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Health Policymaking in the United States

Fourth Edition

Beaufort B. Longest, Jr.

HEALTH POLICYMAKING IN THE UNITED STATES

Fourth Edition

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in Health Administration
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Suite 780
Arlington, VA 22201
(703) 894-0940

For Carolyn

The best wife I could possibly have.
The best mother Lyn, Brant, and Courtland could possibly have.
The best mother-in-law Amy could possibly have.
The best pug owner Abner and Luther could possibly have.
&
The best friend anyone could possibly have.

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LIST OF ACRONYMS AND INITIALS

AAFP	American Academy of Family Physicians
AAHSA	American Association of Homes and Services for the Aging
AAMC	Association of American Medical Colleges
AAP	American Academy of Pediatrics
AARP	American Association of Retired Persons
ACHE	American College of Healthcare Executives
ACP	American College of Physicians
ACS	American Cancer Society
	American College of Surgeons
ADA	American Dental Association
	Americans with Disabilities Act
ADL	activities of daily living
AFDC	Aid to Families with Dependent Children
AHA	American Heart Association
	American Hospital Association
AHCA	American Health Care Association
AHERA	Asbestos Hazard Emergency Response Act
AHIP	America's Health Insurance Plans
AHRQ	Agency for Health Care Research and Quality
AIAMC	Alliance of Independent Academic Medical Centers
AIDS	acquired immunodeficiency syndrome
AMA	American Medical Association
AMC	Academic Medical Center
AMWA	American Medical Women's Association
ANA	American Nurses Association
AoA	Administration on Aging
ARV	antiretroviral medications
AUPHA	Association of University Programs in Health Administration
BBA	Balanced Budget Act
BBRA	Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act
BIO	Biotechnology Industry Organization
BIPA	Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act

CAA	Clean Air Act
CAH	critical access hospital
CARE	Ryan White Comprehensive AIDS Resources Emergency Act
CBA	cost-benefit analysis
CBO	Congressional Budget Office
CCD	Consortium for Citizens with Disabilities
CCU	cardiac care unit
CDC	Centers for Disease Control and Prevention
CEA	cost-effectiveness analysis
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
CFR	*Code of Federal Regulations*
CHAMPUS	Civilian Health and Medical Program of the Uniformed Services
CLIA	Clinical Laboratory Improvements Act
CMS	Centers for Medicare & Medicaid Services
COBRA	Consolidated Budget Reconciliation Act
COGR	Council on Governmental Relations
CON	certificate of need
COTH	Council of Teaching Hospitals and Health Systems
CPS	Current Population Survey
CPSC	Consumer Product Safety Commission
CRS	Congressional Research Service
CT	computed tomography
CV	cardiovascular
CWA	Clean Water Act
DEFRA	Deficit Reduction Act
DHEW	Department of Health, Education and Welfare (now Department of Health and Human Services)
DHHS	Department of Health and Human Services
DI	disability insurance
DOJ	Department of Justice
DRG	diagnosis-related group
DSH	disproportionate share
DSHEA	Dietary Supplement Health and Education Act
EAB	Environmental Appeals Board
EMTALA	Emergency Medical Treatment and Labor Act
EPA	Environmental Protection Agency
EPCRA	Emergency Planning and Community Right-to-Know Act
EPL	effective patient life
ERISA	Employee Retirement Income Security Act

ESA	Endangered Species Act
ESRD	end-stage renal disease
FAHS	Federation of American Hospitals
FDA	Food and Drug Administration
FEC	Federal Election Commission
FECA	Federal Election Campaign Act
FEHBP	Federal Employees Health Benefits Program
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FQPA	Food Quality Protection Act
FR	*Federal Register*
FTE	full-time equivalent
GAO	Government Accountability Office (formerly General Accounting Office)
GDP	gross domestic product
GI	gastrointestinal
GME	graduate medical education
GPO	Government Printing Office
GPRA	Government Performance and Results Act
HCFA	Health Care Financing Administration (now Centers for Medicare & Medicaid Services)
HEAL NY	Health Care Efficiency and Affordability Law for New Yorkers
HI	(Medicare) Health Insurance
HIPAA	Health Insurance Portability and Accountability Act
HIV	human immunodeficiency virus
HMO	health maintenance organization
HPNEC	Health Professions and Nursing Education Coalition
HSA	health systems agency
ICD	implantable cardioverter defibrillator
ICF	intermediate care facility
ICU	intensive care unit
IME	indirect medical education
IOM	Institute of Medicine
IPPS	inpatient prospective payment systems
JCAHO	Joint Commission on Accreditation of Healthcare Organizations
LEPC	local emergency planning committee
LTC	long-term care

MA	Medicare Advantage (formerly Medicare+Choice)
MA-PD	Medicare Advantage prescription drug plan
MBO	management by objectives
MedPAC	Medicare Payment Advisory Commission
MMA	Medicare Prescription Drug, Improvement, and Modernization Act
MPRSA	Marine Protection, Research, and Sanctuaries Act
MRI	magnetic resonance imaging
MSA	Master Settlement Agreement
NAACP	National Association for the Advancement of Colored People
NAAQS	national ambient air quality standard
NACH	National Association of Children's Hospitals
NAE	National Academy of Engineering
NAS	National Academy of Sciences
NCQA	National Committee for Quality Assurance
NCSL	National Conference of State Legislatures
NEPA	National Environmental Policy Act
NGT	Nominal Group Technique
NHSC	National Health Service Corps
NIH	National Institutes of Health
NMA	National Medical Association
NOW	National Organization for Women
NPR	national performance review
NQF	National Quality Forum
NRC	National Research Council
NSAID	non-steroidal anti-inflammatory drug product
OAA	Older Americans Act
OALJ	Office of Administrative Law Judges
OASDI	Old-Age, Survivors, and Disability Insurance
OASI	Old-Age and Survivors Insurance
OBRA	Omnibus Budget Reconciliation Act
ODA	Orphan Drug Act
OECD	Organisation for Economic Co-operation and Development
OMB	Office of Management and Budget
OPA	Oil Pollution Act
OSHA	Occupational Safety and Health Administration
OTC	over the counter
PAC	political action committee
PART	Program Assessment Rating Tool
PBM	pharmacy benefit manager

PDP	prescription drug plan
PhRMA	Pharmaceutical Research and Manufacturers of America
PMA	president's management agenda
PPA	Pollution Prevention Act
PPBS	planning-programming-budgeting system
PPRC	Physician Payment Review Commission
PPO	preferred provider organization
PPS	prospective payment system
PRO	peer review organization
ProPAC	Prospective Payment Assessment Commission
PSO	patient safety organization
PSRO	professional standards review organization
QIO	quality improvement organization
QMB	qualified Medicare beneficiary
RBRVS	resource-based relative value scale
RCRA	Resource Conservation and Recovery Act
RIN	regulation identifier number
RN	registered nurse
ROE	return on equity
SAP	Statement of Administration Policy
SARA	Superfund Amendments and Reauthorization Act
SCHIP	State Children's Health Insurance Program
SDWA	Safe Drinking Water Act
SERC	state emergency response commission
SGR	sustainable growth rate
SHCC	state health coordinating council
SHPDA	state health planning and development agency
SLMB	specified low-income Medicare beneficiary
SNF	skilled nursing facility
SPAP	state pharmaceutical assistance program
SSA	Social Security Administration
SSI	Supplemental Security Income
TANF	Temporary Assistance to Needy Families
TEFRA	Tax Equity and Fiscal Responsibility Act
TSCA	Toxic Substances Control Act
UFMS	Unified Financial Management System
UMRA	Unfunded Mandates Reform Act
UPMC	University of Pittsburgh Medical Center

USADA	U.S. Anti-Doping Agency
USPHS	U.S. Public Health Service
VA	Department of Veterans Affairs
VHA	Veterans Health Administration
WHO	World Health Organization
ZBO	zero-based budgeting

LIST OF WEB SITES

AcademyHealth	www.academyhealth.org
Administration on Aging	www.aoa.gov
Agency for Healthcare Research and Quality	www.ahrq.gov or www.ahcpr.gov
Alliance of Independent Academic Medical Centers	www.aiamc.org
Alliance for Retired Americans	www.retiredamericans.org
America's Health Insurance Plans	www.ahip.org
American Academy of Family Physicians	www.aafp.org
American Academy of Pediatrics	www.aap.org
American Association of Homes and Services for the Aging	www.aahsa.org
American Association of Retired Persons	www.aarp.org
American Cancer Society	www.cancer.org
American College of Healthcare Executives	www.ache.org
American College of Physicians	www.acponline.org
American College of Surgeons	www.facs.org
American Dental Association	www.ada.org
American Health Care Association	www.ahca.org
American Heart Association	www.americanheart.org
American Hospital Association	www.aha.org
American Medical Association	www.ama-assn.org
American Medical Women's Association	www.amwa-doc.org
American Nurses Association	www.ana.org
Americans for Nonsmokers' Rights Foundation	www.no-smoke.org
Association of American Medical Colleges	www.aamc.org
Association of University Programs in Health Administration	www.aupha.org
Baxter Worldwide	www.baxter.com
Biotechnology Industry Organization	www.bio.org
Blue Cross and Blue Shield Association	www.bluecares.com
Census Bureau	www.census.gov
Center for Responsive Politics	www.opensecrets.org
Centers for Disease Control and Prevention	www.cdc.gov
Centers for Medicare & Medicaid Services	www.cms.gov
Code of Federal Regulations	www.gpoaccess.gov/cfr
Congressional Budget Office	www.cbo.gov
Congressional Research Service	www.loc.gov/crsinfo
Consumer Product Safety Commission	www.cpsc.gov
Consortium for Citizens with Disabilities	www.c-c-d.org

Council on Governmental Relations	www.cogr.edu
Council of Teaching Hospitals and Health Systems	www.aamc.org/members/coth/start.htm
Department of Health and Human Services	www.dhhs.gov
Department of Justice	www.usdoj.gov
Department of State	http://usinfo.state.gov/products/pubs/legalotln/index.htm
Department of Veterans Affairs	www.va.gov
Environmental Protection Agency	www.epa.gov
Families U.S.A.	www.familiesusa.org
Federal Budget	www.whitehouse.gov/omb/budget/fy2006/budget.html
Federal Election Commission	www.fec.gov
Federal Judiciary	www.uscourts.gov
Federal Legislation	thomas.loc.gov
Federal Register	www.gpoaccess.gov/fr
Federation of American Hospitals	www.fahs.com
FirstGov	www.firstgov.gov
Food and Drug Administration	www.fda.gov
Government Accountability Office	www.gao.gov
Government Printing Office	www.gpoaccess.gov
Health Professions and Nursing Education Coalition	www.aamc.org/Advocacy/hpnec
Healthy People 2010	www.healthypeople.gov
Hospital and Healthsystem Association of Pennsylvania	www.haponline.org
House Committee on Appropriations	http://appropriations.house.gov
House Committee on Energy and Commerce	http://energycommerce.house.gov
House Committee on Ways and Means	http://waysandmeans.house.gov
House Office of Legislative Counsel	http://legcoun.house.gov/public.htm
Institute of Medicine	www.iom.edu
Joint Commission on Accreditation of Healthcare Organizations	www.jcaho.org
Kaiser Family Foundation	www.kff.org
Library of Congress	www.loc.gov
Master Settlement Agreement	www.naag.org/upload/1032468605_cigmsa.pdf
Medicare Payment Advisory Commission	www.medpac.gov
National Association for the Advancement of Colored People	www.naacp.org

National Association of Children's Hospitals	www.childrenshospitals.net
National Committee for Quality Assurance	www.ncqa.org
National Conference of State Legislatures	www.ncsl.org
National Council of Senior Citizens	www.ncsinc.org
National Institutes of Health	www.nih.gov
National Medical Association	www.natmed.org
National Organization for Women	www.now.org
National Policy Association	www.npa1.org
Occupational Safety and Health Administration	www.osha.gov
Office of Administrative Law Judges, Environmental Protection Agency	www.epa.gov/oalj
Office of Management and Budget	www.whitehouse.gov/omb
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Pharmaceutical Research and Manufacturers of America	www.phrma.org
President's Commission to Strengthen Social Security	www.csss.gov
president's management agenda	www.whitehouse.gov/omb/budgintegration/pma_index.html
Social Security Administration	www.ssa.gov
Senate Committee on Appropriations	http://appropriations.senate.gov
Senate Committee on Finance	http://finance.senate.gov
Senate Committee on Health, Education, Labor, and Pensions	http://help.senate.gov
Senate Office of Legislative Counsel	http://slc.senate.gov/index.htm
Texas Politics	http://texaspolitics.laits.utexas.edu/html/ig/index.html
U.S. Public Health Service	www.usphs.gov
University of Pittsburgh Medical Center	www.upmc.com
White House	www.whitehouse.gov
Wisconsin Medical Society	www.wisconsinmedicalsociety.org
World Health Organization	www.who.int

PREFACE

The myriad decisions that constitute health policy are increasingly important. Health is a personal, high-priority goal of most people, and the pursuit of health is of growing significance to the nation's economy and to its system of social justice. Thus, it should surprise no one that health policy receives a great deal of attention from government.

Health policy is defined in this textbook as the set of authoritative decisions made within government that pertain to health and to the pursuit of health. The phrase *authoritative decisions* is crucial in the definition and refers to decisions that are made anywhere within the three branches of government—at any level of government—and are within the legitimate purview (i.e., within the official roles, responsibilities, and authorities) of those making the decisions.

Through a long history of incremental and modest steps, an extensive array of authoritative decisions that comprise health policy has evolved in the United States. Although this history has been punctuated occasionally by dramatic developments in health policy, especially the emergence of Medicare and Medicaid in 1965, health policymaking is mostly a story of slow but persistent evolution and modification.

Health policy's role in the pursuit of health is played out across many fronts because health is determined by many variables: the physical environment in which people live and work, their biology and behavior, social factors, and access to health services. The effects of health policies are seen in each of these determinants of health.

Whether at the federal, state, or local level, governments formulate, implement, and constantly modify health policies within an intricately choreographed policymaking process. The central and unifying purpose of this book is to provide a comprehensive model of this process for those who have an interest in or a curiosity about health policy and the policymaking process. An understanding of this process is essential to policy competency. For typical health professionals, policy competency is at most a secondary interest. However, a degree of policy competency sufficient to permit one to effectively analyze the public policy environment that affects them and their work—and to exert influence in that environment—is an increasingly important attribute for those whose professional lives are devoted to the pursuit of better health for society.

The model of the health policymaking process presented in this book was first developed, and continues to be refined, for the benefit of my students. The fact that the model proved useful as a framework for their understanding of the extraordinarily complicated process of health policymaking stimulated me to present it to a broader audience, the result of which was the first edition of this book. Through four editions, the book has been and will continue to be used in health policy courses as a means to provide students with an overview of the policymaking process. The model puts the various aspects of policymaking in perspective and serves as a foundation on which students can build their more detailed knowledge of the process—that is to say, they can build their policy competency.

The structure of this textbook largely reflects the model of the policymaking process. Following definitions of health and of health policy in Chapter 1, Chapter 2 emphasizes the ways in which policy affects health determinants. An overview of the context (the political marketplace) and the process of policymaking are presented in Chapter 3. Chapter 4 contains extensive new (since the previous edition) material on policy competency, which is defined as the dual abilities to analyze the public policy environment of a health-related organization or interest group and to exert influence in this environment. This competency is increasingly important to everyone involved professionally in the pursuit of health. Information to strengthen both abilities is also presented. Chapters 5 through 9 describe specific aspects of the policymaking process and follow the model of the process presented in Chapter 3. Chapters 5 and 6 address the agenda-setting and legislation-development aspects of policy formulation, respectively. Chapters 7 and 8 address the rulemaking and operation aspects of policy implementation, respectively. Chapter 9 addresses policy modification, reflecting the fact that all policies are subject to modification.

The book includes three appendixes, one of which lists chronologically the most important federal laws pertaining to health enacted in the United States. In addition to providing synopses of these laws, the chronology illustrates several important characteristics of the nation's health policy. The list clearly shows, for example, that the vast majority of health policies are but modifications of or amendments to previously enacted laws; incrementalism has indeed prevailed in the development of American health policy. The list also shows that health policy mirrors the various determinants of health. There are policies to address the environments in which people live, their lifestyle, and their genetics, as well as numerous policies related to the provision of and payment for health services. The other two appendixes are new to this edition and provide detailed information about Medicare and Medicaid.

In this edition, a popular feature called The Real World of Health Policy has been expanded. These highlighted boxes are placed throughout the text and present excerpts from congressional testimony; examples of rules or

proposed rules issued by implementing agencies; and reprints of illustrative news stories, letters, executive orders, and other documents that illustrate important real-world aspects of the policymaking process. The intent is to enliven the text and to provide useful and illustrative examples.

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CHAPTER

1

HEALTH AND HEALTH POLICY

Health and its pursuit are tightly interwoven into the social and economic fabric of all industrialized nations. Health plays a direct and important role not only in the physical and mental well-being of people but in nations' economies as well. The United States is expected to spend more than $2 trillion in pursuit of health in 2006, representing 16 percent of the nation's gross domestic product (GDP), and to spend about $3.6 trillion, or 18.7 percent of GDP, by 2014 (Heffler et al. 2005). Thus, it is not surprising that government at all levels is keenly interested in health and in how it is pursued. This book is about the intricate process through which government influences the pursuit of health that is public policymaking. Attention is focused primarily on the policymaking process at the federal level, although much of what is covered also applies to policymaking at the state and local levels.

In this chapter, the basic and underpinning definitions of health and health policy—and their relationship to each other—are discussed. In Chapter 2, the impact of policy on health and its pursuit is considered more fully. In Chapter 3, a model of the public policymaking process is outlined and described; this model is specifically applied to health policymaking. The various interconnected parts of the model are then covered in detail in subsequent chapters.

Health Defined

Health is a universally important aspect of human life. Years ago, the World Health Organization (WHO) (www.who.int) defined health as the "state of complete physical, mental, and social well-being, and not merely the absence of disease or infirmity" (WHO 1948). A more contemporary version of this definition, with an important expansion, is provided by David Byrne (2004), the European commissioner for health and consumer protection, who views good health as "a state of physical and mental well-being necessary to live a meaningful, pleasant and productive life. Good health is also an integral part of thriving modern societies, a cornerstone of well performing economies, and a shared principle of European democracies," which can readily be extended to all democracies. In fact, health is a priority in all nations, although the resources available for the pursuit of health vary widely across nations (Reinhardt, Hussey, and Anderson 2004). The reader can find current

information on international health expenditure comparisons for the 30 member countries of the Organisation for Economic Co-operation and Development (OECD), all of which share a commitment to democratic government and market economies, at www.oecd.org.

The way in which health is defined by any nation is important because it reflects the nation's values regarding health, the resources it is prepared to devote to the pursuit of health, and how far the nation would be willing to go in aiding or supporting the pursuit of health among its citizens. A nation in which health is defined broadly and in positive terms—such as the definition provided by Byrne above—will obligate itself to pursue a variety of significant interventions in its efforts to help its members attain desired levels of health. The enormous range of possible targets for intervention in the pursuit of health in any society is illustrated by the fact that health in human beings is a function of many variables, or health determinants as they are often called.

Health Determinants

Both for individuals and for a population of individuals, health determinants include the physical environments in which people live and work; their behaviors; their biology (genetic makeup, family history, and physical and mental health problems acquired during life); a host of social factors that include economic circumstances, socioeconomic position, and income distribution; discrimination based on factors such as race/ethnicity, gender, or sexual orientation and on the availability of social networks or social support; and the health services to which they have access (Blum 1983; Evans, Barer, and Marmor 1994; Berkman and Kawachi 2000).

Healthy People 2010 (www.healthypeople.gov) is a report that details comprehensive national health promotion and disease prevention agendas. The following list of health determinants is adapted from its identification and definition of determinants (U.S. DHHS 2000):

- *Biology* refers to the individual's genetic makeup (those factors with which he or she is born), family history (which may suggest risk for disease), and the physical and mental health problems acquired during life. Aging, diet, physical activity, smoking, stress, alcohol or illicit drug abuse, injury or violence, or an infectious or toxic agent may result in illness or disability and can produce a "new" biology for the individual.
- *Behaviors* are individual responses or reactions to internal stimuli and external conditions. Behaviors can have a reciprocal relationship to biology; in other words, each can react to the other. For example, smoking (behavior) can alter the cells in the lung and result in shortness of breath, emphysema, or cancer (biology), which then may lead an individual to stop smoking (behavior). Similarly, a family history that

includes heart disease (biology) may motivate an individual to develop good eating habits, avoid tobacco, and maintain an active lifestyle (behaviors), which may prevent his or her own development of heart disease (biology).

Personal choices and the social and physical environments surrounding individuals can shape behaviors. The social and physical environments include all factors that affect the life of individuals—positively or negatively—many of which may not be under their immediate or direct control.

- *Social environment* includes interactions with family, friends, coworkers, and others in the community. It also encompasses social institutions such as law enforcement, the workplace, places of worship, and schools. Housing, public transportation, and the presence or absence of violence in the community are among other components of the social environment. The social environment has a profound effect on individual health, as well as on the health of the larger community, and is unique because of cultural customs; language; and personal, religious, or spiritual beliefs. At the same time, individuals and their behaviors contribute to the quality of the social environment.
- *Physical environment* can be thought of as that which can be seen, touched, heard, smelled, and tasted. However, the physical environment also contains less tangible elements such as radiation and ozone. The physical environment can harm individual and community health, especially when individuals and communities are exposed to toxic substances; irritants; infectious agents; and physical hazards in homes, schools, and work sites. The physical environment also can promote good health, for example, by providing clean and safe places for people to work, exercise, and play.
- *Policies and interventions* can have a powerful and positive effect on the health of individuals and the community. Examples include health promotion campaigns to prevent smoking; policies mandating child restraints and safety belt use in automobiles; disease prevention services such as immunization of children, adolescents, and adults; and clinical services such as enhanced mental health care. Policies and interventions that promote individual and community health may be implemented by a variety of agencies, such as transportation, education, energy, housing, labor, justice, and other venues, or through places of worship, community-based organizations, civic groups, and businesses.
- *Quality health services* can be vital to the health of individuals and communities. Expanding access to services is important to eliminate health disparities and to increase the quality and years of healthy life for all people living in the United States. Health services in the broadest sense include not only services received through health services providers

but also health information and services received through other venues in the community.

When considering health in regard to individuals or populations, it is important to remember that people vary along many dimensions, including their health and health-related needs. The citizenry of the United States is remarkably diverse, varying by age, gender, race/ethnicity, and other factors. As Census 2000 revealed, of a total population of 281.4 million people, about 35 million were over the age of 65, and about 17 million of those were over 75 years of age (U.S. Census Bureau 2000). By 2020, these numbers will increase to about 55 million and 23 million, respectively (U.S. DHHS 2004). These demographic changes are important when considering health and its pursuit, because older people consume relatively more health services and their health-related needs differ in significant ways from those of younger people. Older people are more likely to consume long-term-care services and community-based services intended to help them cope with various limitations in the activities of daily living.

In Census 2000, approximately 34 million African Americans and 35 million Latinos were included in the U.S. population total of 281.4 million (U.S. Census Bureau 2000). Each group represented more than 12 percent of the total population. Both groups are presently disproportionately underserved for health services and are underrepresented in all of the health professions. They experience discrimination that affects their health and, as is described in The Real World of Health Policy: Race, Ethnicity, and Health Care, these and other minority populations experience continuing disparities in the burden of illness and death (Krieger 2000; Henry J. Kaiser Family Foundation 2003).

The Real World of Health Policy

Race, Ethnicity, and Health Care

Racial and ethnic disparities in health care—whether in insurance coverage, access, or quality of care—are one of many factors producing inequalities in health status in the United States.[1] Eliminating these disparities is politically sensitive and challenging in part because their causes are intertwined with a contentious history of race relations in America. Nonetheless, assuring greater equity and accountability of the health care system is important to a growing constituency base, including health plan purchasers, payers, and providers of care. To the extent that inequities in the health care system result in lost productivity or use of services at a later stage of illness, there are health and social costs beyond the individual or specific population group.

Background

About 1 in 3 residents of the United States self-identify as either African American, American Indian/Alaska Native, Asian/Pacific American, or Latino. Few would disagree that for most of this nation's history, race was a major factor in determining if you got care, where that care was obtained, and the quality of medical care. However, the influence of race today is more subtle. Public policy efforts, most notably the enactment of Medicaid and Medicare in 1965, along with enforcement of the 1964 Civil Rights Act, have made an enormous difference in reducing the health care divides in the U.S. So much progress has been achieved that many think that the disparities that remain are inconsequential, but they are not.

The Institute of Medicine (IOM) landmark report *Unequal Treatment: Confronting Racial and Ethnic Disparities in Care* provides compelling evidence that racial/ethnic disparities persist in medical care for a number of health conditions and services.[2] These disparities exist even when comparing individuals of similar income and insurance. Evidence of racial/ethnic disparities among patients with comparable insurance and the same illness has been the most troubling since health insurance coverage is widely considered the "great equalizer" in the health system.

The momentum to address health care disparities has grown largely in response to the step taken by the Department of Health and Human Services (DHHS) in 1999, establishing a national goal of eliminating health disparities by the end of this decade. Disparities between racial/ethnic groups and geographic areas were of major concern.[3] The decision for the U.S. to have one set of goals for all Americans, rather than separate goals for the health of whites and minority populations, has helped to focus public and private sector attention on racial/ethnic disparities in the nation's health and thus, health care system.

Policy Challenges in Addressing Health Care Disparities

Although attention to racial/ethnic disparities in care has increased among policymakers, there is little consensus on what can or should be done to reduce these disparities. The U.S. Congress provided early leadership on the issue by legislatively mandating the Institute of Medicine (IOM) (www.iom.edu) study on health care disparities and creating in statute, the National Center on Minority Health and Health Disparities at the National Institutes of Health. Congress also required DHHS to produce an annual report, starting in 2003, on the nation's progress in reducing health care disparities.[4] These efforts have provided an important foundation for addressing health and health care disparities.

The IOM study committee for Unequal Treatment recommended the use of a comprehensive multi-level strategy to address potential causes of racial/ethnic disparities in care that arise from circumstances or interactions at the level of the

patient, provider, and health care system. The recommendations point to four broad areas of policy challenges:

- Raising public and provider awareness of racial/ethnic disparities in care;
- Expanding health insurance coverage;
- Improving the capacity and number of providers in underserved communities; and
- Increasing the knowledge base on causes and interventions to reduce disparities.

NOTES:
1. Disparities in "health care" and in "health" are often discussed as if they are one in the same. A health care disparity refers to differences in, for example, coverage, access, or quality of care that is not due to health needs. A health disparity refers to a higher burden of illness, injury, disability, or mortality experienced by one population group in relation to another. The two concepts are related in that disparities in health care can contribute to health disparities, and the goal of the use of health services is to maintain and improve a population's health. However, other factors (e.g., genetics, personal behavior, and socio-economic factors) also are major determinants of a population's health.
2. Institute of Medicine. 2002. *Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care*. Washington, DC: National Academies Press.
3. U.S. Department of Health and Human Services, *Healthy People 2010*. pp.11–16.
4. U.S. Department of Health and Human Services. 2003. *2003 National Healthcare Disparities Report*. Washington, DC: U.S. Department of Health and Human Services.

SOURCE: Henry J. Kaiser Family Foundation. 2004. "Health Care & the 2004 Elections: Race, Ethnicity and Health Care." October, Report no. 7187. This information was reprinted with permission of The Henry J. Kaiser Family Foundation. The Kaiser Family Foundation, based in Menlo Park, California, is a nonprofit, independent national healthcare philanthropy and is not associated with Kaiser Permanente or Kaiser Industries.

Although the nation's population is diverse, with differences in health-related needs and disparities in health status and access to the benefits of the services of the healthcare system, a rather homogeneous set of values directly affects the basic approach to health in the United States. To a great extent, many in American society place a high value on individual autonomy, self-determination, and personal privacy and maintain a widespread, although not universal, commitment to justice for all of its members. Other characteristics of the core society that significantly influence the pursuit of health include a deep-seated belief in the potential of technological rescue and, although it may be changing, a long-standing obsession with prolonging life with scant regard for the costs of doing so. These values help shape the private and public sectors' efforts related to health, including the elaboration of public policies germane to health and its pursuit.

Health Policy Defined

There are many definitions of public policy, and no universal agreement has been reached on which is best. For example, Peters (2003) defines public

policy as the "sum of government activities, whether acting directly or through agents, as it has an influence on the life of citizens." Birkland (2001, 132) defines public policy as "a statement by government of what it intends to do or not to do, such as a law, regulation, ruling, decision, or order, or a combination of these." Cochran and Malone (1999) define public policy as "political decisions for implementing programs to achieve societal goals." Drawing on these and many other definitions, in this book I define public policy as *authoritative decisions made in the legislative, executive, or judicial branches of government that are intended to direct or influence the actions, behaviors, or decisions of others.*

The phrase *authoritative decisions* is crucial in the definition of public policy. It specifically refers to decisions that are made anywhere within the three branches of government—at any level of government—that are within the legitimate purview (i.e., within the official roles, responsibilities, and authorities) of those making the decisions. The decision makers can be legislators, executives of government (presidents, governors, mayors), or judges. Part of playing these decision-making roles is the legitimate right—indeed, the responsibility—to make certain decisions. For example, legislators are entitled to decide on laws, executives to decide on rules to implement laws, and judges to review and interpret decisions made by others. These relationships are illustrated in Figure 1.1. A useful web site for information about all three branches

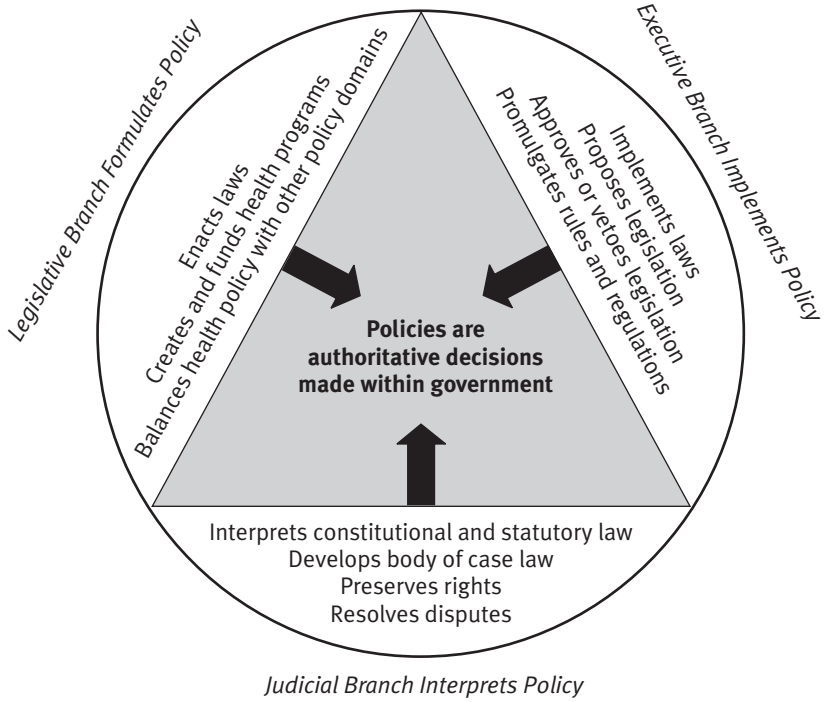


Figure 1.1 Roles of the Three Branches of Government in Policymaking

of the federal government, as well as information about state and local governments, is www.firstgov.gov. FirstGov is an official U.S. government web site.

In the United States, public policies, whether they pertain to health or to other policy domains such as defense, education, transportation, or commerce, are made through a dynamic *public policymaking process*. This process, which is modeled in Chapter 3, involves many interactive participants in three interconnected phases of activities.

When public policies pertain to health or influence the pursuit of health, they are *health policies*. Health policies are established at federal, state, and local levels of government, although usually for different purposes. Generally, health policies affect or influence groups or classes of individuals (e.g., physicians, the poor, the elderly, children) or types or categories of organizations (e.g., medical schools, health plans, integrated healthcare systems, pharmaceutical manufacturers, employers).

At any given time, the entire set of health-related policies, or authoritative decisions that pertain to health, made at any level of government can be said to constitute that level's *health policy*. Thus, health policy is a very large set of decisions reached through the public policymaking process. Some countries, Canada and Great Britain most notably, have developed expansive, well-integrated policies to help shape their society's pursuit of health in fundamental ways. The United States, in contrast, has a few large health-related policies, such as its Medicare program or its regulation of pharmaceuticals, but the U.S. government takes a more incremental or piecemeal approach to health policy. The net result is a very large number of policies, but few of them deal with the pursuit of health in any broad, comprehensive, or integrated way.

Policies made through the *public* policymaking process are distinguished from policies established in the *private* sector. Although discussing private-sector health policies in any depth is beyond the scope of this book, authoritative decisions made in the private sector by executives of healthcare organizations about such issues as their product lines, pricing, and marketing strategies, for example, are policies. Similarly, authoritative decisions made within such organizations as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) (www.jcaho.org), a private accrediting body for health-related organizations, or by the National Committee for Quality Assurance (NCQA) (www.ncqa.org), a private organization involved in assessing and reporting on the quality of managed care plans, are also private-sector health policies.

This book focuses on the public policymaking process and on the public-sector health policies that result from this process. Private-sector health policies also play a vitally important role in the ways society pursues health. The rich and complex blend of public policies and private-sector policies and actions that shape the American pursuit of health is a reflection of the fact that Americans have been extraordinarily reluctant to yield control of the

healthcare system to government. In part, this reflects a unique feature of the American psyche that Morone (1990, 1) captures eloquently when he says,

> At the heart of American politics lies a dread and a yearning. The dread is notorious. Americans fear public power as a threat to liberty. Their government is weak and fragmented, designed to prevent action more easily than to produce it. The yearning is an alternative faith in direct, communal democracy. Even after the loose collection of agrarian colonies had evolved into a dense industrial society, the urge remained: the people would, somehow, put aside their government and rule themselves directly.

In no aspect of American life is this "dread and yearning" more visible or relevant than in regard to health and health policy. Despite government's substantive role in health policy, which is more fully explored in subsequent chapters, and its role as a provider of health services in government facilities, most of the resources used in the pursuit of health in the United States are under the control of the private sector. Even when government is involved in health affairs, it often seeks ways to ensure broader access to health services that are provided predominantly through the private sector. The operation of the Medicare and Medicaid programs provide clear examples of this approach. Public dollars purchase services in the private sector for the beneficiaries of these programs. Overviews of the Medicare and Medicaid programs are provided as Appendixes A and B, respectively, at the end of the book. These programs and the policies that guide them are so important to an understanding of health policy and its impact on health that it is useful to read the overviews now; the information provided will be helpful throughout the book.

