on small entities, analyze effective alternatives that minimize small entity impacts, and make their analyses available for public comment" (SBA 2012). Small entities include small businesses, not-for-profit organizations, and governmental jurisdictions, definitions of which can be found within Section 601 of the RFA. In addition, the U.S. Small Business Administration (SBA) has developed size standards to define small businesses, which can be found in 13 CFR 121.201. The RFA requirements have been extended to small rural hospitals through Section 1102(b) of the Social Security Act (42 U.S.C. §1302). Definitions of "small," "rural," and "hospital" are provided in the Medicare regulations at 42 CFR 412.

If a proposed rule is not expected to have a significant impact on a substantial number of small entities, the agency may certify that this is the case, and must provide a statement providing the factual basis for this determination. If the agency cannot provide this certification, or is uncertain about the rule's impact, it should prepare an Initial Regulatory Flexibility Analysis (IRFA) for publication with the proposed rule. Section 603 of the RFA lists the information that must be included in the IRFA.

For the final rule, if the agency cannot provide this certification or remains uncertain after reviewing public comment on the proposed rule, a Final Regulatory Flexibility Analysis (FRFA) should be prepared and published. The requirements for the FRFA are similar to those for the IRFA and are outlined in Section 604 of the RFA. When it prepares a FRFA, the agency must also publish one or more small entity compliance guides to inform small entities of their obligations and responsibilities under the rule.

Detailed guidance on compliance with the RFA and preparation of the regulatory flexibility analysis can be found in the SBA's *A Guide for Government Agencies: How to Comply with the Regulatory Flexibility Act* (SBA 2012).[111] This document walks agencies through the process of preparing screening analyses and initial and final regulatory flexibility analyses. In addition, HHS's *Guidance on Proper Consideration of Small Entities in Rulemakings of the U.S. Department of Health and Human Services* (HHS 2003) supplements the SBA guidance, providing examples of issues that commonly arise in applying the RFA and SBREFA to HHS rulemakings.

7.2.2 UNFUNDED MANDATES REFORM ACT

The Unfunded Mandates Reform Act (UMRA) (2 U.S.C. §1501 *et seq.*) seeks to curb the practice of imposing unfunded Federal mandates on State and local governments. UMRA Section 1531 requires Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments, and the private sector. Section 1532 requires them to prepare a written statement that assesses the costs, benefits, and other effects of proposed or final rules for significant regulatory actions (2 U.S.C. §1532(a)). UMRA defines significant regulatory actions as those that include a Federal mandate 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) (2 U.S.C. §1532(a)). This threshold is adjusted each year for inflation.

Most of UMRA's requirements are fulfilled by the RIA that is prepared to comply with Executive Orders 12866 and 13563 (Clinton 1993, Obama 2011) and OMB *Circular A-4* (2003), as discussed in the earlier chapters of this guidance. Additional guidance on the preparation of written statements under UMRA can be found in OMB's 1995 "Guidance for Implementing Title II of S.1." In addition, HHS releases an annual memorandum updating the threshold value (adjusted for inflation) for a significant regulatory action (see, for example, HHS 2015).[112]

7.2.3 FEDERALISM

Executive Order 13132, "Federalism" (Clinton 1999), emphasizes consultations with State governments and enhanced sensitivity to their concerns in cases where regulatory or other policy actions impinge on their constitutionally established role as sovereign entities. It requires Federal agencies to develop an accountable process to ensure "meaningful and timely input by state and local officials in the development of regulatory policies that have federalism implications." Section 1(a) defines policies that have federalism implications to include regulations 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."

Under Executive Order 13132, Federal agencies may not issue a regulation with Federalism implications that imposes substantial direct compliance costs and that is not required by statute unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments or the agency consults with State and local governments in the process of developing the proposed regulation. The agency also may not issue a regulation with Federalism implications that preempts a State law without consulting with State and local officials.

[111] This and other material related to implementation of the RFA is available on the Regulatory Flexibility Act (http://www.sba.gov/category/advocacy-navigation-structure/regulatory-flexibility-act) page of the SBA website.

[112] The method and sources used to update this threshold value are described in HHS (2015).

7.2.4 PAPERWORK REDUCTION ACT

The Paperwork Reduction Act (PRA) (44 U.S.C. §3501 *et seq.*) requires Federal agencies to estimate the information collection burden associated with all of their actions. The term "burden" means the time, effort, or financial resources expended by persons to generate, maintain, or provide information to or for a Federal agency. Agencies must obtain approval from OMB prior to requesting the same information from ten or more individuals. Thus, if a proposed regulation will impose such a burden (e.g., a regulation may require regular reporting of compliance data to HHS), the agency must prepare an information collection request (ICR) for review and approval by OMB.

Paperwork burdens or costs are a subset of the total costs of a regulation and should be included in those costs (see Chapter 4).[113] The paperwork burden of a regulation includes the incremental cost of required record keeping, reporting, and public disclosure. It includes only the incremental data collected as a result of the regulation; data collections required by the rule that are already undertaken for other purposes are considered part of the baseline and are not part of the collection burden under the PRA. For example, a rule requiring facilities to maintain records on health and safety-related maintenance practices may not result in an incremental collection burden if these records are already collected by the facility for other purposes, such as payroll. As with estimates of other compliance costs (see Chapter 4), it is important to isolate the incremental burden of the regulation when preparing the ICR.

7.3 ADDRESS INTERNATIONAL EFFECTS

The regulatory analysis should generally focus on benefits and costs that accrue to U.S. citizens and residents. However, regulations that address trade barriers and other market failures may have an effect on both the United States and its trading partners. In cases where regulations have impacts outside of the United States, they should be addressed in a supplementary analysis. Following the guidance in OMB *Circular A-4* (2003), these international effects should be reported separately from those occurring within the U.S.[114]

International effects may include direct economic impacts (e.g., related to increases or decreases in international trade) as well as any other potentially significant effects. For example, increasing safety requirements for U.S.-based food manufacturing may provide health benefits to countries that import this food; decreasing the transmission of disease in the U.S. is likely to decrease the risk of transmission to residents of other countries.

In general, analysis of international effects should include impacts on imports and exports. Partial equilibrium analysis using publicly available information on import supply and demand elasticities can be used to model how a regulation might change the flow of imports and exports. More complicated general equilibrium analysis may be required if an entire sector of the economy is affected. For additional information on these types of modeling, see Chapter 4.

The analysis of international effects may also include impacts on foreign entities whose U.S. operations are affected. It is often difficult to identify U.S. subsidiaries of foreign entities and report impacts to their operations separately from those to U.S.-based businesses. Therefore, impacts on U.S. subsidiaries are often included in the main analysis. If this is the case, and the analyst thinks that impacts on U.S. subsidiaries of foreign entities may be substantial, the analysis should include a qualitative discussion of the effect.

[113] There are important differences in the requirements of the PRA and the best practices for preparing RIAs as discussed in the prior chapters. For a detailed discussion of the PRA requirements, see the sources referenced in Table 7.1.

[114] Executive Order 13069 (Obama 2012) includes requirements for identifying regulations that may have significant international impacts.

For more information on how to address international effects, see OMB's *2008 Report to Congress on the Benefits and Costs of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities* (OMB 2008) and the *Review of the Application of EU and US Regulatory Impact Assessment Guidelines on the Analysis of Impacts on International Trade and Investment* (OMB and the Secretariat General of the European Commission 2008).[115]

[115] OMB's reports to Congress are available on the OIRA Reports to Congress (http://www.whitehouse.gov/omb/inforeg_regpol_reports_congress/) page of its website.

Chapter 8

Communicate the Approach and Results

Regulatory analyses must be clearly and comprehensively documented in an RIA, which may be published in full in the preamble to the *Federal Register* notice for the proposed or final rule, or as a separate report, in which case it must be summarized in the preamble. The RIA must describe the rationale for the regulation, the options considered, the analytic approach, and the results, as well as the implications of uncertainties. For regulations with particularly large or complex impacts, it may be necessary to provide additional information in technical reports that supplement the main analysis.

Without clear communication, the RIA will not meet its intended goal of informing related decisions. This communication should address two audiences. First, it should be written so that members of the lay public can understand the analysis and conclusions. Second, it should provide enough detail so that competent analysts could ideally reconstruct the analysis, or at minimum explore the implications of changing key assumptions. This chapter briefly describes related practices.

8.1 DESCRIBE THE ANALYSIS AND RESULTS

The audience for the RIA is diverse and includes many who lack the technical expertise and knowledge of those who conducted the analysis. Given that the purpose of the analysis is to inform decision-makers and other stakeholders, it is critical that it be described in terms that can be easily understood by a lay audience. At the same time, the documentation must be sufficient to support future work, including replication, testing the effects of alternative assumptions, applying the same or similar approaches in a future analysis, or reconstructing the analysis as part of a retrospective assessment.

The main text should provide a succinct and clear summary of the analysis. Technical details should be provided in appendices or supporting documents. The main text may, for example, include the following major sections, reflecting the requirements in OMB *Circular A-4* (2003) as well as the requirements provided in this guidance document. Those sections that provide analytic results should also include a subsection that discusses the implications of uncertainties, as described in Chapter 6.

1) Executive Summary (see additional discussion below)
2) Statement of the need for the regulation
3) Characterization of the without-regulation baseline
4) Description of the regulatory alternatives (including the preferred alternative)[116]
5) Benefits of the regulatory alternatives
6) Costs of the regulatory alternatives
7) Comparison of benefits and costs
8) Supplementary analyses
    a) Distribution of benefits and costs
    b) Regulatory Flexibility Act analysis
    c) Unfunded Mandates Reform Act analysis
    d) Other analyses
    e) International effects

[116] These alternatives may include both regulatory and non-regulatory approaches, as described in Chapter 2.

In particular, the executive summary must use plain English and be designed to promote public understanding. OMB (2012) suggests that executive summaries include a statement of need for the regulation; a summary of the major provisions of the regulatory action; and, for economically significant rulemakings, a table summarizing the benefits and costs. For additional guidance on the format for Executive Summaries see "Clarifying Regulatory Requirements: Executive Summaries" (OMB 2012).

8.2 PROVIDE SUMMARY TABLES AND FIGURES

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 costs;
- Annualized and present value benefits;
- Net benefits (i.e., benefits minus costs) presented on an annualized basis and, as appropriate, 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 reporting annualized or present value impacts, analysts must indicate the time period over which impacts are estimated.[117] Results should be presented for discount rates of both three and seven percent.

Depending on the complexity of the analysis and the number of cost and benefit categories, the results may be summarized in a single or multiple tables or figures. Each should reference the information sources and note key assumptions. While such exhibits are essential to focus attention on key findings, analysts should keep in mind that some readers will skip over the more detailed technical information in the text. Thus clear labeling is needed to ensure that the contents of the tables and figures are not misinterpreted. Additionally, the associated text should interpret each table or figure for the reader. It may improve communication to supplement the results tables with charts and graphs that summarize and highlight key steps in the analysis as well as the major conclusions and their implications.

For economically significant rules, agencies are also required to provide OMB with an accounting statement that includes a standard table reporting benefit and cost estimates. Figure 8.1 provides a suggested format for this accounting statement, adapted from OMB *Circular A-4*. The accounting statement summarizes the information presented in the RIA and should include:

- Annualized incremental benefit and cost estimates, using real discount rates of three and seven percent, within the following three categories: monetized; quantified, but not monetized; and qualitative, but not quantified or monetized. The primary benefit and cost estimates should reflect the expected values. The minimum and maximum estimates should, if possible, reflect the 5th and 95th percent confidence bounds.
- Annualized incremental transfer estimates, which occur when wealth or income is redistributed without any direct change in aggregate social welfare.
- Information on the effects on State, local, and tribal governments, small businesses, wages, and economic growth.