Forms of Health Policies

Health policies, which were defined earlier as authoritative decisions, take one of several basic forms. Some policies are the decisions made by legislators that are codified in the statutory language of specific pieces of enacted legislation. These are laws. Other policies are the rules and regulations established to implement laws or to operate government and its various programs. Still others are the judicial branch's decisions related to health. Examples of health policies include

- the 1965 federal public law (P.L. 89-97)[1] that established the Medicare and Medicaid programs;
- an executive order regarding operation of federally funded health centers;
- a federal court's ruling that an integrated delivery system's acquisition of yet another hospital violates federal antitrust laws;
- a state government's procedures for licensing physicians;

- a county health department's procedures for inspecting restaurants; and
- a city government's ordinance banning smoking in public places within its borders.

Thus, health policies may take any of several specific forms, and each form is an authoritative decision made within government. These forms of policy are described in the following sections, with examples of each.

Laws

Laws enacted at any level of government are policies. One example of a federal law that is also a health policy is the Breast and Cervical Cancer Prevention and Treatment Act of 2000 (P.L. 106-354), which created an optional Medicaid category for low-income women diagnosed with cancer through the Centers for Disease Control and Prevention's (www.cdc.gov) breast and cervical cancer early detection screening program. State examples include state laws that govern the licensure of health-related practitioners and institutions. Laws, when they are "more or less freestanding legislative enactments aimed to achieve specific objectives" (Brown 1992, 21), are sometimes called programs. The Medicare program is a federal-level example; many laws, most being amendments to prior laws, govern this vast program. The National Institute of Biomedical Imaging and Bioengineering Establishment Act of 2000 is reproduced in The Real World of Health Policy: P.L. 106-580 to provide an example of an actual federal law. Although the reading is lengthy (actually quite short when compared to many laws, which can run into the hundreds of pages), it will be useful to see a federal law in written form. Electronic versions of this and other federal laws dating back to 1973, the 93rd Congress, can be found at http://thomas.loc.gov/, a web site maintained by the Library of Congress to make federal laws readily accessible.

The Real World of Health Policy

P.L. 106-580

National Institute of Biomedical Imaging and Bioengineering Establishment Act

Public Law 106-580

106th Congress

An Act

To amend the Public Health Service Act to establish the National Institute of Biomedical Imaging and Bioengineering.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "National Institute of Biomedical Imaging and Bioengineering Establishment Act".

SEC. 2. FINDINGS.

The Congress makes the following findings:

(1) Basic research in imaging, bioengineering, computer science, informatics, and related fields is critical to improving health care but is fundamentally different from the research in molecular biology on which the current national research institutes at the National Institutes of Health (NIH) (www.nih.gov) are based. To ensure the development of new techniques and technologies for the 21st century, these disciplines therefore require an identity and research home at the NIH that is independent of the existing institute structure.

(2) Advances based on medical research promise new, more effective treatments for a wide variety of diseases, but the development of new, noninvasive imaging techniques for earlier detection and diagnosis of disease is essential to take full advantage of such new treatments and to promote the general improvement of health care.

(3) The development of advanced genetic and molecular imaging techniques is necessary to continue the current rapid pace of discovery in molecular biology.

(4) Advances in telemedicine, and teleradiology in particular, are increasingly important in the delivery of high quality, reliable medical care to rural citizens and other underserved populations. To fulfill the promise of telemedicine and related technologies fully, a structure is needed at the NIH to support basic research focused on the acquisition, transmission, processing, and optimal display of images.

(5) A number of Federal departments and agencies support imaging and engineering research with potential medical applications, but a central coordinating body, preferably housed at the NIH, is needed to coordinate these disparate efforts and facilitate the transfer of technologies with medical applications.

(6) Several breakthrough imaging technologies, including magnetic resonance imaging (MRI) and computed tomography (CT), have been developed primarily abroad, in large part because of the absence of a home at the NIH for basic research in imaging and related fields. The establishment of a central focus for imaging and bioengineering research at the NIH would promote both scientific advance and United States economic development.

(7) At a time when a consensus exists to add significant resources to the NIH in coming years, it is appropriate to modernize the structure of the NIH to ensure that research dollars are expended more effectively and efficiently and that the fields of medical science that have contributed the most to the detection, diagnosis, and treatment of disease in recent years receive appropriate emphasis.

(8) The establishment of a National Institute of Biomedical Imaging and Bioengineering at the NIH would accelerate the development of new technologies with clinical and research applications, improve coordination and efficiency at the NIH and throughout the Federal Government, reduce duplication and waste, lay the foundation for a new medical information age, promote economic development, and provide a structure to train the young researchers who will make the pathbreaking discoveries of the next century.

SEC. 3. ESTABLISHMENT OF NATIONAL INSTITUTE OF BIOMEDICAL IMAGING AND BIOENGINEERING.

(a) In General.—Part C of title IV of the Public Health Service Act (42 U.S.C. 285 et seq.) is amended by adding at the end the following subpart:

Subpart 18—National Institute of Biomedical Imaging and Bioengineering

PURPOSE OF THE INSTITUTE

Sec. 464z. (a) The general purpose of the National Institute of Biomedical Imaging and Bioengineering (in this section referred to as the "Institute") is the conduct and support of research, training, the dissemination of health information, and other programs with respect to biomedical imaging, biomedical engineering, and associated technologies and modalities with biomedical applications (in this section referred to as "biomedical imaging and bioengineering").

(b)(1) The Director of the Institute, with the advice of the Institute's advisory council, shall establish a National Biomedical Imaging and Bioengineering Program (in this section referred to as the "Program").

(2) Activities under the Program shall include the following with respect to biomedical imaging and bioengineering:

(A) Research into the development of new techniques and devices.

(B) Related research in physics, engineering, mathematics, computer science, and other disciplines.

(C) Technology assessments and outcomes studies to evaluate the effectiveness of biologics, materials, processes, devices, procedures, and informatics.

(D) Research in screening for diseases and disorders.

(E) The advancement of existing imaging and bioengineering modalities, including imaging, biomaterials, and informatics.

(F) The development of target-specific agents to enhance images and to identify and delineate disease.

(G) The development of advanced engineering and imaging technologies and techniques for research from the molecular and genetic to the whole organ and body levels.

(H) The development of new techniques and devices for more effective interventional procedures (such as image-guided interventions).

(3)(A) With respect to the Program, the Director of the Institute shall prepare and transmit to the Secretary and the Director of NIH a plan to initiate, expand, intensify, and coordinate activities of the Institute with respect to biomedical imaging and bioengineering. The plan shall include such comments and recommendations as the Director of the Institute determines appropriate. The Director of the Institute shall periodically review and revise the plan and shall transmit any revisions of the plan to the Secretary and the Director of NIH.

(B) The plan under subparagraph (A) shall include the recommendations of the Director of the Institute with respect to the following:

(i) Where appropriate, the consolidation of programs of the National Institutes of Health for the express purpose of enhancing support of activities regarding basic biomedical imaging and bioengineering research.

(ii) The coordination of the activities of the Institute with related activities of the other agencies of the National Institutes of Health and with related activities of other Federal agencies.

(c) The establishment under section 406 of an advisory council for the Institute is subject to the following:

(1) The number of members appointed by the Secretary shall be 12.

(2) Of such members—

(A) six members shall be scientists, engineers, physicians, and other health professionals who represent disciplines in biomedical imaging and bioengineering and who are not officers or employees of the United States; and

(B) six members shall be scientists, engineers, physicians, and other health professionals who represent other disciplines and are knowledgeable about the applications of biomedical imaging and bioengineering in medicine, and who are not officers or employees of the United States.

(3) In addition to the ex officio members specified in section 406(b)(2), the ex officio members of the advisory council shall include the Director of the Centers for Disease Control and Prevention, the Director of the National Science Foundation, and the Director of the National Institute of Standards and Technology (or the designees of such officers).

(d)(1) Subject to paragraph (2), for the purpose of carrying out this section:

(A) For fiscal year 2001, there is authorized to be appropriated an amount equal to the amount obligated by the National Institutes of Health during fiscal year 2000 for biomedical imaging and bioengineering, except that such amount shall be adjusted to offset any inflation occurring after October 1, 1999.

(B) For each of the fiscal years 2002 and 2003, there is authorized to be appropriated an amount equal to the amount appropriated under subparagraph (A) for fiscal year 2001, except that such amount shall be adjusted for the fiscal year involved to offset any inflation occurring after October 1, 2000.

(2) The authorization of appropriations for a fiscal year under paragraph (1) is hereby reduced by the amount of any appropriation made for such year for the conduct or support by any other national research institute of any program with respect to biomedical imaging and bioengineering.

(b) USE OF EXISTING RESOURCES.—In providing for the establishment of the National Institute of Biomedical Imaging and Bioengineering pursuant to the amendment made by subsection (a), the Director of the National Institutes of Health (referred to in this subsection as "NIH")—

(1) may transfer to the National Institute of Biomedical Imaging and Bioengineering such personnel of NIH as the Director determines to be appropriate;

(2) may, for quarters for such Institute, utilize such facilities of NIH as the Director determines to be appropriate; and

(3) may obtain administrative support for the Institute from the other agencies of NIH, including the other national research institutes.

(c) CONSTRUCTION OF FACILITIES.—None of the provisions of this Act or the amendments made by the Act may be construed as authorizing the construction of facilities, or the acquisition of land, for purposes of the establishment or operation of the National Institute of Biomedical Imaging and Bioengineering.

(d) DATE CERTAIN FOR ESTABLISHMENT OF ADVISORY COUNCIL.—Not later than 90 days after the effective date of this Act under section 4, the Secretary of Health and Human Services shall complete the establishment of an advisory

council for the National Institute of Biomedical Imaging and Bioengineering in accordance with section 406 of the Public Health Service Act and in accordance with section 464z of such Act (as added by subsection (a) of this section).

(e) CONFORMING AMENDMENT.—Section 401(b)(1) of the Public Health Service Act (42 U.S.C. 281(b)(1)) is amended by adding at the end the following subparagraph:

(R) The National Institute of Biomedical Imaging and Bioengineering.

SEC. 4. EFFECTIVE DATE.

This Act takes effect October 1, 2000, or upon the date of the enactment of this Act, whichever occurs later.

Approved December 29, 2000.

Rules and Regulations

Another form of policies is the rules and regulations (the terms are used interchangeably in the policy context) established to guide the implementation of laws. Because such rules are authoritative decisions made in the executive branch of government by the organizations and agencies responsible for implementing laws, they fit the definition of public policies. The rules associated with the implementation of complex laws routinely fill hundreds and sometimes thousands of pages. Rulemaking, the processes through which executive branch agencies write the rules to guide implementation of laws, is an important activity in policymaking and is discussed in detail in Chapter 4.

Rules, both in proposed form (for review and comment by those who will be affected by them) and in final form are published in the *Federal Register* (*FR*) (www.gpoaccess.gov/fr), the official daily publication for proposed and final rules, as well as notices of federal agencies and executive orders and other presidential documents. *FR* is published by the Office of the Federal Register, National Archives and Records Administration. Examples of the summaries of a proposed rule and a final rule can be seen in The Real World of Health Policy: Summaries of a Proposed Rule and a Final Rule. Rules can be read in their entirety at www.gpoaccess.gov/fr/index.html.

The Real World of Health Policy

Summaries of a Proposed Rule and a Final Rule

Federal Register: May 18, 2004 (Volume 69, Number 96)
Proposed Rules
Page 28195–28244

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services

42 CFR Parts 403, 412, 413, 418, 460, 480, 482, 483, 485, and 489

Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates, Proposed Rule

AGENCY: Centers for Medicare and Medicaid Services (CMS), DHHS.

ACTION: Proposed rule.

SUMMARY: We are proposing to revise the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital-related costs to implement changes arising from our continuing experience with these systems; and to implement a number of changes made by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108-173), enacted on December 8, 2003. In addition, in the Addendum to this proposed rule, we describe the proposed changes to the amounts and factors used to determine the rates for Medicare hospital inpatient services for operating costs and capital-related costs. These proposed changes would be applicable to discharges occurring on or after October 1, 2004. We also are setting forth proposed rate-of-increase limits as well as proposed policy changes for hospitals and hospital units excluded from the IPPS that are paid on a reasonable cost basis subject to these limits.

Among the policy changes that we are proposing to make are: Changes to the classification of cases to the diagnosis-related groups (DRGs); changes to the long-term care (LTC)-DRGs and relative weights; changes in the wage data, labor-related share of the wage index, and the geographic area designations used to compute the wage index; changes in the qualifying threshold criteria for and the proposed approval of new technologies and medical services for add-on payments; changes to the policies governing postacute care transfers; changes to payments to hospitals for the direct and indirect costs of graduate medical education; changes to the payment adjustment for disproportionate share rural hospitals; changes in requirements and payments to critical access hospitals (CAHs); changes to the disclosure of information requirements for Quality Improvement Organization (QIOs); and changes in the hospital conditions of participation for discharge planning and fire safety requirements for certain health care facilities.

Federal Register: January 5, 2005 (Volume 70, Number 3)
Rules and Regulations
Page 943–1019

Air Quality Designations and Classifications for the Fine Particles (PM2.5) National Ambient Air Quality Standards; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 81

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule sets forth the initial air quality designations and classifications for all areas in the United States, including Indian country, for the fine particles (PM2.5) National Ambient Air Quality Standards (NAAQS). The EPA is issuing this rule so that citizens will know whether the air quality where they live and work is healthful or unhealthful. Health studies have shown significant associations between exposure to PM2.5 and premature death from heart or lung disease. Fine particles can also aggravate heart and lung diseases and have been linked to effects such as cardiovascular symptoms, cardiac arrhythmias, heart attacks, respiratory symptoms, asthma attacks, and bronchitis. These effects can result in increased hospital admissions, emergency room visits, absences from school or work, and restricted activity days.

Individuals that may be particularly sensitive to PM2.5 exposure include people with heart or lung disease, older adults, and children. This rule establishes the boundaries for areas designated as nonattainment, unclassifiable, or attainment/unclassifiable. This rule does not establish or address State and Tribal obligations for planning and control requirements that apply to nonattainment areas for the PM2.5 standards. The EPA will publish a separate rule which will set forth the planning and control requirements that apply to nonattainment areas for the PM2.5 standards.

Operational Decisions

When organizations or agencies in the executive branch of a government, regardless of level, implement laws, they invariably must make many operational decisions as implementation proceeds. These decisions, which are different from the formal rules that also influence implementation, are policies as well. For example, in implementing the Water Quality Improvement Act (P.L. 91-224), the several federal agencies with implementation responsibilities establish operational protocols and procedures that help them deal with those affected by the provisions of this law. These protocols and procedures are a form of policies because they are authoritative decisions. The Real World of Health Policy: The FDA Issues a Press Release illustrates ongoing operational decisions made within the federal Food and Drug Administration (FDA) (www.fda.gov).

The Real World of Health Policy

The FDA Issues a Press Release

U.S. Food and Drug Administration
December 23, 2004

The Food and Drug Administration (FDA) today issued a Public Health Advisory (available at www.fda.gov/cder/drug/advisory/nsaids.htm) summarizing the agency's recent recommendations concerning the use of non-steroidal anti-inflammatory drug products (NSAIDs), including those known as COX-2 selective agents. The public health advisory is an interim measure, pending further review of data that continue to be collected.

In addition, FDA today announced that it is requiring evaluation of all prevention studies that involve the Cox-2 selective agents Celebrex (celecoxib) and Bextra (valdecoxib) to ensure that adequate precautions are implemented in the studies and that local Institutional Review Boards reevaluate them in light of the new evidence that these drugs may increase the risk of heart attack and stroke. A prevention trial is one in which healthy people are given medicine to prevent a disease or condition (such as colon polyps or Alzheimer's disease).

FDA is issuing an advisory because of recently released data from controlled clinical trials showing that the COX-2 selective agents (Vioxx, Celebrex, and Bextra) may be associated with an increased risk of serious cardiovascular events (heart attack and stroke) especially when they are used for long periods of time or in very high risk settings (immediately after heart surgery).

Also, as FDA announced earlier this week, preliminary results from a long-term clinical trial (up to three years) suggest that long-term use of a non-selective NSAID, naproxen (sold as Aleve, Naprosyn and other trade name and generic products), may be associated with an increased cardiovascular (CV) risk compared to placebo.

Although the results of these studies are preliminary and conflict with other data from studies of the same drugs, FDA is making the following interim recommendations:

- Physicians prescribing Celebrex (celecoxib) or Bextra (valdecoxib), should consider this emerging information when weighing the benefits against risks for individual patients. Patients who are at a high risk of gastrointestinal (GI) bleeding, have a history of intolerance to non-selective NSAIDs, or are not doing well on non-selective NSAIDs may be appropriate candidates for Cox-2 selective agents.
- Individual patient risk for cardiovascular events and other risks commonly associated with NSAIDs should be taken into account for each prescribing situation.
- Consumers are advised that all over-the-counter (OTC) pain medications, including NSAIDs, should be used in strict accordance with the label

directions. If use of an (OTC) NSAID is needed for longer than ten days, a physician should be consulted.

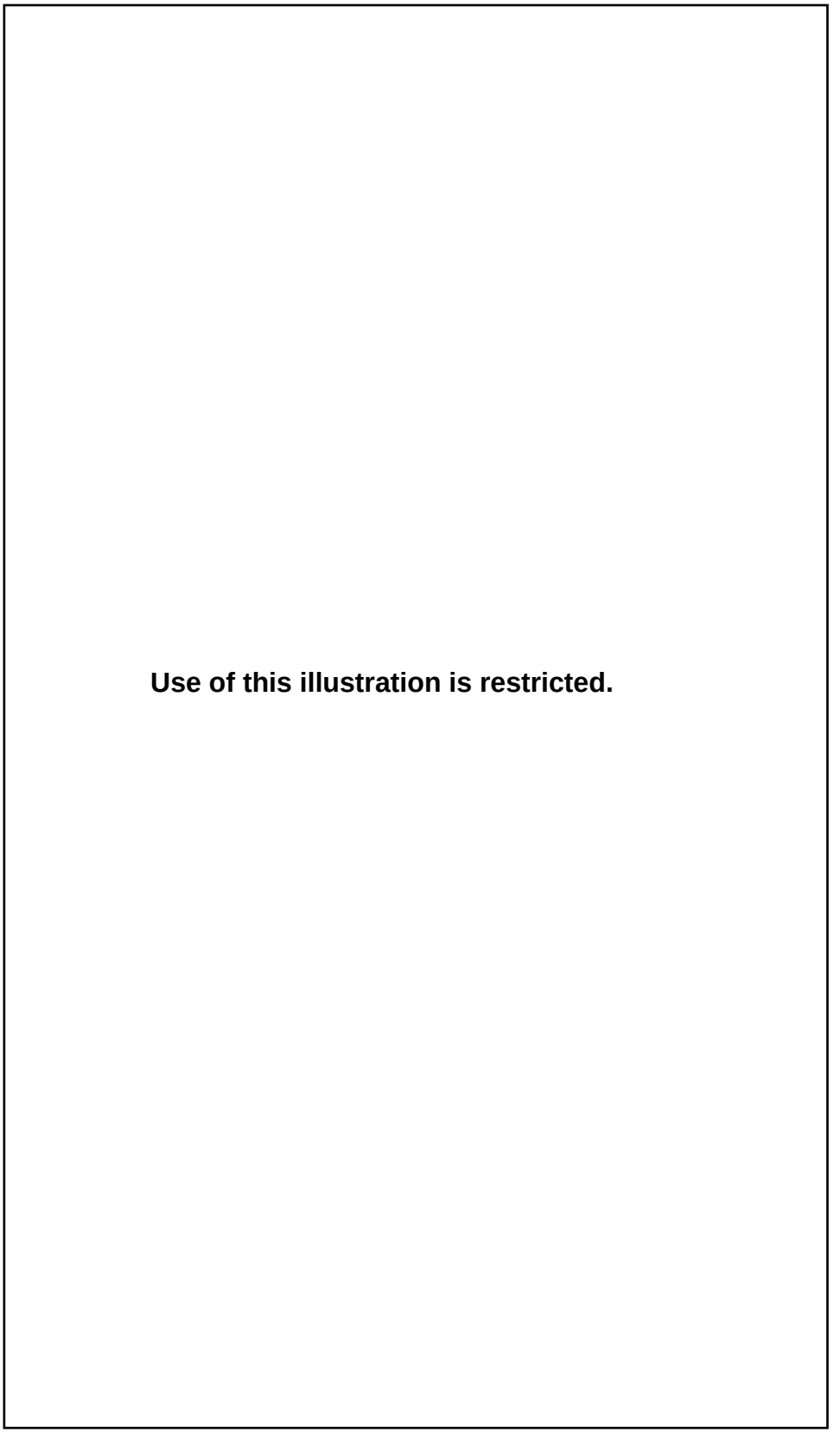
Non-selective NSAIDs are widely used in both over-the-counter (OTC) and prescription settings. As prescription drugs, many are approved for short-term use in the treatment of pain and primary dysmenorrhea (menstrual discomfort), and for longer-term use to treat the signs and symptoms of osteoarthritis and rheumatoid arthritis. FDA has previously posted extensive NSAID medication information at http://www.fda.gov/cder/drug/analgesics/default.htm.

FDA is collecting and will be analyzing all available information from the most recent studies of Vioxx, Celebrex, Bextra, and naproxen, and other data for COX-2 selective and nonselective NSAID products to determine whether additional regulatory action is needed. An advisory committee meeting is planned for February 2005, which will provide for a full public discussion of these issues.

FDA urges health care providers and patients to report adverse event information to FDA via the MedWatch program by phone (1-800-FDA-1088), by fax (1-800-FDA-0178), or by the Internet at http://www.fda.gov/medwatch/index.html.

Judicial Decisions

Judicial decisions are another form of policies. An example is the U.S. Supreme Court's ruling in 2000 (by a 5–4 vote) that the FDA cannot regulate tobacco. Another example is the Supreme Court's decision on January 10, 2005, not to hear an appeal filed by six health insurers in a bid to stop a class-action lawsuit brought by more than 600,000 doctors who claim the companies underpaid them for treating patients. This decision allowed a lower court's ruling to stand, meaning that a class-action suit could proceed in federal court. Both decisions are policies because they are authoritative decisions that have the effect of directing or influencing the actions, behaviors, or decisions of others. The Real World of Health Policy: Connecticut Supreme Court Decides a Case contains an example of how court decisions are authoritative decisions that affect others, often in dramatic ways.


Use of this illustration is restricted.

Another way to consider health policies is to recognize that any type of policy, whether law, rule or regulation, operational decision, or judicial decision, fits into one of several broad categories of policies. The policies are typically divided into distributive, redistributive, and regulatory categories (Birkland 2001). Sometimes the distributive and redistributive categories are combined into an allocative category; sometimes the regulatory category is subdivided into competitive regulatory and protective regulatory categories. For our purposes, as is discussed in the next section, all of the various forms of health policies fit into one of two basic categories—allocative or regulatory.

Categories of Health Policies

In capitalist economies, such as that of the United States, the presumption is that private markets best determine the production and consumption of goods and services, including health services. In such economies, government generally intrudes with policies only when private markets fail to achieve desired public objectives. The most credible arguments for policy intervention in the nation's domestic activities begin with the identification of situations in which markets are not functioning properly.

The health sector is especially prone to situations in which markets do not function very well. Theoretically perfect (i.e., freely competitive) markets, which do not exist in reality but which provide a standard against which real markets can be assessed, require that

- buyers and sellers have sufficient information to make informed decisions;
- a large number of buyers and sellers participate;
- additional sellers can easily enter the market;
- each seller's products or services are satisfactory substitutes for those of their competitors; and
- the quantity of products or services available in the market does not swing the balance of power toward either buyers or sellers.

The markets for health services in the United States violate these underpinnings of competitive markets in a number of ways. Complexity of health services reduces the ability of consumers to make informed decisions without guidance from the sellers or from other advisors. Entry of sellers in the markets for health services is heavily regulated, and widespread insurance coverage affects the decisions of both buyers and sellers in these markets. These and other factors mean that the markets for health services frequently do not function competitively, thus inviting policy intervention.

Furthermore, the potential for private markets on their own to fail to meet public objectives related to health and its pursuit in society is not limited to the production and consumption of health services. For example, markets on their own might not stimulate the conduct of sufficient socially desirable

medical research or the education of enough physicians or nurses without the stimulus of policies that subsidize certain costs associated with these ends. These and many similar situations in which markets do not lead to desired outcomes provide the underlying philosophical basis for the establishment of public policies to correct market-related problems or shortcomings.

The nature of the problems or shortcomings of the market that health policies are intended to overcome or ameliorate shape the policies in a direct way. Based on their primary purposes, health policies fit broadly into allocative or regulatory categories, although the potential for overlap is considerable between the two categories.

Allocative Policies

Allocative policies are designed to provide net benefits to some distinct group or class of individuals or organizations at the expense of others to ensure that public objectives are met. Such policies are in essence subsidies through which policymakers seek to alter demand for or supply of particular products and services or to guarantee access to products and services for certain people. For example, on the basis that without subsidies to medical schools, markets would undersupply the preparation of physicians, government has heavily subsidized the medical education system. Similarly, on the basis that markets would undersupply hospitals in sparsely populated regions or low-income areas, government subsidized the construction of hospitals for many years.

Other subsidies have been used to ensure that certain people have access to health services. The most important examples of such policies, based on the magnitude of expenditures, are the Medicare and Medicaid programs. Medicare expenditures exceeded $309 billion in 2005 and could reach $532 billion by 2013; Medicaid expenditures exceeded $319 billion in 2005 and could reach $628 billion by 2013 (Heffler et al. 2004). As noted earlier, Appendixes A and B contain descriptions of the Medicare and Medicaid programs. Additional information about the Medicare program is found at http://research.aarp.org/health/fs103_medicare.html#pdf and at http://www.kff.org/medicare/index.cfm and about the Medicaid program at http://research.aarp.org/health/fs102_medicaid.html and http://www.kff.org/medicaid/index.cfm.

In addition to the massive Medicare and Medicaid allocative policies, federal funding to support access to health services for Native Americans, veterans, and migrant farm workers and state funding for mental institutions are other examples of allocative policies that are intended to assist individuals in gaining access to needed services. Some think of subsidies as reserved for people on the basis of their impoverishment. However, subsidies such as those inherent in much of the financial support for medical education, the Medicare program (the benefits of which are not based primarily on the financial need of the recipients), and the exclusion from taxable income of employer-provided

health insurance benefits illustrate that poverty is not a necessary condition for the receipt of the subsidies available through the allocative category of health policies.

Regulatory Policies

Policies designed to influence the actions, behaviors, and decisions of others by directive are regulatory policies. In a variety of ways, all levels of government establish regulatory policies. As with allocative policies, government establishes such policies to ensure that public objectives are met. The five basic categories of regulatory health policies are

1. market-entry restrictions;
2. rate- or price-setting controls on health services providers;
3. quality controls on the provision of health services;
4. market-preserving controls; and
5. social regulation.

The first four categories are variations of economic regulation; the fifth seeks to achieve such socially desired ends as safe workplaces, nondiscriminatory provision of health services, and reduction in the negative externalities (side effects) that can be associated with the production or consumption of products and services.

Market-entry-restricting regulations include those through which health-related practitioners and organizations are licensed. Planning programs, through which approval for new capital projects by health services providers must be obtained from the state before the projects can proceed, are also market-entry-restricting regulations.

Although price-setting regulation is generally out of favor, some aspects of the pursuit of health are subject to price regulations. The federal government's control of the rates at which it reimburses hospitals for care provided to Medicare patients and its establishment of a fee schedule for reimbursing physicians who care for Medicare patients are examples of price regulation that carries enormous impact.

A third class of regulations are those intended to ensure that health services providers adhere to acceptable levels of quality in the services they provide and that producers of health-related products such as imaging equipment and pharmaceuticals meet safety and efficacy standards. For example, FDA is charged to ensure that new pharmaceuticals meet these standards. In addition, the Medical Devices Amendments (P.L. 94-295) to the Food, Drug and Cosmetic Act (P.L. 75-717) placed all medical devices under a comprehensive regulatory framework administered by FDA.

Because the markets for health services do not behave in truly competitive ways, government intervenes in these markets by establishing and enforcing rules of conduct for market participants. These rules of conduct form a

fourth class of regulation, market-preserving controls. Antitrust laws, such as the Sherman Antitrust Act, the Clayton Act, and the Robinson-Patman Act, which are intended to maintain conditions that permit markets to work well and fairly, are good examples of this type of regulation.

The four classes of regulations outlined above are all variations of economic regulation. The primary purpose of social regulation, the fifth class, is to achieve such socially desirable outcomes as workplace safety and fair employment practices and to reduce such socially undesirable outcomes as environmental pollution and the spread of sexually transmitted diseases. Social regulation usually has economic impact, but the impact is secondary to the primary purposes of the regulations. Federal and state laws pertaining to environmental protection, disposal of medical wastes, childhood immunization requirements, and the mandatory reporting of communicable diseases are but a few obvious examples of social regulations at work in the pursuit of health.

Whether public policies take the form of laws, rules and regulations, operational decisions, or judicial decisions, they are always established within the context of a complex public policymaking process. Both allocative and regulatory policies are made within the process, and the activities and mechanisms used to create both categories of policies are essentially identical. A comprehensive model of this process, which applies to any level of government, is presented in Chapter 3. Before examining the model, however, it will be useful to consider the ways that health policies affect health and its pursuit. A direct and crucially important connection between health policies and health, which makes an understanding of the health policymaking process all the more important to everyone involved in the pursuit of health, is described briefly in the next section and more extensively in Chapter 2.

The Connection Between Health Policy and Health

From government's perspective, the central purpose of health policy is to enhance health or to facilitate its pursuit by the citizenry. Of course, it is possible for other purposes to be served through specific health policies, including providing economic advantages to certain individuals and organizations. But the defining purpose of health policy, so far as government is concerned, is to support the people in their quest for health.

Health policies have their impact on health through an intervening set of variables, or health determinants. The health determinants, in turn, directly affect health. Thus, when examining the ways in which health policy can affect health, consider the role of health policy in the following health determinants:

- the physical environments in which people live and work;
- the behavioral choices that people make and the role that biology plays in their health;

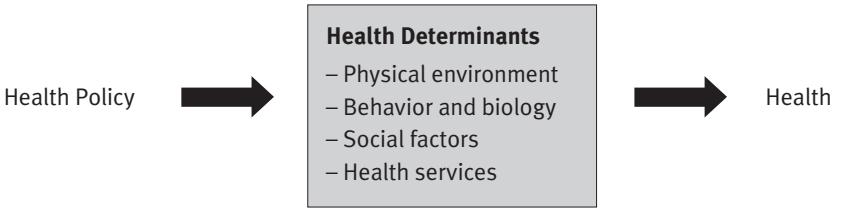


Figure 1.2 The Impact of Policy on Health Determinants and on Health

- the social factors that affect people's health, including their economic circumstances; their socioeconomic position in society; the income distribution within the society; discrimination based on factors such as race/ethnicity, gender, or sexual orientation; and the availability of social networks or social support; and
- the health services available to people and their access to these services.

Health policies have effects on each of these determinants of health, and thus on health itself, as shown in Figure 1.2. The nature of these effects is explored more fully in Chapter 2. First, however, it will be useful to comment briefly on the increasingly important roles of states in health policy and on the concept of policy competency.

Health Policy in the States

An unsettled debate over the appropriate distribution between a strong central federal government and the states regarding health policy responsibilities dates from the nation's founding. Over the years, the balance has shifted from time to time, with the federal government playing an especially dominant role in health policy for most of the period since the mid-1960s. In recent years, however, stimulated by changes in states' responsibilities for operating the Medicaid program and the failure in the early 1990s of federally led attempts at comprehensive health reform, the traditional health policy roles of the states have been reinforced and, in some states, new, broader roles in health policy have been undertaken.

Traditionally, the states have played substantial roles in several areas of health policy. Lipson (1997) identifies three in particular: (1) financing or paying for health services for several categories of people; (2) ensuring the public's health; and (3) regulating health-related professionals and organizations, including health insurance organizations and plans. In recent years, a fourth role has been added in some states: experimenting with comprehensive health reform strategies.

In their role as payers, states assume significant responsibility for funding their Medicaid programs. Although the costs of these programs are shared with the federal government, this program typically consumes 21 percent or more of state budgets (National Association of State Budget Officers 2004). Medicaid is among the highest policy priorities—let alone health policy priorities—for the states. In addition to their funding roles in the Medicaid program, the states also typically pay the costs of providing health insurance benefits for state employees and their dependents and, in many states, for other public-sector workers such as teachers. It is highly likely that states will continue to play increasingly important funding roles as part of their health policy responsibilities.

States also have major health policy responsibilities in protecting the public's health, their oldest and most fundamental responsibility in the pursuit of health. States were granted constitutional authority to establish laws that protect the public's health and welfare. This responsibility engages states in protecting the environment (the federal government delegates to the states responsibility for monitoring the environment and ensuring that environmental standards are met within their boundaries); ensuring safe practices in workplaces and food service establishments; mounting programs to prevent injuries and promote healthy behaviors; and providing health services such as public health nursing and communicable disease control, family planning and prenatal care, and nutritional counseling.

In their role as regulators of health-related professionals and organizations, states rely on their legal authority to regulate almost every aspect of the healthcare system and many other aspects of the overall pursuit of health. The states license and regulate the various health professions through the provisions of their practice acts, and they license and monitor health-related organizations. States also establish and monitor compliance with environmental quality standards.

A particularly important aspect of the role of states in health-related regulation is their responsibility for the health insurance industry as it operates within their boundaries. States control the content, marketing, and price of health insurance products and health plans because the 1945 McCarran-Ferguson Act (P.L. 79-15) left most insurance regulation to the states. However, some more recent changes in federal law illustrate both the current status of the tenuous line between federal and state regulation of this important aspect of the nation's pursuit of health and portend continued vagueness in these relationships in the future.