[117] As discussed in Chapter 2, for meaningful comparison, benefits and costs should be measured over the same time period. When some impacts are assessed over longer periods than others to provide important information for decision-making, the results for the additional period should be reported separately to avoid misleading comparisons.

FIGURE 8.1. TEMPLATE FOR OMB ACCOUNTING STATEMENT

OMB #: **Agency/Program Office:**
Rule Title:
RIN#: **Date:**

Economic Data: Costs and Benefits Statement							
				Units			
Category	Primary Estimate	Low Estimate	High Estimate	Year Dollars	Discount Rate	Period Covered	Notes
Benefits							
Annualized Monetized $ millions/year					7%		
					3%		
Annualized Quantified					7%		
					3%		
Qualitative							
Costs							
Annualized Monetized $ millions/year					7%		
					3%		
Annualized Quantified					7%		
					3%		
Qualitative							
Transfers							
Federal Annualized Monetized $ millions/year					7%		
					3%		
From/To	From:			To:			
Other Annualized Monetized $ millions/year					7%		
					3%		
From/To	From:			To:			
Effects							
State, Local or Tribal Government:							
Small Business:							
Wages:							
Growth:							

In addition to the present value and annualized results, OMB *Circular A-4* suggests that the analyst include separate schedules of undiscounted monetized benefits and costs showing the type and timing of these effects, as discussed in Chapter 5. These undiscounted results should be presented in constant dollars for each year of the analytic time horizon. Again, this schedule could be presented in a table or as a bar chart or other graphic.

In sum, presenting the analysis so that it can be easily understood by decision-makers and stakeholders may require significant effort to clearly and concisely describe the options assessed, the analytic approach, and the results. Without such effort, the analysis may not play its intended role in the decision-making process, and may be misconstrued in ways that lead to significant and unnecessary controversy. Avoiding technical jargon, and using tables and graphics to illustrate key points, will aid in ensuring that the analysis is useful for decision-making.

Chapter 9

Conduct Retrospective Analysis

Executive Order 13563 directs each Federal agency to establish a plan for ongoing retrospective review of existing significant regulations to identify those that can be eliminated as obsolete, unnecessary, burdensome, or counterproductive, or that can be modified to be more effective, efficient, flexible, and streamlined (Obama 2011, HHS 2011).[118] The initial HHS plan was finalized in August 2011 and has been subsequently updated.[119]

The plan describes HHS's approach for identifying regulations for review as part of an ongoing process and lists factors HHS routinely considers in this review (HHS 2011). The factors include many that can be evaluated qualitatively; for example, identifying redundant or obsolete regulations or requirements. While important for a broader program of retrospective review, such qualitative analysis is not the focus of this guidance. Rather, this chapter describes HHS's approach for quantitative retrospective analysis of the benefits and costs of selected economically significant regulations.

Quantitative retrospective benefit-cost analysis may serve several purposes, ranging from assessing the effectiveness of a single regulation to evaluating the overall use of benefit-cost analysis in the regulatory development process. The next section discusses the conceptual framework in greater detail. We follow with an overview of the approach to retrospective benefit-cost analysis, including a generalized discussion of analytic steps.

9.1 BASIC CONCEPTS

The general purpose of the prospective, or *ex ante*, analysis discussed in the previous chapters of this guidance is to determine whether the benefits of the regulation are likely to exceed costs (i.e., whether benefits minus costs, or net benefits, are positive) and to identify the regulatory alternative likely to generate the largest net benefits. Figure 9.1 identifies several ways in which subsequent retrospective, or *ex post*, analysis of benefits and costs may be useful.[120]

FIGURE 9.1. USES OF RETROSPECTIVE BENEFIT COST ANALYSIS

1. Evaluate whether existing regulations continue to be justified in economic terms (i.e., produce positive net benefits).
2. Support identification of changes to existing regulations that will decrease their costs or increase their benefits.
3. Provide insight into the accuracy of *ex ante* estimates of regulatory benefits and costs, particularly whether they tend to be over- or underestimated.
4. Identify ways to improve the accuracy of future cost-benefit analyses.

A primary goal is to assess whether the regulation has achieved the desired outcome. For example, if its purpose was to reduce new cases of heart disease, analysts would seek empirical evidence of this impact. While potentially difficult to obtain, this information is a necessary to determine whether net benefits are positive.

Additionally, retrospective benefit-cost analysis "can help identify specific regulations that are ripe for regulatory reform, since their benefit-cost balance may be more or less favorable than originally expected" (OMB 2005). Importantly, OMB notes that "a validation study designed to determine the accuracy of *ex ante*

[118] Aldy (2014) discusses the historical development of the retrospective review process within the Federal government and potential improvements.

[119] See the HHS website for the 2011 plan (http://www.hhs.gov/open/execorders/13563) as well as updates and an opportunity for public input regarding which regulations to review.

[120] This discussion is based largely on OMB (2005); more information is provided in subsequent reports such as OMB (2011c).

estimates does not by itself provide full guidance on the desirability of reforming the existing regulation" (OMB 2005, p. 41). For example, regulated entities may have incurred costs that will not be recovered if the regulation is retracted.[121]

Retrospective analysis may also inform the modification of an existing regulation with the goal of increasing its net benefits, regardless of whether net benefits are positive or negative as currently implemented. New information about key assumptions or inputs may suggest opportunities for optimizing the regulation.

After an agency has completed retrospective review of multiple regulations, it can identify whether it has a tendency to systematically over- or underestimate costs or benefits, and the extent to which over- or underestimation is attributable to various factors.[122] This information might highlight the need for additional uncertainty analysis, as well as ways in which future analyses can be improved.[123] It might also provide insight into how much weight should be granted to the cost-benefit analysis in the decision-making process as agencies promulgate new regulations (OMB 2005).

Finally, such information may identify ways to improve the accuracy of future *ex ante* analyses. For example, it may demonstrate that agencies routinely underestimate the ability of regulated entities to reduce costs as they gain experience with a particular regulation.[124] In certain cases, a regulation may motivate affected entities to go beyond the required compliance standards, resulting in additional health or other improvements not included in *ex ante* benefits estimates.[125] A better understanding of how affected entities respond to regulation will help improve the accuracy of future *ex ante* analysis.[126]

9.2 GENERAL APPROACH

In general, analysts should pursue retrospective benefit-cost 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) and where available data allow for meaningful assessment of impacts. Below, we first discuss challenges to estimating the effect of the regulation and addressing the time frame over which the impacts occurred, then describe the overall framework for the analysis.

9.2.1 ESTIMATING THE IMPACT OF THE REGULATION

The public or decision-makers may presume that retrospective analysis will be more accurate than prospective analysis because analysts can simply "tally" benefits and costs that have actually occurred. In other words, retrospective analysis may be perceived as a simple accounting exercise. However, correctly measuring incremental effects on a retrospective basis presents similar challenges to estimating impacts prospectively and is also subject to substantial uncertainty. The key challenge to *ex post* analysis is isolating the incremental effects

[121] Such incurred, or "sunk" costs have zero opportunity costs because these resources have already been used and cannot be used again. When the analytic goal is to determine whether to revise or vacate an existing regulation, and significant costs have been incurred, a prospective analysis of retracting the existing regulation may be more appropriate than a retrospective evaluation.

[122] An agency might also use retrospective review to better understand the cumulative effect of multiple regulations aimed at reducing the same risk.

[123] For review of the results of retrospective benefit-cost analyses of Federal regulations see, for example, Harrington et al. (2000), Harrington (2006), and Morgenstern (2015).

[124] A substantial body of literature on "learning by doing" examines declines in the per-unit cost of producing or using a new technology as experience with the technology increases over time, as discussed in Chapter 4 and EPA (2010).

[125] For example, in 2003, FDA promulgated a final regulation requiring that trans fatty acids be declared in the nutrition label of conventional foods and dietary supplements on a separate line immediately under the line for the declaration of saturated fatty acids. Subsequent review of industry compliance with the regulation revealed that the informational nature of the regulation and the desire to maintain market share for certain food products created incentives for the industry to find ways to reduce trans fatty acids in foods to a degree that exceeded FDA's expectations. As a result, *ex ante* estimates of costs and health benefits may have been understated.

[126] In addition to improving the accuracy of future *ex ante* analysis, a better understanding of how affected entities respond to regulations may identify more efficient methods of achieving similar policy objectives. For example, if analysts learn that assuming complete compliance with future regulations overstates actual compliance rates, they may determine that increasing enforcement resources for existing regulations will achieve better health outcomes for less cost than introducing additional regulations.

of the regulation. As with *ex ante* analysis, identifying incremental effects requires comparing two scenarios: the world with the regulation (the "incremental scenario") and the world without the regulation (the "baseline scenario" in *ex ante* analysis, as discussed in Chapter 2, or "counterfactual scenario" in *ex post* analysis).[127]

In *ex ante* analysis both scenarios occur in the future; neither is observed. Ideally, analysts do not assume that current conditions will persist in the future; the baseline is the evolution of the existing, observed world. Both the baseline and incremental scenarios are subject to significant uncertainty associated with assumptions about likely future health and economic conditions without the regulation, compliance with the regulation, and behavioral responses that may affect implementation (e.g., innovation by the regulated community).

In *ex post* analysis, uncertainty may be reduced because the world with the regulation (the incremental scenario) can be observed. What were included as probabilities or expected values in the *ex ante* analysis can be replaced with actual outcomes, to the extent that it is possible to separate the effects of the regulation from other factors. The agency may have data on compliance rates, or it may be able to obtain more accurate information on key assumptions, such as the number of units of a drug sold. In other cases, it may be difficult to separate the effects of the regulation from other factors. For example, the incidence of the health conditions addressed by the regulation may be rising or falling due to medical innovations, changing demographics, or other causes. The extent to which the regulation has accelerated a decrease in incidence, or offset what would have otherwise been an even larger increase, may be difficult to isolate, even using sophisticated statistical tools. Furthermore, analysts must still model the counterfactual scenario, which cannot be observed. Assumptions about what the world would have been like without the regulation introduce uncertainty to estimates of the incremental impacts.[128,129]

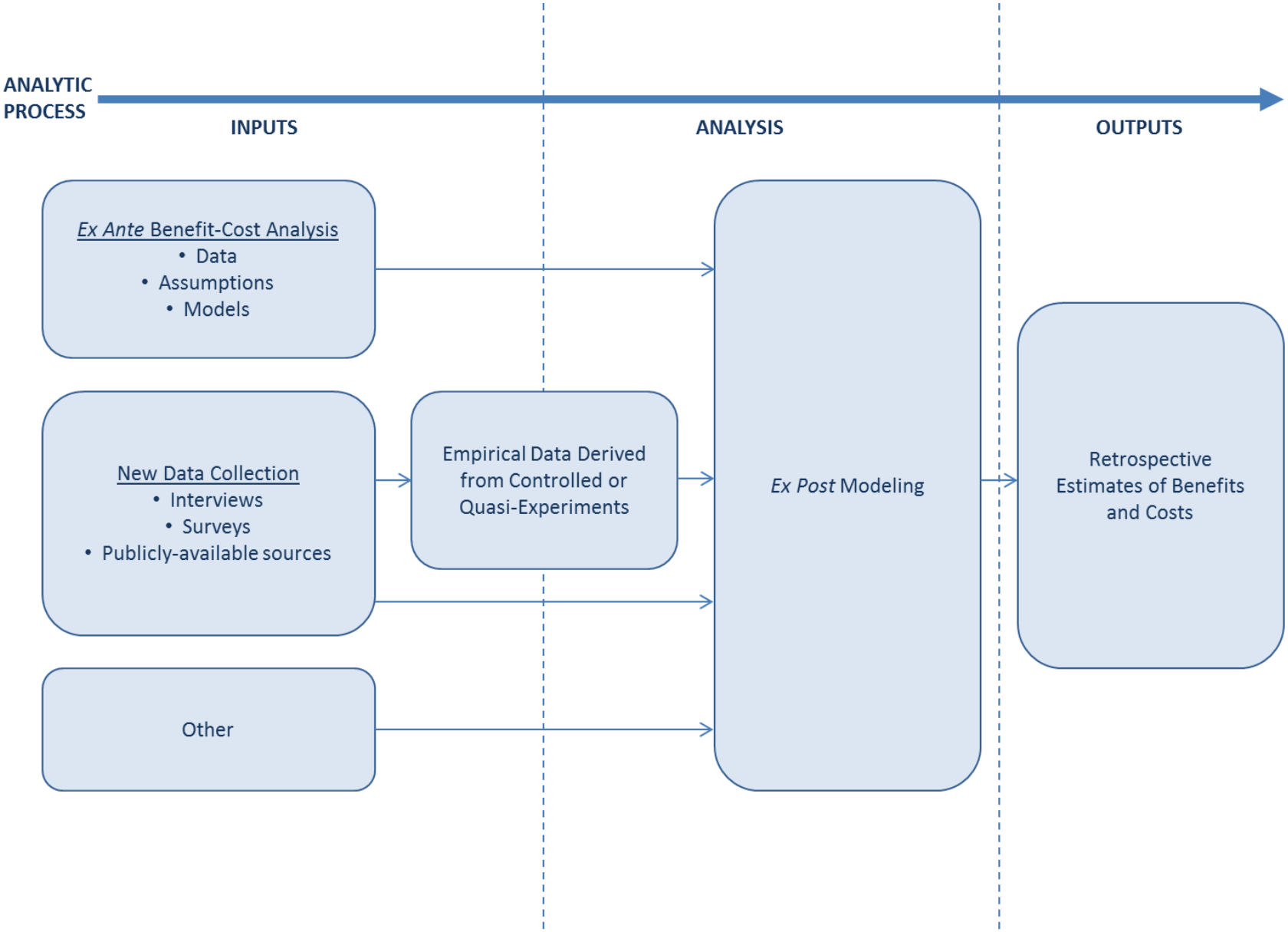
The major components of a retrospective benefit-cost analysis are the same as the RIA components illustrated in Figure 1.1. Figure 9.2 illustrates the process used to construct new models and highlights differences in the data and information potentially available for retrospective benefit-cost analysis. The process begins with the evaluation of existing information and the collection of new data. Relevant information may be obtained from a variety of sources, including the *ex ante* analysis previously developed in support of the regulation, newly available public information, surveys, or other sources. Retrospective analysis, like prospective analysis, is subject to the requirements of the PRA, which may limit an agency's ability to conveniently collect new data.

[127] The relevant comparison is the world with and without the regulation, not the world before and after the regulation is implemented. For example, a regulated entity's operating costs after a regulation takes effect may be influenced by market conditions or other factors unrelated to the regulation. Simply comparing costs before and after the regulation takes effect, without accounting for these other changes, could be misleading.

[128] *Ex ante* analysis estimates net benefits conditional on one or more sets of assumptions about the future, and sometimes uncertainty with regard to estimated net benefits may be aggregated over sets of future uncertain factors. In contrast, *ex post* analysis estimates net benefits conditional on specific realization of at least some of the *ex ante* uncertain factors. When using *ex post* analysis to judge the accuracy of *ex ante* estimates, this difference affects the interpretation and must be recognized.

[129] Many *ex ante* actions are undertaken to protect against uncertain adverse events. If the event does not occur, that does not necessarily mean that the regulation was unwarranted. For example, a vaccination policy does not necessarily have negative net benefits if the disease does not materialize; the insurance against possible disease provides its own benefit. Uncertainty about the likelihood of occurrence should be considered in the retrospective analysis as well as the prospective analysis.

FIGURE 9.2. RETROSPECTIVE ANALYSIS PROCESS



As indicated by the figure, data from two types of experiments might be available for these analyses: controlled or quasi-experiments. In the best case, the agency would design the regulation to allow for a controlled experiment, enabling analysts to empirically estimate the impact of the regulation with a high degree of confidence by comparing otherwise-identical treatment (i.e., subject to the regulation) and control (i.e., not subject to the regulation) groups.[130] This information on actual effects can replace assumptions about likely effects in the cost and benefit models. However, implementation of a controlled experiment is often at odds with regulatory design, which targets the populations in need of intervention or, for fairness, applies equally to everyone. Alternatively, in certain circumstances opportunities for natural or quasi-experimental designs, where natural randomization is exploited, may exist. For example, analysts may be able to identify unregulated comparison groups if (1) the regulation is phased in through time (new products are subject to the regulation while similar, older products are exempt); or (2) the regulation is not implemented uniformly across all geographic areas (e.g., implementation may differ across states).[131]

Such controlled or quasi-experiments may provide the best assessment of the actual effects of existing regulations because they are based on observed outcomes and data.[132] However, in practice, they may be too small in scale to be extrapolated to a national level, or the conditions necessary for successful experiments may be unavailable. For example, in many cases Federal regulations apply broadly to the general population. Thus, comparable control groups do not exist. Comparing populations through time may be more feasible; however, changes in underlying economic or health conditions may complicate such comparisons. Some of these challenges may be overcome using simple regression analysis or more sophisticated econometric modeling techniques.[133] In addition, regulations should be designed to ensure that monitoring or other data are available for use in future retrospective assessments.

The input data and additional analytic results are then used to update existing *ex ante* models or create new *ex post* models, as discussed in greater detail later in this chapter. At the conclusion of the process, decision-makers would use the results of the *ex post* modeling effort to evaluate the regulations. The process may be iterative as new data or insights are identified.

9.2.2 ADDRESSING THE TIMING OF THE IMPACTS

Below, we address two additional technical issues. They include defining the period of analysis and calculating present value and annualized impacts. While these issues are also relevant to prospective analysis, they may be addressed differently in retrospective analysis, depending on the period of interest.

Determining the time horizon: In retrospective analysis, defining the relevant time horizon is fairly simple. As with prospective analysis, the retrospective analysis should start in the year the impacts were first incurred, even if that period predates the effective date of the final regulation. For example, many regulated entities may incur costs in anticipation of upcoming regulations as they prepare to meet the regulation's effective date. These costs should be included in the analysis.

The end date is determined by the date when the retrospective analysis is undertaken or the most recent date for which retrospective data are available. To the extent that agencies wish to project impacts into the future based on new information collected in the retrospective analysis, additional prospective results should be clearly

[130] For a discussion of regulatory design intended to foster such experiments, see Greenstone (2009).

[131] For example, the National Traffic Highway Safety Administration (NHTSA) often issues standards applying only to new vehicles. Thus, it can estimate the efficacy of new safety equipment by comparing contemporaneous accident reports for new vehicles to similar records for older vehicles manufactured prior to the effective date of the final regulation (Lutter 2013).

[132] For two examples of these types of experiments conducted in the context of public health policy, see Newhouse and the Insurance Experiment Group (1996) and Baicker et al. (2013).

[133] For an informative discussion of the use of controlled and quasi-experiments in policy evaluation and the statistical analysis of such empirical data, see HM Treasury (2011), Chapter 9. For additional guidance on the design and conduct of such experiments, see Box et al. (2005).

separated and reported, as prospective analysis requires a different set of assumptions to address the future baseline and incremental scenarios.

Where the benefits and costs of a regulation are expected to occur unevenly through time, the analysts should consider the full time period over which the regulation was implemented. Longer timeframes may be particularly important when positive health impacts are not expected to be measurable until many years after the regulation goes into effect. In such cases, a longer timeframe ensures that all significant one-time benefits and costs are captured in the analysis. However, if benefits and costs are likely to remain constant through the period of the analysis, it may be sufficient to model impacts for a single year.[134]

Finally, if the agency wishes to compare the results of *ex ante* and *ex post* analyses, it must model the same time periods. However, this may not always be possible, particularly if the agency reviews the regulation within the first few years of implementation. In such cases, analysts should adjust *ex ante* estimates to exclude years not analyzed in the *ex post* analysis. Agencies should also ensure that the identical time periods are covered when comparing *ex ante* and *ex post* estimates of annualized impacts.

Calculating present value and annualized impacts: Regardless of whether impacts occur in the future or the past, time preferences matter. Resources allocated to compliance in prior years could have been used for other purposes. Benefits accrued earlier are generally more valuable than those accrued later. If analysts are interested in comparing the results of the retrospective analysis to the prospective analysis, they should report benefits and costs in present value terms using the same base year (see Chapter 5). Generally, the starting point (base year) is the year the regulation went into effect or the first year costs or benefits were incurred. Alternatively, impacts may be reported on an annualized basis. In either case, the stream of benefits and costs should also be reported by year and in constant, undiscounted dollars for those years.

9.2.3 FRAMING THE *EX POST* MODELING EFFORT

Earlier in this chapter, Figure 9.2 describes the general components of retrospective analysis, including inputs, analysis, and outputs. This section provides additional discussion of the choices analysts face during the analysis, particularly the *ex post* modeling effort. Generally, analysts should follow a phased approach to ensure that their work is carefully focused and useful for decision-making, following the steps listed in Figure 9.3 as discussed below.

Prior to initiating any retrospective modeling effort, analysts should consider the purpose of the effort, as the goal may affect the content of the analysis (see Figure 9.1). Based on that purpose, they should develop reasonable stopping rules to define the scope of the analysis. These rules are designed to focus analysts on answering the pertinent question related to a particular regulation, while avoiding unnecessary and expensive data collection and analysis.

Analysts should follow a stepwise progression: (1) simple screening analysis; (2) revisions to existing models developed for the *ex ante* regulatory analysis; and (3) entirely new modeling efforts, as indicated in greater detail in Figure 9.3. For example, if the purpose of the effort is to determine whether the benefits of a regulation exceed costs, and a simple screening analysis can answer this question, additional modeling efforts may not be necessary.

[134] Such a situation seems unlikely given continued changes in the size of the U.S. economy. But per capita effects might be roughly constant and reporting them would be perhaps as useful as reporting totals.

FIGURE 9.3. SUGGESTED STEPS FOR *EX POST* MODELING

LEVEL OF EFFORT	STEPS
Lowest ⇩	***Screening Analysis*** • Conduct case studies of incurred costs or benefits. • Conduct a simple bounding analysis with assumptions based on observed data.
⇩	***Adjust Existing Ex Ante Model Assumptions and Data*** In addition to the above screening tools, • Identify the key assumptions or data sources influencing the impact estimates in the *ex ante* model. • Focus retrospective research efforts on refining these assumptions and data, such as through natural or controlled experiments or other data collection efforts. • Update counterfactual and incremental scenarios using the existing model and this new information. • Evaluate the validity of existing models and whether they will achieve the goals of the retrospective analysis (e.g., whether they accurately depict the response of the regulated community).
⇩ **Highest**	***Construct a New Model*** In addition to, or in place of, adjustments to the *ex ante* model, • Use existing and new information to construct a new model of impacts. • Ensure the new model captures missing categories of benefits and costs or unanticipated responses by the affected community.