For example, the 1974 Employee Retirement Income Security Act (P.L. 93-406), commonly known as ERISA, preempts the states' regulation of pensions and self-insured employer health plans. The 1985 Consolidated Omnibus Budget Reconciliation Act (P.L. 99-272), also known as COBRA 1985, gives people leaving a job in any state the right to retain their existing

employer-provided health insurance for up to 18 months by paying the premiums directly, plus a small surcharge. The 1996 Health Insurance Portability and Accountability Act (P.L. 104-191), also known as HIPAA, provides employees who work for companies that offer health insurance benefits guaranteed access to health insurance if and when they change jobs or become unemployed. The legislation also guarantees renewability of health insurance coverage so long as premiums are paid.

In recent years, a fourth health policy role has gained momentum and importance in many states: a willingness to experiment with comprehensive approaches to healthcare reform. The states have long been viewed as laboratories for public policymaking (Sparer and Brown 1996). According to this viewpoint, states try various solutions to problems, and the results are meant to demonstrate the possible usefulness of these solutions for other states and in some instances for federal policymakers.

In reality, the role of states as laboratories for health policy has not been played particularly well to date. As Davidson (1997, 894) notes in speaking of the states' efforts at comprehensive reform of their healthcare systems, "On the one hand, we have fifty individual political markets which, implicitly, act or fail to act for their own reasons; on the other hand, we have the phenomenon of many, if not most, states taking up the same thorny topic in the same period." In other words, a variety of states, each pursuing solutions to the same problem in idiosyncratic ways under unique sets of reasons in the same time frames, are unlikely to treat each other as laboratories or to benefit much from the other's experiences. This view is supported by Oliver and Paul-Shaheen (1997, 721), who conclude from their study of six states that enacted major health reform legislation in recent years that the wide variation among their approaches to reform "casts doubt on the proposition that states can invent plans and programs for other states and the federal government to adopt for themselves." However, whether the states are particularly good laboratories for other states or for the federal government, they are playing increasingly larger roles in health policy innovation. In the absence of federal solutions, they must find solutions to their own problems.

States continue to struggle with a number of health policy issues, and they will face them well into the future. The National Conference of State Legislatures (NCSL) (www.ncsl.org) tracks healthcare issues in the broad areas of access, providers and services, children and adolescent health, women and reproductive health, pharmaceuticals, genetics, long-term care, mental health and substance abuse, oral health, and rural health. States' efforts to find solutions to the health-related problems facing their citizens, coupled with continuing expansion of their traditional role in health policy, mean that states will have significant and growing role in future health policy.

A great deal of current information about state health policy is available from the Kaiser Family Foundation at www.kff.org in the section on State

Health Policy. From this site, one can also link to www.statehealthfacts.org, which contains state-level data on demographics, health, and health policy, including health coverage, access, financing, and state legislation and budgets.

The Role and Importance of Policy Competency in the Pursuit of Health

Because there is a powerful connection between health policy and health, anyone professionally involved in the pursuit of health through any of the determinants shown in Figure 1.2 has a vested interest in understanding the health policymaking process—at both state and federal levels. An understanding of this process is important to developing a higher degree of *policy competency*. Much more is said about policy competency in Chapter 4, and in many ways this book is about enhancing the policy competency of healthcare managers and other health professionals. Suffice it to say in this chapter that policy competency is composed of the dual abilities to analyze the impact of public policies on one's domain of interest or responsibility and to exert influence in the public policymaking process.

The single most important factor in policy competency—including the ability to analyze the impact of public policies or to exert influence in the policymaking process—is to understand the public policymaking process as a *decision-making* process. Public policies, including health policies, are decisions, albeit decisions made in a particular way by particular people. Thus, understanding policymaking means understanding a particular type of decision making, including its context, participants, and processes.

As will be discussed throughout the book, the decision-making process through which public policies are made includes three tightly interwoven and interdependent phases: formulation, implementation, and modification. The phases do not unfold in neat sequence. Instead, they blend together in a gestalt of actors, actions, and, sometimes, inactions that yield policies. Figure 1.3 illustrates the closely intertwined nature of the relationships among the phases of policymaking.

This figure of the policymaking process emphasizes the continuous interrelationships and flows among the phases of the process. It also illustrates the cyclical character of public policymaking and shows it as an ongoing phenomenon, one without a definitive beginning or ending. In this view of public policymaking, policy formulation (making the decisions that are policies) is inextricably connected to policy implementation (taking actions and making additional decisions, which are themselves policies, necessary to implement policies). Neither phase is complete without the other. Because neither formulation nor implementation achieves perfection or exists in a static world, policy modification is a vitally necessary and complementary third component in the process. Modifications in previously formulated and implemented

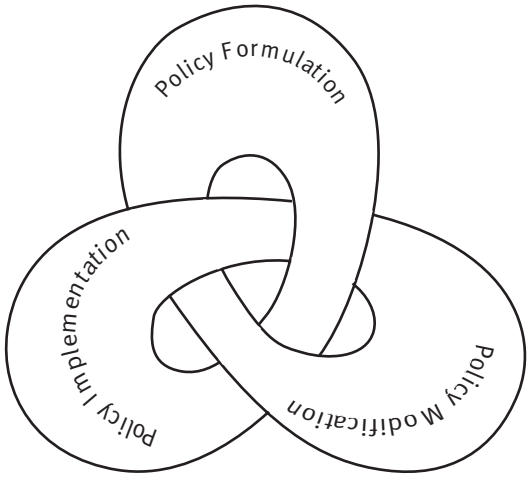


Figure 1.3 The Intertwined Relationships Among Policy Formulation, Implementation, and Modification

policies can range across a gamut from minor alterations in implementation to new rules and regulations used in implementation to modest amendments to existing legislation to fundamental policy changes reflected in new public laws. Chapter 3 describes this process in more detail.

Increasingly, policy competency is important to those who wish to be effectively involved in the pursuit of health. Within the context of the political marketplace, where public policymaking occurs, many participants seek to further their objectives by influencing the outcomes of this process and by more accurately predicting the outcomes of the process. Policy competency is an important ingredient for success in this arena.

An adequate degree of policy competency is necessary to understand what might result from the policymaking process that could affect a vital interest and to effectively participate in the policymaking process. Through competent participation, one can exert influence on future health policies and, thus, on the determinants of health and ultimately on health itself. This competency is built on a base of understanding of the public policymaking process, which is modeled and discussed in Chapter 3. First, however, in Chapter 2 a fuller consideration is given to the critical relationship between public policy and the pursuit of health.

Summary

Good health is defined as "a state of physical and mental well-being necessary to live a meaningful, pleasant and productive life. Good health is also an integral part of thriving modern societies, a cornerstone of well performing economies, and a shared principle of European democracies," which can

readily be extended to all democracies (Byrne 2004). Thinking of health in this way emphasizes the need to address many variables, or health determinants, if health is to be affected: the physical environments in which people live and work; their behaviors and genetics; social factors, including economic circumstances, socioeconomic position, income distribution, discrimination based on factors such as race/ethnicity, gender, or sexual orientation and the availability of social networks or social support; and the type, quality, and timing of health services that people receive.

Health policies are defined as authoritative decisions made within government that are intended to direct or influence the actions, behaviors, or decisions of others pertaining to health and its determinants. These policies are the principal means through which government in a developed society helps shape the pursuit of health by its members. These decisions can take the form of laws, rules and operational decisions made in the context of implementing laws, and judicial decisions. Health policies, like other public policies, can fit into broad allocative or regulatory categories.

The chapter concludes by defining *policy competency* as the dual abilities to analyze the impact of public policies on one's domain of interest or responsibility and to exert influence in the public policymaking process. This competency begins with an understanding of the public policymaking process and can be very useful to healthcare managers and other health professionals, who can use them in affecting health by affecting the determinants of health.

Discussion Questions

1. Define health. What are the determinants of health in humans?
2. Define public policies and health policies.
3. What forms do health policies take? Give an example of each.
4. Compare and contrast the two basic categories of health policies.
5. Discuss the connection between health policies, health determinants, and health.
6. Discuss the role of states in health policy.
7. What is policy competency? Why is it important to anyone who is interested in being involved in the pursuit of health?

Note

1. Federal public laws are given a number that designates both the enacting Congress and the sequence in which the law was enacted. P.L. 89-97, for example, means that this law was enacted by the 89th Congress and was the 97th law passed by that Congress. A briefly annotated chronological list of important federal laws pertaining to health can be found in Appendix C.

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CHAPTER

2

IMPACT OF HEALTH POLICY

As discussed in the previous chapter, health policies are consciously made authoritative decisions. Thus, policies *always* are developed to achieve someone's policy objectives. That is, policies are developed as a means to achieve someone's desires or preferences. The relationship between objectives and policies in and of itself makes no assumptions about either the appropriateness or the attainability of objectives; it merely recognizes the innate relationship between objectives and the policies that are intended to achieve them.

Policy objectives provide a useful starting place in understanding policies. The relationship between objectives and policies per se makes no assumptions about whose objectives are being pursued or in what mix the objectives of various individuals, organizations, and interest groups are being pursued, although this is obviously instrumental in determining the types of policies that are developed. The objectives toward which health policies are directed exert a powerful influence on the ultimate shape of policies. The set of objectives to which past health policies have been directed offer insight into what may prevail in the future.

Because health in human beings is a function of a number of interrelated environmental; behavioral; and biological, social, and service determinants (see Figure 1.2), health policies have emerged to meet specific objectives related to each type of variable. As a result, the United States now has a multitude of health policy objectives—very large in number and unranked in relation to each other—in a variety of areas. Under the expansive rubric of the nation's health policy can be found an intermingled set of objectives pertaining, among other factors, to

- adding years and quality to life;
- eliminating disparities in health and in access to health services among segments of the population;
- improving access to, reducing the costs of, and increasing the quality of health services;
- protecting the nation's citizens from terrorism;
- removing from the environment substances and conditions that have a negative impact on health;
- advancing the scientific and technological base of the pursuit of health;
- improving the housing and living conditions of the nation's citizens;
- improving the economic circumstances of the nation's citizens;

- making people more safety conscious on highways and in other potentially dangerous places;
- advancing educational opportunity and attainment for the nation's citizens;
- improving nutrition of the nation's citizens;
- moderating consumption of food, drink, and chemicals; and
- modifying unsafe sexual behaviors and practices.

This multiple and diverse pattern of objectives is very likely to continue. Coupled with persistent concern about how to pay for achieving any and all of these objectives, this plethora has stimulated a vast montage of poorly integrated—sometimes even conflicting—policies.

Objectives for each of the numerous and varied policies—even if each of the objectives is clear cut and rational—should not be mistaken for a comprehensive and integrated set of health policy objectives for the nation. This larger, more difficult, and much more important challenge still awaits the attention of health policymakers, who show few signs of taking it on and who work within a policymaking process that neither encourages nor facilitates the necessary attention to coordination and integration of multiple policies. Meeting this challenge will require extraordinarily coordinated thinking. Such thinking is made more difficult by the splintering effect of the diversity of individuals, organizations, and interest groups seeking to influence policymakers' thinking and actions so that they reflect the idiosyncratic interests and preferences of those who have the power to exert influence.

Coordinated thinking and decision making about health policy objectives by policymakers is also made more difficult by other structural characteristics of the American policymaking process. The process has a number of features that work to splinter thinking and isolate decisions rather than to stimulate comprehensive visions of where policies should lead the nation and ideas on how to orchestrate the integrated set of decisions needed to realize the vision. The constitution-based separation of powers, important though it is in maintaining the integrity of the democratic form of government, nevertheless permits good policies formulated in one branch to be poorly implemented in another. Perhaps as often, splendid ideas generated by those with implementation roles fall on deaf ears of legislators unwilling to entertain or consider them.

The unsuccessful effort at broad-scale health reform initiated by the Clinton administration in the early 1990s, despite varying opinions of the specific details of the plan outlined in the president's Health Security proposal, was a laudable attempt toward broader thinking regarding health policy (Hacker 1997). But the focus of that large plan was singularly on reforming the way the nation's health services were organized and financed. These services play a vital part in society's larger pursuit of health, but only a part.

Truly expansive health policy thinking must also incorporate attention to the physical and social environments in which people live and work and must give more attention to their behaviors and biology as important determinants of their health. Continued myopia may prevail, in large measure because of the nature of the political arena in which health policy is forged. This arena is more fully described in Chapter 3.

Health Policy and Health Determinants

As was discussed briefly in Chapter 1, health policies affect health through their effects on health determinants. These effects and the impact of health policies on individuals, organizations, and interest groups are explored in more detail in this chapter. It is important to understand the effects of health policies—both on health determinants and, ultimately, on individuals, organizations and systems, and interest groups—to fully appreciate the important role health policy plays in the nation's pursuit of health. Recall that health in individuals and populations is determined by the following:

- physical environments in which people live and work;
- behavioral choices that people make and the role that biology plays in their health;
- social factors that affect people's health, including their economic circumstances; their socioeconomic position in society; the income distribution within the society; discrimination based on factors such as race/ethnicity, gender, or sexual orientation; and the availability of social networks or social support; and
- health services available to people and their access to these services.

The nature of the impact of health policy on these health determinants is described in the following sections.

Health Policies and the Physical Environment

When people are exposed to harmful agents such as asbestos, dioxin, excessive noise, ionizing radiation, or toxic chemical and biological agents, their health is directly affected. Dangerous exposure possibilities pervade the physical environments of many people. Some of the exposure is through such agents as synthetic compounds that are introduced into the environment as by-products of technological growth and development. Some exposure is through wastes that result from the manufacture, use, and disposal of a vast range of products. And some of the exposure is through naturally occurring agents such as carcinogenic ultraviolet radiation from the sun or naturally occurring radon gas in the soil.

Often, the hazardous effects of naturally occurring agents are exacerbated by combination with agents introduced by human activities. For example, before its ban, the widespread use of Freon in air conditioning systems and of chloroflourocarbons in aerosolized products reduced the protective ozone layer in Earth's upper atmosphere, allowing an increased level of ultraviolet radiation from the sun to strike the planet's inhabitants. Similarly, exposure to naturally occurring radon gas appears to act synergistically with cigarette smoke as a carcinogenic hazard.

The health effects of exposure to hazardous agents, whether they are introduced into the environment or occur naturally, are well understood. Air, polluted by a number of agents, has a direct, measurable effect on such diseases as asthma, emphysema, and lung cancer and on the aggravation of cardiovascular disease. Asbestos, which can still be found in buildings constructed prior to its ban, causes pulmonary disease. Lead-based paint, when ingested, causes permanent neurological defects in infants and young children. This paint is still found in older buildings and is especially concentrated in poorer urban communities.

Over many decades, government has been involved in a variety of efforts to exorcize environmental health hazards through public policies. Examples of federal policies include the Clean Air Act (P.L. 88-206), the Flammable Fabrics Act (P.L. 90-189), the Occupational Safety and Health Act (P.L. 91-596), the Consumer Product Safety Act (P.L. 92-573), the Noise Control Act (P.L. 92-574), and the Safe Drinking Water Act (P.L. 93-523).

Health policies, such as the one shown in The Real World of Health Policy: Boston City Council Resolves to Eliminate Dioxin Emissions, that mitigate the negative influences of the physical environments in which people live and work or that take advantage of positive potential for environmental conditions to affect health are important aspects of any society's ability to help its members achieve higher levels of health. But there are other determinants of health as well, which provide additional avenues to improved health.

The Real World of Health Policy

Boston City Council Resolves to Eliminate Dioxin Emissions

CITY OF BOSTON
IN CITY COUNCIL

Councillors Felix D. Arroyo, John M. Tobin, Jerry P. McDermott, Maura A. Hennigan, Michael P. Ross, Chuck Turner, Charles C. Yancey and Michael F. Flaherty.

WHEREAS: The term "dioxin" refers to a group of chemicals that includes furans and biphenyl compounds (the most well-known dioxin being 2,3.7.8-TCDD), and dioxin is a potent human carcinogen and an endocrine-disrupting chemical affecting thyroid and steroid hormones, scientifically linked to endometriosis, immune system impairment, diabetes, neurotoxicity, birth defects, testicular atrophy and reproductive dysfunction; and

WHEREAS: Dioxin is a toxic waste byproduct that occurs when chlorinated products are manufactured and incinerated, and/or as the US Environmental Protection Agency has created an inventory table that lists 32 sources of dioxin in the United States, recognizing that this is the most current Environmental Protection Agency list available, but not necessarily reflective of all current industry practices with respect to dioxin; and

WHEREAS: Cost competitive alternatives are available for many products that create dioxin; and

WHEREAS: Fire fighters and other "first responders" face disproportionately high exposures to dioxin and other hazards from building fire; and

WHEREAS: The cities of Seattle, San Francisco, and Oakland, as well as the states of Washington, Oregon and New Hampshire, have all established laws, policies, and/or initiatives to eliminate and reduce dioxin exposure wherever possible; and

WHEREAS: Potential adverse effects from dioxin can be reduced through City of Boston purchasing decisions that reduce or eliminate products that create or release dioxin and utilize existing less toxic and cost-competitive alternatives for many products; **Therefore be it**

RESOLVED: That the Boston City Council encourages elimination of dioxin emissions through its procurement practices wherever possible and urges the Purchasing Department and other appropriate Departments of the City of Boston (i) to develop and apply criteria that differentiate between products that release dioxin during manufacture and/or disposal and those products that do not and (ii) to examine the dioxin reduction programs in the cities of San Francisco and Seattle; and BE IT FURTHER

RESOLVED: That the Boston City Council shall cooperate with the Purchasing Department, other appropriate City Departments, and other interested persons to develop an Implementation Plan with reduction targets for dioxin pollution. Within one year of passage

of this Resolution, the City will report on their progress and will achieve an Implementation Plan for the purchase of products on behalf of City departments, offices, and agencies by six months thereafter. The Implementation Plan shall include identification and analysis of City uses of dioxin-generating products, and purchasing shall be prioritized based on dioxin-reduction opportunity, technical and economic feasibility, and protection of human health and the environment. Generally, the use of an alternative product should be considered economically feasible if its cost, including the cost of conversion, is equivalent to the full costs of the dioxin-generating product.

Filed In City Council: August 27, 2003

Passed Unanimously (13-0) by vote of the Boston City Council on October 29, 2003

SOURCE: Boston City Council resolution 1099, October 29, 2003.

Health Policies and Human Behavior and Biology

As Rene Dubos (1959, 110) observed decades ago, "To ward off disease or recover health, men [as well as women and children] as a rule find it easier to depend on the healers than to attempt the more difficult task of living wisely." The price of this attitude is partially reflected in the causes of death in the United States. Ranked from highest to lowest by the Centers for Disease Control and Prevention (CDC 2005), the ten leading causes are heart disease, cancer, stroke, chronic lower respiratory diseases, accidents, diabetes, pneumonia/influenza, Alzheimer's disease, nephritis/nephritic syndrome/nephrosis, and septicemia.

Behaviors—including choices about the use of tobacco and alcohol, diet and exercise, illicit drug use, sexual behavior, and violence—and genetic predispositions influence many of these causes of death and help explain the pattern. Furthermore, underlying the behavioral factors and choices are such root factors as stress, depression, anger, hopelessness, and emptiness, which are exacerbated by economic and social conditions. In short, behaviors are heavily reflected in the diseases that kill and debilitate Americans.

Science has shown that changes in behaviors can change the pattern of causes of death. The death rate from heart disease, for example, has declined dramatically in recent decades. Although aggressive early treatment has played a role in reducing this rate, better control of several behavioral risk factors—including cigarette smoking, elevated blood pressure, elevated levels of cholesterol, poor diet and lack of exercise, and elevated stress—explain

much of this improvement. Even with this impressive improvement, however, heart disease remains the most common cause of death and will continue to be a significant cause for the foreseeable future. Cancer death rates continue to grow, with much of the increase attributable to lung cancer, a type of cancer that is strongly correlated with behavior. The Real World of Health Policy: Smokefree Laws describes the extent of state and local laws intended to restrict where smoking is allowed.

The Real World of Health Policy

Smokefree Laws

Americans for Nonsmokers' Rights Foundation (www.no-smoke.org) tracks the numbers of local and state laws in effect that restrict where smoking is permitted. As of January 4, 2005 the numbers of such laws were as follows:

Local

- A total of 1,903 municipalities in the United States have local laws in effect that restrict where smoking is allowed.
- A total of 358 of these 1,903 municipalities have a 100 percent smokefree provision in effect at the local level—either in workplaces*, and/or restaurants**, and/or bars.
- There are 267 municipalities with a local law in effect that requires 100 percent smokefree workplaces*.
- There are 221 municipalities with a local law in effect that requires 100 percent smokefree restaurants**.
- There are 165 municipalities with a local law in effect that requires 100 percent smokefree bars.
- There are 131 municipalities with a local law in effect that requires both workplaces* and restaurants** be 100 percent smokefree.
- There are 162 municipalities with a local law in effect that requires both restaurants** and bars be 100 percent smokefree.
- There are 97 municipalities with a local law in effect that requires workplaces*, restaurants**, and bars be 100 percent smokefree.

  Note: Since some of the above have 100 percent smokefree coverage in more than one category, *the numbers are not mutually exclusive.*

State and Local

- Across the United States, 4,831 municipalities are covered by a 100 percent smokefree provision in workplaces*, and/or restaurants**,

and/or bars, by either a state or local law, representing 35.0 percent of the US population.
- There are 30 states with local laws in effect that require 100 percent smokefree workplaces* and/or restaurants** and/or bars.

STATE

- There are 10 states with state laws in effect that require 100 percent smokefree workplaces* and/or restaurants** and/or bars:
  - California: Restaurants** and Bars
  - Connecticut: Restaurants** and Bars
  - Delaware: Workplaces*, Restaurants** and Bars
  - Florida: Workplaces* and Restaurants**
  - Idaho: Restaurants**
  - Maine: Restaurants** and Bars
  - Massachusetts: Workplaces*, Restaurants** and Bars
  - New York: Workplaces*, Restaurants** and Bars
  - South Dakota: Workplaces*
  - Utah: Restaurants**

*Includes both public and private non-hospitality workplaces, including, but not limited to, offices, factories, and retail stores.
**Includes any attached bar in the restaurant.

SOURCE: American Nonsmokers' Rights Foundation. 2005. "Overview List—How Many Smokefree Laws?" [Online information; retrieved 6/9/05.] Current numbers of laws can be seen at http://www.no-smoke.org/pdf/mediaordlist.pdf. Reprinted with permission.

Health Policies and Social Factors

In addition to their physical environments, behaviors, and genetics, a number of social factors, many of them interconnected, play roles in the health of people. Chronic unemployment, the absence of a supportive family structure, poverty, homelessness, and discrimination, among other social factors, affect the health of people as surely, and often as dramatically, as harmful viruses or carcinogens.

People who live in poverty experience measurably worse health status (more frequent and more severe health problems) than people who are more affluent (Phipps 2003; Mullahy, Robert, and Wolfe 2001). African Americans, Latinos, and Native Americans, who are disproportionately represented below the poverty line, experience worse health status than the white majority (National Center for Health Statistics 2004).

The poor also obtain their health services in a different manner than the more affluent. Instead of receiving care that is coordinated, continuing, and comprehensive, the poor are far more likely to receive a patchwork of services,

often provided by public hospitals, clinics, and local health departments. In addition, poor people are more often treated episodically, with one provider intervening in one episode of illness and another provider handling the next episode.

The impact of economic conditions on the health of children is especially dramatic (Wood 2003). Impoverished children have higher rates of low birth weight and more conditions that limit school activity compared to other children. These children are more likely to become ill and to have more serious illnesses than other children because of their increased exposure to harmful environments, inadequate preventive services, and limited access to health services.

Economic circumstances are only part of a larger set of social factors that unevenly affect people in their quest for health. Living in an inner-city or rural setting often increases the challenge of finding health services because the availability of providers is not adequate in many of these locations. Lack of adequate information about health and health services is a significant disadvantage, one compounded by language barriers, functional illiteracy, or marginal mental retardation. Even cultural backgrounds and ties, especially among many Native Americans, Latinos, and Asian immigrants, for all the support they can provide, sometimes also create a formidable barrier between people and the mainline healthcare system.

A good example of health policy intended to address social factors is one designed to expand health insurance coverage for uninsured, low-income children. P.L. 105-33, the Balanced Budget Act of 1997, contains provisions for expanding health insurance coverage of children by establishing the State Children's Health Insurance Program (SCHIP). This policy, as well as many others, has partially addressed some of the social factors that affect health. However, a great deal remains to be done. An agenda in this area has been proposed by the leaders of the National Policy Association (www.npa1.org) and AcademyHealth (www.academyhealth.org). Based on the relationships established by research between health and social factors, these two organizations have urged that health policy be developed to address social factors in the following five specific areas (Auerbach, Krimgold, and Lefkowitz 2000, 15–16):

1. Investing in young children through policies that explicitly recognize the importance of early development throughout the life span. Examples include improved parenting programs, comprehensive preschool programs, family support, and education.
2. Providing services and opportunities for the neediest through policies that seek to confer the benefits of higher socioeconomic status on those at the lower end of the scale, to prevent discrimination, and to foster a civil society. Examples are improvements in housing, education, nutrition, job training, disease prevention, and access to healthcare.

3. Improving the work environment, including appropriate involvement of employees in decision making, more employee control over work, a greater variety of work, opportunities for development, appropriate compensation and rewards, increased job security, improved leave policies, and worker protections.
4. Strengthening support at the community level through policies that build social networks, encourage economic development and empowerment, increase civic participation and trust, and reduce or mitigate the effects of economic and racial segregation.
5. Creating a more equal economic environment through tax, transfer, and employment policies. Examples include increases in the Earned Income Tax Credit, minimum wage, unemployment compensation, and welfare payments in states where they are low. Other examples include managing the economy to continue to buffer business cycle extremes and keep unemployment low.

Health Policies and Health Services

Another important determinant of health is the availability of and access to health services, which are any of a host of "specific activities undertaken to maintain or improve health or to prevent decrements of health" (Longest, Rakich, and Darr 2000, 5). Health services can be preventive (e.g., behavior modification, blood pressure screening, mammography); acute (e.g., surgical procedures, antibiotics to fight infection); chronic (e.g., control of diabetes or hypertension); restorative (e.g., physical rehabilitation of a stroke or trauma patient); or palliative (e.g., pain management or comfort measures in terminal stages of disease) in nature.

The production and distribution of health services require a vast set of resources, including money, human resources, and technology, all of which are heavily influenced by health policies. Health services are provided through the healthcare system, which comprises the organizations and systems or networks of organizations that transform these resources into health services and distribute them to consumers. The system itself is also influenced by health policies. Similar to their impact on the other determinants of health, health policies have major bearing on the nature of the health services available to people through their impact on the resources required to produce the services, as well as on the healthcare system through which the services are organized, delivered, and paid for. Policies' effect on the resources used to provide health services are examined in the next sections, beginning with monetary resources.

Money

As shown in Table 2.1, national health expenditures are expected to continue to grow. They may exceed $3.5 trillion by 2014. These expenditures, representing about 16 percent of the gross domestic product (GDP) in 2006,

TABLE 2.1
National Health Expenditures (NHE), Aggregate and Per Capita Amounts, and Share of Gross Domestic Product (GDP), Selected Calendar Years 1993–2014

Spending category	*1993*	*1998*	*2002*	*2003*	*2004*[a]	*2005*[a]	*2006*[a]	*2014*[a]
NHE (billions)	$888.1	$1,150.9	$1,559.0	$1,678.9	$1,804.7	$1,936.5	$2,077.5	$3,585.7
Health services and supplies	856.3	1,112.6	1,499.8	1,614.2	1,735.5	1,862.5	1,997.8	3,451.3
Personal health care	775.8	1,009.8	1,342.9	1,440.8	1,549.0	1,663.6	1,781.3	3,067.0
Hospital care	320.0	378.5	484.2	515.9	551.8	588.6	623.5	1,007.2
Professional services	280.7	375.7	503.0	542.0	581.2	623.6	667.4	1,161.3
Physician and clinical services	201.2	256.8	340.8	369.7	397.2	425.7	453.8	782.5
Other professional services	24.5	35.5	46.1	48.5	52.2	55.6	59.6	102.3
Dental services	38.9	53.2	70.9	74.3	79.1	84.1	90.0	146.9
Other personal health care	16.1	30.2	45.3	49.5	52.8	58.2	63.9	129.7
Nursing home and home health	87.6	123.1	143.1	150.8	160.6	170.9	181.9	290.5
Home health care[b]	21.9	33.6	36.5	40.0	45.2	50.0	54.8	95.9
Nursing home care[b]	65.7	89.5	106.6	110.8	115.4	121.0	127.1	194.6
Retail outlet sales of medical products	87.5	132.5	212.6	232.1	255.4	280.5	308.5	608.0
Prescription drugs	51.3	87.3	161.8	179.2	200.5	223.5	249.3	521.3
Durable medical equipment	12.8	16.9	19.6	20.4	21.2	21.7	22.4	31.6
Nondurable medical products	23.4	28.4	31.1	32.5	33.7	35.3	36.8	55.1
Government administration and net cost of private health insurance	53.3	64.9	105.7	119.7	128.2	135.4	147.3	252.9
Government public health activities	27.2	37.9	51.2	53.8	58.3	63.6	69.2	131.4
Investment	31.8	38.3	59.2	64.6	69.2	74.0	79.7	134.4
Research[c]	15.6	20.5	36.5	40.2	43.1	46.4	50.5	90.7
Construction	16.2	17.7	22.7	24.5	26.1	27.6	29.1	43.6
NHE per capita	$3,353.9	$4,097.9	$5,317.4	$5,670.5	$6,039.8	$6,423.1	$6,830.2	$11,045.8
Population (millions)	264.8	280.8	293.2	296.1	298.8	301.5	304.2	324.6
GDP, billions of dollars	$6,642.3	$8,747.0	$10,487.0	$11,004.0	$11,719.3	$12,375.5	$13,019.1	$19,179.9
Real NHE[d]	$1,009.4	$1,192.9	$1,497.6	$1,583.8	$1,665.8	$1,752.5	$1,843.2	$2,623.8
Chain-weighted GDP index	0.88	0.96	1.04	1.06	1.08	1.11	1.13	1.37
Personal health care deflator[e]	0.82	0.94	1.08	1.12	1.16	1.20	1.25	1.68
NHE as percent of GDP	13.4%	13.2%	14.9%	15.3%	15.4%	15.6%	16.0%	18.7%

SOURCES: Centers for Medicare and Medicaid Services, Office of the Actuary; and U.S. Department of Commerce, Bureau of Economic Analysis and Bureau of the Census.

NOTES: Numbers may not add to totals because of rounding. 1993 marks the beginning of the shift to managed care.

[a] Projected.

[b] Freestanding facilities only. Additional services of this type are provided in hospital-based facilities and counted as hospital care.

[c] Research and development expenditures of drug companies and other manufacturers and providers of medical equipment and supplies are excluded from "research expenditures" but are included in the expenditure class in which the product falls.

[d] Deflated using GDP chain-type price index (2000 = 100.0).

[e] Personal health care (PHC) chain-type index is constructed from the producer price index for hospital care, nursing home input price index for nursing home care, and consumer price indices specific to each of the remaining PHC components (2000 = 100.0).

SOURCE: Heffler et al. (2005). Reprinted with permission of Project HOPE.

could rise to 18.7 percent of GDP by 2014 (Heffler et al. 2005). The United States spends more on health than does any other country, in total and on a per capita basis (OECD 2004), in large part because of "higher U.S. per capita gross domestic product (GDP) as well as a highly complex and fragmented payment system that weakens the demand side of the health sector and entails higher administrative costs" (Reinhardt, Hussey, and Anderson 2004, 10). Other countries have been far more likely to adopt policies such as global budgets for their healthcare systems or to impose restrictive limitations on the supplies of health services.

The implications of the level of health expenditures and projected future increases are significant. The increasing health expenditures in part reflect higher prices. These higher prices have reduced access to health services by making it more difficult for many people to purchase either the services or the insurance needed to cover those services. For many workers, the increases in health expenditures have absorbed much of the growth of their real compensation, meaning lower wages as employers spend more to provide health insurance benefits. Some employers have dropped health insurance altogether. The number of people without health insurance in the United States grew from 39.6 million in 2000 to 44.7 million in 2003 (Kaiser Commission on Medicaid and the Uninsured 2004).

Because federal and state governments now spend so much on health, rising health expenditures have put substantial pressures on their budgets. As health expenditures consume a growing portion of government resources, it becomes more difficult for government to support other priorities such as education or homeland security. The Real World of Health Policy: Estimated Cost of the Medicare Prescription Drug Benefit, 2004–2013 illustrates the high cost of this added benefit in the Medicare program.

The Real World of Health Policy

Estimated Cost of the Medicare Prescription Drug Benefit, 2004–2013

The Congressional Budget Office (CBO) (www.cbo.gov) produces analyses to inform Congressional policymaking. As a nonpartisan Congressional agency, CBO does not make recommendations about policy. It does, however, provide analyses that can be useful to policymakers in their deliberations, as was done as Congress considered the addition of a prescription drug benefit to the Medicare program.

The recently enacted Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) contains many provisions that affect the

Medicare program specifically and the U.S. health sector more generally. This paper focuses on the provisions that establish a new outpatient prescription drug benefit under Medicare and explains the basis for and rationale behind the Congressional Budget Office's (CBO's) cost estimate of those provisions. CBO estimated that, on net, the Medicare drug benefit would increase mandatory outlays by $407 billion for fiscal years 2004 to 2013 and would raise federal revenues by $7 billion over that period. Those estimates consist of many components and reflect the complex interactions of the law's many provisions (see Exhibit 1). In describing how CBO derived its estimates, this paper also presents the agency's analysis of how the drug benefit is anticipated to operate in practice. Taken as a whole, the MMA's other provisions would reduce outlays by $13 billion and revenues by $7 billion, in CBO's estimation, for a net savings of $6 billion. As a result, the MMA would increase deficits—or reduce surpluses—by $394 billion over the 2004–2013 period (reflecting an increase of $395 billion in federal outlays and an increase of $0.5 billion in federal revenues).