If analysts are interested not just in whether the regulation was effective, but also in the accuracy of the *ex ante* cost and benefit estimates, additional modeling may be required. They should first review the key assumptions or data sources driving the results of the *ex ante* analysis, particularly if the appropriateness of these is uncertain and they substantially affect the results. Analysts should focus their research on refining or updating these key factors.[135] Variations of the original *ex ante* models could be used to estimate the incremental change compared with the counterfactual scenario. However, such an approach assumes that the original models accurately characterize the implementation of the regulation and linkages to resulting benefits and costs.[136]

In some cases, through interviews with affected entities, additional data collection, or the results of controlled or quasi-experiments, analysts may determine that the *ex ante* models did not accurately characterize the impacts of the regulation. For example, compliance costs may be lower than anticipated if affected entities develop innovative methods of compliance, or improvements in overall productivity reduce all costs, including compliance costs. Or underlying market conditions may fundamentally change, making substitute sources of

[135] It is particularly helpful if the original *ex ante* analysis clearly identifies key assumptions and sources of uncertainty. Sensitivity analysis can be used to demonstrate the importance of each uncertain variable.

[136] A particularly well-known example of a regulation where the *ex ante* models did not accurately predict the behavioral response of the regulated community is the case of EPA's regulation of sulfur dioxide (SO_2) emissions. As described in Harrington et al. (2000), emissions reductions exceeded expectations for several reasons, including greater than expected efficacy of pollution control equipment, innovation by the regulated community, and changes in market conditions. The SO_2 regulation illustrates circumstances that would necessitate new cost and benefit modeling to accurately estimate the net benefits of the regulation.

goods or materials available to offset costs or benefits. In other cases, the agency may learn that key categories of benefits and costs were omitted from the original analysis. Based on this new information, analysts may decide to develop new models of benefits and costs.

In sum, conducting retrospective analysis requires thinking carefully about its goals. In some cases, revisiting the prospective analysis from an *ex post* perspective will provide important insights into the benefits and costs of the regulation. In other cases, prospective analysis of the benefits and costs of eliminating or modifying the regulation may be useful – instead of, or in addition to, the *ex post* analysis. In either case, the level of effort should be tailored to the purpose of the review.

Appendix A

Agency Checklist: Regulatory Impact Analysis (OMB 2010)

This appendix replicates OMB's 2010 Checklist, which is also available at: https://www.whitehouse.gov/omb/inforeg_regpol_agency_review.

With this document, the Office of Information and Regulatory Affairs is providing a checklist to assist agencies in producing RIAs, as required for economically significant rules by Executive Order 12866 and OMB *Circular A-4*.

Nothing herein alters, adds to, or reformulates existing requirements in any way. Moreover, this checklist is limited to the requirements of Executive Order 12866 and Circular A-4; it does not address requirements imposed by other authorities, such as the National Environmental Policy Act, the Regulatory Flexibility Act, the Unfunded Mandates Reform Act, the Paperwork Reduction Act, and various Executive Orders that require analysis. Executive Order 12866 and Circular A-4, as well as those other authorities, should be consulted for further information.

Checklist for Regulatory Impact Analysis:

- Does the RIA include a reasonably detailed description of the **need for the regulatory action**?[1,2]
- Does the RIA include an explanation of how the regulatory action will **meet that need**?[3]
- Does the RIA use an appropriate **baseline** (i.e., best assessment of how the world would look in the absence of the proposed action)?[4]
- Is the information in the RIA based on **the best reasonably obtainable scientific, technical, and economic information** and is it presented in an **accurate, clear, complete, and unbiased manner**?[5]
- Are the data, sources, and methods used in the RIA provided to the public **on the Internet** so that a qualified person can reproduce the analysis?[6]
- To the extent feasible, does the RIA quantify and monetize the anticipated **benefits** from the regulatory action?[7,8]
- To the extent feasible, does the RIA quantify and monetize the anticipated **costs**?[9]
- Does the RIA explain and support **a reasoned determination that the benefits of the intended regulation justify its costs** (recognizing that some benefits and costs are difficult to quantify)?[10]
- Does the RIA assess the **potentially effective and reasonably feasible alternatives**?[11]
    - Does the RIA assess the benefits and costs of different regulatory provisions separately if the rule includes a number of distinct provisions?[12]
    - Does the RIA assess at least one alternative that is less stringent and at least one alternative that is more stringent?[13]
    - Does the RIA consider setting different requirements for large and small firms?[14]
- Does the preferred option have the highest **net benefits** (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity), unless a statute requires a different approach? [15]
- Does the RIA include an explanation of why the planned regulatory action is **preferable** to the identified potential alternatives?[16]
- Does the RIA use appropriate **discount rates** for benefits and costs that are expected to occur in the future?[17]
- Does the RIA include, if and where relevant, an appropriate **uncertainty analysis**?[18]

- Does the RIA include, if and where relevant, a separate description of **distributive impacts** and **equity**?[19]
  - Does the RIA provide a description/accounting of transfer payments?[20]
  - Does the RIA analyze relevant effects on disadvantaged or vulnerable populations (e.g., disabled or poor)?[21]
- Does the analysis include a clear, plain-language **executive summary**, including an **accounting statement** that summarizes the benefit and cost estimates for the regulatory action under consideration, including the qualitative and non-monetized benefits and costs?[22]
- Does the analysis include a clear and transparent **table** presenting (to the extent feasible) anticipated benefits and costs (quantitative and qualitative)?[23]

NOTES

1. Required under Executive Order 12866, Section 6(a)(3)(B)(i): "The text of the draft regulatory action, together with a reasonably detailed description of the need for the regulatory action and an explanation of how the regulatory action will meet that need."
2. Circular A-4 states: "If the regulation is designed to correct a significant market failure, you should describe the failure both qualitatively and (where feasible) quantitatively." (P. 4)
3. See note 1 above.
4. Circular A-4 states: "You need to measure the benefits and costs of a rule against a baseline. This baseline should be the best assessment of the way the world would look absent the proposed action… In some cases, substantial portions of a rule may simply restate statutory requirements that would be self-implementing, even in the absence of the regulatory action. In these cases, you should use a pre-statute baseline." (P. 15-16)
5. Circular A-4 states: "Because of its influential nature and its special role in the rulemaking process, it is appropriate to set minimum quality standards for regulatory analysis. You should provide documentation that the analysis is based on the best reasonably obtainable scientific, technical, and economic information available… you should assure compliance with the Information Quality Guidelines for your agency and OMB's Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies..." (P. 17). The IQ Guidelines (paragraph V.3.a) define objectivity to include "whether disseminated information is being presented in an accurate, clear, complete, and unbiased manner."
   http://www.whitehouse.gov/omb/assets/omb/fedreg/reproducible2.pdf
6. Circular A-4 states: "A good analysis should be transparent and your results must be reproducible. You should clearly set out the basic assumptions, methods, and data underlying the analysis and discuss the uncertainties associated with the estimates. A qualified third party reading the analysis should be able to understand the basic elements of your analysis and the way in which you developed your estimates. To provide greater access to your analysis, you should generally post it, with all the supporting documents, on the internet so the public can review the findings." (P. 17). OMB IQ Guidelines (paragraph V.3.b.ii) further states: "If an agency is responsible for disseminating influential scientific, financial, or statistical information, agency guidelines shall include a high degree of transparency about data and methods to facilitate the reproducibility of such information by qualified third parties."
7. Required under Executive Order 12866, Section 6(a)(3)(C)(i): "An assessment, including the underlying analysis, of benefits anticipated from the regulatory action (such as, but not limited to, the promotion of the efficient functioning of the economy and private markets, the enhancement of health and safety, the protection of the natural environment, and the elimination or reduction of discrimination or bias) together with, to the extent feasible, a quantification of those benefits."

8. Circular A-4 states: "You should monetize quantitative estimates whenever possible. Use sound and defensible values or procedures to monetize benefits and costs, and ensure that key analytical assumptions are defensible. If monetization is impossible, explain why and present all available quantitative information." (P. 19). Circular A-4 also offers a discussion of appropriate methods for monetizing benefits that might not easily be turned into monetary equivalents.

9. Required under Executive Order 12866, Section 6(a)(3)(C)(ii): "An assessment, including the underlying analysis, of costs anticipated from the regulatory action (such as, but not limited to, the direct cost both to the government in administering the regulation and to businesses and others in complying with the regulation, and any adverse effects on the efficient functioning of the economy, private markets (including productivity, employment, and competitiveness), health, safety, and the natural environment), together with, to the extent feasible, a quantification of those costs;" See also note 6 above.

10. Executive Order 12866, Section 1(b)(6) states that to the extent permitted by law, "[e]ach agency shall assess both the costs and the benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs." As Executive Order 12866 recognizes, a statute may require an agency to proceed with a regulation even if the benefits do not justify the costs; in such a case, the agency's analysis may not show any such justification.

11. Required under Executive Order 12866, Section 6(a)(3)(C)(iii): "An assessment, including the underlying analysis, of costs and benefits of potentially effective and reasonably feasible alternatives to the planned regulation, identified by the agencies or the public (including improving the current regulation and reasonably viable nonregulatory actions)..."

12. Circular A-4 states: "You should analyze the benefits and costs of different regulatory provisions separately when a rule includes a number of distinct provisions." (P. 17)

13. Circular A-4 states: "you generally should analyze at least three options: the preferred option; a more stringent option that achieves additional benefits (and presumably costs more) beyond those realized by the preferred option; and a less stringent option that costs less (and presumably generates fewer benefits) than the preferred option." (P. 16)

14. Circular A-4 states: "You should consider setting different requirements for large and small firms, basing the requirements on estimated differences in the expected costs of compliance or in the expected benefits. The balance of benefits and costs can shift depending on the size of the firms being regulated. Small firms may find it more costly to comply with regulation, especially if there are large fixed costs required for regulatory compliance. On the other hand, it is not efficient to place a heavier burden on one segment of a regulated industry solely because it can better afford the higher cost. This has the potential to load costs on the most productive firms, costs that are disproportionate to the damages they create. You should also remember that a rule with a significant impact on a substantial number of small entities will trigger the requirements set forth in the Regulatory Flexibility Act. (5 U.S.C. 603(c), 604)." (P. 8)

15. Executive Order 12866, Section 1(a) states: "agencies should select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity) unless a statute requires another regulatory approach."

16. Required under Executive Order 12866, Section 6(a)(3)(C)(iii): "An assessment, including the underlying analysis, of costs and benefits of potentially effective and reasonably feasible alternatives to the planned regulation, identified by the agencies or the public (including improving the current regulation and reasonably viable nonregulatory actions), and an explanation why the planned regulatory action is preferable to the identified potential alternatives."

17. Circular A-4 contains a detailed discussion, generally calling for discount rates of 7 percent and 3 percent for both benefits and costs. It states: "Benefits and costs do not always take place in the same time period. When they do not, it is incorrect simply to add all of the expected net benefits or costs without taking account of when they actually occur. If benefits or costs are delayed or otherwise separated in time from each other, the difference in timing should be reflected in your analysis.... For regulatory analysis, you should provide estimates of net benefits using both 3 percent and 7 percent.... If your rule will have important intergenerational benefits or costs you might consider a further sensitivity analysis using a lower but positive discount rate in addition to calculating net benefits using discount rates of 3 and 7 percent." (PP. 31, 34, 36)

18. Circular A-4 provides a detailed discussion. Among other things, it states: "Examples of quantitative analysis, broadly defined, would include formal estimates of the probabilities of environmental damage to soil or water, the possible loss of habitat, or risks to endangered species as well as probabilities of harm to human health and safety. There are also uncertainties associated with estimates of economic benefits and costs, such as the cost savings associated with increased energy efficiency. Thus, your analysis should include two fundamental components: a quantitative analysis characterizing the probabilities of the relevant outcomes and an assignment of economic value to the projected outcomes." (P. 40). Circular A-4 also states: "You should clearly set out the basic assumptions, methods, and data underlying the analysis and discuss the uncertainties associated with the estimates." (P. 17)

19. Executive Order 12866, Section 1(b)(5) states; "When an agency determines that a regulation is the best available method of achieving the regulatory objective, it shall design its regulations in the most cost-effective manner to achieve the regulatory objective. In doing so, each agency shall consider incentives for innovation, consistency, predictability, the costs of enforcement and compliance (to the government, regulated entities, and the public), flexibility, *distributive impacts*, and *equity*" (emphasis added). Circular A-4 states: "The term 'distributional effect' refers to the impact of a regulatory action across the population and economy, divided up in various ways (e.g., income groups, race, sex, industrial sector, geography)… Your regulatory analysis should provide a separate description of distributional effects (i.e., how both benefits and costs are distributed among sub-populations of particular concern) so that decision makers can properly consider them along with the effects on economic efficiency… Where distributive effects are thought to be important, the effects of various regulatory alternatives should be described quantitatively to the extent possible, including the magnitude, likelihood, and severity of impacts on particular groups." (P. 14)

20. Circular A-4 states: "Distinguishing between real costs and transfer payments is an important, but sometimes difficult, problem in cost estimation. . . . Transfer payments are monetary payments from one group to another that do not affect total resources available to society. . . . You should not include transfers in the estimates of the benefits and costs of a regulation. Instead, address them in a separate discussion of the regulation's distributional effects." (P. 14)

21. Circular A-4 states: "Your regulatory analysis should provide a separate description of distributional effects (i.e., how both benefits and costs are distributed among sub-populations of particular concern) so that decision makers can properly consider them along with the effects on economic efficiency. Executive Order 12866 authorizes this approach. Where distributive effects are thought to be important, the effects of various regulatory alternatives should be described quantitatively to the extent possible, including the magnitude, likelihood, and severity of impacts on particular groups." (P. 14)

22. Circular A-4 states: "Your analysis should also have an executive summary, including a standardized accounting statement." (P. 3). OMB recommends that: "Regulatory analysis should be made as transparent as possible by a prominent and accessible executive summary—written in a "plain language" manner designed to be understandable to the public—that outlines the central judgments that support

regulations, including the key findings of the analysis (such as central assumptions and uncertainties)…If an agency has analyzed the costs and benefits of regulatory alternatives to the planned action (as is required for economically significant regulatory actions), the summary should include such information." See *2010 Report to Congress on the Benefits and Costs of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities*, page 51. Available at: http://www.whitehouse.gov/sites/default/files/omb/legislative/reports/2010_Benefit_Cost_Report.pdf

23. Circular A-4 states: "You need to provide an accounting statement with tables reporting benefit and cost estimates for each major final rule for your agency." (P. 44). Circular A-4 includes an example of a format for agency consideration. OMB recommends "that agencies should clearly and prominently present, in the preamble and in the executive summary of the regulatory impact analysis, one or more tables summarizing the assessment of costs and benefits required under Executive Order 12866 Section 6(a)(3)(C)(i)-(iii). The tables should provide a transparent statement of both quantitative and qualitative benefits and costs of the proposed or planned action as well as of reasonable alternatives. The tables should include all relevant information that can be quantified and monetized, along with relevant information that can be described only in qualitative terms. It will often be useful to accompany a simple, clear table of aggregated costs and benefits with a separate table offering disaggregated figures, showing the components of the aggregate figures. To the extent feasible in light of the nature of the issue and the relevant data, all benefits and costs should be quantified and monetized. To communicate any uncertainties, we recommend that the table should offer a range of values, in addition to best estimates, and it should clearly indicate impacts that cannot be quantified or monetized. If nonquantifiable variables are involved, they should be clearly identified. Agencies should attempt, to the extent feasible, not merely to identify such variables but also to signify their importance." See *2010 Report to Congress on the Benefits and Costs of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities*, page 51. Available at: http://www.whitehouse.gov/sites/default/files/omb/legislative/reports/2010_Benefit_Cost_Report.pdf

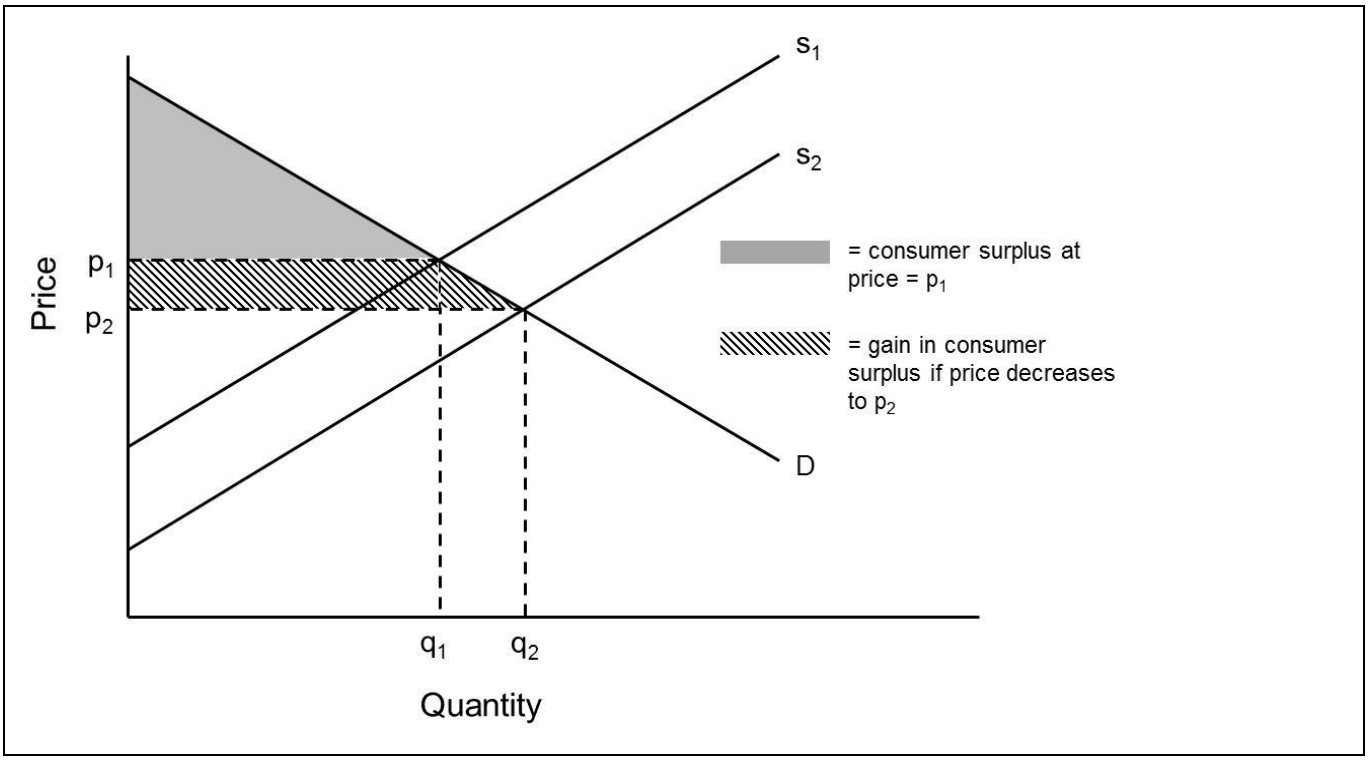
Appendix B

Consumer and Producer Surplus

As discussed in Chapter 3, a key assumption that underlies benefit-cost analysis is that benefit values are determined by the change in the amount by which aggregate WTP exceeds the market price, or "consumer surplus." When WTP exceeds price, the individual benefits from the fact that he or she can acquire the good or service for less than his or her willingness to pay. If price exceeds WTP, the individual would not purchase the good or service, choosing to use the money for other things. The difference between WTP and price can be aggregated across individuals to determine the consumer surplus associated with different price levels. Consumers generally benefit from price decreases, because WTP then exceeds price by a larger amount, and vice-versa.

This relationship is illustrated by Figure B.1. The horizontal axis represents the quantity of the good (q), the vertical axis represents its price (p). The market demand curve (D) indicates both consumers' WTP at each quantity and the quantity that would be purchased at each price.[137] Similarly, the supply curve (S) indicates both the marginal cost of supply at each quantity and the quantity that would be supplied at each price. The equilibrium market price is determined by where the two curves intersect. At this point, only consumers whose WTP exceeds the price purchase the good, and only producers whose cost of supply is less than the price produce it. For example, at price p_1, consumers would purchase quantity q_1. The shaded area above the price line and below the demand curve indicates the amount by which WTP exceeds price; i.e., consumer surplus at price p_1.

FIGURE B.1. CHANGE IN CONSUMER SURPLUS DUE TO A PRICE DECREASE



[137] Depending on the good or service, the prices represented in this schedule may reflect time costs or other factors that influence demand, in addition to the "sticker price" viewed by the consumer. Demand curves can also be developed for nonmarket goods, using the techniques described in Chapter 3 to estimate WTP.

If the price decreases, the quantity demanded rises as some consumers choose to purchase the good at the lower price rather than buying other goods or services. If changes in supply lead price to drop from p_1 to p_2, consumers would increase their purchases to quantity q_2.

When the price falls from p_1 to p_2, consumers benefit in two ways. First, they pay less for the q_1 units they continue to buy. Second, they buy $q_2 - q_1$ additional units for which WTP exceeds p_2 but does not exceed p_1. (The size of the increase in q is often summarized by the "demand elasticity," defined as the proportional change in q divided by the proportional change in p.) The area marked with diagonal lines indicates the gain in consumer surplus that results from the price decrease from p_1 to p_2.[138]

Similar concepts apply to producers. Regulatory compliance costs may affect the price and quantity of goods exchanged in the market, leading to changes in producer surplus. These relationships are illustrated by Figure B.2 for a competitive market.[139] In this case, we illustrate a cost increase that results from compliance with a new regulation. As in the earlier figure, the horizontal axis represents the quantity of the good (q) and the vertical axis represents its price (p); the market demand curve (D) indicates both consumers' WTP at each quantity and the quantity that would be purchased at each price; the supply curve (S) indicates both the marginal cost of supply at each quantity and the quantity that would be supplied at each price; and the equilibrium market price is determined by where the supply and demand curves intersect.

If the cost of supplying the good increases as a result of the regulation, the supply curve shifts upwards, from s_1 to s_2, reducing consumer surplus (the area between the demand curve and the price line). Producer surplus, which reflects the difference between the market price and supply costs (the area above the supply curve and below the price line), also decreases. For example, at price p_1 producers will supply quantity q_1. When supply costs increase, producers will provide a smaller quantity for each price and demand a higher price for each quantity. Thus the market price will increase to p_2 and the quantity sold will decrease to q_2.

The area bounded by the two supply curves and the new quantity line represents the increased cost of producing the quantity that is demanded at the new price.[140] In addition, the reduction in output results in a deadweight loss represented by the solid triangle, indicating forgone net benefits. This deadweight loss is part of the costs of the regulation.[141] Thus the net reduction in the total surplus (consumer plus producer) is a real cost to society. The question for analysts is whether these costs are greater or less than aggregate WTP for the regulation's benefits.