Exhibit 1 CBO's Estimate of the Total Cost of the Medicare Prescription Drug Benefit, Fiscal Years 2004 to 2013

(Billions of Dollars)	*Total Cost of the Benefit*
Changes to Direct Federal Spending	
Payments to Medicare drug plans for basic benefits and administrative costs	507
Beneficiaries' premiums	–131
Subsidies for employer and union drug plans	71
Subsidies for low-income benefits	192
Federal Medicaid spending	–142
Transfers from states' Medicaid programs	–88
Other effects on federal spending	–2
Total[a]	407
Changes to Federal Revenues	7
Net Budgetary Impact of the Drug Benefit Provisions	400
Net Budgetary Impact of the MMA's Other Provisions	–6
Net Budgetary Impact of the MMA	394
Memorandum:	
Net Change to Direct Federal Spending	395

NOTE: MMA = Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

[a] Figures for the total impact on direct spending of the drug benefit provisions differ slightly from figures previously released by CBO because certain expenditures have been reclassified from Part D to other provisions of the MMA and vice versa. That difference does not affect CBO's overall cost estimate, however. See Congressional Budget Office, *The Budget and Economic Outlook: Fiscal Years 2005 to 2014* (January 2004), pp. 12–13.

SOURCE: Congressional Budget Office. 2004. *A Detailed Description of CBO's Cost Estimate for the Medicare Prescription Drug Benefit*. Washington, DC: Congressional Budget Office, Section 2.

Human Resources

The talents and abilities of a large and diverse workforce comprise another of the basic resources used to provide health services. These human resources are directly affected by health policies. There are more than 13 million health-related workers in the United States today, and 10 of the 20 occupations projected to grow the fastest are concentrated in health services. About 16 percent of all new wage and salary jobs created between 2002 and 2012 will be in health services—3.5 million jobs, which is more than in any other industry (U.S. Department of Labor 2005). The significant impact of policies on health-related human resources can be seen clearly in the nation's supply of physicians and registered nurses.

There are about 782,000 physicians in the United States (National Center for Health Workforce Analysis 2003). Over time, the supply has changed dramatically: The number of physicians doubled from the mid-1960s to the mid-1990s, to a considerable extent in response to federal policies intended to increase their supply, including the Health Professions Educational Assistance Act of 1963 (P.L. 88-129) and its amendments of 1965, 1968, and 1971.

Currently, a great deal of attention is focused on issues surrounding the shortage of registered nurses (RNs). The National Center for Health Workforce Analysis has studied the magnitude of this problem; its analysis

TABLE 2.2 National Supply and Demand Projections for FTE Registered Nurses, 2000–2020

Year	*Supply*	*Demand*	*Excess or Shortage (Supply Less Demand)**	*Percent Shortage*
2000	1,889,243	1,999,950	−110,707	−6
2001	1,912,667	2,030,971	−118,304	−6
2002	1,937,336	2,062,556	−125,220	−6
2003	1,959,192	2,095,514	−136,322	−7
2004	1,989,329	2,128,142	−138,813	−7
2005	2,012,444	2,161,831	−149,387	−7
2006	2,028,548	2,196,904	−168,356	−8
2007	2,039,772	2,232,516	−192,744	−9
2008	2,047,729	2,270,890	−223,161	−10
2009	2,059,099	2,307,236	−248,137	−11
2010	2,069,369	2,344,584	−275,215	−12
2011	2,075,891	2,379,719	−303,828	−13
2012	2,075,218	2,426,741	−351,523	−14
2013	2,068,256	2,472,072	−403,816	−16
2014	2,061,348	2,516,827	−455,479	−18
2015	2,055,491	2,562,554	−507,063	−20
2016	2,049,318	2,609,081	−559,763	−21
2017	2,041,321	2,656,886	−615,565	−23
2018	2,032,230	2,708,241	−676,011	−25
2019	2,017,100	2,758,089	−740,989	−27
2020	2,001,998	2,810,414	−808,416	−29

* Negative numbers indicate a shortage.

SOURCE: National Center for Workforce Analysis (2002).

demonstrates a serious shortage in the supply of RNs and projects the shortage to worsen in future years. As stated in the report, and as shown in Table 2.2, "the shortage is expected to grow relatively slowly until 2010, by which time it will have reached 12 percent. At that point demand will begin to exceed supply at an accelerated rate and by 2015 the shortage, a relatively modest 6 percent in the year 2000, will have almost quadrupled to 20 percent. If not addressed, and if current trends continue, the shortage is projected to grow to 29 percent by 2020" (National Center for Health Workforce Analysis 2002, Section 1).

Because the shortage is already a problem, concerted efforts will be made to alleviate the shortage before it worsens to an intolerable level. The Real World of Health Policy: Addressing the Nursing Shortage contains a background brief on this issue that outlines the context of the shortage and summarizes some of the efforts to address it, including state and national policy activities.

The Real World of Health Policy

Addressing the Nursing Shortage

Registered nurses (RNs) constitute the largest single healthcare profession in the United States. Since World War II, hospitals in the United States have had to cope with cyclical shortages of nurses. In 2000, the national supply of FTE [full-time equivalent] registered nurses was estimated at 1.89 million while the demand was estimated at 2 million, a shortage of 110,000 or six percent. By 2020, the shortage is projected to grow to an estimated 808,400 nurses or 29 percent. This shortage is not just in hospitals, but also in nursing homes, which project that they will need 66 percent more RNs in 2020 based on 1991 data.

In 2002, many national reports attempted to quantify the nursing shortage and explain the threat this problem poses to healthcare delivery. According to a report released by the Health Resources and Services Administration within the U.S. Department of Health and Human Services, the number of states with a shortage of RNs is expected to grow from 30 states in 2000 to 44 states in 2020. Surveys and studies published in 2002 in the *New England Journal of Medicine*, *Journal of the American Medical Association*, and by the Joint Commission on Accreditation of Healthcare Organizations all confirm that the shortage of RNs is influencing the delivery of healthcare in the U.S and negatively affecting patient outcomes.

This and other research suggests that the current shortage is the product of several trends including: steep population growth in several states, a diminishing pipeline of new students to nursing, a decline in RN earnings relative to other career options, an aging nursing workforce, low job satisfaction and poor working

conditions that contribute to high workforce attrition rates, and an aging population that will require intense healthcare services. These issues are occurring just as the majority of nurses are retiring and job opportunities within healthcare are expanding.

Typical solutions to address past nursing shortages have included wage increases and recruiting nurses from other countries, such as Canada, English-speaking Caribbean and African countries, Great Britain, India and the Philippines. Given the complex causes of the current shortage described above, however, experts increasingly recognize that these short-term solutions will have little impact.

Addressing the current shortage requires efforts aimed both at recruitment and retention of nurses. Recruitment refers to the need to continuously attract new entrants into the nursing profession. Strategies include wage increases and international recruitment discussed above, as well as improving financial aid in the form of scholarships and loans, and targeting underrepresented and nontraditional groups such as minorities and men. They also include advertising campaigns and promotions to advance messages about the rewards of a nursing career, such as the $20 million "Campaign for Nursing's Future" recently undertaken by Johnson & Johnson.

Retention strategies focus on both retaining current nurses and encouraging those who have left nursing careers to reenter the workforce. Improving workplace conditions and enhancing the education and professional development of nurses are primary retention strategies. High levels of job dissatisfaction related to scheduling, unrealistic workloads, mandatory overtime, and hospital administrators' lack of responsiveness to nurses' concerns have resulted in high turnover and early retirement among RNs.

Some states have made efforts to ensure safer working conditions for nurses by passing legislation concerning minimum staffing ratios and prohibiting mandatory overtime practices. California is a prominent example. In 1999, the California legislature enacted a law mandating patient-to-nurse ratios for its hospitals beginning in 2003. As many as 19 other states have introduced similar legislation. Moreover, as of December 2002, eight states had implemented laws or regulations that ban or limit mandatory overtime, and twenty-one more had introduced legislation or regulation.

The chief federal response addressing the current nursing shortage—the Nurse Reinvestment Act of 2002—includes both recruitment and retention strategies. The law authorizes the following provisions: loan repayment programs and scholarships for nursing students; public service announcements to encourage more people to enter the nursing profession; career ladder programs for those who wish to advance within the profession; best practice grants for nursing administration; long-term care training grants to develop and incorporate gerontology curriculum into nursing programs; and a fast-track faculty loan repayment program for nursing students who agree to teach at a school of nursing.

Numerous professional nursing associations supported the Nurse Reinvestment Act and it received additional support from other professional bodies, including the American Hospital Association, the American Medical Association, the American College of Physicians, and the American Society of Internal Medicine. On February 18, 2003, both chambers of Congress passed the $397.4 billion FY 2003 Omnibus Appropriations bill and thus the Nurse Reinvestment Act (PL 107-205) was enacted and funded. The FY 2003 appropriations amounted to $113 million, a $20 million increase over FY 2002.

These state and federal initiatives indicate that professional organizations, healthcare institutions, and other experts have succeeded in alerting policy makers to the problems associated with a shortage of a skilled nursing workforce. If forecasts of a massive gap between the supply and demand for nurses in the future are correct, however, it is likely that the scope and scale of initiatives—particularly, the level of financial resources from public and private sources—will need to be significantly expanded to reverse current trends.

As policymakers debate the issues related to the nursing shortage, discussion will likely focus on several key issues:

- How and why is this current nursing shortage different from previous shortages? Do the policy options address the current problems or are they responding to historical problems?
- How does the nursing shortage affect the quality of care for patients?
- Is assuring an adequate nurse workforce a federal responsibility? What is the correlation, if any, between the availability of nurses in the health workforce and the nature and funding of federal discretionary nursing programs?
- What other federal policies affect the demand for and supply of nurses?
- What is the nature of states "safe staffing" legislation? Why are states addressing the nursing shortage this way? Does this policy have potential unintended consequences? Will an inability to find enough qualified RNs force hospitals to eliminate beds and reduce access to care?
- Do state nursing policies affect the supply of nurses from state to state? If so, how?

SOURCE: Henry J. Kaiser Family Foundation. 2004. "Addressing the Nursing Shortage: Background Brief." [Online brief; retrieved 3/05.] www.kaiseredu.org. This information was reprinted with permission of The Henry J. Kaiser Family Foundation. The Kaiser Family Foundation, based in Menlo Park, California, is a nonprofit, independent national healthcare philanthropy and is not associated with Kaiser Permanente or Kaiser Industries.

The brief was prepared by Jason Gerson and Thomas Oliver, Bloomberg School of Public Health, Johns Hopkins University. The brief was updated March 2004 and accessed on March, 2005 at www.kaiseredu.org/IssueModules/Addressing/index.cfm.

Technology

A third type of resource used in providing health services and on which health policies have significant impact is health-related technology. Broadly defined, technology is the application of science to the pursuit of health. Technological advances result in better pharmaceuticals, devices, and procedures used in providing health services. A major influence on the pursuit of health in the United States, technology has eradicated many diseases and greatly improved diagnoses and treatment for others. In fact, diseases that once were not even diagnosed are now routinely and effectively treated. Advancing technology has brought medical science to the early stages of understanding disease at the molecular level and intervening in diseases at the genetic level.

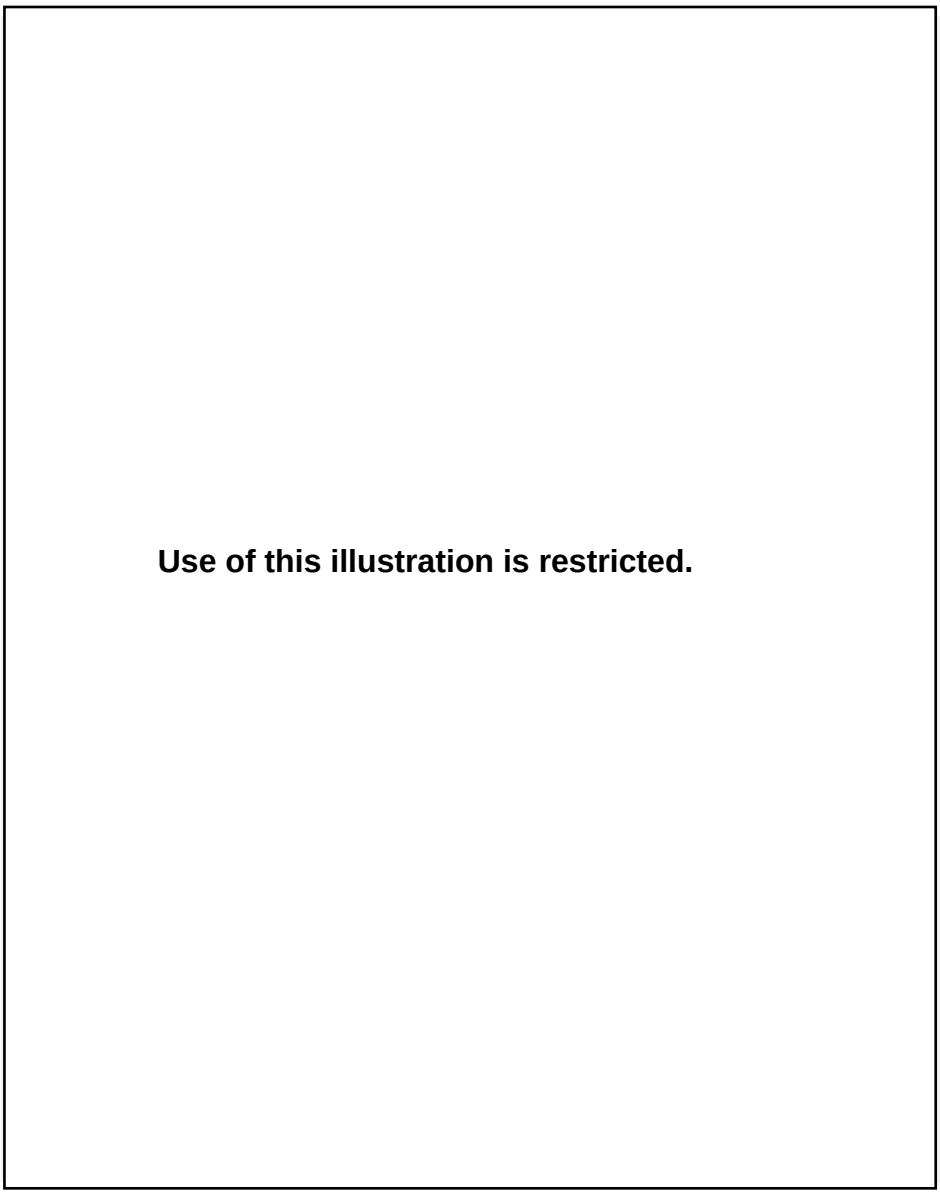
The United States produces and consumes more, and spends far more for, health-related technology than any other nation; it has provided technology with a uniquely favorable economic and political environment. As a result, health-related technology is widely available in the United States.

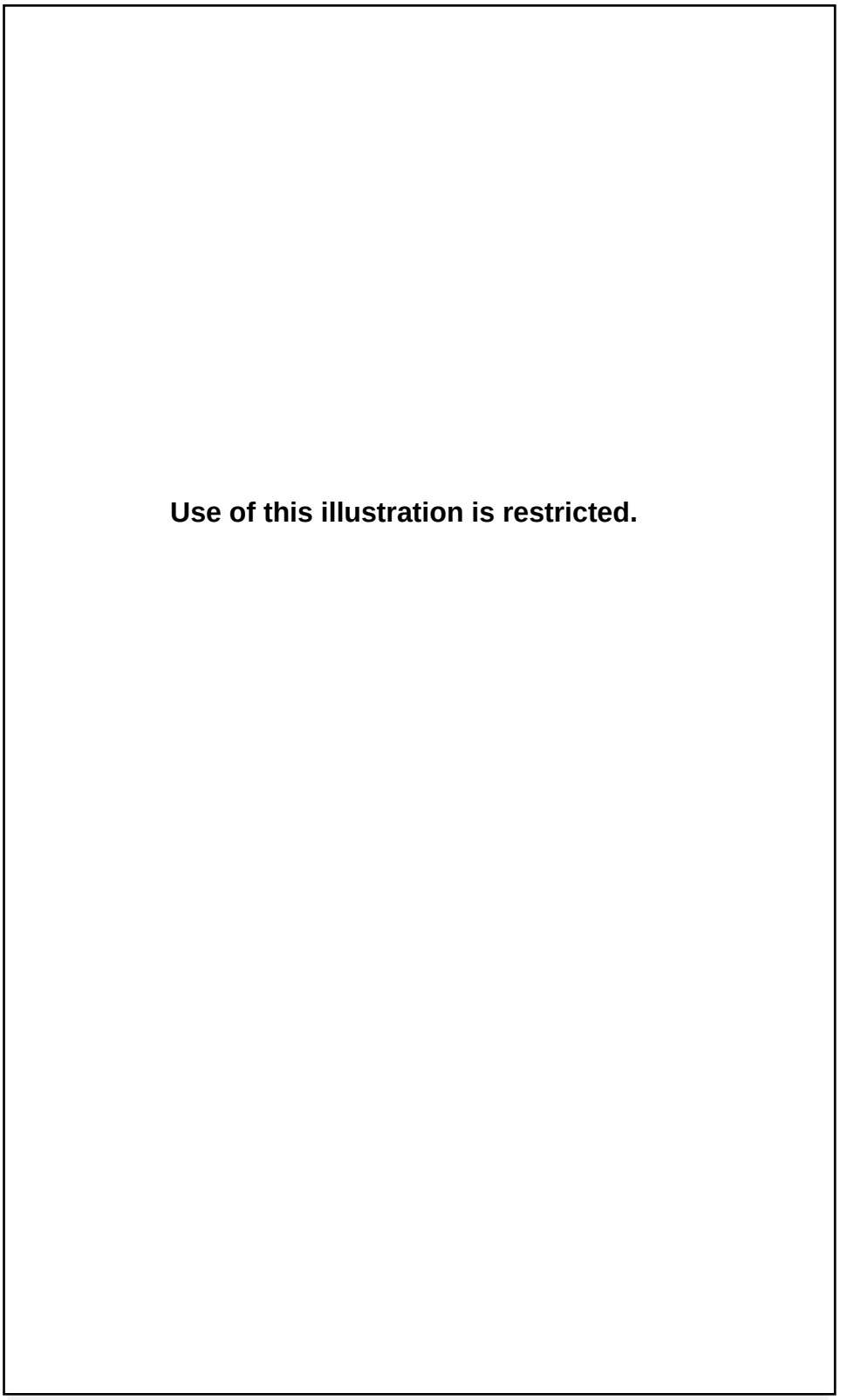
Funding for the research and development (R&D) that leads to new technology is an important way in which health policy affects the pursuit of health, although the private sector also pays for a great deal of the R&D that leads to new health-related technology. The United States has a long history of support for the development of health-related technology through policies that directly support biomedical research and that encourage private investment in such research. The National Institutes of Health (NIH 2005) budget is more than $27 billion in 2005. In addition, encouraged by policies that permit firms to recoup their investments in research and development, private industry also spends heavily on biomedical R&D. In fact, the Pharmaceutical Research and Manufacturers of America (PhRMA) (www.phrma.org) reports that its member companies spent $38.8 billion on research in 2004.

Another way in which health policy affects technology is through the application of regulatory policies, such as those promulgated by the Food and Drug Administration (FDA) as a means of ensuring technology's safety and efficacy. "FDA is responsible for the safety and efficacy of most food products and all human and veterinary drugs, biologic products, medical devices, cosmetics, and products emitting radiation that are sold within U.S. borders—a list that accounts for an estimated 20 percent of consumer spending, valued at approximately $1.5 trillion" (Slater 2005). FDA's mission is to promote and protect the public health by permitting safe and effective medical products to reach the market in a timely way and by monitoring products for continued safety after they are in use. This process does not always go smoothly, as The Real World of Health Policy: The FDA Issues a Press Release, which appears in Chapter 1, illustrates.

With advances in technology, the costs of health services have risen as the new technology is utilized and paid for. One paradox of advancing health-related technology is that, even as people live longer because of these advances, they then may need and utilize additional health services. The net effect drives

up health expenditures both for the new technology and for other services consumed over a longer life span. The costs associated with use of technology generate policy issues of their own, as can be seen in The Real World of Health Policy: Medicare Makes a Coverage Decision. This real world example pertains to Medicare's decision to cover implantable cardioverter defibrillators (ICDs). [See also Hlatky, Sanders, and Owens (2005) on this policy decision]. A good overview of the complex process through which Medicare decides whether to cover new items or services is found in "An Introduction to How Medicare Makes Coverage Decisions" (MedPAC 2003, 245–50.)




Use of this illustration is restricted.

the study aimed to clarify how best to prevent sudden cardiac arrest in such patients—who typically are left breathing heavily after even modest activity because their hearts are functioning at low efficiency. Cardiac arrest is especially common in such patients, often after a bout of rhythm abnormality.

It differs from a heart attack, in which the heart stops beating because of an interruption of the flow of blood to the heart.

The new study compared three therapies.

One group received standard care for congestive heart failure, including ACE inhibitor medicines and, in many cases, beta blockers and statins.

A second group got standard care plus daily doses of amiodarone (brand name Cordarone), proved to correct potentially deadly rhythm abnormalities—or arrhythmias—after they occur. Although the drug is widely prescribed to people with congestive heart failure, it has never been tested to see whether it can prevent, as opposed to treat, the flutters that so often kill those patients.

Patients in the third group had ICDs surgically implanted near their left shoulder. The device, about the size of a credit card but thicker, can send 750-volt shocks to a heart that has descended into an arrhythmic state known as ventricular defibrillation, the extremely rapid but useless kind of beat that is the hallmark of sudden cardiac death. The devices are already approved by the FDA for use in people who have survived such an event. But their lifesaving value in people merely at increased risk had never been proved before the study published today.

The devices were made and provided by Medtronic Inc., a major manufacturer of implantable cardiac devices, which had no role in the analysis or publication of results.

Surprisingly, after about four years of treatment, amiodarone offered no survival benefit and may have even precipitated some deaths.

"We believed putting patients on this drug was a good thing. This study proved that to be incorrect," said Richard Luceri, director of the arrhythmia center at Holy Cross Hospital in Fort Lauderdale, Fla., who implanted many of the study's ICDs.

But while 29 percent of the patients receiving standard therapy died during the study, only 22 percent of those with ICDs died. That seven-percentage-point difference amounts to a 23 percent reduction in the number of deaths. That suggests that tens of thousands of lives could be saved each year with wider use of ICDs.

The saved lives came with a cost: Because the vast majority of ICDs never needed to fire, many people underwent modest but real risks for no benefit. Infections and other significant problems appeared in 14 percent of patients who got the devices.

"The problem is, you don't know who is the one who's going to drop dead and who's not," said study leader Gust H. Bardy, director of the Seattle Institute for Cardiac Research.

The Medicare follow-up could help answer that question. The new study suggested, for example, but could not prove, that the one-third of study participants who were most severely ill were not helped by their ICDs.

At the same time, data trends in the study suggest that many of those whose ICDs never went off are likely to be saved by the devices in years to come. Although the study itself has formally ended, such hints could be confirmed or debunked with ongoing Medicare-required data collection.

SOURCE: Weiss, R. 2005. "Medicare to Cover Cardiac Device: Plan Raises Issue of Line Between Care and Research" *Washington Post*, January 20, A01. **© 2005, The Washington Post, reprinted with permission.**

Health Policy and Individuals, Organizations, and Interest Groups

In previous sections, we considered how health policy affects the determinants of health: the physical environment, human behavior and biology, social factors, and health services. It is also useful to consider the impact of policies on individuals, organizations, and interest groups. At the level of individuals, it is important to remember that health is a state that exists in everyone and that health policy can affect the pursuit of this state by and for everyone. However, the impact of policies can be experienced by individuals in different ways, under different circumstances, to different degrees, at different times, and, therefore, with varying levels of interest.

Many organizations actively participate in the nation's pursuit of health. People who are employed in these organizations, who govern them, or who independently practice their professions within them, have an intense interest in health policies that affect these organizations. The mission and purpose of the organizations are directly affected by health policies, as are day-to-day operations.

Individuals and organizations that have the greatest or most concentrated interest in the policymaking process are more likely to become involved with formal interest groups as a means of more effectively addressing their interests. Because interest groups are explored more fully in other chapters, suffice it to say here that they are groups of people with similar policy goals who band together to pursue those goals. Thus, it is useful to consider the impact of health policies on individuals, on organizations that participate in the pursuit of health, and on health-related interest groups to which individuals and organizations can belong.

Health Policy and Individuals

The impact of health policy at the level of individuals is very real and very important, and the consequences of health policies for individuals can be

enormous. Government engages in health policymaking primarily to support the nation's citizens in their quest for health, although secondary purposes, such as the economic interests of certain participants involved in the activities related to the pursuit of health, may also be served. As discussed in the "Health Policy and Health Determinants" section above, the mechanism of governmental support for the pursuit of health is the impact that health policy has on the determinants of human health: the physical and social environments in which people live and work; their behaviors and biology; and the type, quality, and timing of the health services they receive. As reflected in The Real World of Health Policy: The Number of Uninsured Individuals Is Large and Growing, for example, whether individuals have health insurance affects their access to health services and their health.

The Real World of Health Policy

The Number of Uninsured Individuals Is Large and Growing

The National Academy of Sciences (NAS) is a private, not-for-profit, self-perpetuating society of distinguished scholars engaged in scientific and engineering research and dedicated to the furtherance of science and technology and to their use for the general welfare. Upon the authority of the charter granted to it by Congress in 1863, NAS is mandated to advise the federal government on scientific and technical matters. NAS includes the Institute of Medicine (IOM), the National Academy of Engineering (NAE), and the National Research Council (NRC). Collectively, these organizations are called the National Academies. Specifically, IOM (www.iom.edu) serves as adviser to the nation to improve health, striving to provide advice that is unbiased, based on evidence, and grounded in science. A recent series of IOM analyses has focused on the consequences for people who lack health insurance.

The lack of health insurance coverage for a substantial number of Americans has been a public policy problem throughout the past century and particularly over the past three decades. Three years ago, following a decade of strong economic growth but little progress reducing the number of uninsured, the problem was urgent; 39 million people under age 65 reported having been without insurance during the entire previous year.[1] In 2000, the Institute of Medicine (IOM) formed an expert Committee on the Consequences of Uninsurance to study the issue comprehensively, examining the effects of the lack of health coverage on individuals, families, communities, and the broader society.[2] Now, after a significant economic downturn, 17.2 percent of the population under age 65 is uninsured and the number has grown to over 43 million. One in three Americans were uninsured for a month or more during a two-year period (1996–1997) (Short 2001). Fewer people have access to coverage at work, more people find the costs of private coverage too expensive, and others

lose public coverage because of changed personal circumstances, administrative barriers, and program cutbacks. The situation is even more dire now than when the study began and it is expected to worsen in the foreseeable future because of federal and state budget constraints limiting public coverage programs, increasing costs of healthcare and insurance premiums, and continuing high rates of unemployment.

Why Should Policy Makers And The Public Care About Coverage?

The Committee has conducted an exhaustive review of the scientific evidence on the consequences of uninsurance and finds that having no insurance decreases access to health services and reduced access to healthcare among the uninsured is associated with poorer health. The lack of coverage is not only associated with negative effects on the uninsured individual but also has implications for the entire family of the uninsured person and the community in which he or she lives, and economic costs to society nationally (Institute of Medicine 2001, 2002a; b; 2003a; b). In short, in a series of five reports the Committee concluded that:

- The number of uninsured individuals under age 65 is large, growing, and has persisted even during periods of strong economic growth.
- Uninsured children and adults do not receive the care they need; they suffer from poorer health and development, and are more likely to die early than are those with coverage.
- Even one uninsured person in a family can put the financial stability and health of the whole family at risk.
- A community's high uninsured rate can adversely affect the overall health status of the community, its healthcare institutions and providers, and the access of its residents to certain services.
- The estimated value across the population in healthy years of life gained by providing health insurance coverage is almost certainly greater than the additional costs of an "insured" level of services for those who now lack coverage.[3]

Notes

1. The estimate of the uninsured is based on the Census Bureau's annual March Current Population Survey (CPS), as are all annual estimates of the uninsured population of the United States presented in this report, unless otherwise noted. The CPS may overestimate the number of uninsured for the entire calendar year and does not account for all who are uninsured for shorter time periods (CBO 2003).
2. In this study, the focus is on people with no health insurance, such as "major medical" coverage for hospitalization and outpatient medical

services, either for short or long periods. The Committee does not address *underinsurance*, that is, health plans that offer less than adequate coverage with excessive out-of-pocket payments, maximum benefit limits, or exclusion of specific services, such as mental health treatment. The problems of *underinsurance* are generally less severe than those of *uninsurance*, involve different policy issues, and require the collection of different types of information.

3. An "insured" level of services reflects the current average benefits under Medicaid or private health insurance for those under age 65.

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SOURCE: Committee on the Consequences of Uninsurance, Board on Health Care Services, Institute of Medicine. 2004. *Insuring America's Health: Principles and Recommendations*, 1–3. Washington, DC: National Academies Press. Reprinted with permission of the National Academy of Sciences, courtesy of the National Academies Press.

Although the determinants of health are important to individuals, the relationship between health policy and the hundreds of millions of individuals who are affected is highly idiosyncratic. The clearer, or at least simpler, way to visualize the relationship between policies and those affected by them is to examine the relationship between policies and collectives or groups of individuals, that is, between policies and organizations and interest groups. Even so, it is important to remember that eventually all health policy affects individuals. People breathe cleaner or dirtier air, eat more or less healthful food, have more open or restricted access to health services, and benefit from more or fewer technological advances as a direct result of health policies.

Health Policy and Health-Related Organizations

The existence and accomplishments of many organizations are affected by health policies. Certainly, the missions, objectives, and internal structures and resources, including the quality of their leadership, greatly influence the accomplishments of these organizations. However, the performance levels achieved by these organizations—whether measured in terms of contribution to health outcomes for customers, financial strength, reputation, growth, competitive position, scope of services provided, or some other parameter—are also heavily influenced by the nature of the opportunities and threats imposed on them from their external environments.

The external environments faced by health-related organizations include biological, cultural, demographic, ecological, economic, ethical, legal, policy, psychological, social, and technological dimensions. Policies that affect an organization are only part of its external environment, although they may constitute a critically important part. As Figure 2.1 illustrates, policies, along with the other variables in the external environment of an organization, provide an organization with a set of opportunities and threats to which it can—indeed, must—respond.

The organization responds to these threats and opportunities with strategies and organizational structures created to carry out the strategies. The quality of the strategies and structures, in terms of their ability to make

Figure 2.1 The Relationship Between an Organization's External Environment and Its Performance

appropriate responses to the relevant threats and opportunities, results in organizational performance. But, importantly, the series of events that culminates in organizational performance is triggered by the opportunities and threats the organization faces, which are the direct result of conditions in the organization's external environment, including the public policies that affect it. Thus, it is useful to consider the specific nature of health policy concerns and interests of some of the organizations in the health sector.

A rich variety of organizations populate the health sector; their diversity defies easy categorization, although a common thread among them is that they are all affected by and have interests in health policies. Hospitals, state or county health departments, health maintenance organizations (HMOs), hospices, and nursing homes are examples of health services providers. Although no guarantees can be made for the future, abundant evidence indicates that, for the most part, the organizations that provide health services in the United States have developed under extraordinarily favorable public policies. For example, enactment in 1946 of the Hospital Survey and Construction Act (P.L. 79-725) placed Congress squarely in support of expanded availability of health services and improved facilities. This legislation, known as the Hill-Burton Act after its authors, provided funds for hospital construction and marked the beginning of a decades-long program of extensive federal developmental subsidies aimed at increasing the availability of health services.

Another important aspect of the development of health-related organizations, also supported and facilitated by public policy, has been the expansion of health insurance coverage. Beginning during World War II, when wages were frozen for many workers, health insurance and other benefits in lieu of wages became attractive features of the American workplace. Encouraged by policies that excluded these fringe benefits from income taxes and by a U.S. Supreme Court ruling that employee benefits, including health insurance, could be legitimately included in the collective bargaining process, employer-provided health insurance benefits grew rapidly in the middle decades of the twentieth century (America's Health Insurance Plans 2002).

Beyond private-sector growth in health insurance coverage, Medicare and Medicaid legislation was passed in 1965, providing more access to mainstream health services through publicly subsidized health insurance for the aged and many of the poor. With enactment of these programs, fully 85 percent of the American population had some form of health insurance.

Although public policies have been extremely important factors in the development of health-related organizations, the vast majority of them have emerged in the context of a market economy. Thus, much about the healthcare system in the United States has been shaped by the market forces of supply and demand and by the related decisions and actions of the buyers and sellers in this marketplace. The combination of market forces and public policies has shaped a complex and dynamic healthcare system.

In the healthcare system, health services are provided through a large and diverse variety of organizations. One way to envision the diversity of these health services organizations is to consider a continuum of health services that people might use over the course of their lives and to think of the organizational settings that provide them (Longest, Rakich, and Darr 2000). The continuum could begin before birth with organizations (or programs) that minimize negative environmental impact on human fetuses or that provide genetic counseling, family planning services, prenatal counseling, prenatal ambulatory care services, and birthing services. This would be followed early in life by pediatric ambulatory services; pediatric inpatient hospital services, including neonatal and pediatric intensive care units (ICUs); and both ambulatory and inpatient psychiatric services for children.

For adults, the most relevant health services organizations are those providing adult ambulatory services, including ambulatory surgery centers and emergency and trauma services; adult inpatient hospital services, including routine medical, surgical, and obstetrical services, as well as specialized cardiac care units (CCUs), medical ICUs, surgical ICUs, and monitored units; stand-alone cancer units, with radiotherapy capability and short-stay recovery beds; ambulatory and inpatient rehabilitation services, including specific subprograms for orthopedic, neurological, cardiac, arthritis, speech, otologic, and other services; ambulatory and inpatient psychiatric services, including specific subprograms for psychotics, day programs, counseling services, and detoxification; and home health care services.

In their later years, people might add to the list of relevant health services organizations those providing skilled and intermediate nursing services; adult day care services; respite services for caregivers of homebound patients, including services such as providing meals, visiting nurse and home health aides, electronic emergency call capability, cleaning, and simple home maintenance; and hospice care, palliative care, and associated family services, including bereavement, legal, and financial counseling.

The health services produced in the healthcare system have traditionally been provided by autonomous or independent health services organizations, with little attention to coordination of the continuum of services. Reflecting strongly held preferences for independence and autonomy among the leaders of most of these organizations—Ummel (1997, 13) characterizes this phenomenon as a "deeply rooted fixation on autonomy"—the organizations remained essentially independent of each other except for their arm's-length transactions and economic exchanges.

More recently, however, many health services organizations have significantly changed how they relate to each other (Shortell et al. 2000). Mergers, consolidations, acquisitions, and affiliations between and among previously independent organizations are now commonplace. At the extreme end of this activity is vertical integration, in which many organizations join into unified

organizational arrangements or systems of organizations. The development of vertically integrated systems capable of providing a largely seamless continuum of health services—including primary, acute, rehabilitation, long-term, and hospice care—increasingly characterizes healthcare.