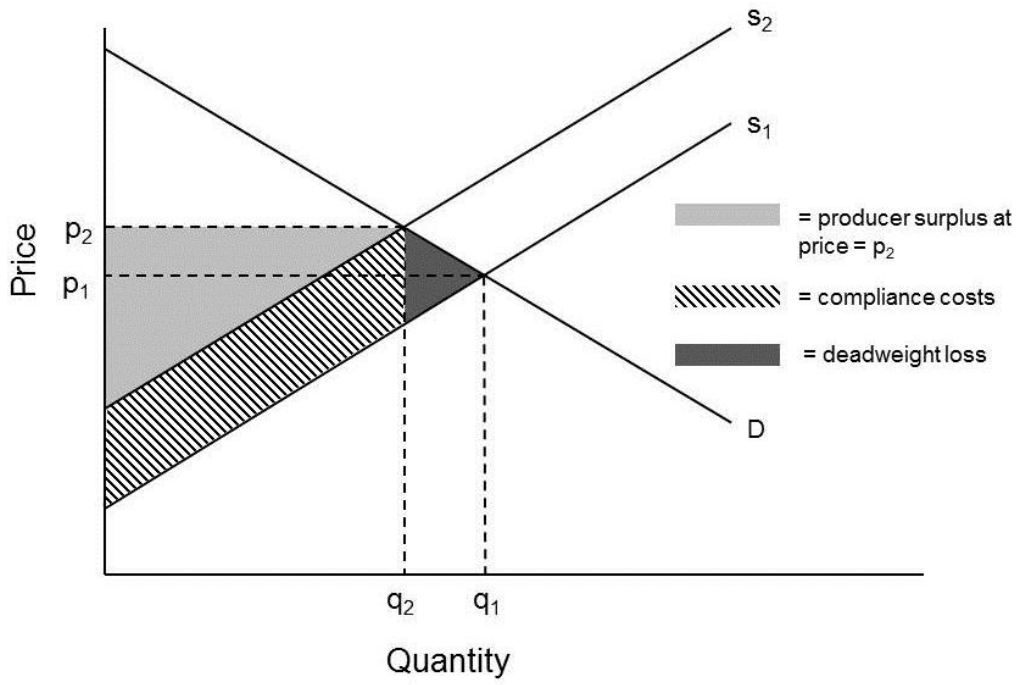
[138] When the price falls, some consumers who purchase the good at p_1 might purchase more units and some who do not purchase it at p_1 may purchase at the lower price p_2. In this case, the graph displays aggregate demand by all consumers; it does not indicate what quantity each consumer purchases. A similar graph could be drawn for an individual consumer.

[139] For a more detailed discussion of these concepts, see Boardman et al. (2011).

[140] As noted elsewhere, the real resource cost of producing a good may differ from the supply cost when the resource costs are not equal to the private costs, due to externalities, taxes, subsidies, or monopoly producers.

[141] Note that the deadweight loss results from changes in both producer and consumer surplus.

FIGURE B.2. CHANGE IN PRODUCER SURPLUS DUE TO A COST INCREASE



Appendix C

Methods for Estimating QALYs

As discussed in Chapter 3, estimating QALYs involves first determining the effect of a health state on HRQL, then multiplying HRQL by the duration of the health state. While the HRQL associated with a health state is likely to vary among individuals, in practice a common value is typically used for each state, representing a population average. This appendix introduces methods for estimating HRQL; more information on the implementation of these methods and their advantages and limitations is provided in Institute of Medicine (2006).

HRQL can be estimated directly or indirectly. Commonly used direct methods include the standard gamble, time tradeoff, and visual analog scale, administered in interviews or a survey. The standard gamble approach asks respondents to compare living the rest of their life (T years) in the health state of interest with a gamble between living the rest of their life in full health (with probability p) and immediate death (with probability 1 – p). The probability p* at which the individual is indifferent is his or her HRQL for that health state. This follows because living the rest of his or her life in the specified health state yields p* T QALYs (i.e., T years weighted by an HRQL of p*) and the gamble provides an expected value of p* T QALYs (i.e., a p* chance of T QALYs (T years weighted by an HRQL of 1) plus a complementary chance of zero QALYs (immediate death)).

The time tradeoff approach asks respondents to compare living the rest of their life (T years) in the health state of interest with living a shorter period (qT years) in full health, followed by death. The value q* at which the individual is indifferent is his or her HRQL for the health state. This follows because living T years with HRQL q* provides q* T QALYs, and living q* T years in full health also provides q* T QALYs.

The visual analog scale does not require a comparison of different future lives. It simply asks the individual to rate the health state of interest on a visual scale where one end is described as being as bad as dead and labeled 0, and the other is described as full health and labeled 100. (Alternatively, the individual may be asked to report a number between 0 and 100 rather than marking it on the scale.) HRQL is then defined as the response divided by 100.

An indirect method to estimate HRQL is to apply one of several generic HRQL indices, examples of which include the EurQol- (EQ)-5D, the Health Utilities Index (HUI), and the Quality of Well-Being (QWB) scale. Each describes health status by employing a classification system with several dimensions. In the case of the EQ-5D, these include mobility, self-care, usual activities, pain, and anxiety and depression. A particular health state is rated within each dimension; for example, as causing no, some, or extreme mobility problems. The HRQL associated with each health state is then calculated by applying a scoring function, developed by eliciting HRQL for some of the health states through a population survey using one of the direct methods described earlier. These indices have the advantage of standardizing the approach for describing each health state and providing a convenient method to calculate HRQL. The results will vary, however, depending on which index is applied, given differences in the attributes they include and in the scoring functions.

Once HRQL is determined for a particular health state, it is multiplied by the duration of that state to estimate the associated QALYs. The QALYs can then be summed across health states (e.g., acute and chronic phases) associated with a particular illness, and across the illnesses associated with a particular hazard. For regulatory analysis, health status with the regulation must be compared to health status in the absence of the regulation, which is likely to be less than full health. In particular, health status generally deteriorates with age, so that average HRQL for older individuals is generally less than 1.0 (see, for example, Hamner et al. 2006). Expected QALYs are calculated by weighting the HRQL experienced in each future year of life by the probability of living that year (i.e., by the survival curve). In addition, future QALYs are usually discounted using the same discount rates as for monetary values.

References

Akobundu, E., J. Ju, L. Blatt, and C.D. Mullins. 2006. "Cost-of-Illness Studies: A Review of Current Methods." *Pharmacoeconomics*. 24(9): 869-890.

Aldy, J.E. 2014. Learning from Experience: An Assessment of the Retrospective Reviews of Agency Rules and the Evidence for Improving the Design and Implementation of Regulatory Policy. Prepared for the Administrative Conference of the United States. https://www.acus.gov/research-projects/retrospective-review-agency-rules

Aldy, J.E. and W.K. Viscusi. 2007. "Age Differences in the Value of Statistical Life: Revealed Preference Evidence." *Review of Environmental Economics and Policy*. 1(2): 241-260.

Alolayan, M.A., J.S. Evans, and J.K. Hammitt. 2015. "Valuing Mortality Risk in Kuwait: Stated-Preference with a New Consistency Test." *Environmental and Resource Economics*. Early view.

Arias, E. 2014. "United States Life Tables, 2009." *National Vital Statistics Reports*. 62(7). http://www.cdc.gov/nchs/products/life_tables.htm

Auerswald, P., S. Kauffman, J. Lobo, and K. Shell. 2000. "The Production Recipes Approach to Modeling Technological Innovation: An Application to Learning by Doing." *Journal of Economic Dynamics & Control*. 24: 389-450.

Baicker, K., S.L. Taubman, H.L. Allen, M. Bernstein, J.H. Gruber, J.P. Newhouse, E.C. Schneider, B.J. Wright, A.M. Zaslasky, and A.N. Finkelstein. 2013. "The Oregon Experiment – Effects of Medicaid on Clinical Outcomes." *New England Journal of Medicine.* 368: 1713-1722.

Baloff, N. 1971. "Extension of the Learning Curve – Some Empirical Results." *Operational Research Quarterly (1970-1977).* 22(4): 329-340.

Berck, P. and S. Hoffman. 2002. "Assessing the Employment Impacts of Environmental and Natural Resource Policy." *Environmental and Resource Economics*. 22: 133-156.

Bloom, B.S., D.J. Bruno, D.Y. Maman, and R. Jayadevappa. 2001. "Usefulness of U.S. Cost of Illness Studies in Healthcare Decision Making." *Pharmacoeconomics*. 19(2): 207-213.

Boardman, A.E., D.H. Greenberg, A.R. Vining, and D.L. Weimer. 2011. *Cost-Benefit Analysis: Concepts and Practice (Fourth Edition)*. Upper Saddle River, N.J.: Pearson.

Box, G.E., W.G. Hunter, J.S. Hunter. 2005. *Statistics for Experimenters: Design, Innovation, and Discovery*. Hoboken, N.J.: John Wiley & Sons.

Cameron, T.A. and J.R. DeShazo. 2013. "Demand for Health Risk Reductions." *Journal of Environmental Economics and Management*. 65: 87-109.

Centers for Disease Control and Prevention, Division for Heart Disease and Stroke Prevention, State Heart Disease and Stroke Prevention Program. 2007. *Evaluation Guide: Developing and Using a Logic Model.* http://www.cdc.gov/dhdsp/programs/spha/evaluation_guides/docs/logic_model.pdf

Clinton, W.J. 1993. "Executive Order 12866: Regulatory Planning and Review." *Federal Register*. 58(190): 51735-51744. http://www.whitehouse.gov/omb/inforeg_regmatters

Clinton, W.J. 1994. "Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations." *Federal Register*. 59(32): 7629-7633. http://www.archives.gov/federal-register/executive-orders/clinton.html

Clinton, W.J. 1997. "Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks." *Federal Register*. 62(78): 19885-19888. http://www.archives.gov/federal-register/executive-orders/clinton.html

Clinton, W.J. 1999. "Executive Order 13132: Federalism." *Federal Register*. 64(153):43255-43259. https://www.federalregister.gov/articles/1999/08/10/99-20729/federalism

Congressional Budget Office. 2015. *The 2015 Long-Term Budget Outlook*. https://www.cbo.gov/publication/50250

Cooke, R.M. 1991. *Experts in Uncertainty: Opinion and Subjective Probability in Science*. New York, N.Y.: Oxford University Press.

Corso, P.S., J.K. Hammitt, and J.D. Graham. 2001. "Valuing Mortality-Risk Reduction: Using Visual Aids to Improve the Validity of Contingent Valuation." *Journal of Risk and Uncertainty*. 23(2): 165-184.

Cropper, M., J.K. Hammitt, and L.A. Robinson. 2011. "Valuing Mortality Risk Reductions: Progress and Challenges." *Annual Review of Resource Economics*. 3: 313-336.

Cutler, D.M., A. Jessup, D. Kenkel, and M.A. Starr. 2015. "Valuing Regulations Affecting Addictive or Habitual Goods." Journal of Benefit-Cost Analysis. 6:247-280. http://journals.cambridge.org/action/displayAbstract?fromPage=online&aid=9950790&fulltextType=RA&fileId=S2194588815000445

Drummond, M.F., M.J. Sculpher, K. Claxton, G.L. Stoddart, and G.W. Torrance. 2015, *Methods for the Economic Evaluation of Health Care Programmes, 4th Edition*. Oxford, U.K.: Oxford University Press.

Dutton, J.M. and A. Thomas. 1984. "Treating Progress Functions as a Managerial Opportunity." *Academy of Management Review*. 9(2): 235-247.

Epple, D., L. Argote, and R. Davadas. 1991. "Organizational Learning Curves: A Method for Investigating Intra-plant Transfer of Knowledge Acquired Through Learning by Doing." *Organizational Science*. 2(1): 58-70.

Freeman, A.M. III, J.A. Herriges, and C.L. Kling. 2014. *The Measurement of Environmental and Resource Values: Theory and Methods* (Third Edition). New York, N.Y.: RFF Press.

Greenstone, M. 2009. "Toward a Culture of Persistent Regulatory Experimentation and Evaluation." Published in *New Perspectives on Regulation*. D. Moss and J. Cisterino (eds.). Cambridge, M.A.: The Tobin Project, Inc.

Hammitt, J.K. 2000. "Valuing Mortality Risk: Theory and Practice." *Environmental Science and Technology*. 34: 1396-1400.

Hammitt, J.K. 2002. "QALYs versus WTP." *Risk Analysis*. 22(5): 985-1001.

Hammitt, J.K. 2007. "Valuing Changes in Mortality Risk: Lives Saved versus Life Years Saved." *Review of Environmental Economics and Policy*. 1(2): 228-240.

Hammitt, J.K. 2013. "Admissible Utility Functions for Health, Longevity, and Wealth: Integrating Monetary and Life-Year Measures." *Journal of Risk and Uncertainty*. 47: 311-325

Hammitt, J.K. and K. Haninger. 2010. "Valuing Fatal Risks to Children and Adults: Effects of Disease, Latency, and Risk Aversion." *Journal of Risk and Uncertainty*. 40: 57-83.

Hammitt, J.K. and L.A. Robinson. 2011. "The Income Elasticity of the Value per Statistical Life: Transferring Estimates Between High and Low Income Populations." *Journal of Benefit-Cost Analysis*. 2: Art. 1. http://journals.cambridge.org/action/displayAbstract?fromPage=online&aid=9455893&fulltextType=RA&fileId=S2152281200000024

Hanmer, J. W.F. Lawrence, J.P. Anderson, R.M. Kaplan, D.G. Fryback. 2006. "Report of Nationally Representative Values for the Noninstitutionalized US Adult Population for 7 Health-Related Quality-of-Life Scores." *Medical Decision Making*. 26(4): 391-400.

Haninger, K. and J.K. Hammitt. 2011. "Diminishing Willingness to Pay per Quality-Adjusted Life Year: Valuing Acute Foodborne Illness." *Risk Analysis*. 31(9): 1363-1380.

Harrington, W., R. Morgenstern, and P. Nelson. 2000. "On Accuracy of Regulatory Cost Estimates." *Journal of Policy Analysis and Management*. 19(2): 297-322.

Harrington, W. 2006. *Grading Estimates of the Benefits and Costs of Federal Regulation: A Review of Reviews.* Resources for the Future Discussion Paper 06-39. http://www.rff.org/files/sharepoint/WorkImages/Download/RFF-DP-06-39.pdf

Hersch, J. and W.K. Viscusi. 2010. "Immigrant Status and the Value of Statistical Life." *Journal of Human Resources.* 45: 749-771.

Hirth, R.A., M.E. Chernew, E. Miller, A.M. Fendrick, and W.G. Weissert. 2000. "Willingness to Pay for a Quality-adjusted Life Year: In Search of a Standard." *Medical Decision Making*. 20: 332-342.

HM Treasury. 2011. *The Magenta Book: Guidance for Evaluation*. https://www.gov.uk/government/publications/the-magenta-book

Institute of Medicine. 2006. *Valuing Health for Regulatory Cost-Effectiveness Analysis*. (W. Miller, L.A. Robinson, and R.S. Lawrence, eds.) Washington, D.C.: The National Academies Press. http://www.nap.edu/catalog.php?record_id=11534

Kling, C.L. et al. 2011. "Review of 'Valuing Mortality Risk Reductions for Environmental Policy: A White Paper' (December 10, 2010)." Memorandum to Lisa P. Jackson, EPA Administrator, from the EPA Science Advisory Board and Environmental Economics Advisory Committee. EPA-SAB-11-011. http://yosemite.epa.gov/sab/sabproduct.nsf/02ad90b136fc21ef85256eba00436459/34d7008fad7fa8ad8525750400712aeb!OpenDocument&TableRow=2.3#2

Kniesner, T.J. and W.K. Viscusi. 2005. "Value of a Statistical Life: Relative Position vs. Relative Age." *American Economic Review*. 95(2): 142-146.

Kniesner, T. J., W.K. Viscusi, and J.P. Ziliak. 2010. "Policy Relevant Heterogeneity in the Value of Statistical Life: New Evidence from Panel Data Quantile Regressions." *Journal of Risk and Uncertainty*. 40: 15-31.

Krupnick, A. 2007. "Mortality-risk Valuation and Age: Stated Preference Evidence." *Review of Environmental Economics and Policy*. 1(2): 261-282.

Larg, A. and John R. Moss. 2011. "Cost-of-Illness Studies: A Guide to Critical Evaluation." *Pharmacoeconomics*. 29(8): 653-671.

Lee, J.M. and L.O. Taylor. 2013. "Randomized Safety Inspections and Risk Exposure on the Job: Quasi-Experimental Estimates of the Value of a Statistical Life." Center for Economic Studies, U.S. Census Bureau. Discussion Paper CES 14-05.

Lipscomb, J., M. Drummond, D. Fryback, M. Gold, and D. Revicki. 2009. "Retaining, and Enhancing, the QALY." *Value in Health*. 12(Supp. 1): S18-S26.

Lofgren, H., R.L. Harris, and S. Robinson. 2002. "A Standard Computable General Equilibrium (CGE) Model in GAMS." International Food Policy Research Institute.

Lund, J.L., K.R. Yabroff, Y. Ibuka, L.B. Russell, P.G. Barnett, J. Lipscomb, W.F. Lawrence, and M.L. Brown. 2009. "Inventory of Data Sources for Estimating Health Care Costs in the United States." *Medical Care*. 47(7, Supp. 1): S127-S142.

Lutter, R. 2013. "Regulatory Policy: What Role for Retrospective Analysis and Review?" *Journal of Benefit-Cost Analysis*. 4(1): 17-38.

Morgan, M.G. and M. Henrion. 1990. *Uncertainty: A Guide to Dealing with Uncertainty in Quantitative Risk and Policy Analysis.* Cambridge, U.K.: Cambridge University Press

Morgenstern, R. 2013. "Analyzing the Employment Impacts of Regulation." Published in *Does Regulation Kill Jobs?* C. Coglianese, A. Finkel, and C. Carrigan (eds.). Philadelphia, P.A.: University of Pennsylvania Press.

Morgenstern, R.D. 2015. *The RFF Regulatory Performance Initiative: What Have We Learned?* Resources for the Future Discussion Paper 15-47. http://www.rff.org/files/document/file/RFF-DP-15-47.pdf

Newhouse, J.P. and the Insurance Experiment Group. 1996. *Free for All? Lessons from the RAND Health Insurance Experiment*. Cambridge, M.A.: Harvard University Press.

O'Hagan, A., C.E. Buck, A. Daneshkah, J. Eiser, P. Garthwaite, D. Jenkinson, J. Oakely, T. Rakow. 2006. *Uncertain Judgements: Eliciting Experts' Probabilities*. Chichester, U.K.: John Wiley & Sons Ltd.

Obama, B. 2011. "Executive Order 13563: Improving Regulation and Regulatory Review." *Federal Register*. 76(14): 3821-3823. http://www.whitehouse.gov/omb/inforeg_regmatters

Obama, B. 2012. "Executive Order 13609: Promoting International Regulatory Cooperation." *Federal Register.* 77(87): 26413-26415. https://www.whitehouse.gov/the-press-office/2012/05/01/executive-order-promoting-international-regulatory-cooperation

Raiffa, H. 1968. *Decision Analysis.* Reading, M.A.: Addison-Wesley.

Robinson, L.A. and J.K. Hammitt. 2011. "Behavioral Economics and Regulatory Analysis." *Risk Analysis.* 31(9): 1408-1422.

Robinson, L.A. and J.K. Hammitt. 2013. "Skills of the Trade: Valuing Health Risk Reductions in Benefit-Cost Analysis." *Journal of Benefit-Cost Analysis*. 4(1): 107-130. http://journals.cambridge.org/action/displayAbstract?fromPage=online&aid=9456622&fulltextType=RA&fileId=S2194588800000518

Robinson, L.A. and J.K. Hammitt. 2016. "Valuing Reductions in Fatal Illness Risks: Implications of Recent Research." *Health Economics.* 25(8):1039-1052.

Scotton, C.R. 2013. "New Risk Rates, Inter-Industry Differentials and the Magnitude of VSL Estimates." *Journal of Benefit-Cost Analysis*. 4(1): 39-80.

Shogren, J.F. 2005. "Experimental Methods and Valuation." Published in *Handbook of Environmental Economics.* K-G Maler and J.R. Vincent (eds.). 2: 969-1027.

Small Business Administration. 2012. *A Guide for Government Agencies: How to Comply with the Regulatory Flexibility Act*. http://www.sba.gov/advocacy/guide-government-agencies-how-comply-regulatory-flexibility-act

Smith, V.K., S.K. Pattanayak, and G.L. van Houtven. 2006. "Structural Benefits Transfer: An Example Using VSL Estimates." *Ecological Economics*. 60: 361-371.

Sullivan, P.W. and V. Ghushchyan. 2006. "Preference-Based EQ-5D Index Scores for Chronic Conditions in the United States." *Medical Decision Making*. 26(4): 410-420. http://www.ohsu.edu/epc/mdm/webResources.cfm

Sundra, D.L., J. Scherer, and L. Anderson. 2003. *A guide on logic model development for CDC's Prevention Research Centers*. Atlanta, GA: Centers for Disease Control and Prevention, Prevention Research Centers Program Office. https://www.bja.gov/evaluation/guide/documents/cdc-logic-model-development.pdf

Sunstein, C. 2010a. "Disclosure and Simplification as Regulatory Tools." Memorandum for the Heads of Executive Departments and Agencies from the Administrator, Office of Information and Regulatory Affairs, U.S. Office of Management and Budget. http://www.whitehouse.gov/omb/inforeg_regpol_agency_review/

Sunstein, C. 2010b. "Information Collection under the Paperwork Reduction Act." Memorandum for the Heads of Executive Departments and Agencies, and Independent Regulatory Agencies from the Administrator, Office of Information and Regulatory Affairs, U.S. Office of Management and Budget. http://www.whitehouse.gov/sites/default/files/omb/assets/inforeg/PRAPrimer_04072010.pdf

Thorat, T., M. Cangelosi, and P.J. Neumann. 2012. "Skills of the Trade: The Tufts Cost-Effectiveness Analysis Registry." *Journal of Benefit-Cost Analysis*. 3(1): Art. 1. http://journals.cambridge.org/action/displayAbstract?fromPage=online&aid=9456538&fulltextType=RA&fileId=S2194588800000336

U.S. Department of Health and Human Services. 2003. *Guidance on Proper Consideration of Small Entities in Rulemakings of the U.S*. Department of Health and Human Services.

U.S. Department of Health and Human Services. 2011. *Plan for Retrospective Review of Existing Rules.* https://www.whitehouse.gov/omb/oira/regulation-reform

U.S. Department of Health and Human Services. 2015. *Annual Update to the Unfunded Mandates Reform Act Threshold for 2014 is $141 million*.

U.S. Department of Transportation. 2015a. "Guidance on Treatment of the Economic Value of a Statistical Life (VSL) in Departmental Analyses – 2015 Adjustment." Memorandum to Secretarial Officers and Modal Administrators from K. Thomson, General Counsel, and C. Monje, Assistant Secretary for Policy. http://www.dot.gov/regulations/economic-values-used-in-analysis.