Health services in the future may in fact be organized and delivered through even more extensively integrated systems and networks in which providers, spanning the full continuum of health services, are integrated with health plans or insurers and perhaps with suppliers to form entities that tie together many categories of organizations involved in the pursuit of health. Although limited in number and scope, some more fully integrated systems have already formed. Whether the integration of insurers and health plans with delivery systems will be successful is unclear, but these more fully integrated systems or networks of organizations can provide an extensive and coordinated continuum of health services to enrolled populations and may be the future of the nation's decreasingly fragmented approach to its pursuit of health.

The policy interests of service provider organizations may vary, but certain generic policy interests are widely shared among their leaders. The attention of those in charge of provider organizations tends to be sharply focused, for example, on policies that might affect access to their services, the costs of those services, or their revenues from them. These leaders also typically tend to be concerned about policies that relate to the structure of the healthcare system, including antitrust issues involved in mergers and consolidations, policies that relate to meeting the needs of special populations that they may serve, policies pertaining to quality assurance, and a number of ethical and legal issues that arise in providing access to affordable health services of an appropriate quality to all who need them. The Real World of Health Policy: The Hospital and Healthsystem Association of Pennsylvania's 2005 State Legislative Agenda outlines the types of policies that the association pursues on behalf of its member hospitals and health systems.

The Real World of Health Policy

The Hospital and Healthsystem Association of Pennsylvania's 2005 State Legislative Agenda

Healthcare Financing—Guarantee fair and adequate financing and insurance practices by all payors.

- Prevent payment cuts to hospitals under Medical Assistance, and seek equity in payment policies.
- Advocate for greater inclusion of hospitals in economic stimulus programs.

- Advocate for insurer accountability to advance fair and responsible insurance practices.
- Protect Pennsylvania hospitals from losing their federal designation as critical access hospitals.
- Advocate for state initiatives to increase access to healthcare coverage for the uninsured.
- Seek continued commitment of tobacco settlement funds for health-related purposes.

Medical Liability—Improve the system by containing costs and preserving access to healthcare services.

- Seek re-enactment of joint and several liability reform legislation.
- Seek additional reforms, including limits on non-economic damages, to lower costs and establish predictability and stability in the liability insurance market.
- Protect newly enacted reforms from legal challenges or legislative repeals.
- Seek continued Mcare Fund assessment abatement; work toward close out of Mcare fund.
- Promote less costly and more efficient methods to resolve liability disputes.

Workforce Issues—Assist hospitals in retaining and recruiting their professional and support workforce.

- Advocate for incentives and support to expand nursing and allied health workers education capacity.
- Oppose legislation that would exacerbate workforce shortages, prevent healthcare workers from practicing to the fullest potential of clinical capabilities, or impose additional administrative burdens.
- Support employer referencing immunity legislation that grants protections to hospitals.

Quality and Patient Safety—Assist hospitals improving the quality of care, outcomes, and patient safety.

- Advocate for continued implementation of patient safety reporting system as a learning organization that provides useful knowledge to enable patient safety improvement and risk reduction.
- Advocate for new licensure law that establishes standards that are evidence based, allow for flexibility, and enable hospitals to provide quality and safe care in a cost-effective manner.
- Secure new funding sources for hospitals to acquire and maintain patient safety technology.
- Seek quality and access standards for healthcare facilities regardless of setting or ownership.

SOURCE: Hospital and Healthsystem Association of Pennsylvania. 2005. "2005 State Legislative Agenda." [Online information; retrieved 1/21/05.] www.haponline.org/legislative/agenda/issues/. Reprinted with permission.

Related to, but different from, the organizations that provide health services directly are a variety of health-related organizations that produce resources for the service providers to use in conducting their work or in facilitating this work in some way. This category of organizations can be called *secondary provider organizations.* It includes educational institutions that help produce the healthcare system's workforce; insurance companies and health plans that organize and facilitate payment for health services, at least those insurers and plans that are not integrated into provider systems; and pharmaceutical, medical supply, and biomedical technology companies, among others, whose products are used in providing health services.

Secondary provider organizations have health policy interests of their own. For example, The Real World of Health Policy: Funding Health Professions Education illustrates that the policy interests and goals of educational organizations and programs involved in producing the health workforce are not surprising; they are especially interested in policies that affect the resources used in their educational missions, such as faculty, buildings, and equipment. Interest is also keen in policies that relate to licensure and practice guidelines as well as in those that may influence the demand for their programs' graduates, including policies that affect the number of people covered under public insurance programs and the extent of this coverage. They are also interested in policies that affect the ability of people to pay for education.

The Real World of Health Policy

Funding Health Professions Education

As described on its web site, www.aamc.org/advocacy/hpnec, "the Health Professions and Nursing Education Coalition (HPNEC) (www.aamc.org/Advocacy/hpnec) is an informal alliance of over 50 organizations representing a variety of schools, programs, health professionals and students dedicated to educating professional health personnel. Together, the members of HPNEC advocate for adequate and continued support for the health professions and nursing education programs authorized under Titles VII and VIII of the Public Health Service Act. The members of the Coalition believe these programs are essential to the development and training of tomorrow's health professionals and are critical to providing continued health services to underserved and minority communities." HPNEC wrote the following letter in support of restoring funding for health professions and nursing education that was cut in President Bush's fiscal year 2005 budget proposal:

June 18, 2004

The Honorable Ralph Regula
Chairman
Subcommittee on Labor, Health and Human Services,
Education and Related Agencies
Committee on Appropriations
U.S. House of Representatives
Washington, DC 20515

Dear Chairman Regula:

The undersigned organizations write to urge you to restore funding to the Title VII health professions programs to at least the FY 2003 level of $308 million and provide an increase for the Title VIII nursing programs in FY 2005.

The president's proposed FY 2005 budget eliminates most of the funding for the Title VII health professions programs, by providing just $11 million for these programs, a 96 percent cut below the current year. These are the only federal programs designed to train providers in interdisciplinary settings to meet the needs of special and underserved populations, as well as increase minority representation in the healthcare workforce.

The programs help address the geographic maldistribution of providers by training them to deliver care in underserved areas, including rural and inner-city communities. Reports state that the graduates of these programs are up to 10 times more likely to practice in medically underserved areas than graduates of non- funded programs, and at times, they serve as the only source of healthcare in many disadvantaged communities. Any decreases to these programs would hamper their ability to continue to prepare an array of health professionals to help fill the healthcare delivery gaps across the country.

We understand that there are many competing priorities in your fiscal year 2005 bill; however, sustaining these programs' funding is essential to maintaining the training infrastructures in health professions schools nationwide. We urge you to restore funding to the Title VII health professions programs to at least the FY 2003 level of $308 million and provide an increase to the Title VIII nursing programs during consideration of the FY 2005 Labor, Health and Human Services, and Education bill.

Thank you for your consideration of this request. We look forward to working with you to ensure the continuation of congressional support for these critical programs.

Sincerely,

Alliance for Academic Internal Medicine
Ambulatory Pediatric Association
American Academy of Family Physicians
American Academy of Pediatric Dentistry
American Academy of Pediatrics
American Academy of Physician Assistants
American Association of Colleges of Nursing
American Association of Colleges of Osteopathic Medicine

American Association of Colleges of Pharmacy
American College of Physicians
American College of Preventive Medicine
American Dental Association
American Dental Education Association
American Dental Hygienists' Association
American Geriatrics Society
American Medical Students Association
American Nurses Association
American Occupational Therapy Association
American Pediatric Society
American Psychological Association
American Psychiatric Nurses Association
American Society for Clinical Laboratory Science
American Society for Clinical Pathology
Association of American Medical Colleges
Association of Departments of Family Medicine
Association of Family Practice Residency Directors
Association of Medical School Pediatric Department Chairs
Association of Minority Health Professions Schools
Association of Professors of Medicine
Association of Program Directors in Internal Medicine
Association of Schools of Allied Health Professions
Association of Teachers of Preventive Medicine
Association of Women's Health, Obstetric and Neonatal Nurses
Clerkship Directors in Internal Medicine
Hispanic-Serving Health Professions Schools, Inc.
HIV Medicine Association
NAADAC—The Association for Addiction Professionals
National AHEC Organization
National Association of Social Workers
National Hispanic Medical Association
National League for Nursing
National Rural Health Association
North American Primary Care Research Group
Society for Adolescent Medicine
Society for Pediatric Research
Society of General Internal Medicine
Society of Teachers of Family Medicine

SOURCE: Health Professions and Nursing Education Coalition (HPNEC). 2004. [Online letter; retrieved 1/22/05.] www.aamc.org/advocacy/hpnec/correspondence/061804.pdf. Reprinted with permission from HPNEC, which is supported by the Association of American Medical Colleges.

Health plans and insurance organizations are vitally interested in policies that affect their operations and decisions. Because insurers and health plans are licensed by the states, they have interests in both federal and state health policies that affect their markets and operations. Similarly, pharmaceutical and biotechnology firms and companies in the medical supply business have wide-ranging health policy interests, including specific interests in policies that affect their markets, products, and profits.

Indeed, all service provider organizations, as well as the secondary providers that supply them with needed resources, are interested in health policy, if only because policy affects their performance levels. Mesch (1984) constructed a set of questions that people in senior-level management positions can use to determine the relative interest they might have in the impact of

public policies on their organization or system. The questions, in an adapted form, are as follows:

- Do public policies influence your organization's or system's capital allocation decisions or its strategic plans for services and markets?
- Have previous strategic plans been scrapped or substantially altered because of changes in public policy?
- Is your organization's or system's industry becoming more competitive? More marketing oriented? More technology dependent?
- Does the interplay between public policies and the other variables in your organization's or system's external environment seem to be influencing strategic decisions?
- Are you and other senior-level managers in your organization or system displeased with the results of past strategic planning because of surprises resulting from changes in public policies that affected your organization's or system's performance?

If the managers of a health-related organization, whether a service provider or a secondary provider of resources, can answer yes to even one of these questions, then they are likely to be very interested in the public policymaking process and in relevant policies. If the answer to most or all of the questions is yes, as is typically the case for contemporary health-related organizations, they will consider interest in their organization's public policy environment to be absolutely imperative and will make strong operational commitments to understanding and effectively responding to the threats and opportunities presented to their organization or system by public policy (Longest 2001, 2003).

Health Policy and Health-Related Interest Groups

Health services and secondary provider organizations, as discussed in the previous section, are not the only entities with health policy concerns and interests. A wide variety of health-related interest groups, including some that are consumer based or that are organized around individual health practitioner memberships, exist because of the collective interests of their individual or organizational members in health policymaking and the resulting health policies.

As will be discussed more fully in Chapter 3, one of the most significant features of the policymaking process and its political environment in the United States, as much in health as in any other domain, is the presence of a large number of interest groups whose purpose is to serve the collective interests of their members. These groups seek to analyze the policymaking process to discern policy changes that might affect their members and inform them about such changes. They also seek to influence the process to provide the group's members with some advantage. The interests of their constituent members define the health policy interests of these groups.

Some of the health-related interest groups have service provider organizations and systems as their members. Hospitals can join the American Hospital Association (AHA) (www.aha.org), long-term-care organizations can join the American Health Care Association (AHCA) (www.ahca.org) or the American Association of Homes and Services for the Aging (AAHSA) (www.aahsa.org), and health insurers and health plans can join America's Health Insurance Plans (AHIP) (www.ahip.org).

Other interest groups represent individual health practitioners. Physicians can join the American Medical Association (AMA) (www.ama-assn.org). African American physicians may also choose to join the National Medical Association (NMA) (www.natmed.org), and female physicians may also choose to join the American Medical Women's Association (AMWA) (www.amwa-doc.org). In addition, physicians have the opportunity to affiliate with groups, usually termed "colleges" or "academies," where membership is based on medical specialty. Prominent examples are the American College of Surgeons (ACS) (www.facs.org) and the American Academy of Pediatrics (AAP) (www.aap.org). Other personal membership groups include the American College of Healthcare Executives (ACHE) (www.ache.org), American Nurses Association (ANA) (www.ana.org), and American Dental Association (ADA) (www.ada.org), to name only a few.

Often, in addition to national interest groups, service provider organizations as well as individual health practitioners can join state and local groups, usually affiliates or chapters of national groups, that also represent their interests. For example, states have state hospital associations and state medical societies. Many urban centers and densely populated areas even have groups at the regional, county, or city level.

The secondary provider organizations also have their own interest groups. Examples include the following:

- Association of American Medical Colleges (AAMC) (www.aamc.org)
- Association of University Programs in Health Administration (AUPHA) (www.aupha.org)
- Biotechnology Industry Organization (BIO) (www.bio.org)
- Blue Cross and Blue Shield Association (www.bluecares.com)
- Pharmaceutical Research and Manufacturers of America (PhRMA) (www.phrma.org)

Like groups whose members are service providers, these groups, whose members are secondary providers, also focus particularly on policies that affect their members directly.

In addition to interest groups of service and secondary providers, there are a number of interest groups to which individuals—as individuals or consumers rather than as executives or health practitioners—can belong. Reflecting the diversity of the population from which their members are drawn,

groups with individual member constituencies are varied. In forming what Buchholz (1994) calls "solidarity groups," some of these groups are based at least in part on feelings of common identity based on a shared characteristic such as race, gender, age, or connection to a specific disease or condition. Examples include the following:

- American Association of Retired Persons (AARP) (www.aarp.org)
- American Heart Association (AHA) (www.americanheart.org)
- National Association for the Advancement of Colored People (NAACP) (www.naacp.org)
- National Organization for Women (NOW) (www.now.org)

Interest groups such as NAACP and NOW serve the health interests of their members as part of much broader agendas focused generically on racial and gender equality. Although the Fourteenth Amendment to the U.S. Constitution guarantees equal protection under the law, American history clearly shows how difficult this equality has been to achieve. Interest groups such as NAACP and NOW have made their central public policy goal equality at the polls; in the workplace; and in education, housing, health services, and other facets of life in the United States.

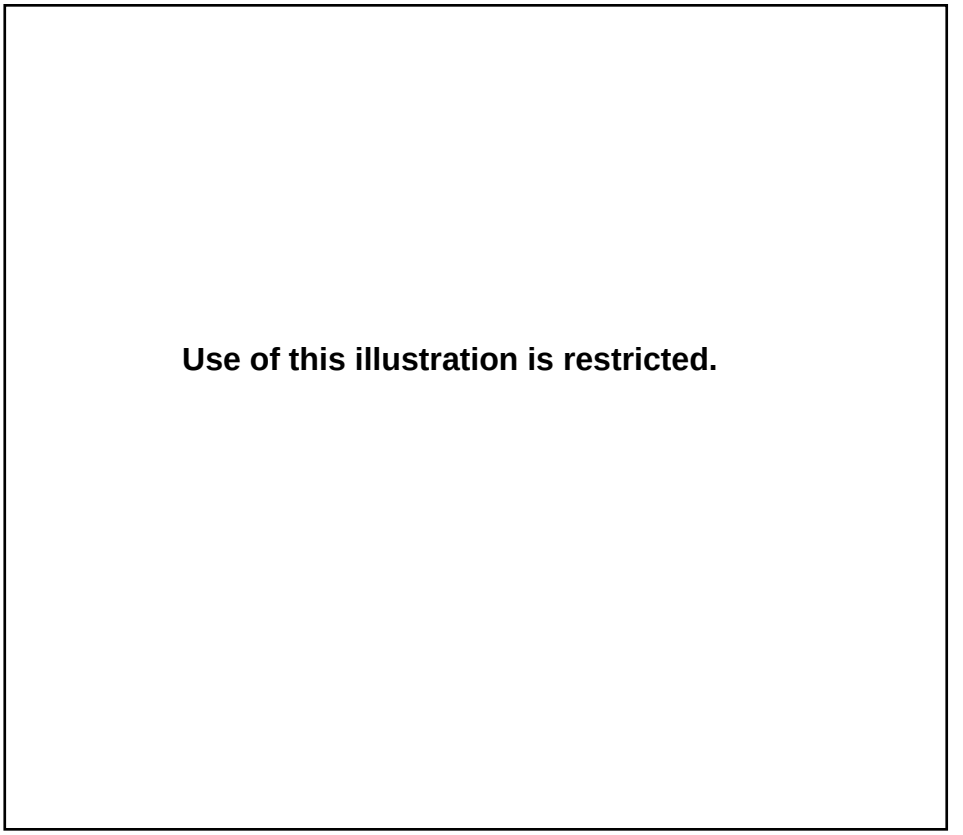
The specific health policy interests of groups representing African Americans encompass adequately addressing this population segment's unique health problems—widespread disparities in health status and access to health services; higher infant mortality; higher exposure to violence among adolescents; higher levels of substance abuse among adults; and, compared to other segments of the population, earlier deaths from cardiovascular disease and many other causes. Similarly, groups representing the interests of women seek to address their unique health problems. In particular, they focus on such health-related interests as breast cancer, childbearing, osteoporosis, family health, and funding for biomedical research on women's health problems.

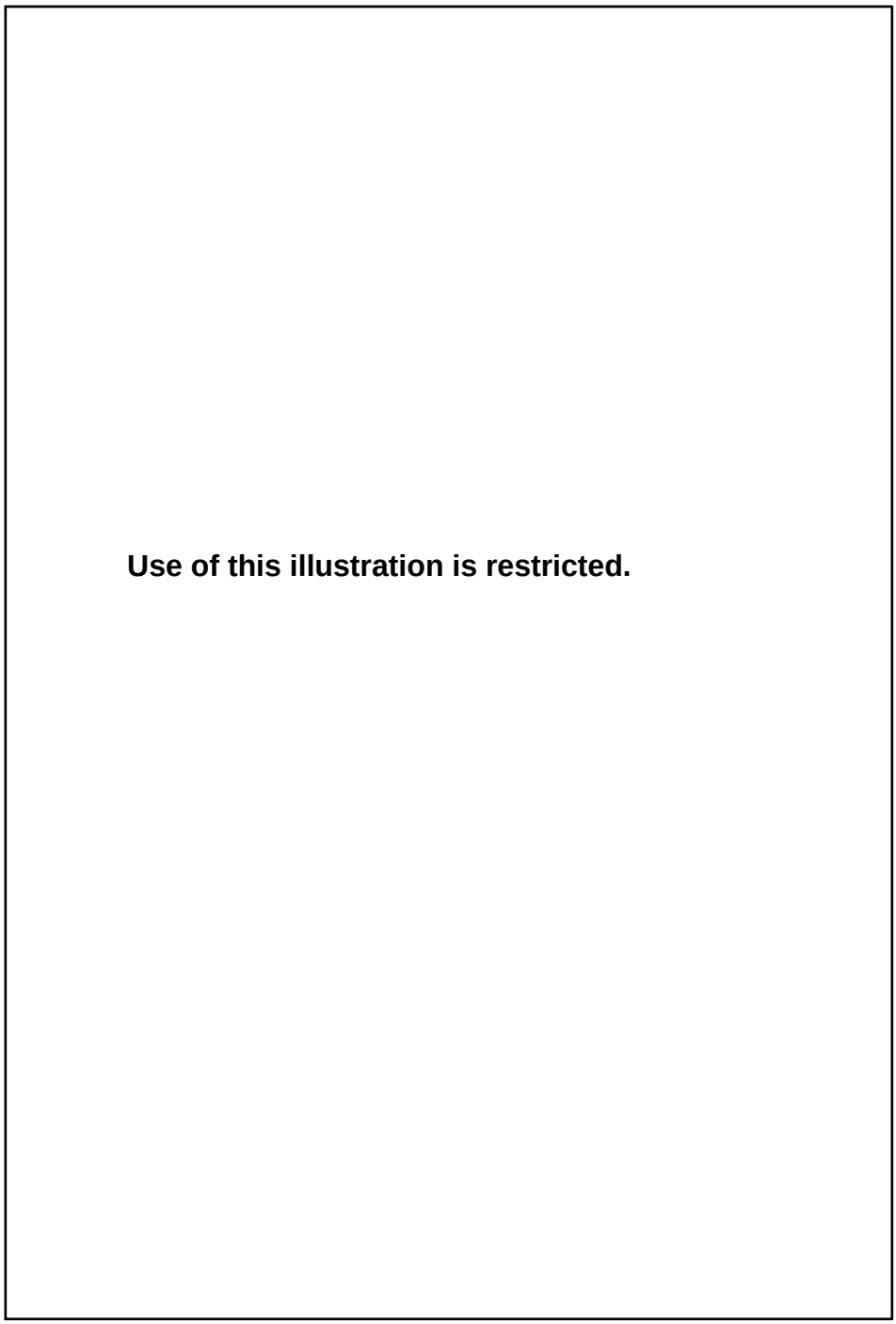
A growing proportion of the American population is over the age of 65. The elderly have specific health interests related to their stage of life; as people age, they consume relatively more healthcare services and their healthcare needs differ from those of younger people. They also become more likely to consume long-term-care services and community-based services intended to help them cope with various limitations in the activities of daily living. In addition to their unique health needs, older citizens have a special health policy history and, therefore, a unique set of expectations and preferences regarding the nation's health policy. The Medicare program, in particular, includes extensive provisions for health benefits in the context of the nation's social insurance support for its older citizens and is a key feature of this history. Building on the specific interests of older people and their preferences to preserve and extend their healthcare benefits through public policies, organizations such as AARP and the National Council of Senior Citizens (www.ncscinc.org) have

become important organizations for addressing the health policy interests of their members.

Other interest groups with individual constituencies reflect member interests based primarily on specific diseases or conditions, such as the American Cancer Society (ACS) (www.cancer.org) or the Consortium for Citizens with Disabilities (CCD) (www.c-c-d.org). The American Heart Association (AHA), for example, has 22.5 million volunteers and donors. Its overall goal is the reduction of disability and death from cardiovascular diseases and stroke.

AHA pursues its goal through a number of avenues, including direct funding of research, public and professional education programs, and community programs designed to prevent heart disease. It also seeks to serve its members' interests through influencing public policy related to heart disease. As AHA (2005) notes on its web page, "In working to fulfill its mission, the Association plans, coordinates and implements a federal, state and local legislative and regulatory program in conjunction with its affiliates." The Real World of Health Policy: American Heart Association's Federal Public Policy Agenda outlines AHA's federal policy agenda and is typical of the way that many interest groups seek to serve their membership by outlining and pursuing clear-cut public policy agendas on behalf of the members.





Summary

Health policies have a direct and often dramatic impact on the determinants of health. These determinants include the physical environments in which

people live and work; their behaviors and biology; social factors such as their economic circumstances, their socioeconomic position in society, the income distribution within the society; discrimination based on factors such as race/ethnicity, gender, sexual orientation, and the availability of social networks/social support; and their access to appropriate health services.

In addition to the impact of health policies on health determinants and, through this impact, their relationship to the health of individuals and populations, health policies also affect the lives of individuals in other ways. Furthermore, policies have important effects on health-related organizations and interest groups. Health policy is of consequence to some people, organizations and systems, and interest groups for reasons apart from its effect on the health of individuals. The ability of health-related organizations to fulfill their mission is heavily influenced by such factors as the relative generosity or parsimony of reimbursement policies. Interest groups exist to serve the interests of their members, and these interests often involve a role in exerting influence in the development of health policy.

Discussion Questions

1. Discuss the impact of health policies on the physical environment.
2. Discuss the impact of health policies on human behavior and biology.
3. Discuss the impact of health policies on the social factors that help determine health.
4. Discuss the impact of health policies on health services in terms of the money, human resources, and technology used to produce these services.
5. Discuss the impact of health policies on individuals, on health-related organizations, and on interest groups.

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CHAPTER

3

CONTEXT AND PROCESS OF HEALTH POLICYMAKING

Whether health policies take the form of laws, rules or regulations, operational decisions, or judicial decisions, as described in Chapter 1, they are all decisions, and they are made through a complex decision-making process. With certain variations, policies at the federal, state, and local levels of government are made through similar processes. Furthermore, the structure of the decision-making process is the same for all policy domains, whether the domain is health, education, defense, taxes, welfare, or other domains. Although health policy is the focus, all public policy is made through a decision-making process called policymaking.

The domain of health policy is very broad because health is a function of multiple determinants: the physical environment within which people live and work, their behaviors and biology, social factors, and the health services to which they have access. Not only is the health policy domain broad but also there are numerous overlaps and blurred lines between the health domain and other policy domains. For example, it is impossible, as a practical matter, to consider health policy aside from its relationship to tax policy. Health policy cannot be separated from the fact that government must finance, essentially through taxes, the services or programs established by health policy, whether in the form of health services for the beneficiaries of the Medicare program, research in biomedical laboratories, or other services. At a minimum, any dollars spent as a result of health policies always have alternative uses in other domains to which the money could be directed by policymakers.

Another example of how policy domains overlap is the 1996 Personal Responsibility and Work Opportunity Reconciliation Act (P.L. 104-193), also known as the Welfare Reform Act, which had significant health implications. In addition to the obvious impact of changes in the nation's welfare policy on such health determinants as the social and economic environments faced by affected people, this law affects eligibility for the Medicaid program in a fundamental way. Since the establishment of the Medicaid program in 1965, eligibility for a key welfare benefit, Aid to Families with Dependent Children (AFDC), and eligibility for Medicaid benefits have been linked. Families receiving AFDC have been automatically eligible for Medicaid and enrolled in the Medicaid program. The Welfare Reform Act, however, replaced AFDC with the Temporary Assistance to Needy Families (TANF) block grant. Under the provisions of the TANF block grant, states are given broad flexibility to

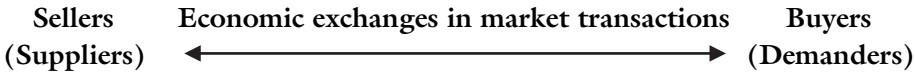
design income support and work programs for low-income families with children and are required to impose federally mandated restrictions, such as time limits, on federally funded assistance.

The Welfare Reform Act does provide that children and parents who would have qualified for Medicaid based on their eligibility for AFDC continue to be eligible for Medicaid, but, in the absence of AFDC, states find it necessary to use different mechanisms to identify and enroll former AFDC recipients in their Medicaid programs. This example of the overlap between the policy domains of health and welfare is typical of the ways in which policy in one domain relates to policy in other domains. The European Commissioner for Health and Consumer Protection states this relationship as follows: "To achieve good health, we need to look at the grass root problems—poverty, social exclusion, healthcare access. We need to understand how different socioeconomic and environmental factors affect health. And then we need to make all these factors work together for good health. Good health must become the driving force behind all policy-making" (Byrne 2004, 2).

The purpose of this chapter is to present both a model of the public policymaking process and a description of the political context within which the policymaking process takes place. The political context—or political marketplace, as it is often called—is discussed first.

The Context of Health Policymaking: The Political Marketplace

A useful conceptualization of the political marketplace for health policies can be based on the operation of traditional economic markets because economic markets and political markets share a number of characteristics. Many different kinds of products and services, including those used in the pursuit of health, are bought and sold in the context of economic markets. In these markets, willing buyers and sellers enter into economic exchanges involving something of value to both parties. One party demands and the other supplies. By dealing with each other through market transactions, individuals and organizations buy needed resources and sell their outputs. These relationships can be summarized as follows:



Because people are calculative regarding the relative rewards and costs incurred in the exchanges they make in markets, they negotiate these exchanges. Negotiation (or bargaining) involves two or more parties attempting to settle what each shall give and take (or perform and receive) in an economic

transaction between them. The next section shows a parallel between this feature of economic markets and the operation of political markets. In the interactions of negotiation that take place in an economic market, the parties attempt to agree on a mutually acceptable outcome in a situation where their preferences for outcomes are usually negatively related. Indeed, if the preferences for outcomes are positively related, an agreement can be reached almost automatically.

More typically, among parties to a negotiation, at least two types of issues must be resolved through the negotiations. One type involves the division of resources—the so-called tangibles of the negotiation, such as who will receive how much money and what products or services in the exchange. Another type centers on the resolution of the psychological dynamics and the satisfaction of personal motivations of the parties in the negotiations. These issues are the so-called intangibles of the negotiation and can include such notions as appearing to win or lose, to compete effectively, or to cooperate fairly.

Negotiations in economic exchange situations usually follow one of two strategic approaches: cooperative (win/win) or competitive (win/lose) strategies. The choice of the negotiating strategy best used in any particular situation is a function of the interaction of several variables. Greenberger et al. (1988) contrast the optimal conditions for the use of cooperative negotiating strategies with the optimal conditions for competitive strategies. Cooperative negotiating strategies work best when

- the tangible goal of both negotiators is to attain a specific settlement that is fair and reasonable;
- sufficient resources are available in the environment for both negotiators to attain their tangible goal, more resources can be attained, or the situation can be redefined so that both negotiators can "win";
- each negotiator thinks it is possible for both of them to attain their goals through the negotiation process; or
- the intangible goals of both negotiators are to establish a cooperative relationship and to work together toward a settlement that maximizes their joint outcomes.

Competitive negotiating strategies work best when

- the tangible goal of both negotiators is to attain a specific settlement or to get as much as they possibly can;
- resources available are not sufficient for both negotiators to attain their goals, or their desire to get as much as possible makes it impossible for one or both to actually attain their goals;
- both negotiators think it is impossible for both of them to attain their goals simultaneously; or
- the intangible goal of both negotiators is to beat the other.

The Operation of Political Markets

Much about the operation of economic markets applies to the way political markets operate. Health policies—indeed, all public policies—are made within the context of political markets, which in many ways operate like traditional economic markets. There are, however, some notable differences between economic and political marketplaces. The most fundamental difference is that buyers or demanders in economic markets express their preferences by spending their own money. That is, buyers in economic markets reap the benefits of their choices, and they also directly bear the costs of their choices. In political markets, on the other hand, the linkage between who receives benefits and who bears costs is not so direct. Feldstein (2001), for example, observes that public policies that impose costs on future generations are routinely established. The nature of the political marketplace dictates that many of the decisions of contemporary policymakers are influenced by the preferences of current voters, perhaps to the detriment of future generations. As The Real World of Health Policy: The Outlook for Social Security illustrates, this phenomenon can be seen in policies related to decisions about such allocative policies as Social Security and Medicare.

The Real World of Health Policy

The Outlook for Social Security

Under current law, outlays for Social Security will rise from about 4.4 percent of gross domestic product (GDP) today to more than 6 percent of GDP 30 years from now, the Congressional Budget Office (CBO) projects. In later years, spending will continue to grow steadily, though more slowly. That projection is necessarily uncertain. But past variation in the economic and demographic factors underlying the projection suggests that over the next 50 to 100 years, Social Security's demand for economic resources will range between 5 percent and 8 percent of GDP.

By contrast, federal revenues dedicated to Social Security are expected to remain close to their current level—about 5 percent of GDP—over that period. As a result, outlays are projected to begin exceeding revenues in 2019, with the gap growing ever wider thereafter. Even if outlays for Social Security turn out to be lower than expected and revenues higher, a gap is likely to remain. Only four approaches to closing that gap are possible, each of which has its own drawbacks:

- The benefits that are scheduled to be paid to future recipients under current law could be reduced, lowering Social Security's contribution to their income.

- The taxes that fund Social Security could be raised to draw additional resources from the economy to the program.
- The resources consumed by other federal programs could be reduced to cover the gap between Social Security's outlays and revenues.
- The federal government's borrowing could be increased, which would be another way to draw more resources from the economy to Social Security. That borrowing would need to be repaid by future generations, however, either through increased taxes or reduced federal spending.

Social Security is not the only source of pressure on the overall federal budget. The aging of the U.S. population—which is the main source of the projected increase in Social Security spending—will also raise costs for other entitlement programs. In particular, CBO projects that expenditures for Medicare and Medicaid will grow even faster than Social Security outlays because of rising healthcare costs. Unless taxation reaches levels that are unprecedented in the United States, current spending policies are likely to prove financially unsustainable over the long term because they will lead to an ever-growing burden of federal debt held by the public, which will have a corrosive and potentially contractionary effect on the economy.[1]

The Social Security Program at Present

In 2003, the federal government spent a total of $479 billion on the Social Security program. That year, about 47 million people received Social Security benefits—29.5 million retired workers; 5.9 million disabled workers; and 11.6 million family members of retired, disabled, or deceased workers. Social Security has two parts.[2] The Old-Age and Survivors Insurance (OASI) program provides benefits to retired workers, members of their families, and their survivors. The Disability Insurance (DI) program pays benefits to disabled workers younger than the normal retirement age and their dependents.[3] OASI is by far the larger program: last year it accounted for about 85 percent of spending for the two parts combined (referred to as OASDI). On average, retired workers received about $11,060 in OASI benefits in 2003, and disabled workers received $10,340 in DI benefits.

Benefits are financed primarily through payroll taxes, with half collected from employers and half from workers.[4] The combined tax rate, currently 12.4 percent, is levied on wages and self-employment income covered by the OASDI program, up to the taxable maximum of $87,900. (That threshold rises annually with average earnings in the economy.) Last year, about 154 million workers were covered by Social Security and paid some payroll taxes. Their average taxable earnings were $28,100—for a total taxable payroll of $4.3 trillion and total payroll tax revenues of $534 billion. (The Medicare program is partially funded by a separate payroll tax, which raised $149 billion in 2003. References in this report to payroll taxes refer to Social Security taxes.)

The Social Security system also receives revenues from income taxes that the approximately one-third of beneficiaries with the highest income pay on their Social Security benefits.[5] Those revenues are far smaller than payroll tax receipts: $13 billion in 2003.[6]

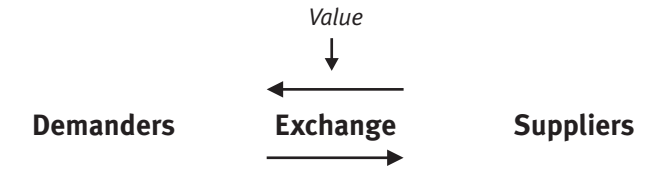
Social Security is currently running an annual surplus. In 2003, dedicated revenues exceeded outlays by $68 billion. Viewed as a component of the overall budget, that surplus helped reduce the government's total deficit in 2003. However, Social Security also has a distinct, specific accounting structure. Revenues from payroll taxes and the taxation of benefits are credited to the budget's OASI and DI trust funds. Any revenues not needed to pay for benefits or administrative expenses are invested in government bonds. The interest that the bonds earn (a total of $85 billion in 2003) is credited to the trust funds. But because that interest represents the government paying itself, it provides no net revenues to the government and has no effect on the total budget.[7]

The trust funds serve mainly as an accounting mechanism to track revenues and outlays for Social Security. The funds' balance represents the total amount that the government is legally authorized to spend on Social Security. That balance provides only a limited perspective on the program's finances, however, because it does not consider the interaction with other federal tax and spending programs. Although the Social Security system is authorized to spend certain amounts, the resources to finance those outlays derive from the budget as a whole—and ultimately from the economy.

NOTES

1. See Congressional Budget Office, *The Long Term Budget Outlook*, December 2003.
2. For more information about Social Security's structure and benefits, see Congressional Budget Office, *Social Security: A Primer*, September 2001, Chapter 2. The numbers in this paragraph are as of December 31, 2003.
3. In Social Security, the "normal retirement age" is the age at which a worker becomes eligible for full retirement benefits. It is 65 for people born in or before 1937 and higher for those born later, rising to 67 for people born after 1959.
4. Economists generally agree that workers effectively pay the full tax because employers pass on their share to workers in the form of lower compensation.
5. All of the projections presented in this study are made under the assumption that the laws governing Social Security will not change. Such a baseline approach means that future analyses of proposed changes to the program can be compared with these projections to clearly identify the effects of the proposals. However, future revenues from income taxes paid on Social Security benefits depend on future income tax law, which is logically distinct from Social Security law and could be amended many times in coming years (excerpted from the original).
6. Some additional federal revenues from the taxation of Social Security benefits are allocated to Medicare's Hospital Insurance Trust Fund, but that stream of revenues is not considered in this report.
7. See Congressional Budget Office, *The Impact of the Trust Fund Programs on Federal Budget Surpluses and Deficits*, Long-Range Fiscal Policy Brief No. 5, November 4, 2002.

SOURCE: Congressional Budget Office. 2004. *The Outlook for Social Security.* [Online report; retrieved 1/23/05.] http://www.cbo.gov/showdoc.cfm?index=5530&sequence=0.



Structurally and operationally, a political market is very much like an economic market.

FIGURE 3.1 The Operation of Political Markets

Feldstein (2001) also points out that decision makers in political markets use different decision criteria than those used in traditional economic markets. In both markets, thoughtful decision makers take into account both the benefits and the costs of their decisions. In political markets, however, decision makers may use different time frames. Because legislators stand for periodic reelection, they typically favor policies that provide immediate benefits to their constituencies, and they tend to weigh only, or certainly more highly, immediate costs. Unlike most decision makers in economic markets, where the costs and benefits of decisions are taken into account over the long run, decision makers in political markets are more likely to base decisions on whether immediate benefits exceed immediate costs. An obvious consequence of this is that policies with immediate benefits, but with burdensome future costs, occur.

The differences between the operations of economic and political markets notwithstanding, both those who "supply" policies and those individuals or groups who "demand" policies recognize the innate value of policies. In political markets, both suppliers and demanders stand to reap benefits or incur costs because of policies. Policies are valued commodities in the political marketplace. These relationships are shown in Figure 3.1.

Given that demanders and suppliers in political markets will enter into exchanges involving policies, it is important to know who the demanders and suppliers are and what motivates their decisions and actions in these markets.

Demanders and Suppliers of Health Policies

Think of political markets as operating similarly to economic markets—that is, as markets in which something of value is exchanged between suppliers and demanders. This permits public policies to be viewed as valued commodities, as a

means of satisfying certain demanders' wants and needs in much the same way that products and services produced and sold in the private sector's economic markets serve to satisfy demanders (usually called consumers). In private markets, demanders seek products and services that satisfy them. In political markets, demanders seek public policies that satisfy their preferences. Policymakers are in a position to supply the public policies that demanders seek.

The Demanders of Health Policies

Broadly, the demanders of health policies can include anyone who considers such policies to be relevant to the pursuit of health for themselves or others about whom they care or who considers such policies to be a means to some other desired end, such as economic advantage. It is these desired ends of enhanced health or other advantages that motivate the participation of demanders in political markets, just as desired ends motivate participation in economic markets.

For individuals, however, effective participation in the political marketplace presents certain problems and limitations. For example, to participate effectively, individuals must acquire substantial amounts of policy-relevant information, which can require considerable amounts of time and money. Beyond this, individual participants or demanders often must be prepared to expend additional resources—again, money and time—in support of achieving desired policies. This expense problem is exacerbated by the fact that any particular health policy might have significant, or even noticeable, benefits for only a relatively small number of individuals. Consequently, demanders participate as individuals to a very limited degree in the political markets for policies.

Organizations, with their pooled resources, have a significant advantage over individuals in the political marketplace. They may have the necessary resources both to garner needed policy-relevant information and to support their efforts to achieve desired policies. Their pooled resources are not their only advantage over individuals in the political marketplace. The health policy interests of organizations may be very concentrated. A change in Medicare policy that results in an increased deductible of $100 per year for certain individuals is one thing; a policy change that results in several million dollars of revenue for a health services organization is quite another. Organizations tend to be more effective demanders of health policy than individuals, in part because the stakes for them tend to be higher.

The most effective demanders of policies, however, are the well-organized interest groups. (More is said about interest groups and their role in influencing the public policymaking process in subsequent chapters.) Interest groups are groups of people or organizations with similar policy goals that enter the political process to try to achieve those goals. By combining and concentrating the resources of their members, interest groups can have a much greater impact in political markets than either individuals or organizations.

In effect, interest groups provide their members, whether they are individuals or organizations, with greater opportunities to participate effectively in the political marketplace. This is what the American Medical Association (AMA) (www.ama-assn.org) does for individual physicians, what the American Association for Retired Persons (AARP) (www.aarp.org) does for older individuals; and what the Pharmaceutical Research and Manufacturers of America (PhRMA) (www.phrma.org) does for its member companies. Because of their powerful roles in political markets, interest groups, as demanders of health policy, are described more fully in the next section.

Interest Groups in the Political Marketplace

Interest groups arise in democratic societies because many people realize that the opportunities to achieve particular benefits or other desired outcomes are enhanced through collective action within the political marketplace, specifically through influencing the public policymaking process. (An excellent background resource on interest groups is found at http://texaspolitics.laits.utexas.edu/html/ig/index.html.) They are ubiquitous in the United States as much in the health domain as in any other. However, as Table 3.1 shows on the following page, the relative influence of interest groups in political markets varies across states.

The right to organize interest groups, as well as to participate in them, is granted and protected by the U.S. Constitution. The First Amendment to the Constitution guarantees the American people the right "peaceably to assemble, and to petition the Government for a redress of grievances." However, constitutional guarantees notwithstanding, from the nation's beginning to the present day, political theorists have disagreed about whether interest groups play positive or negative roles in American political life (Ornstein and Elder 1978; Moe 1980; Ciglar and Loomis 2002; Peters 2003; Edwards, Wattenberg, and Lineberry 2003).

James Madison, writing in several of *The Federalist Papers* in 1787, discusses the relationship of groups, which he called "factions," to democratic government. In *Federalist* Number 10, he defines a faction as "a number of citizens, whether amounting to a majority or a minority of the whole, who are united and actuated by some common impulse of passion, or of interest, adverse to the rights of citizens, or to the permanent and aggregate interests of the community." Madison felt strongly that factions, or interest groups, were inherently bad. He also believed, however, that the formation of such groups was a natural outgrowth of human nature (he writes in *Federalist* Number 10 that "the latent causes of faction are sown into the nature of man") and that government should not seek to check this activity.

In his wisdom, Madison felt that what he called the "mischiefs of faction" could and should be contained by setting the "ambition" of one faction against the selfish preferences and behaviors of other factions or groups. So

TABLE 3.1 Comparing Interest Group Strength Across the States

Use of this table is restricted.

began an enduring history of uncertainty about and ambiguity toward the role of interest groups in public policymaking in the United States. One point about which there is neither uncertainty nor ambiguity, however, is that interest groups play an active role in the public policymaking process. Reflecting widely divergent views on the manner in which interest groups play their role in this process, two distinct perspectives on ways in which groups influence policymaking have emerged: the pluralist and the elitist models.

The Pluralist Perspective

People who hold the pluralist perspective on the role of interest groups in policymaking believe that because so many interest groups are operating, everyone's interests can be represented by one or more of them. Adherents to the pluralist model usually maintain that interest groups play an essentially positive role in public policymaking. They argue that a very large variety of interest groups compete with and counterbalance each other in the political marketplace, where public policymaking occurs. Pluralists do not question that some groups are stronger than others. However, pluralists contend that as groups seek their preferred outcomes, power is widely dispersed among competing groups, with groups winning some of the time and losing some of the time.

Pluralist theory about how the policymaking process works includes several interconnected arguments that, when taken together, constitute what has come to be called a group theory of politics (Truman 1993). The central tenets of the group theory of how the public policymaking process works, at all levels of government, include the following:

- Interest groups provide essential linkages between people and their government.
- Interest groups compete among themselves for outcomes of the policymaking process, with the interests of some groups counterbalanced by the interests of others.
- No group is likely to become too dominant in the competition; as groups become powerful, other countervailing interests organize or existing groups intensify their efforts. An important mechanism for maintaining balance among the competing groups is their ability to rely on various sources of power. Groups representing concentrated economic interests may have money, but consumer groups may have larger numbers of members.
- The competition among interest groups is basically fair. Although there are exceptions, groups typically play by the rules of the game.

In the face of a large and growing number of interest groups, some observers have concluded that the pluralist approach of encouraging and facilitating the formation of interest groups is out of control. Indeed, a very large number of groups have emerged to play parts in the American policymaking process. There are more than 22,200 associations of national scope today in such domains as business, education, religion, science, and health—all actively pursuing a variety of policy interests on behalf of their members (Hunt 2002). The problem, according to the critics of pluralism, is not merely the large number of groups but also the fact that government seems to consider the demands and preferences of all interest groups to be legitimate.

There is little argument that government does attempt to satisfy the preferences of many interests, sometimes in conflicting ways. Lowi (1979)

coined the phrase "interest group liberalism" to refer to his view of the federal government's excessive deference to interest groups. Others call the phenomenon "hyperpluralism" (Edwards, Wattenberg, and Lineberry 2003).

Whether they call it interest group liberalism or hyperpluralism, critics of the pluralist approach to the role of interest groups in the public policymaking process strongly agree on the following two points:

1. Interest groups have become too influential in the policymaking process. Satisfying their multiple and often conflicting demands seems to drive government rather than government being driven by a desire to base policy decisions on considerations of what is best for the nation as a whole—that is, on the public interest.
2. Seeking to satisfy the multiple and often conflicting demands of various interest groups leads to confusion, contradiction, and even paralysis in the policymaking process. Rather than making a difficult choice between satisfying X or Y, government seems frequently to pretend that there is no need to make the choice and seeks to satisfy both X and Y.

In addition to those who criticize the pluralist approach as dysfunctional and out of control are those who believe that the perspective itself is misguided, even wrong. Instead of everyone having a chance to participate in influencing the policymaking process through one group or another, some people believe that such influence actually resides only in the hands of an elite few.

The Elitist Perspective

Whereas pluralists point with pride to the remarkable number of organized groups actively and aggressively participating in the American process of public policymaking, people holding the elitist perspective point out how relatively powerless and ineffectual most groups are. The elitist perspective on the role of interest groups, which is the opposite of the pluralist viewpoint, grows out of a power elite model of American society.

This model is based on the idea that real political power in the United States is concentrated in the hands of the very small proportion of the population that controls the nation's key institutions and organizations and much of its wealth. In the elitist perspective, these so-called "big interests" look out for themselves in part by disproportionately influencing, if not controlling, the public policymaking process. It is debatable whether this model accurately reflects the nature of the American political marketplace, but it does represent the opinions of a growing majority of Americans concerning which members of the society have the most influence in the political marketplace.

The elitist theory holds that a power elite, often referred to as "the establishment," acts as a gatekeeper to the public policymaking process. That is, unless the power elite considers an issue to be important, the issue does not

even get on the policy agenda. Furthermore, the theory holds, once an issue is on the agenda, public policies made in response to triggering problems mostly reflect the values, ideologies, and preferences of this governing elite (Dye 2004). Thus, the power elite dominates public policymaking through its superior position in society. It shapes the formulation of policies and controls their implementation by taking powerful roles in the nation's economic and social systems. It has been argued that the nation's social and economic systems in fact depend on the power elite's consensus regarding the fundamental values of the system, and the only policy alternatives that will be given serious consideration are those that fall within the shared consensus (Dye 2002).

The central tenets of the power elite theory relating to the role of interest groups in policymaking stand in stark contrast to the pluralist perspective. These tenets are as follows (Dye and Zeigler 2006; Edwards, Wattenberg, and Lineberry 2003):

- Real political power resides in a very small number of groups; the large number of interest groups is practically meaningless because the power differentials among them are so great. Other groups may win minor policy victories, but the power elite always prevails on the significant policy issues.
- Members of the power elite share a consensus or near consensus on the basic values that should guide public policymaking: private property rights, the preeminence of markets and private enterprise as the best way to organize the economy, limited government, and the importance of both individual liberty and individualism.
- Members of the power elite have a strong preference for incremental changes in public policies. Incrementalism in policymaking permits time for the economic and social systems to adjust to changes without feeling threatened, with minimal economic dislocation or disruption and with minimal alteration in the social system's status quo.
- Elites protect their power bases. Some limited movement of non-elites into elite positions is permitted to maintain social stability, but only after non-elites clearly accept the elites' consensus values.

Which Perspective Is Correct?

Those who hold the power elitist perspective challenge those who hold the pluralist perspective by pointing to the highly concentrated and interlocked power centers in American society. Studies of the concentration of political power do find that about one-third of the top leadership positions in the United States—on corporate, foundation, and university governing boards, for example—are held by people who occupy more than one such position (Dye 2002).

Those who prefer the pluralist perspective, however, are equally quick to cite numerous examples in which those who traditionally have been grossly

underrepresented in the inner circles of the power elite have succeeded in their collective efforts to influence significantly the public policymaking process in the United States. African Americans, women, and consumers in general provide powerful examples of the ability of groups once ignored by policymakers to organize as effective interest groups and redirect the course of the public policymaking process in dramatic ways.

Neither the pluralist nor the elitist perspective alone fully explains how the interests of individuals or of organizations, acting through interest groups, relate to the public policymaking process. The results of that process affect to varying degrees the interests of all individuals and all organizations. Many, if not all, individuals and organizations with interests can influence the policymaking process, although, again, not to equal degrees. Both the elitist and the pluralist approaches have something of value to contribute to efforts at understanding the roles that interest groups play in the marketplace for public policies. Whether such groups play their roles proactively, by seeking to stimulate new policies that serve the interests of their members, or reactively, by seeking to block policy changes that they do not believe serve their members' best interests, they are intrinsic to the public policymaking process. Interest groups provide their members a way to link their policy preferences into a more powerful, collective voice that greatly increases the likelihood of a significant influence on policymaking.

The Suppliers of Health Policies

Because policies are made in the executive, legislative, and judicial branches of government, the list of potential suppliers of health policies—the policymakers—is lengthy. Members of each branch of government play a role as supplier of policies in the political market, although each branch plays its role in different ways.

Legislators as Suppliers

One group of public policy suppliers is elected legislators, whether members of the U.S. Congress, state legislatures, or city councils. Few aspects of the political marketplace are as interesting, or as widely observed and studied, as the question of motives for the policymaking decisions and actions of elected legislators. To a large extent, this intense interest in the motivations of policy suppliers reflects the desire by policy demanders for some effective means to pursue their desired policies by exerting influence over the suppliers.

Although neither extreme fully reflects the motivations of legislators, the end points on a continuum of behaviors that policymakers might exhibit can be represented by those who seek to maximize the public interest on one end and by those who seek to maximize self-interest on the other end. A legislator at the public interest extreme would always seek policies that maximize the public interest, although the true public interest might not always be easy to identify. A legislator whose motivations lie at the self-interest extreme

would always behave in a manner that maximizes self-interest, whether that interest is reelection, money, prestige, power, or whatever appeals to the self-serving person.

In the political marketplace, legislators can be found all along the continuum between extreme public-interest and extreme self-interest motivations. Although some people incorrectly ascribe dominant self-interest motives to all legislators, the actions and decisions of most legislators, most of the time, are more likely to reflect a complex mixture of the two motivations, with exclusively self-interested or public-interested motives only rarely dominating decisions.

Motives aside, legislators at all levels of government are key suppliers of policies, especially of policies in the form of laws. In political markets, legislators constantly calculate the benefits and costs of their policymaking decisions and consider who will reap these benefits and bear these costs. Factoring in the interests they choose to serve, they make their decisions accordingly. Their calculations are complicated by the fact that the costs and benefits of a particular decision often affect many different people in different ways.

In effect, policies typically create winners and losers. The gains enjoyed by some people come at the financial expense of others, or at least at the expense of having someone's problems ignored or someone's preferred solutions postponed. Without overgeneralization, it is fair to say that most of the time most legislators seek to maximize their own net political gains through their policy-related decisions because reelection is an abiding objective.

In view of the reality of winners and losers being created by most policies, legislators may find that their best strategy is to permit the winners their victory, but not by a huge margin, and in so doing cushion the impact on the losers. For example, suppose a legislator is considering a policy that would increase health services for an underserved population but at the expense of higher taxes on others. Options include various policies with the following outcomes: (1) few services at relatively low cost, (2) more services at higher cost, and (3) many services at very high cost. Facing such a decision, and applying the concept of net political gain, policymakers might opt for the provision of a meaningful level of services, but one far below what could have been provided and at a cost below what would have been required for a higher level of services. The "winners" receive more services, but the expense for the "losers," who have to pay for the new services, is not as great as it might have been. Through such "political calculus," legislators routinely seek to maximize their net political gains.

Executives and Bureaucrats as Suppliers

At all levels of government, members of the executive branch play an important role as suppliers of policies, although their role differs from that of legislators. Presidents, governors, mayors, and other senior public-sector executives

offer policies in the form of legislative proposals and seek to have legislators enact their preferred policies. Chief executives, as well as those in charge of government departments and agencies, also make policies directly in the form of rules or regulations used to guide the implementation of laws and in the operational protocols and procedures they use to operationalize the policies they are responsible for implementing. Career bureaucrats who also participate in these activities and thus become suppliers of policies in the political marketplace join elected and appointed executives and managers in their rulemaking and operational duties.

Elected and politically appointed officials of the executive branch often are affected by the same self-interest/public-interest dichotomy that affects legislators; reelection concerns in particular often directly influence their decisions. Like legislators, elected and politically appointed members of executive branches are apt to calculate the net political gains available through their policy-related decisions and actions. As a result, their motivations and behaviors are often quite similar to those of legislators as they participate in the political marketplace. However, there are some important differences between the motivations and behaviors of elected and appointed members of the executive branch of a government and the elected members of its legislative branch.

The most fundamental difference derives from the fact that the executive branch generally bears greater responsibility than does the legislative branch for the state of the economy and is widely perceived to bear even more responsibility than it actually does. Presidents, governors, and mayors, along with their top appointees, are held accountable much more explicitly for economic conditions than Congress, state legislatures, or city councils. Although legislators do not escape this responsibility altogether, the public typically lays most of the responsibility for the economy at the feet of the executive branch. Even when people do blame the legislative branch, they tend, at least in part, to hold the entire Congress or the state or city legislature collectively responsible rather than to blame individual legislators.

The concentration of responsibility for the condition of the economy in the executive branch heavily influences the decision making that takes place there. Because of the close connection between government's budget and the state of the economy, the budget implications of policy decisions will be very carefully weighed in the executive branch. Not infrequently, positions on health policies will differ between the legislative and executive branches because members in the two branches attach different degrees of importance to the budget implications of the policies they are considering.

Career bureaucrats, or civil servants, in the executive branch, whose participation in rulemaking and operations makes them suppliers of policies, also participate in policymaking in the legislative branch. When they collect, analyze, and transmit information about policy options and initiate policy proposals in their areas of expertise, they are important participants

in policymaking within the legislative branch. However, the motivations and behaviors of career bureaucrats tend to differ from both those of legislators and those of elected or appointed members of executive branches.

The behaviors and motivations of career bureaucrats in the public sector are often analogous to those of employees in the private sector. Workers in both settings typically seek to satisfy certain of their personal needs and desires through their work. This can obviously be categorized as serving their self-interests in both cases. But government employees are no more likely to be totally motivated by self-interests than are private sector workers. Most workers in both sectors are motivated by similar blends of self-interest and interest in what is good for the larger society.

However, it is also fair to point out that most career bureaucrats watch a constantly changing mix of elected and senior government officials—with an equally dynamic set of policy preferences—parade past them, while they remain as the most permanent human feature of government. It should surprise no one that career bureaucrats develop a strong sense of identification with their home department or agency or that they develop attitudes of protectiveness toward it. This protectiveness is most visible in the relationships between government agencies or departments and those with legislative oversight over them, including authorization, appropriation, and performance review responsibilities. Many career bureaucrats equate the well-being of their agencies, in terms of their size, budgets, and prestige, with the public interest. This obviously is not always the case.

The Judiciary as Supplier

The judicial branch of government also is a supplier of policies. For example, whenever a court interprets an ambiguous law, establishes judicial procedure, or interprets the U.S. Constitution, it makes policies. These activities are not conceptually different from those involved when legislators enact public laws or when members of the executive branch establish rules and regulations to guide implementation of laws or make operational decisions regarding their implementation. All of these activities represent policymaking because they lead to authoritative decisions made within government for the purpose of influencing or directing the actions, behaviors, and decisions of others.

Policymaking in the judicial branch, however, does differ in certain ways from that in the legislative and executive branches, not only in focus but in operation as well. The responsibilities of courts require them to focus narrowly on the issues involved in specific cases or situations. This stands in stark contrast to the wide-open, if not chaotic, political arena in which most other public policymaking occurs.

The courts are involved in numerous and diverse aspects of health policy, reflecting the entire range of determinants of health (i.e., physical environment, behavior and genetics, social factors, and health services). For

example, in a 1980 opinion in what is called the benzene case, the U.S. Supreme Court invalidated an Occupational Safety and Health Administration (OSHA) (www.osha.gov) rule limiting benzene to no more than one part per million parts in the air in workplaces. In the court's view, OSHA had not found a significant risk to the health of workers before issuing the rule. In the past decade, the courts have been especially active in health policy regarding the organization and delivery of health services in the following four specific areas (Anderson 1992; Potter and Longest 1994):

1. the coverage decisions made by insurers in both the private and public sectors;
2. the Medicaid program's payment rates to hospitals and nursing homes;
3. the antitrust issues involved in hospital mergers; and
4. issues related to the charitable mission and tax-exempt status of not-for-profit hospitals.

The heart of the judiciary's ability to supply policies lies in its role in interpreting the law. This power includes the power to declare federal and state laws unconstitutional—that is, to declare laws enacted by the legislative branch to be null and void. This role of the courts is clearly illustrated in The Real World of Health Policy: Arizona Abortion Regulation Invades Privacy, Appeals Court Says. The judiciary also interprets the meaning of laws, an important role because many public laws contain vague language. A particularly important element in its role as suppliers of policies rests on the fact that the courts can exercise the powers of nullification, interpretation, and application to the rules and regulations established by the executive branch in carrying out its implementation responsibilities.

The Real World of Health Policy

Arizona Abortion Regulation Invades Privacy Appeals Court Says

Associated Press Story
David Kravets
June 19, 2004

San Francisco—Legislation requiring Arizona abortion clinics to submit to warrantless searches and to make patient files available to state regulators is an unconstitutional invasion of privacy, a federal appeals court ruled Friday.

The Arizona Legislature adopted those rules and others in 1999 in response to the death of Lou Anne Herron, who bled to death following a clinic abortion. The doctor, John Biskin, was convicted of manslaughter.

A panel of the 9th U.S. Circuit Court of Appeals sent the case back to lower courts to determine whether other regulations imposed on Arizona abortion clinics also should be thrown out.

The rules on warrantless searches violate constitutional restrictions on searches and seizures, Judge Sidney Thomas wrote in the 3–0 decision.

Thomas added that requiring clinics to submit patient files to state regulators on demand violates patients' privacy rights.

The appeals court said privacy rights also were violated by a requirement that abortion clinics send ultrasound results to an outside third party to examine. Doctors sometimes perform ultrasounds to determine the gestational age of a fetus.

The court ruled on a lawsuit brought by a Tucson abortion clinic. A federal judge had blocked the rules from being enforced, pending the outcome of litigation.

Priscilla Smith, a director at the Center for Reproductive Rights, which sought to overturn the legislation, said women seeking abortions might avoid clinics if their names and records would be turned over to state health officials.

The contested rules are "an example of folks who want to place burdens on abortion providers while trying to capitalize on a tragedy," she said.

Clarke Forsythe, an attorney for Americans United For Life, an anti-abortion group that backed the legislation, said the court's ruling was a "terrible decision for the protection of the health of women in Arizona."

He said the regulations "are designed to make sure women like Lou Anne Herron are not killed or injured in substandard clinics."

The Arizona attorney general has defended the regulations. Spokeswoman Andrea Esquer said state lawyers were reviewing the decision and had no immediate comment.

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An example of the interpretative role of the courts in health policymaking is the ruling by the U.S. Supreme Court in April 1995 that the federal Employee Retirement Income Security Act (ERISA) (P.L. 93-406) does not preclude states from setting hospital rates. The case that resulted in this ruling arose out of New York's practice of adding a surcharge to certain hospital bills to raise money to help pay for health services for some of the state's low-income citizens. The state's practice was challenged by a group of commercial insurers and HMOs and by New York City (Green 1995). A number of health-related interest groups filed a joint *amicus curiae* (friend of the court) brief in the case in which they asserted that Congress, in enacting ERISA, never intended for it to be used to challenge state health reform plans and initiatives. The Supreme Court's ruling is seen generally as supportive of state efforts to

broaden access to health services for their poorer residents through various reforms and initiatives.

Health policymaking within the judicial branch of government is far more prevalent in state courts and lower federal courts than in the U.S. Supreme Court. A state-level example of courts making important health policy can be seen in Pennsylvania in cases involving the tax-exempt status of healthcare organizations. In one 1995 case, for example, the Indiana County, Pennsylvania, Court of Common Pleas rebuffed the leaders of Indiana Hospital in their appeal to have the hospital's tax-exempt status restored after the exemption had been revoked by the county in 1993. In making its ruling, the court held that the hospital failed to adequately meet one of the state's tests through which an organization qualifies for tax exemption. Among other criteria, at the time of this case, the state required a tax-exempt organization "to donate or render gratuitously a substantial portion of its services."

In making its ruling, the Indiana County court took note of the fact that Indiana Hospital's uncompensated charity care in fiscal year 1994 had amounted to approximately 2 percent of its total expected compensation and contrasted this with an earlier case resulting from the revocation of the tax-exempt status of a nursing home in the state. The state supreme court decision in the St. Margaret Seneca Place nursing home case (*St. Margaret Seneca Place v. Board of Property Assessment Appeals and Review, County of Allegheny, PA*) had been that the nursing home did meet the state's test because it demonstrated that it bore more than one-third of the cost of care for half of its patients.

The variation in these and several other Pennsylvania cases in the courts' interpretation of the state's partial test for tax-exempt status (i.e., the requirement that a tax-exempt organization is "to donate or render gratuitously a substantial portion of its services") led to enactment in 1997 of clarifying legislation on this and other points regarding the determination of tax-exempt status. Late in that year, the governor of Pennsylvania signed into law House Bill 55, known as the Institutions of Purely Public Charity Act, or Act 55. This act permits an institution to meet the charitable purpose test and qualify for tax exemption if it has a charitable mission, is free of private profit motive, is designated a 501(c)(3) by the federal government, and is organized for any of the following reasons:

- relief of poverty;
- advancement and provision of education, including secondary education;
- advancement of religion;
- prevention and treatment of disease or injury, including mental retardation and mental illness;
- government or municipal purposes; or

- accomplishment of a purpose that is recognized as important and beneficial to the public and that advances social, moral, or physical objectives.

The act specifically clarified, quite liberally, how an institution could meet the requirement for donating or rendering gratuitously a substantial portion of its services. Act 55 established 3 percent of an institution's total operating expenses as the necessary contribution of charitable goods or services. In this instance, court decisions were policies themselves, and the impact of the decisions eventually led to a significant change in Pennsylvania's public laws.

It is generally acknowledged that, because the pursuit of health in the United States is so heavily influenced by laws and regulations, the courts are a major factor in the development and implementation of health policies (Christoffel 1991; Gostin 2000). The courts include not only the federal court system but also the systems of the 50 states and the territories. Each of these systems has developed in idiosyncratic ways, and each has a constitution to guide it, specific legislation to contend with, and its own history of judicial decisions. A great deal of information on the structure and operation of the U.S. legal system can be found in the outline of the legal system provided by the U.S. Department of State at http://usinfo.state.gov/products/pubs/legalotln/index.htm.

Although the federal and state courts play significant roles as suppliers of policies, their behaviors and motivations as well as their roles differ significantly from those of participants in the legislative and executive branches. In their wisdom, the drafters of the U.S. Constitution created the three branches and ensured under Article III the judicial branch's independence, at least mostly so, from the other branches.

An independent judiciary facilitates adherence to the rules of the game by which all participants in the policymaking process must play. Federal judges are appointed rather than elected, and the appointments are for life. Consequently, federal judges, once they occupy these roles, are not subject to the same self-interest concerns related to reelection that many other policymakers must face. This enhances their ability to act in the public interest, although judges, like all policymakers, vary in their personal commitments to this objective.

Interplay Among Demanders and Suppliers in the Political Marketplace

Within the context of the political marketplace, many participants—both demanders and suppliers of policies—seek to further their objectives. The various

objectives can be self-interest objectives involving some health or economic advantage or public-interest objectives based on views about what is best for the public, or at least some specific subset of society such as the elderly, poor, or medically underserved. In both cases, the outcome depends greatly on the relative abilities of some participants in the exchanges within the marketplace to influence actions, behaviors, and decisions of other participants.

It is important for anyone interested in the political marketplace to realize that not all participants have equal footing. Participants have different amounts of power and influence for use in this market, just as they do in economic markets.

Power and Influence in Political Markets

Influence in political markets, just as in private economic markets, is "simply the process by which people successfully persuade others to follow their advice, suggestion, or order" (Keys and Case 1990, 38). But to have influence, one must also have power. Power, in the context of market relationships and exchanges, whether in economic or political markets, is the potential to exert influence. More power means more potential to influence others. Therefore, an understanding of influence requires an understanding of power.

Those who wish to exert influence in the political marketplace must first acquire power, using the various sources of such power that might be available to them (Alexander and Morlock 1997). The classic scheme for categorizing the sources or bases of interpersonal power includes legitimate, reward, coercive, expert, and referent power (French and Raven 1959). Several of these bases of interpersonal power have direct application to the issue of the power of individuals, organizations, and interest groups in political markets.

Legitimate power, for example, derives from relative position in a social system or in an organization or group; this form of power is also called *formal power* or authority. It exists because it is advantageous to assign or ascribe certain powers to individuals, organizations, or groups for them to be able to fulfill their duties or to perform their work effectively. Thus, elected officials, appointed executives, and judges, as well as health professionals, corporation executives, union leaders, and many other individual participants in the political marketplace possess certain legitimate power that accompanies their social or organizational positions. Similarly, certain organizations and interest groups, including both suppliers and demanders of policies, possess legitimate or formal power. That is, they can exert influence in the policymaking process because they are recognized as legitimate in the process.

Reward power is based on the ability of one person, organization, or group to reward others when they comply with preferences regarding decisions and actions. Reward power stems in part from the legitimate power a person, organization, or group holds. Reward power comes in many forms. Within organizations, it includes the obvious: pay increases, promotions, work

and vacation schedules, recognition of accomplishments, and such status symbols or perks as club memberships and office size and location. In economic markets, reward power lies in the hands of consumers by virtue of their buying power. In political markets, reward power is more likely to come in the form of such political capital as favors that can be provided or exchanged, specific influence with particular individuals or groups, and whatever influence can be stored for later use. *Coercive power* is the opposite of reward power and is based on the capacity to withhold or to prevent someone from obtaining desired rewards.

Expert power, which tends to reside in individuals more so than the other sources of power, but which can also reside in a group or organization, derives from possessing expertise valued within the political marketplace, such as expertise in solving problems or performing crucial tasks. People with expert power often occupy formal positions of authority in organizations or groups, which transfers some of the expert power to that organization or group. People with expert power that can be exercised in the policymaking arena may also be trusted advisers or associates of other participants in the political marketplace.

Referent power derives from the fact that some people, organizations, and interest groups engender admiration, loyalty, and emulation from others to such an extent that they gain power to exert influence as a result. In the marketplace for policies, this form of power, when it pertains to individuals, is called *charismatic power*. Charismatic power usually belongs to a select few people, who typically have very strong convictions about the correctness of their preferences and great self-confidence in their own abilities and who are widely perceived to be legitimate agents of change. It is rare for a person, organization, or interest group to be able to gain sufficient power to heavily influence policymaking simply from referent or charismatic power, even in political markets where charisma is highly valued. But it can certainly give the other sources of power in the political marketplace a boost.

Importantly, for the use of power and for understanding its impact, these bases of power in the political marketplace are interdependent. They can and do at times complement or conflict with each other. For example, people, organizations, or groups that are in a position to use reward power and who do so wisely can strengthen their referent power. Conversely, those who abuse coercive power might quickly weaken or lose their referent power. Effective participants in the marketplace for policies—those individuals, organizations, and groups that succeed at translating their power into influence—tend to be fully aware of the sources of their power and to act accordingly. They seem to understand intuitively the costs and benefits associated with using each kind of power they possess and can draw on them appropriately in different situations and with various people they wish to influence.

Power and Influence of Interest Groups

Some interest groups, including several in the health domain, have been extraordinarily powerful and influential participants in the political marketplace. These groups are very effective demanders of public policies. To fully appreciate the extent of their power and the influence it permits, it is necessary to understand *iron triangles*, a model of the relationships that sometimes exist among participating individuals, organizations, and groups in the political marketplace.

Any policy domain, whether it be health or another domain such as defense or education, attracts a set of participating individuals, organizations, and groups, each of which has some stake in the policies affecting the domain and thus seeks to play a role in policymaking in the domain. Some of the participants, or stakeholders, in a domain demand policies; others supply policies. These stakeholders form a *policy community*, whose members share an interest in a particular policy domain.