U.S. Department of Transportation. 2015b. "Revised Departmental Guidance on Valuation of Travel Time in Economic Analysis." Memorandum to Secretarial Officers and Modal Administrators from C. Monje, Assistant Secretary for Transportation Policy; prepared by R. Endorf, Economist. https://www.transportation.gov/administrations/office-policy/2015-value-travel-time-guidance.

U.S. Environmental Protection Agency. 2007. *Benefits and Costs of the Clean Air Act – Direct Costs and Uncertainty Analysis.* Report to the Honorable Stephen L. Johnson, Administrator, U.S. Environmental Protection Agency from James K. Hammitt, Chair, Advisory Council on Clean Air Compliance Analysis. EPA-Council-07-002.

U.S. Environmental Protection Agency. 2010. *Valuing Mortality Risk Reductions for Environmental Policy: A White Paper (Review Draft)*. Prepared by the National Center for Environmental Economics for consultation with the Science Advisory Board – Environmental Economics Advisory Committee. http://yosemite.epa.gov/ee/epa/eed.nsf/pages/MortalityRiskValuation.html.

U.S. Environmental Protection Agency. 2014. *Guidelines for Preparing Economic Analysis*. EPA 240-R-10-001. http://yosemite.epa.gov/ee/epa/eed.nsf/pages/guidelines.html.

U.S. Food and Drug Administration. 2003. "Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims: Final Regulation." *Federal Register*. 68: 41434-41506.

U.S. Office of Management and Budget. 1995. "Guidance for Implementing Title II of S.1." Memorandum to the Heads of Executive Departments and Agencies from Alice M. Rivlin, Director. http://www.whitehouse.gov/sites/default/files/omb/memoranda/m95-09.pdf

U.S. Office of Management and Budget. 2003. *Circular A-4: Regulatory Analysis*. http://www.whitehouse.gov/omb/inforeg_regpol_agency_review/

U.S. Office of Management and Budget. 2005. *Validating Regulatory Analysis: 2005 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities*. http://www.whitehouse.gov/omb/inforeg_regpol_reports_congress/

U.S. Office of Management and Budget. 2008. *2008 Report to Congress on the Benefits and Costs of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities*. http://www.whitehouse.gov/omb/inforeg_regpol_reports_congress/

U.S. Office of Management and Budget. 2010. *Agency Checklist: Regulatory Impact Analysis*. http://www.whitehouse.gov/omb/inforeg_regpol_agency_review/

U.S. Office of Management and Budget. 2011a. *Regulatory Impact Analysis: Frequently Asked Questions (FAQs)*. http://www.whitehouse.gov/omb/inforeg_regpol_agency_review/

U.S. Office of Management and Budget. 2011b. *Regulatory Impact Analysis: A Primer*. http://www.whitehouse.gov/omb/inforeg_regpol_agency_review/

U.S. Office of Management and Budget. 2012. *Clarifying Regulatory Requirements: Executive Summaries*. http://www.whitehouse.gov/omb/inforeg_regpol_agency_review/

U.S. Office of Management and Budget and the Secretariat General of the European Commission. 2008. *Review of the Application of EU and US Regulatory Impact Assessment Guidelines on the Analysis of Impacts on International Trade and Investment*. http://www.whitehouse.gov/omb/oira_irc_europe

Viscusi, W.K. 2004. "The Value of Life: Estimates with Risks by Occupation and Industry." *Economic Inquiry*. 42(1): 29-48.

Viscusi, W.K. 2013. "Using Data from the Census of Fatal Occupational Injuries (CFOI) to Estimate the 'Value of a Statistical Life'." *Monthly Labor Review*. Bureau of Labor Statistics

Viscusi, W.K. 2015. "The Role of Publication Selection Bias in Estimates of the Value of a Statistical Life." *American Journal of Health Economics*. 1(1): 27-52.

Viscusi W.K. and J.E. Aldy. 2003. The Value of a Statistical Life: A Critical Review of Market Estimates throughout the World. *Journal of Risk and Uncertainty.* 27(1): 5–76.

Weimer, D.L. and A.R. Vining. 2011. *Policy Analysis: Concepts and Practices (Fifth Edition).* Upper Saddle River, N.J.: Pearson.

Wholey, J.S., H.P. Hatry, and K.E. Newcomer (eds.). 2010. *Handbook of Practical Program Evaluation*. San Francisco, CA: Jossey-Bass.

Yabroff, K.R. et al. (eds.). 2009. "Health Care Costing: Data, Methods, Future Directions." *Medical Care.* 47(7): Supplement 1.

Index

Glossary

Accounting Costs: Actual expenses plus depreciation of capital equipment (Chapter 4).

Annualized Value: The constant annual amount, which, if paid each year over a defined time period, has the same present value as a specified series of unequal payments over the same period (Chapter 5).

Baseline: Expected future conditions in the absence of a new regulation or other policy change (Chapter 2).

Benefits: For the purpose of HHS regulatory analysis, the value of the intended outcomes of a regulation or other policy, such as reductions in mortality or morbidity risks, as well as any countervailing effects on these outcomes, such as health risk increases. Note that analyses not subject to this guidance may use differing definitions when categorizing outcomes as benefits or costs (Chapter 2).

Benefit Transfer: The application of values from the available research to a policy context that differs in some respects from the context studied. Involves evaluating the quality of the research and its applicability to the policy context (Chapter 3).

Bounding Analysis: The application of reasonable high and low parameter values to determine the extent to which the analytic results might change given the likely variation in the values (Chapter 6).

Breakeven Analysis: The value of an unknown or uncertain parameter at which benefits and costs would be equal, indicating how large the value would need to be to bridge the gap between the quantified benefits and costs. Also referred to as “threshold” analysis (Chapter 6).

Capital Cost: The value of resources, including equipment, buildings, and land, that are not immediately consumed in the production process (Chapter 4).

Compliance Cost: The value of resources, including labor, capital, and materials, used to implement a regulation or other policy. Includes only those resources expended by the entities and individuals directly responsible for implementation; excludes impacts on prices or other market conditions (Chapter 4).

Consumer Price Index (CPI): An index maintained by the U.S. Bureau of Labor Statistics that indicates changes in the prices paid by consumers for a market basket of goods and services over time. May be used to adjust values measured in current dollars to a common dollar year so that analyses can be conducted in real dollars, avoiding the need to adjust for expected inflation (Chapter 5).

Consumer Surplus: The difference between the maximum an individual would be willing to pay for a good or service and the market price (Chapter 3, Appendix B).

Costs: For the purpose of HHS regulatory analysis, the value of the inputs required to implement a regulation or other policy, including labor, capital, and materials, as well as any offsetting savings. Note that analyses not subject to this guidance may use differing definitions when categorizing outcomes as benefits or costs (Chapter 2).

Deadweight Loss: The net loss in consumer and producer surplus that accrues when government intervention or other factors prevent the market from reaching a competitive equilibrium (Appendix B).

Discounting: The process for converting values that accrue in different years to their present value, to reflect individual time preferences and the value of investments forgone (Chapter 5).

Distribution: The allocation of benefits, costs, or net benefits across different population groups, defined, for example, by income level (Chapter 7).

Experiments: Comparison of outcomes across groups who are similar or identical except for their exposure to a regulation or other policy (Chapter 9).

Gross Domestic Product (GDP) Implicit Price Deflator: A measure reported by the U.S. Bureau of Economic Analysis that indicates the ratio of the market value of goods and services in current dollars to its the value in chained (constant) dollars. May be used to adjust values measured in current dollars to a common dollar year so that analyses can be conducted in real dollars, avoiding the need to adjust for expected inflation (Chapter 5).

General Equilibrium Models: Models that can be used to estimate the economy-wide impact of a regulation or other policy with large impacts (Chapter 4).

Health-Related Quality of Life (HRQL): A numerical indicator of health status estimated using a scale anchored at zero and one, where one corresponds to full health and zero corresponds to a state that is as bad as dead (Chapter 3, Appendix C).

Income Elasticity: The proportional change in price or quantity associated with a change in real income. When used in estimating the VSL, it indicates the proportional change in value (i.e., unit price) associated with an income change (Chapter 3).

Inflation: Economy-wide increases in prices (Chapter 5).

Net Benefits: The difference, benefits minus costs (Chapter 2).

Nominal Value: Values expressed in current-year dollars, reflecting the effects of both inflation and real changes in value over time (Chapter 5).

Opportunity Cost: The benefits of the best alternative use of specified resources, which is forgone when resources are used for one purpose and hence cannot be used for other purposes (Chapter 4).

Partial Equilibrium Models: Models that describe the effects of a regulation or other policy in one market, which can be used to estimate the impact on an industry or group of industries (Chapter 4).

Present Value: The value of a stream of benefits, costs, or net benefits discounted to reflect their value in a common year (Chapter 5).

Probabilistic Analysis: The use of distributions of parameter values to explore the effects of uncertainty on an analytic result. Often employs Monte Carlo simulation techniques, which involve taking multiple random draws from the distribution for each critical parameter, calculating the model output for each draw, and using the results to represent the distribution of the outcome measure (Chapter 6).

Producer Surplus: The difference between the revenue producers receive and their cost of production (Chapter 4, Appendix B).

Quality-Adjusted Life Year (QALY): A nonmonetary measure that integrates the duration and severity of illness. Calculated by multiplying the amount of time an individual spends in a health state by the HRQL associated with that state, and summing over health states (Chapter 3, Appendix C).

Real Value: Values adjusted to a common dollar year (constant dollars), removing the effects of inflation (Chapter 5).

Retrospective Analysis (*ex post*): Assessment of the impacts of a regulation or a policy after it has been implemented, looking back to compare its impacts to what might have otherwise occurred, in contrast to prospective (*ex ante*) analysis which involves predicting future impacts (Chapter 9).

Revealed Preference Methods: Estimation of values based on observed market prices or behaviors (Chapter 3).

Screening Analysis: Use of readily available information and simple assumptions to provide preliminary information on potential impacts; may aid in targeting future work (Chapter 2).

Sensitivity Analysis: Varying one or more key parameter values to explore the effects of uncertainty on the analytic results (Chapter 6).

Social cost: The sum of the opportunity costs associated with the implementation of a regulation or other policy (Chapter 4).

Standing: The definition of whose benefits and costs are to be counted in an analysis. For HHS regulatory analysis, generally includes all U.S. residents (Chapter 2).

Stated Preference Methods: Estimation of values based on surveys or other self-reported data (Chapter 3).

Statistical Cases: Risk changes summed over the affected population; for example, if 10,000 people each experience a risk reduction of 1 in 10,000, then one statistical case has been averted (Chapter 3).

Transfer Payment: Monetary payments between individuals or groups that do not affect the total resources available to society (Chapter 4).

Uncertainty: Lack of knowledge about a parameter value that could be addressed by more research (Chapter 6).

Value per Quality-Adjusted Life Year (QALY): The marginal rate of substitution between money in a defined period and health-adjusted life years remaining; often approximated by dividing a value per statistical life (VSL) estimate by expected remaining QALYs (Chapter 3).

Value per Statistical Life (VSL): The marginal rate of substitution between money in a defined time period and mortality risk; often approximated by dividing individual willingness to pay for a small risk change by the risk change (Chapter 3).

Value per Statistical Life Year (VSLY): The marginal rate of substitution between money in a defined period and life years remaining; often approximated by dividing a VSL estimate by remaining life expectancy (Chapter 3).

Variability: "Real world" heterogeneity of a parameter value (Chapter 6).

Willingness to Pay (WTP): The maximum amount of money an individual would exchange to obtain an improvement, given his or her budget constraints, such that his or her wellbeing is as good with the improvement and having made the payment as without (Chapter 3).