Traditionally, the membership in the policy community formed around a particular policy domain such as health has included any legislative committees with jurisdiction in the domain, the executive branch agencies responsible for implementing public laws in the domain, and the private-sector interest groups involved in the domain. The first two categories are suppliers of the policies demanded by the third category. This triad of organized interests has been called an iron triangle because its three sides provide stability and the ability to withstand attempts to make undesired changes in the status quo, at least when all three sides of the triangle are in accord on the appropriate policies in the domain.

A policy community that could be appropriately characterized as a very strong and stable iron triangle dominated the health policy domain until the early 1960s, when battle lines began to be drawn over the eventual shape of Medicare policy. This triangle featured a small number of powerful interest groups with concordant views that, for the most part, had sympathetic partners in the legislative committees and in the relevant implementing agencies of government.

During this period, the private-sector interest group members of the iron triangle that dominated health policy, notably AMA and the American Hospital Association (AHA) (www.aha.org), joined later by the American College of Physicians (ACP) (www.acponline.org) and the American College of Surgeons (ACS) (www.facs.org), generally held a consistent view of the appropriate policies in this domain. Their shared view of optimal health policy was that government should protect the interests of health services providers and not intervene in the financing or delivery of health services (Peterson 1993). Under the conditions and expectations extant in these largely straightforward relationships, it was relatively simple for the suppliers and demanders

of policies to satisfy each other. This triangle was unbreakable into the second half of the twentieth century.

Beginning with the policy battles over Medicare and with the addition of Medicaid to the debate, however, the dynamics of the situation began to change dramatically. Fundamental differences emerged among the participants in the health policy community in terms of their views of optimal health policy. An example of such differences is clearly reflected in The Real World of Health Policy: Dueling Press Releases on Prescription Drug Importation.

The Real World of Health Policy

Dueling Press Releases on Prescription Drug Importation

In mid-2004, two senators introduced Senate Bill 2328, known as the Pharmaceutical Market Access and Drug Safety Act of 2004. Their intent was for the proposed legislation to amend the Federal Food, Drug, and Cosmetic Act (FFDCA) to revise provisions governing the importation of prescription drugs. The proposed legislation would require the Secretary of Health and Human Services to promulgate regulations allowing the importation of prescription drugs by registered exporters or registered importers from Canada within 90 days of passage of the act and from Australia, European Union countries, Japan, New Zealand, or Switzerland within one year. Two important interest groups expressed substantial differences on this legislation, as follows.

Statement by the American Association of Retired Persons (AARP), June 16, 2004

AARP today is endorsing the bipartisan bill (S. 2328)—sponsored by Senators Byron Dorgan (D-ND) and Olympia Snowe (R-ME), and 23 cosponsors—to legalize the safe importation of prescription drugs, beginning with Canada. This is another important step to help lower drug prices. We will aggressively work for its passage.

The Medicare Modernization Act is an important foundation, but much more must be done to control the cost of prescription drugs, and to make sure that our members and their families have access to the drugs they need. AARP recently released a study showing that prescription drug prices in 2003 increased at nearly triple the rate of inflation. Americans need affordable prescription drugs now.

Though not a complete solution to the problem of high drug costs, safe and legal importation will help put downward pressure on prices and enable consumers to secure additional savings.

AARP is engaged in a national prescription drug affordability campaign that includes importation as one of several measures to contain prices. Other steps

include advocacy to lower state prescription drug spending, litigation, calling on the industry to limit price increases to the rate of inflation, shining a spotlight on prices (our Watchdog program), promoting the use of appropriate generics and speeding their availability to market, and educating consumers about the wise use of medications and the new Medicare law, including the Medicare discount card.

It is a national embarrassment that citizens must purchase from other countries to afford prescription drugs. It is no longer a question of *whether* we should allow the importation of drugs from abroad. Importation is already happening on a large scale; we must ensure that there is a system in place for guaranteeing safety and cost savings.

The Dorgan-Snowe legislation contains important safety standards urged by AARP, including a system of registration, inspection, and tracking of imported drugs; anti-tampering and anti-counterfeiting technologies; and labeling of imported drugs. The legislation also includes a requirement for a website and toll-free telephone number that consumers can use to locate reputable sites for the purchase of imported drugs.

Also critical to the legislation are measures to prevent pharmaceutical companies from limiting supplies of drugs to entities from which lower cost pharmaceuticals would be imported. These are elements AARP considers important to any legislation.

This bill meets the challenges of designing an importation program that protects the integrity of pharmaceuticals and provides a streamlined process that enables consumers to access lower cost drugs. We will work hard for enactment this year.

Statement by the Pharmaceutical Research and Manufacturers of America (PhRMA) on AARP's Endorsement of S. 2328, June 17, 2004.

AARP's embrace of legislation that poses serious patient safety risks is disappointing.

S. 2328 would allow pharmaceutical products into this country that have not been approved by the Food and Drug Administration (FDA) or properly regulated by any other agency.

The bill would allow products to be transshipped to unsuspecting American patients from countries that don't have the same safety standards as the U.S., that don't regulate transshipped products and that, in some cases, have counterfeiting problems.

An expensive and complex new importation program would have to be implemented within the unrealistic time frame of 90 days. And importation would be automatically extended to 19 other countries after the first year, even if safety problems were identified and the FDA had concerns about administering a new importation program properly.

Importation also could involve high product-liability insurance costs and it would be a threat to the innovation of the world's most innovative pharmaceutical and biotechnology research industry, which provides 60 percent to 70 percent of the world's new medicines. We should not be importing the government-mandated price controls of other countries that have hurt the ability of their pharmaceutical companies to create new medicines.

Moreover, analysis from the nonpartisan Congressional Budget Office suggests that after the middlemen of any importation scheme receive their cut, the savings to patients could be less than one percent.

We should be focusing on the safe, practical alternatives to risky importation, including Medicare-approved discount cards and the hundreds of patient-assistance and discount programs that help millions of patients every year and the provision of more and better drug coverage.

SOURCES: American Association of Retired Persons (AARP). 2004. [Online press release; retrieved 6/15/05.] *www.aarp.org/research/press-center/presscurrentnews/a2004-06-15-importation.html*. Reprinted with permission from AARP.

Pharmaceutical Research and Manufacturers of American (PhRMA). 2004. [Online press release; retrieved 6/15/05.] *www.phrma.org/mediaroom/press/releases/17.06.2004.1029.cfm*. Reprinted with permission from PhRMA.

Today, there is rarely a solid block of concordant private sector interests driving health policy decisions. For example, fundamental differences over questions of optimal policy shattered the old homogeneous position on health policy between AMA and AHA. Even more damaging, a process of splintering within the memberships of these groups began. For example, the medical profession no longer speaks through the single voice of AMA; organizations such as ACP and the American Academy of Family Physicians (AAFP) (www.aafp.org) can and sometimes do support different policy choices. Similarly, AHA now is joined in policy debates by the diverse preferences of organizations representing the specific interests of teaching hospitals, public hospitals, for-profit hospitals, or some other subset of hospitals. These changes among the private-sector interest groups eroded the previous solidarity between their concordant interests and the public-sector members of the health policy community.

Rather than an iron triangle, the contemporary health policy community is more accurately described as "heterogeneous and loosely structured, creating a network whose broad boundaries are defined by the shared attentiveness of participants to the same issues in the policy domain" (Peterson 1993, 409). There is an important difference, however, between shared attentiveness to health policy issues and agreed-on positions on optimal health policy or on issues related to it. The loss of concordance among the members

of the old iron triangle in health policy has somewhat diminished the power of certain interest groups. Nevertheless, they remain highly influential, and other interest groups have been able to assume influential roles in health policymaking as well. On balance, interest groups remain extraordinarily powerful influences in health policymaking.

Ethics in the Political Marketplace

A fundamental fact about political markets as places where individuals, organizations, and groups seek to further their policy objectives is that humans control them. Thus, various mixes of altruism and egoism influence what takes place in political markets. Human control of the public policymaking process means that its operation as well as its outcomes and consequences are directly affected by the ethics of those who participate in the process.

Ethics play an important part in the operation of political markets and in the public policymaking processes that unfold within them. Ethical considerations help shape and guide the development of new policies by contributing to ways in which problems are defined and their policy solutions are structured. Ethical behavior, for any and all participants in the political markets where policymaking occurs, is guided by four philosophical principles: respect for the autonomy of other people, justice, beneficence, and nonmaleficence.

The ethical principle of respect for *autonomy* is based on the concept that individuals have the right to their own beliefs and values and to the decisions and choices that further these beliefs and values. This ethical principle undergirds much of the formal system of government that the nation's founders envisioned. Beauchamp and Childress (2001) have pointed out that no fundamental inconsistency or incompatibility exists between the autonomy of individuals and the authority of government so long as government's authority does not exceed the limits set by those who are governed. In this context, autonomy pertains to the rights of citizenship in the United States. Specifically, autonomy relates to the rights of individuals to independent self-determination regarding how they live their lives and to their rights regarding the integrity of their bodies and minds. Respect for autonomy in health policymaking influences issues that pertain to privacy and individual choice, including behavioral or lifestyle choices.

Public policymaking that reflects a respect for the principle of autonomy can sometimes be better understood in contrast to its opposite—paternalism. Paternalism implies that someone knows what is best for other people. Policies guided by a preference for autonomy limit paternalism. One of the most vivid examples of the influence of the principle of autonomy in health policymaking is the 1990 Patient Self-Determination Act (P.L. 101-508). This policy is designed to give individuals the right to make decisions concerning their medical care, including the right to accept or refuse treatment and the right to formulate advance directives regarding their care.

These directives allow competent individuals to give instructions about their healthcare, to be implemented at some later date should they then lack the capacity to make medical decisions. In concept, this policy gives people the right to exercise their autonomy in advance of a time when they might no longer be able to exercise that right actively. In the absence of such directives, decisions may fall to the courts. On occasion they have done so, generating national attention. Well-known cases include Karen Ann Quinlan (in 1976, a New Jersey court ruled in favor of the removal of a respirator from the brain-damaged woman); Nancy Cruzan (in 1990, the U.S. Supreme Court ruled that a feeding tube could be withdrawn); and Terri Schiavo (in 2005, a Florida court judge ruled that the feeding tube keeping her alive in a persistent vegetative state could be removed, and following unprecedented action by Congress, a federal judge refused to order the reinsertion of the feeding tube [Goodnough and Hulse 2005; Findlaw.com 2005]).

The principle of respect for autonomy includes several other elements that are especially important in guiding ethical behavior in policymaking. One of these is telling the truth. Respect for people as autonomous beings implies honesty in relationships. Closely related to honesty is the element of confidentiality. Confidences broken in the policymaking process can impair the process. A third element of the autonomy principle that is important to the policymaking process is fidelity. This means doing one's duty and keeping one's word. Fidelity is often equated with keeping promises. When participants in the policymaking process tell the truth, honor confidences, and keep promises, the process is more ethically sound than if these things are not done.

Another ethical principle of significant importance to public policymaking is the principle of *justice*. The degree of adherence to this principle directly affects the policymaking process and policies themselves. In Rawls's (1971, 5) words, "One may think of a public conception of justice as constituting the fundamental charter of a well-ordered human association." Much of its impact on policies and policymaking hinges on defining justice as fairness (Rawls 1971). The principle of justice also includes the concept of just deserts, which holds that justice is done when a person receives that which he or she deserves (Beauchamp and Childress 2001).

The practical implications for health policymaking of the principle of justice are felt mostly in terms of distributive justice—that is, in terms of fairness in the distribution of health-related benefits and burdens in society. It has been argued that (Gostin 2000, 104–05)

> Public health policy is just (fair) where, to the extent possible, it provides services to those in need and imposes burdens and costs on those who endanger the public health. Services provided to those without need are wasteful and, given scarce resources, may deny benefits to those with genuine need. Regulation aimed at

persons or businesses where there is no danger imposes costs and burdens without a corresponding public benefit. Ideally, services should be allocated on the basis of need and burdens should be imposed only where necessary to prevent a serious health risk.

The most difficult policy question deriving from application of the ethical principle of justice is, of course, what is fair? The various participants in political markets and in the health policymaking process hold varying opinions on the issue of what is fair distribution of the benefits and burdens involved in the pursuit of health in American society. Useful insight into the range of possible views on fairness in this matter can be gained from considering the three most prominent perspectives on justice.

The *egalitarian* perspective of justice holds that everyone should have equal access to both the benefits and the burdens arising from the pursuit of health and that fairness requires recognition of different levels of need. The influence of the egalitarian view of justice can be seen in a number of health policies. Policies intended to remove discrimination in the provision of health services reflect the preference for equality; those intended to provide more resources to people who need them most (e.g., Medicare for the elderly, Medicaid for the poor) are also based on an egalitarian view of fairness.

The *libertarian* perspective of fairness requires a maximum of social and economic liberty for individuals. Policies that favor unfettered markets as the means of distributing the benefits and burdens associated with the pursuit of health reflect the libertarian theory of justice.

The third perspective, the *utilitarian* view of fairness, is best served when public utility is maximized. This is sometimes expressed as the greatest good for the greatest number. Many health policies, including those pertaining to restricting pollution, ensuring safe workplaces, and controlling the spread of communicable diseases, have been heavily influenced by a utilitarian view of what is just in the distribution of the benefits and burdens arising from the American pursuit of health.

The principle of justice provides much of the underpinning for all health policies, whether they are in the allocative or regulatory categories. Allocative policies that adhere closely to the principle of justice allocate benefits and burdens according to the provisions of a morally defensible system rather than through arbitrary or capricious decisions. Regulatory policies that are guided by the principle of justice have a fair and equitable impact on those to whom the regulations are targeted. The nation's legal system exists in part to help ensure that the principle of justice is respected in the formulation and implementation of public policies and to serve as an appeals mechanism for those who believe that the process has not adequately honored this principle.

Two other ethical principles have direct relevance to public policymaking: beneficence and nonmaleficence. *Beneficence* in policymaking means that

participants in the process act with charity and kindness; that is, they overtly seek to do good. This principle is widely reflected in policies through which benefits in some tangible form are provided. Thus, application of the principle of beneficence characterizes such allocative policies as the Medicare and Medicaid programs. But beneficence includes the complex concept of balancing benefits and burdens. Participants in the political marketplace who seek policies that benefit them or their interests exclusively while burdening others violate the principle of beneficence. Policymakers who are guided by the principle of beneficence make decisions that maximize the net benefits to society as a whole and balance fairly the benefits and burdens of their decisions.

Nonmaleficence, a principle with deep roots in medical ethics, is exemplified in the dictum *primum non nocere*—first, do no harm. Policymakers who are guided by the principle of nonmaleficence make decisions that minimize harm. The principles of beneficence (do good) and nonmaleficence (do no harm) are clearly reflected in health policies that seek to ensure the quality of health services and products. The Real World of Health Policy: Centers for Medicare & Medicaid Services (CMS) Seeks Public Comment on Standardized Quality Measures Recommended for Ambulatory Care and Patient Perspectives on Hospital Care provides an example of such policy. Similarly, policies such as those that the Food and Drug Administration uses to ensure the safety of pharmaceuticals and the policies that established and maintain the Agency for Healthcare Research and Quality (AHRQ) (www.ahrq.gov or www.ahcpr.gov) are also examples of policies that reflect the principles of beneficence and nonmaleficence.

The Real World of Health Policy

Centers for Medicare & Medicaid Services (CMS) Seeks Public Comment on Standardized Quality Measures Recommended for Ambulatory Care and Patient Perspectives on Hospital Care

CMS Press Release
November 16, 2004

Medicare is taking another important step to improve the quality of healthcare by identifying and requesting public comment on standard information to be used to publicly report both on how well a physician treats certain illnesses and patient perspectives on the quality of care received during a hospital stay.

"We are one step closer to bringing more useful information about the quality of care patients receive from their physicians and hospitals to help them make informed decisions about their care," said Health and Human Services

Secretary Tommy G. Thompson. "Having 'apples-to-apples' comparisons will also help us address the strengths and weaknesses of healthcare providers so they can improve the quality of the care patients get."

As part of Medicare's comprehensive quality improvement efforts, the Centers for Medicare & Medicaid Services (CMS) has submitted standardized measures, called ambulatory care measures, to the National Quality Forum (NQF) for review and comment. The measures will be used to pay physicians to monitor, report on, and improve the care provided to Medicare beneficiaries. The NQF is a non-profit organization that provides endorsement of consensus-based national standards for measurement and public reporting of healthcare performance data.

An additional set of survey questions to measure patient perspectives on the care they receive when they are hospitalized was also submitted to NQF for their consensus-based endorsement process. CMS will also publish a *Federal Register* notice asking for public comment and input about the survey questions.

"We have already begun to see improvements in the quality of care available in the nation's nursing homes and home health agencies since that information has first been measured and publicly reported," said CMS Administrator Mark B. McClellan, M.D., Ph.D. "We're continuing to work closely with the experts to help us make sure we are asking the right questions to improve the already high quality of care available in the nation's hospitals and to begin to focus new attention on the quality of care available in doctors' offices."

As part of the Hospital Quality Initiative, CMS intends to publicly report a broad set of hospital clinical measures along with measures of hospital patient perspectives on care. CMS has been working closely with HHS' Agency for Healthcare Research and Quality (AHRQ) to develop a standardized survey tool to assess patient perspectives, called HCAHPS. AHRQ conducted a very careful, multi-step process to develop HCAHPS that included consumer testing, stakeholder and public input, a pilot test in three states, additional small-scale field tests, and extensive psychometric analysis. CMS anticipates that hospitals will begin data collection using HCAHPS in 2005.

The questions selected for consensus review look at key areas including overall ratings of the hospital, communication with doctors, communication with nurses, responsiveness of hospital staff, pain control, communication about medicines, cleanliness and quiet of the hospital environment, and discharge information. The recommended questions are meant to complement, not replace, information hospitals currently collect to support improvements they use to support their own improvements in customer service and care.

Public reporting of data to improve quality of care began in 2003 under the auspices of the National Hospital Quality Alliance, a public-private effort on quality reporting that supported the development of Medicare's Hospital Quality Initiative. The Hospital Quality Alliance is a joint effort of the American Hospital Association, the Federation of American Hospitals, the American Association of Medical Colleges, the Joint Commission on Accreditation of Healthcare

Organizations, National Quality Forum, the American Nurses Association, the American Medical Association, the AFL-CIO, AARP, the Consumer-Purchaser Disclosure Project, the National Association of Children's Hospitals and Related Organizations, CMS and AHRQ. Later this month, CMS will post updated quality information reported by nearly 4,000 hospitals on ten hospital measures at www.cms.hhs.gov.

Beginning early in 2005, the hospital quality data will be available on the CMS website for consumers www.medicare.gov or by calling 1-800-MEDICARE (800-633-4227). CMS currently publishes quality information on www.medicare.gov for Medicare and Medicaid-certified nursing homes, Medicare-certified home health agencies, dialysis facilities and Medicare Advantage plans. The agency's overall quality initiative also focuses on improving the quality of care in home health agencies, nursing homes and hospitals using hands-on training and resources from Medicare's Quality Improvement Organizations.

The proposed ambulatory care measures—those that look at the quality of care available in doctors' offices—are part of an effort with the American Medical Association's Physician Consortium for Performance Improvement and the National Committee for Quality Assurance. The goal is to measure the improvement of care for such clinical conditions as coronary artery disease and heart failure, diabetes, high blood pressure, osteoarthritis, asthma, behavioral health, prenatal care and preventive care. CMS anticipates that the approved measures will be incorporated into ongoing quality improvement efforts and demonstrations that will be underway in early 2005.

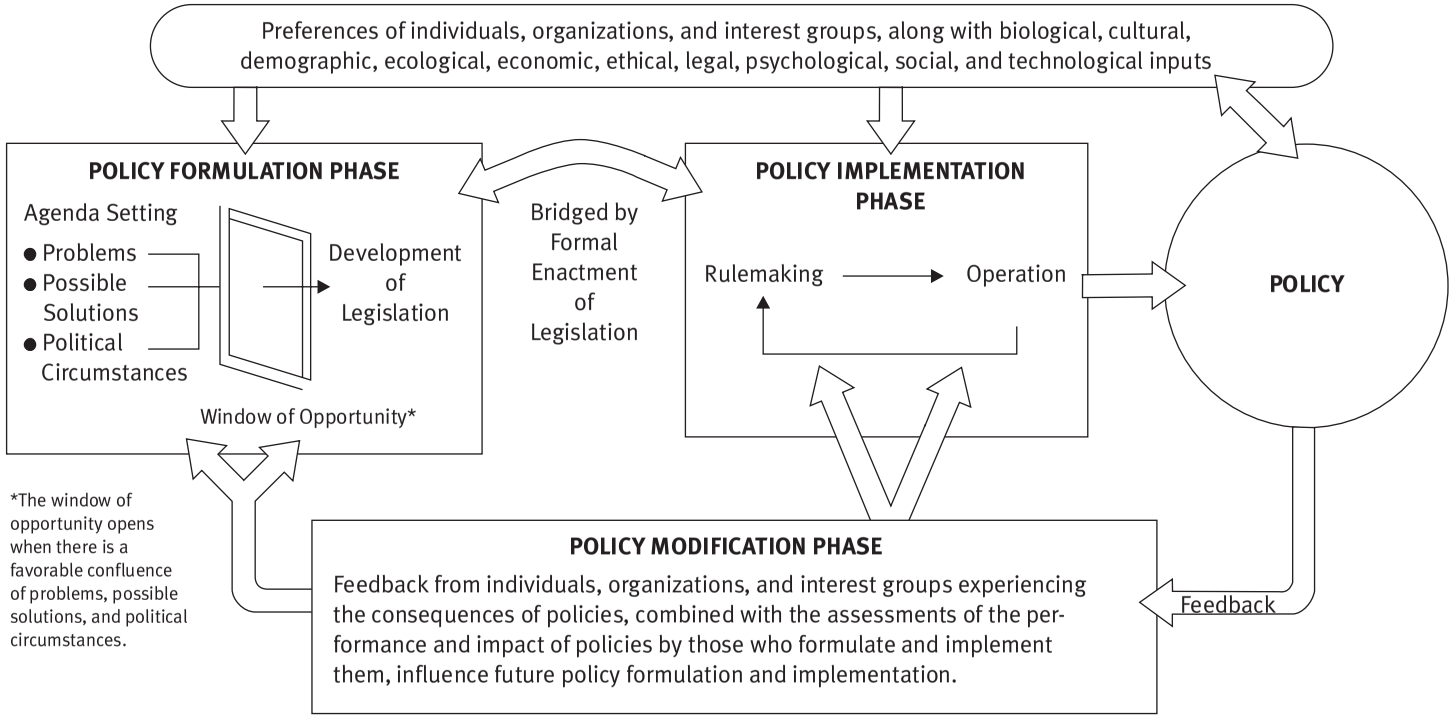
SOURCE: Centers for Medicare & Medicaid Services. 2004. [Online press release; retrieved 1/28/05.] Reprinted from www.cms.hhs.gov/media/press/release.asp?Counter=1259.

Having considered the context within which health policies are made, especially the structure and operations of the political markets for policies, and having identified the demanders and suppliers who interact in these markets as well as some of the important operational and ethical aspects of these interactions, it is now possible to consider the intricate process through which public policies are made. The consideration begins in this chapter at the conceptual level; an applied discussion of the policymaking process follows in subsequent chapters.

A Conceptual Model of the Public Policymaking Process

The most useful way to conceptualize a process as complex and intricate as the one through which public policies are made is through a schematic model of the process. Although such models, like the one presented here, tend

FIGURE 3.2 A Model of the Public Policymaking Process in the United States



to be oversimplifications of real processes, they nevertheless can accurately reflect the component parts of the process as well as their interrelationships. Figure 3.2 is a model of the public policymaking process in the United States. The component parts of the model serve to structure much more detailed discussions of the process in subsequent chapters. Several key features of the policymaking process, as reflected in this model, are discussed next and are important to understanding the policymaking process.

Policymaking Is a Cyclical Process

As the model in Figure 3.2 illustrates, the policymaking process is distinctly cyclical. The circular flow of the relationships among the various components of the model reflects one of the most important features of public policymaking. The process is a continual cycle in which all decisions are subject to subsequent modification. Public policymaking, including that in the health domain, is a process within which numerous decisions are reached but then revisited as circumstances change. This cyclical nature of health policymaking, in which decisions are made and then revisited, can be seen in the pattern of Medicare policy presented in The Real World of Health Policy: Medicare Revisited—Again and Again.

The Real World of Health Policy

Medicare Revisited—Again and Again

This chronological list contains some of the key legislative changes that have been made in the Medicare program since its enactment. The list reflects how frequently and substantively the program has been modified.

1965 Medicare was enacted as Title XVIII of the Social Security Act, extending health coverage to almost all Americans aged 65 or older. Medicare was implemented and more than 19 million individuals enrolled on July 1, 1966.

1972 Medicare eligibility was extended to individuals under age 65 with long-term disabilities and to individuals with end-stage renal disease (ESRD). Medicare was given the authority to conduct demonstration programs.

1977 The Health Care Financing Administration (HCFA) was established to administer the Medicare program. On July 1, 2001, HCFA became the Centers for Medicare & Medicaid Services (CMS).

1980 Coverage of Medicare home health services was broadened. Medicare supplemental insurance, also called "Medigap," was brought under Federal oversight.

1982 The Tax Equity and Fiscal Responsibility Act made it easier and more attractive for health maintenance organizations to contract with the Medicare program. In addition, the Act expanded CMS's quality oversight efforts through Peer Review Organizations (PROs).

1983 An inpatient acute hospital prospective payment system (PPS) for the Medicare program, based on patients' diagnoses, was adopted to replace cost-based payments.

1985 The Emergency Medical Treatment and Labor Act (EMTALA) required hospitals participating in Medicare that operated active emergency rooms to provide appropriate medical screenings and stabilizing treatments.

1988 The Medicare Catastrophic Coverage Act, which included the most significant changes since enactment of the Medicare program, improved hospital and skilled nursing facility benefits for beneficiaries, covered mammography, and included an outpatient prescription drug benefit (The Medicare Catastrophic Coverage Act) and a cap on patient liability.

The Qualified Medicare Beneficiary (QMBs) program was established to pay Medicare premiums and cost sharing charges for beneficiaries with incomes and resources below established thresholds.

1989 The Medicare Catastrophic Coverage Act of 1988 was repealed after higher-income elderly protested new premiums. A new Medicare fee schedule for physician and other professional services, a resource-based relative value scale, replaced charge-based payments. Limits were placed on physician balance billing above the new fee schedule. Physicians were prohibited from referring Medicare patients to clinical laboratories in which the physicians, or physicians' family members, have a financial interest.

1990 Specified Low-Income Medicare beneficiary eligibility group was established (SLMBs) for Medicaid programs to pay Medicare premiums for beneficiaries with incomes at least 100 percent but not more than 120 percent of the FPL and limited financial resources. Additional federal standards for Medicare supplemental insurance were enacted.

1996 The Health Insurance Portability and Accountability Act of 1996 (HIPAA) had implications for the Medicare program. The Act created the Medicare Integrity Program which dedicated funding to program integrity activities and allowed CMS to competitively contract for program integrity work. HIPPA also created national administrative simplification standards for electronic healthcare transactions that applied to Medicare.

1997 The Balanced Budget Act of 1997 (BBA) changed Medicare in a number of ways, including:

- established an array of new Medicare managed care and other private health plan choices for beneficiaries, offered through a coordinated open enrollment process;
- expanded education and information to help beneficiaries make informed choices about their healthcare;
- required CMS to develop and implement five new prospective payment systems for Medicare services (for inpatient rehabilitation hospital or unit services, skilled nursing facility services, home health services, hospital outpatient department services, and outpatient rehabilitation services);
- slowed the rate of growth in Medicare spending and extending the life of the trust fund for 10 years;
- provided a broad range of beneficiary protections;
- expanded preventive benefits; and
- called for testing other innovative approaches to payment and service delivery through research and demonstrations.

1998 The internet site www.medicare.gov was launched to provide updated information about Medicare.

1999 The toll-free number, 1-800-MEDICARE (1-800-633-4227), became available nationwide. The first annual *Medicare & You* handbook was mailed to all Medicare beneficiary households.

1999 The Ticket to Work and Work Incentives Improvements Act of 1999 (TWWIIA) expanded the availability of Medicare and Medicaid for certain disabled beneficiaries who return to work. The Balanced Budget Refinement Act of 1999 (BBRA) increased payments for some Medicare providers.

2000 The Benefits Improvement and Protection Act (BIPA) further increased Medicare payments to providers and managed healthcare organizations, reduced certain Medicare beneficiary copayments, and improved Medicare's coverage of preventive services.

2003 The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) made the most significant changes to Medicare since the program began. MMA creates a prescription drug discount card until 2006, allows for competition among health plans to foster innovation and flexibility in coverage, covers new preventive benefits, and makes numerous other changes. In 2006, the new voluntary Part D outpatient prescription drug benefit will be available to beneficiaries from private drug plans as well as Medicare Advantage plans. Employers who provide retiree drug coverage comparable to Medicare's will be eligible for a federal subsidy.

Medicare will consider beneficiary income for the first time: beneficiaries with incomes less than 150 percent of the federal poverty limit will be eligible

for subsidies for the new Part D prescription drug program; beneficiaries with higher incomes will pay a greater share of the Part B premium starting in 2007.

SOURCE: U.S. Department of Health and Human Services. 2004. Excerpted from "Key Milestones in CMS Programs." [Online information; retrieved 1/29/05.] www.cms.hhs.gov/about/history/milestones.asp.

Policymaking Is Influenced by External Factors

Another important feature of the public policymaking process shown in Figure 3.2 is that the entire process is influenced by factors external to the process itself. This makes the policymaking process an *open system*, one in which the process interacts with and is affected by events and circumstances in its external environment. This important phenomenon is shown in the model by the impact of the preferences of the individuals, organizations, and interest groups that are affected by policies—along with biological, cultural, demographic, ecological, economic, ethical, legal, psychological, social, and technological inputs—on the policymaking process.

Legal inputs, which include decisions made in the courts, are themselves policies as was discussed in Chapter 1. In addition, however, decisions made within the legal system are important influences on the other decisions made within the policymaking process. Legal inputs help shape all other policy decisions, including reversing them on occasion when they are not consistent with the constitution.

The impact of technology provides another example of the effect of external factors on the policymaking process. The United States is the world's major producer and consumer of health-related technology. As the policymaking model shows, technological inputs flow into the policymaking process. Among other impacts, the costs of new technologies must be factored into public, as well as private, insurance programs. The Real World of Health Policy: Congressional Budget Office Director Testifies on the Role of Technology in the Continuing Growth in Health Care Spending discusses the role of technology in health spending and its impact on health policymaking. Figure 3.2 also shows that technology is affected by the policies produced by the process. Congressional decisions regarding the annual funding for the National Institutes of Health are good examples of such impacts.

The Real World of Health Policy

Congressional Budget Office Director Testifies on the Role of Technology in the Continuing Growth in Health Care Spending

The following statement is excerpted from testimony provided by Douglas Holtz Eakin, director of the Congressional Budget Office, before the U.S. Senate

Committee on Health, Education, Labor, and Pensions(help.senate.gov), January 28, 2004.

* * *

Most analysts agree that the perennial increases in health care spending that have occurred over recent decades are associated with the diffusion of new medical technologies, or as one analyst has described it, "the enhanced capabilities of medicine."[1] Recent advances, including pharmaceutical innovations, have made available to patients and physicians a wealth of new medical therapies, many unheard of in even the relatively recent past. The economic incentives for innovation and the development, deployment, and utilization of new technologies in the U.S. health care system has led generally to higher levels of spending. Some medical advances permit the treatment of previously untreatable conditions, introducing new categories of spending. Others, relative to older modes of treatment, improve medical outcomes at added cost, expanding existing spending.

It is occasionally suggested that advances in technology can lead to reduced spending, and that may be the case in some instances. Vaccinations, for example, may sometimes offer the potential for savings, and certain types of preventive medical care may help some patients avoid costly acute care hospitalizations. But, overall, examples of new therapies for which long-term savings have been clearly demonstrated are few. Improvements in medical care that decrease mortality by helping patients avoid or survive acute health problems paradoxically increase overall spending on health care, as those (surviving) patients live to utilize health services through old age.

Even when a particular service becomes cheaper to provide over time, higher aggregate spending can still result as practice patterns emerge and the service is used with greater frequency. Comparing increased expenditures on computers and information technology with those on health care is instructive. As technological innovations permitted profitable computer processing at a fraction of the previous cost, total spending on computers did not decrease—it skyrocketed, as more consumers made more intensive use of what became available. Why do few people regard increasing spending on information technology as a problem requiring a remedy? Let me suggest that the reason is that the market for information technology works the way a market is intended to function: businesses and consumers weigh alternatives and face the full costs of what they use. In health care, two factors combine to produce a different result: payments made by third parties typically buffer patients from the full cost of the medical services they use, and the inherent complexity of medical practice forces patients to rely on the judgment of providers who, depending on the reimbursement system, may have an incentive to provide more care (under a fee-for-service arrangement) or less care (under capitation).

Other factors have also contributed to increases in health spending. One obvious example is the aging of the population. Among adults, medical spending

generally increases with age. As the number of elderly people rises with the aging of the very large baby-boom generation, health spending will naturally grow. However, over the past half century, aging has played a relatively minor role in the very large increases in spending that have occurred.

Other contributing factors include the growth in personal income over time and the spread of health plans over recent decades. Because medical care is a desired service, people naturally purchase more of it as their income increases. And health insurance, as economists are fond of pointing out, effectively drives down the cost of care from the consumer's perspective, resulting in a higher quantity demanded than would otherwise be the case. But the best estimates of the effects of those two factors suggest that they, too, fail to explain much of the surge in spending in recent decades.

Claims are often heard about unwarranted expenditures. One example is so-called defensive medicine, which refers to medical tests or procedures of little or no clinical value that are ordered by physicians solely in the interest of avoiding lawsuits. Another example is what some people term physician-induced demand, which refers to spending that is brought about at least in part by providers' desire to augment their own income. While the magnitude of spending associated with such practices has been the subject of considerable debate, those factors do not appear to explain much of the growth in spending.[2]

What I have presented here is a simple discussion of a complex issue, and I do not intend for it to represent an exhaustive or definitive review of the subject. The association between technological change and rising medical expenditures is the manifestation of a complex system of economic incentives that need to be examined in more detail. A greater understanding of the possible role of the third-party payment system in creating incentives for innovation and the diffusion of technologies, for example, could inform public policy aimed at addressing the continuing increases in spending. At the same time, policymakers could choose to spend more in light of the quality enhancements resulting from the remarkable medical advances that have been made in recent years. The point to emphasize (and about which there is general consensus) is that the way new medical technologies have been adopted and utilized has generally led to more health spending over time; that factor lies at the heart of increasing expenditures for health care. In the absence of a change in overall incentives, those pressures can be expected to continue.

* * *

NOTES:

1. Joseph P. Newhouse. 1993. "An Iconoclastic View of Health Cost Containment," *Health Affairs*, Vol. 12, supplement, pp. 152–171.

2. An important distinction must be drawn between the level of health spending and its rate of growth. At any given moment, some amount of unneeded expenditure is likely, but regardless of the magnitude of that amount, few analysts believe that such expenditures can account for much of the large spending increases that have taken place. The elimination of unneeded expenditures, while certainly desirable, would offer only temporary relief from increasing expenditures, as the underlying source of spending growth can be expected to eventually reemerge.

SOURCE: Eakin, D. H. 2004. Testimony before the United States Senate Committee on Health, Education, Labor, and Pensions, January 28. [Online testimony (excerpted); retrieved 1/29/05.] The entire testimony can be read at www.cbo.gov/ftpdocs/49xx/doc4989/01-28-Health Testimony.pdf.

The Components of the Policymaking Process Are Interactive and Interdependent

A third important feature of the policymaking model is that while it emphasizes the various distinct component parts or phases of the policymaking process, it also shows that they are highly interactive and interdependent. The conceptualization of the public policymaking process as a set of interrelated phases has been used by a number of authors, although there is considerable variation in labeling the phases of activities in these models as well as in their comprehensiveness. Paul-Shaheen (1990) applies such a model specifically to health policymaking.

The public policymaking process modeled in Figure 3.2 includes the following three interconnected phases:

1. policy formulation, which incorporates activities associated with setting the policy agenda and, subsequently, with the development of legislation;
2. policy implementation, which incorporates activities associated with rulemaking that help guide the implementation of policies and the actual operationalization of policies; and
3. policy modification, which allows for all prior decisions made within the process to be revisited and perhaps changed.

The formulation phase (making the decisions that lead to public laws) and the implementation phase (taking actions and making additional decisions necessary to implement public laws) are bridged by the formal enactment of legislation, which shifts the cycle from its formulation to implementation phase; that is, once enacted as laws, policies remain to be implemented.

Implementation responsibility rests mostly with the executive branch, which includes many departments that have significant health policy implementation responsibilities, such as the Department of Health and Human Services (DHHS) (www.dhhs.gov) and the Department of Justice (DOJ) (www.usdoj.gov) as well as independent federal agencies, such as the Environmental Protection Agency (EPA) (www.epa.gov) and the Consumer Product Safety Commission (CPSC) (www.cpsc. gov). These and many other departments and agencies in the executive branch of government exist primarily to implement the policies formulated in the legislative branch in the form of public laws. This relationship between policy formulation and implementation is illustrated in the list of major federal laws that the EPA is responsible for implementing found in The Real World: Laws Implemented by EPA.

The Real World of Health Policy

Laws Implemented by EPA

The mission of the Environmental Protection Agency (EPA) (www.epa.gov) is to protect human health and the environment. Established in 1970, EPA develops and enforces regulations that implement environmental laws enacted by Congress. EPA's FY 2005 Annual Plan and Budget includes a budget of $7.8 billion and almost 18,000 employees. The major pieces of legislation that EPA implements or partially implements include the following.

National Environmental Policy Act (NEPA) (1969)—NEPA is the basic national charter for protection of the environment. It establishes policy, sets goals, and provides means for carrying out the policy.

The Clean Air Act (CAA) (1970)—CAA is the comprehensive federal law that regulates air emissions from area, stationary, and mobile sources. This law authorizes EPA to establish national ambient air quality standards (NAAQS) to protect public health and the environment.

The Clean Water Act (CWA) (1977)—Growing public awareness of and concern for controlling water pollution led to enactment of the Federal Water Pollution Control Act Amendments of 1972. As amended in 1977, this law became commonly known as the Clean Water Act. CWA established the basic structure for regulating discharges of pollutants into the waters of the United States. It gave EPA the authority to implement pollution control programs such as setting wastewater standards for industry.

Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or Superfund) (1980)—CERLA created a tax on the chemical and petroleum industries and provided broad federal authority to respond directly to releases or threatened releases of hazardous substances that may endanger public health or the environment. Over five years, $1.6 billion was collected, and the tax went to a trust fund for cleaning up abandoned or uncontrolled hazardous waste sites. CERCLA established prohibitions and requirements concerning closed and abandoned hazardous waste sites, provided for liability of persons responsible for releases of hazardous waste at these sites, and established a trust fund to provide for cleanup when no responsible party could be identified.

The Emergency Planning & Community Right-to-Know Act (EPCRA) (1986)—EPCRA was enacted by Congress as the national legislation on community safety. This law was designated to help local communities protect public health, safety, and the environment from chemical hazards. To implement EPCRA, Congress required each state to appoint a state emergency response commission (SERC). The SERCs were required to divide their states into emergency planning districts and to name a local emergency planning committee (LEPC) for each district.

The Endangered Species Act (ESA) (1973)—ESA provides a program for the conservation of threatened and endangered plants and animals and the habitats in which they are found. EPA's decision to register a pesticide is based in part on the risk of adverse effects on endangered species as well as environmental fate (how a pesticide will affect habitat).

Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (1972)—FIFRA provides for federal control of pesticide distribution, sale, and use. It gives EPA authority not only to study the consequences of pesticide usage but also to require users (farmers, utility companies, and others) to register when purchasing pesticides. Through later amendments to the law, users also must take exams for certification as applicators of pesticides. All pesticides used in the United States must be registered (licensed) by EPA.

Federal Food, Drug, and Cosmetic Act (FFDCA) (1938)—FFDCA extended federal authority to ban new drugs from the market until they were approved by the Food and Drug Administration (FDA). The law also gave the federal government more extensive power in dealing with adulterated or mislabeled food, drugs, and cosmetic products.

Food Quality Protection Act (FQPA) (1996)—FQPA amended the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA). These amendments fundamentally changed the way EPA regulates pesticides. The requirements included a new safety standard—reasonable certainty of no harm—that must be applied to all pesticides used on foods.

The Occupational Safety and Health Act (OSHA) (1970)—OSHA was enacted to ensure worker and workplace safety. It requires employers to provide workers with a place of employment free from recognized hazards to safety and health, such as exposure to toxic chemicals, excessive noise levels, mechanical dangers, heat or cold stress, or unsanitary conditions.

The Oil Pollution Act (OPA) (1990)—OPA streamlined and strengthened EPA's ability to prevent and respond to catastrophic oil spills. It established a trust fund, financed by a tax on oil, to fund the clean—up of spills when the responsible party is incapable of doing so or unwilling to do so.

The Pollution Prevention Act (PPA) (1990)—PPA focused industry, government, and public attention on reducing the amount of pollution through cost-effective changes in production, operation, and raw materials use. Opportunities for source reduction are often not realized because existing regulations and the industrial resources required for compliance focus on treatment and disposal. Source reduction is fundamentally different than waste management or pollution control.

The Resource Conservation and Recovery Act (RCRA) (1976)—RCRA gave EPA the authority to control hazardous waste from the "cradle to the grave." This

includes the generation, transportation, treatment, storage, and disposal of hazardous waste.

The Safe Drinking Water Act (SDWA) (1974)—SWDA was established to protect the quality of drinking water in the United States. This law focuses on all waters actually or potentially designed for drinking use, whether from aboveground or underground sources. It authorized EPA to establish safe standards of purity and required all owners or operators of public water systems to comply with primary (health-related) standards.

The Superfund Amendments and Reauthorization Act (SARA) (1986)—SARA amended the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) to reflect EPA's experience in administering the complex Superfund program during its first six years and made several important changes and additions to the program. SARA

- stressed the importance of permanent remedies and innovative treatment technologies in cleaning up hazardous waste sites;
- required Superfund actions to consider the standards and requirements found in other state and federal environmental laws and regulations;
- provided new enforcement authorities and settlement tools;
- increased state involvement in every phase of the Superfund program;
- increased the focus on human health problems posed by hazardous waste sites;
- encouraged greater citizen participation in making decisions on how sites should be cleaned up; and
- increased the size of the trust fund to $8.5 billion.

The Toxic Substances Control Act (TSCA) (1976)—TSCA gave EPA the ability to track the industrial chemicals produced or imported into the United States. EPA repeatedly screens these chemicals and can require reporting or testing of those that may pose an environmental or human-health hazard. EPA can ban the manufacture and import of those chemicals that pose an unreasonable risk.

SOURCE: Environmental Protection Agency. 2001. Adapted from "Major Environmental Laws." [Online information; retrieved 1/30/05.] http://www.epa.gov/epahome/laws.htm.

It is important to remember that some of the decisions made within the implementing entities, as they implement policies, become policies themselves. For example, rules and regulations promulgated to implement a law and operational protocols and procedures developed to support a law's implementation are just as much policies as is the law itself. Similarly, judicial decisions regarding the applicability of laws to specific situations or regarding the appropriateness of the actions of implementing organizations are decisions

that are themselves public policies. Policies are established within both the policy formulation and the policy implementation phases of the overall process.

The policy modification phase exists because perfection cannot be achieved in the other phases and because policies are established and exist in a dynamic world. Suitable policies made today may become inadequate with future biological, cultural, demographic, ecological, economic, ethical, legal, psychological, social, and technological changes. Pressure to change established policies may come from new priorities or perceived needs by the individuals, organizations, and interest groups that are affected by the policies.

Policy modification, which is shown as a feedback loop in Figure 3.2, may entail nothing more than minor adjustments made in the implementation phase or modest amendments to existing public laws. In some instances, however, the consequences of implementing certain policies can feed back all the way to the agenda-setting stage of the process. For example, formulating policies to contain the costs of providing health services—a key challenge facing policymakers today—is to a large extent an outgrowth of the success of previous policies that expanded access and subsidized an increased supply of human resources and advanced technologies to be used in providing health services.

Policymaking Is a Highly Political Process

One feature of the public policymaking process that the model presented in Figure 3.2 cannot adequately show—but one that is crucial to understanding the policymaking process—is the political nature of the process in operation. While there is a belief among many people—and a naïve hope among still others—that public policymaking is a predominantly rational decision-making process, this is not the case.

The process would no doubt be simpler and better if it were driven exclusively by fully informed consideration of the best ways for policy to support the nation's pursuit of health, by open and comprehensive debate about such policies and by the rational selection from among policy choices strictly on the basis of ability to contribute to the pursuit of health. Those who are familiar with the policymaking process, however, know that it is not driven exclusively by these considerations. A wide range of other factors and considerations influence the process. The preferences and influence of interest groups, political bargaining and vote trading, and ideological biases are among the most important of these other factors. This is not to say that rationality plays no part in health policymaking. On a good day, it will gain a place among the flurry of political considerations, but "It must be a very good and rare day indeed when policymakers take their cues mainly from scientific knowledge about the state of the world they hope to change or protect" (Brown 1991, 20).

The highly political nature of the policymaking process in the United States accounts for very different and competing theories about how this

process plays out. At the opposite ends of a continuum sit what can be characterized as strictly public-interest and strictly self-interest theories of how policymakers behave. Policies made entirely in the public interest would be those that result when all participants act according to what they believe to be the public's interest. Alternatively, policies made entirely through a process driven by self-interests would reflect an intricate calculus of the interplay among the various self-interests of the diverse participants. Policies resulting from these two hypothetical extremes of the way people might behave in the policymaking process would indeed be very different.

In reality, however, health policies always reflect various mixes of public-interest and self-interest influences. The balance between the public and self-interests being served are important to the ultimate shape of health policies. For example, the present coexistence of the extremes of excess (exorbitant incomes of some physicians and health plan managers, esoteric technologies, and various overcapacities in the healthcare system) alongside true deprivation (lack of insurance for millions of people and inadequate access to basic health services for millions more) resulting from or permitted by some of the nation's existing health policies suggests that the balance has been tipped too often toward the service of self-interests.

This aside, public policymaking in the health domain in the United States is a remarkably complex and interesting process, although clearly an imperfect process. The intricacies of the process are explored more thoroughly in subsequent chapters, where each of its interconnected phases is examined in more detail. One should keep in mind as the separate components of the public policymaking process are examined that policymaking in general is a highly political process, that it is continual and cyclical in its operation, that it is heavily influenced by factors external to the process, and that the component phases and the activities within the phases of the process are highly interactive and interdependent. Before examining the phases of the policymaking process in more detail, however, Chapter 4 will explore the concept of *policy competence* and how possession and practice of this competence can assist those who wish to contribute to the pursuit of health.

Summary

Health policies, like those in other domains, are made within the context of the political marketplace, where demanders for and suppliers of policies interact. The demanders of policies include all of those who view public policies as a mechanism through which to meet some of their health-related objectives or other objectives, such as economic advantage. Although individuals alone can demand public policies, the far more effective demand emanates from organizations and especially from organized interest groups. The suppliers of

health policy include elected and appointed members of all three branches of government as well as the civil servants who staff the government.

The interests of the various and diverse demanders and suppliers in this market cannot be completely coincident—often they are in open conflict—and the decisions and activities of any participants always affect and are affected by the activities of other participants. Thus, public policymaking in the health domain, as well as in other domains, is very much a human process, a fact with great significance for the outcomes and consequences of the process, as well as for the importance of ethical behavior by all involved in the process.

The policymaking process itself is a highly complex, interactive, and cyclical process that incorporates formulation, implementation, and modification phases. These phases are discussed in turn in subsequent chapters, following a discussion of the concept of *policy competence,* which is presented first in the next chapter.

Discussion Questions

1. Compare and contrast the operation of traditional economic markets with political markets.
2. Who are demanders and suppliers of health policies? What motivates each in the political marketplace?
3. Compare and contrast the pluralist and elitist perspectives on interest groups in the political marketplace.
4. Define power and influence. What are the sources of power in political markets?
5. What role does the application of ethical principles play in policymaking?
6. Draw a schematic model of the public policymaking process.
7. Describe the general features of the model drawn in question 6.

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CHAPTER

4

POLICY COMPETENCY

The impact of health policies—that is, the authoritative decisions made within government—was discussed extensively in Chapter 2. Individuals, communities, and populations, as well as health-related organizations and groups, feel the effects of health policies. To varying degrees depending on the relative importance of the impact of policies on them, all share two related areas of concern about policies and the process that produces them.

1. They want to know how policies will affect them and the people and things that they care about or for which they are responsible. In other words, they have a discernment or analytical interest in policymaking and its results. People normally want information about anything that affects them, including health policies, and they prefer to have this information before they feel the impact so they can prepare for it.
2. They want to be able to influence the policymaking process and thereby the policies that affect them. These effects can, after all, be direct and of significant consequence. As a result of specific policies, for instance, certain people gain or lose access to a particular medical procedure or obtain or fail to obtain grants to support research projects. Certain organizations see demand for their services increase or decrease or see their revenues and expenses rise or fall.

Possession of the dual capabilities to successfully *analyze* and *influence* the public policymaking process was termed *policy competency* in Chapter 1. This chapter describes in more depth how the demanders of health policies—whether individuals, organizations, or interest groups—can more effectively analyze and influence the policymaking process—that is, how they can enhance their policy competency. First, however, a brief discussion about the concept of competency provides necessary background.

As has been noted, "Definitions and terminology surrounding the concept of competency are replete with imprecise and inconsistent meanings, resulting in a certain level of bewilderment among those seeking to identify the concept" (Shewchuck, O'Connor, and Fine 2005, 33). For our purposes, we will use the following definition of a competency (Lucia and Lepsinger 1999):

> a cluster of related knowledge, skills, and ability (sometimes referred to by the acronym SKA) that: 1) affect a major part of one's job (a role or responsibility), 2) correlate with performance on the job, 3) can be measured against well accepted standards, and 4) can be improved by training and development.

Thus, policy competency means the knowledge, skills, and abilities that permit one to successfully analyze the public policymaking process to the point of accurately assessing its impact on his or her domain of interest or responsibility on the one hand and to successfully exert influence in the public policymaking process on the other hand. Obviously, policy competency comes in degrees, and the policy competency of demanders of policies certainly is not the only variable or factor that affects the decisions made by suppliers of policies. However, policy competency of demanders of policies can and often does play a role in policymaking and its results. Consider, for example, the potential role of policy competency in influencing the allocation decisions described in The Real World of Health Policy: Neighboring States Allocate Their Tobacco Settlement Funds Differently.

The Real World of Health Policy

Neighboring States Allocate Their Tobacco Settlement Funds Differently

In 1998, 46 states joined in the Master Settlement Agreement (MSA) (which can be read at www.naag.org/upload/1032468605_cigmsa.pdf) with the tobacco industry. The agreement was estimated to total $206 billion over the first 25 years and placed no restrictions on how states would use their share of these funds. Ohio's share was estimated to be approximately $10 billion, and Pennsylvania's share was estimated to be approximately $11 billion. As the allocations of these funds in the two states in 2004 show, they have made different decisions about how to use the money. There is substantial variation across states in the purposes for which tobacco settlement funds have been allocated (McKinley, Dixon, and Devore 2003). While economic and budgetary conditions in various states, along with their priorities and needs, help shape the patterns of allocation of the tobacco settlement funds, the relative policy competency of those who compete for shares of the funds also come into play.

Ohio's Allocation of Annual Appropriation of Tobacco Settlement Funds, SFY2004

	OH $	*OH %*	*US $*	*US %*
Tobacco Use Prevention	771,000	0.2	266,771,000	1.9
Health Services	12,600,000	3.4	2,252,483,000	16.0
Long-Term Care	NA[1]	NA[1]	391,384,000	2.8

(*continued*)

Ohio's Allocation of Annual Appropriation of Tobacco Settlement Funds, SFY2004 (*continued*)

	OH $	*OH %*	*US $*	*US %*
Health Research	23,300,000	6.3	226,574,000	1.6
Education	35,700,000	9.7	379,374,000	2.7
Children and Youth (Non-health)	NA[1]	NA[1]	231,399,000	1.6
Tobacco Farmers	16,300,000	4.4	294,685,000	2.1
Endowments and Reserves	NA[1]	NA[1]	195,442,000	1.4
Other	280,518,000	76.0	9,857,395,000	69.9
Total	369,189,000	100.0	14,095,507,000	100.0

Pennsylvania's Allocation of Annual Appropriation of Tobacco Settlement Funds, SFY2004

	PA $	*PA %*	*US $*	*US %*
Tobacco Use Prevention	51,600,000	12.0	266,771,000	1.9
Health Services	172,100,000	40.0	2,252,483,000	16.0
Long-Term Care	90,300,000	21.0	391,384,000	2.8
Health Research	81,800,000	19.0	226,574,000	1.6
Education	NA[1]	NA[1]	379,374,000	2.7
Children and Youth (Non-health)	NA[1]	NA[1]	231,399,000	1.6
Tobacco Farmers	NA[1]	NA[1]	294,685,000	2.1
Endowments and Reserves	34,400,000	8.0	195,442,000	1.4
Other	NA[1]	NA[1]	9,857,395,000	69.9
Total	430,200,000	100.0	14,095,507,000	100.0

[1] Not applicable because state has not appropriated or allocated funds for this activity.

Definitions

Tobacco-use Prevention: includes community and school-based tobacco-use prevention programs, anti-media campaigns, tobacco control measures and tobacco cessation treatment.

Health Services: includes funding for Medicaid, SCHIP, rural health, maternal and child health, treatment of mental illness and substance abuse, primary care, etc.

Long-Term Care: includes funding for respite care, home- and community-based waivers and prescription assistance.

Health Research: includes funding for biomedical research. Education: includes funding for kindergarten through grade 12 education and tuition for and scholarships to community colleges, colleges and universities.

Children and Youth (Non-health): includes funding for early childhood programs, after-school adolescent programs and juvenile justice programs.

Tobacco Farmers: includes funding for individual tobacco farmers and quota holders and community and rural development programs to attract industry to rural areas.

Endowments and Budget Reserve: includes rainy day funds and endowments established to fund program activities with the earnings. Most, but not all, of these endowments are for health services.

Other: includes a wide variety of activities, including tax relief, water resource projects and debt reduction.

SOURCE: Henry J. Kaiser Family Foundation. 2004. "Allocation of Annual Appropriation of Tobacco Settlement Funds, SFY2004." [Online article; retrieved 3/13/05.] www.statehealthfacts.org. This information was reprinted with permission of The Henry J. Kaiser Family Foundation. The Kaiser Family Foundation, based in Menlo Park, California, is a nonprofit, independent national healthcare philanthropy and is not associated with Kaiser Permanente or Kaiser Industries.

It is useful to remember from the earlier discussion in Chapter 1 that the single most important factor in policy competency—whether the skills, knowledge, and ability to analyze and assess impact or to exert influence in the policymaking process—is to understand the public policymaking process as a *decision-making* process. Public policies, including health policies, are decisions, albeit decisions made in a particular way by particular people. Thus, policy competency requires an understanding of the context, participants, and processes of this particular type of decision making. In short, it requires an understanding of what we will call the *public policy environment* of a particular entity. This environment is formed by the policymaking process, its results, and all of the forces that can affect the process that have relevance to the entity.

Organization Design to Support Policy Competency

One of the important responsibilities of senior-level managers is to establish the intentional patterns of relationships among human and other resources within their domains of responsibility. These patterns of relationships are called *organization designs*. Specifically, the patterns of relationships among human and other resources established by managers are *formal* organization designs. This distinction is important; coexisting within formal organization designs are *informal* structures that exist because people working together

within formal designs invariably establish relationships and interactions that lie outside the boundaries of the formal structure. All organization designs have both formal aspects, which are developed by managers, and informal aspects, which reflect the wishes and preferences of other participants (Longest 2004).

Formal organization designs begin with the designation of individual positions. Positions are subsequently *staffed* as individuals are attracted to occupy them. Individual positions are the basic building block of organization designs, although they are typically clustered into teams or work groups. In larger entities, work groups may be clustered into divisions or other units. When this occurs, issues of how the various work groups and clusters of work groups are integrated and coordinated become important design concerns.

Entities, at least those with sufficient resources, typically build into their structures some formal means of accomplishing effective environmental analyses and of exerting influence in their public policy environments, although the approach of any organization or interest group may be idiosyncratic to its situation, as suggested by the examples of organization designs in The Real World of Health Policy: Different Organization Designs to Support Policy Competency. Responsibility for analyzing an entity's public policy environment, as well as the responsibility for seeking to influence events and outcomes in its public policy environment, rests predominantly with those at the entity's strategic apex. That is, the responsibility rests with senior-level managers and governing board members. These leaders, especially in large entities, may be assisted by specialized staff organized for the purpose of fulfilling these responsibilities.

The Real World of Health Policy

Different Organization Designs to Support Policy Competency

Information taken from the web sites of the governmental affairs departments of three representative interest groups and provided by the vice president of government relations at a large academic medical center provides examples of the structures and objectives of these units.

American Academy of Pediatrics (AAP) (www.aap.org). The academy's Department of Federal Affairs has been its link to federal legislative activities in Washington, DC, for more than 30 years. Pediatricians who wish to make a difference in child and adolescent health through Congress and/or federal agencies are given the information and tools necessary to become effective child advocates. This office helps them prepare to offer testimony in legislation development or to meet with representatives or senators. AAP's policy agenda includes access to healthcare for all children, immunizations, services for children with disabilities, injury

prevention, and Medicaid. It is interested in policy affecting legislation and regulations involving the education of new physicians, the ethics of medical practice, biomedical research, and clinical laboratory testing, for example. The Department of Federal Affairs has the following three functions:

1. to ensure that policymakers in both Congress and federal agencies are apprised of academy policies;
2. to design, implement, and negotiate successful strategies to attain desired legislative outcomes; and
3. to represent the academy with relevant interest groups.

Wisconsin Medical Society (www.wisconsinmedicalsociety.org). The society's mission is "to advance the science and art of medicine for the people of Wisconsin; ensure physicians are equipped to deal effectively with the economic and political aspects of practice; and serve as the patient and physician advocate to government and other relevant publics." Its Advocacy and Policy Department is responsible for the combined activities of legislative affairs (lobbying), policy research and development, and WISMedPAC, the society's political action committee. Members of the lobbying team represent the society before the state and federal governments. On the state level, this includes the legislature and a variety of government agencies. The policy staff assists the lobbyists in seeking to affect legislation and rule changes. The society regularly submits testimony to the state legislature. The department staff collaborates with a variety of patient advocacy organizations to strengthen mutual political agendas. In addition, staff communicates with other medical societies, the American Medical Association, and both state and national specialty societies to learn from related legislative activities in other states.

Council on Governmental Relations (COGR) (www.cogr.edu). The council is an association of 150 leading research-intensive universities that are recipients of a significant share of the federal funds available to higher education through contracts and grants for research and scholarship. COGR concerns itself with the influence of government regulations, policies, and practices on the performance of research conducted at colleges and universities. COGR's primary function is to help develop policies and practices that fairly reflect the mutual interest and separate obligations of federal agencies and universities in federal research and training. COGR deals mainly with policies and technical issues involved in the administration of federally sponsored programs at universities. The council concerns itself with the influence of government regulations, policies, and practices on the performance of research conducted at colleges and universities. As part of this process, COGR provides advice and information to its membership and makes certain that federal agencies understand academic operations and the burden their proposed regulations might impose on colleges and universities.

University of Pittsburgh Medical Center (UPMC) (www.upmc.com). The organizational structure of this academic medical center includes a vice president for government relations, who has overall responsibility for analyzing and influencing the center's public policy environment at the local, state, and federal levels and reports to the center's senior vice president. The vice president is directly engaged in federal relations and has a director of state government relations reporting to him. The vice president is responsible for keeping the senior managers "informed up to the minute" on relevant federal and state policies, including legislative and regulatory matters. This vice president performs the following specific functions:

- identifies and analyzes relevant legislative and regulatory matters;
- recommends appropriate responses to legislative and regulatory matters of interest;
- carries out the responses, including facilitating the participation of others in the responses; and
- advocates proactively in specific policy areas, including Medicare reimbursement, biomedical research funding, and transplantation issues.

Management literature is replete with recommendations to create specialized administrative units to analyze and influence public policy environments (Swayne, Duncan, and Ginter 2002; Sanchez and Heene 2001). In the health domain, when analyzing and influencing an organization's or interest group's public policy environment is made a high priority by an entity, its leaders typically establish a specialized department or unit, usually called the public affairs department or government (sometimes called governmental) affairs (or relations) department to do much of the actual work involved. Some very large organizations and many interest groups divide government relations into separate departments or units within a department, one for the federal government and another for state government. The directors of such departments often report to the chief executive officer (CEO), because CEOs have vital interests in the public policy environments of the entities they lead. Departments or units devoted to governmental affairs mainly serve to enhance the policy competency of the entity's senior-level managers, especially its CEO. If these units are well designed and staffed with capable people—who are themselves policy competent—they can give an entity and its leaders the enormous advantage of lead time in dealing with its public policy environment.

Analyzing a public policy environment well enough to predict with reasonable accuracy future decisions that will be made in the policymaking process can provide the luxury of more lead time for those who are affected by policies. When the leaders of organizations or groups are able to anticipate policy changes months—or better still, years—ahead of when they actually

occur, their responses can be more thoughtful and usually more effective or appropriate.

Beyond giving themselves the advantages of longer lead times to prepare for policy shifts and changes, those who understand emerging policies or modifications in existing policies can be positioned to exert influence on emerging policies to the advantage of their entities. They foresee both the emergence and impact of relevant public policies on their domains of responsibility. This foresight—derived from policy competency—serves as a basis for efforts to participate in shaping the nature and scope of policies that will affect their organizations or groups (Longest 1997).

But how is such prescience to be achieved? The answer lies in how the analysis component of policy competency is approached. People who look beyond specific decisions reflected in public policies to the larger public policy environments from which policies derive have a great advantage over those who merely wait until a policy is determined and then react to it. Wayne Gretzky, a great former hockey player, is commonly known to have said, "Most players skate to the puck. I skate to where the puck will be. This has made all the difference in my success." People not only benefit when they focus on the policies that affect their domains but also gain much greater advantage when they focus on why and how these policies emerge. Those who broadly focus on the public policy environment of their domain increase their chances of anticipating policy changes in advance of when the changes actually occur.

This anticipatory focus—thinking about where the puck is going, not simply where it is—also facilitates the effective exertion of influence on the factors that lead, ultimately, to policies. It provides an opportunity to actually influence policies in their emergent states. Leaders of entities who understand the public policy environments, with all their complex interplay of actors, actions, inactions, and other variables, are better equipped to both anticipate and influence policies than their less informed—or less policy competent—counterparts. They are prepared to ask more anticipatory, "what if," questions. There is always a vast difference between leading an entity based on solid predictions of *future* policies and reacting to announced changes, or even to soon-to-be-announced changes. Proactive preparation and the opportunity to exert influence on the ultimate shape of policies are possible with enough foreknowledge. After policy changes occur, only reaction is possible, typically with inadequate time for thoughtful responses if caught by surprise.

Analyzing Public Policy Environments

Implicit in policy competency of the leaders of organizations or groups is the capability to accurately analyze the public policy environment of their entity. Such analyses include understanding the strategic consequences of events and

forces in an entity's public policy environment. Policy-competent leaders are able to assess the impacts, both in terms of opportunities and threats, of public policies on their domains and, because they can do this in advance of the impact, are able to position themselves and their organization or group to make strategic adjustments that reflect planned responses to these impacts.

Consider as an example the strategic importance of policy changes proposed for New York's Medicaid program in Governor George Pataki's 2005 budget address, which is excerpted in The Real World of Health Policy: Governor Proposes Major Changes in Medicaid Program. The proposed changes could affect many policy demanders, including acute and long-term-care service providers and their interest groups, county governments, and the Medicaid population in New York. The policy competency of these and others affected by any changes that are eventually made will be very important to their capabilities to both influence the ultimate outcome and prepare for the impact of changes in policy. In view of the importance of policy competency to those who stand to gain or lose from policy, the next two sections contain extensive discussions of the components of policy competency: analyzing policy environments and influencing policy environments.

The Real World of Health Policy

Governor Proposes Major Changes in Medicaid Program

On January 18, 2005, George E. Pataki, governor of New York, gave the annual Executive Budget Address (which can be read in its entirety at www.state.ny.us/governor). In an excerpted portion of the speech shown below, Governor Pataki outlined significant changes he would like to see made in New York's Medicaid program. If these proposals become policies in New York, they could have significant implications for many constituents of the Medicaid program.

* * *

New York has the finest healthcare system in the nation. From access to the latest medicines and life saving medical technology to the best doctors and hospitals anywhere, we truly have a healthcare system to be proud of.

But if we are to maintain the high quality of our healthcare system we must take action to address the rapidly escalating costs of Medicaid.

We all know that the cost of Medicaid is crushing taxpayers.

New York's Medicaid program is the most expensive in the nation. If left unchecked, within the next six years Medicaid costs could actually consume more than half of our entire state budget.

We cannot allow this to happen.

The budget I propose today keeps state and local Medicaid spending flat and reduces the program's burden on New York City, on our counties and their taxpayers.

It provides real, immediate relief to New York City and county governments with a beneficial fiscal impact this year of $577 million.

Beginning in 2006, the budget caps local government Medicaid payments at a maximum growth rate of 3.5 percent, and lowers that rate permanently to 3 percent by 2008.

And starting in 2008, this budget calls for a complete State administrative takeover of Medicaid.

But merely redistributing the burden is not enough. The State can no more afford to pay for the current and future costs of Medicaid than counties can.

Shifting the cost of Medicaid from the real property taxpayers in the counties to the state taxpayers without reform is nothing more than an empty promise.

Many of us have been working to address this issue for years. The recommendations in my Executive Budget take ideas from many corners including the Berger Working Group and the Senate Task Force on Medicaid Reform, led by Senators Hannon, Meier and Rath.

My budget proposes a four point plan to address this matter. It includes proposals aimed at the critical issues of: Cost Containment, Excess Capacity, Facility Infrastructure and Long-Term Care.

Real Medicaid reform is about more than cost containment—it's about restructuring the delivery of healthcare to make it smarter, more affordable, more efficient and higher quality.

First, we must implement a series of cost containment measures. Let me be clear, there can be no Medicaid takeover without cost containment.

While we control costs, we must modernize and strengthen our healthcare facilities in a way that recognizes how important they are to delivering these vital healthcare services.

That's why the second point of my plan addresses the issue of excess capacity. We cannot afford to invest more in underutilized facilities. My Executive Budget creates the Commission on Health Care in the 21st Century to make the difficult recommendations to right-size the healthcare system.

But even as we make these tough decisions, let's make sure that those facilities most in demand are up to the challenges of the 21st Century.

That's why the third point of my plan creates the new Health Care Efficiency and Affordability Law for New Yorkers (HEAL NY)—a $250 million program this year that will fund healthcare facility and technology upgrades throughout the State.

Finally, we must make the system better, more accessible and more flexible to meet New Yorkers' individual needs.

The fourth element of my proposal is a package of initiatives that will dramatically improve the long-term care options available to seniors and their

families. Long-term care, particularly nursing home care is one of the most expensive aspects of Medicaid.

Because we know a nursing home should be an option, but not the only option, I am advancing the new Access to Home Program that will help families make the structural improvements that allow elderly or disabled loved ones to continue living at home. And because more and more seniors can and want to stay in their own homes, the budget also doubles the State's investment in home services for the elderly.

These long-term care initiatives are not only the right thing to do - they are what our seniors want and they also cost less than the alternatives that exist today.

Each of these four critical elements is necessary if we are going to reduce the costs of the Medicaid system while improving care.

* * *

SOURCE: George E. Pataki, Governor of New York State. 2005 Budget Address, January 18, 2005, Albany, New York.

Benefits of and Limitations to Effectively Analyzing Public Policy Environments

A number of concrete benefits derive from the effective analysis of any organization's or interest group's public policy environment by its leaders. Such analysis permits its leaders to

- classify and organize complex information about the public policymaking process and about forces and pressures that affect the process;
- identify and assess current public policies that do or will affect their entity;
- identify and assess the formulation of emerging public policies—including new laws, amendments, and changes in rules—that might eventually affect their entity;
- speculate in a systematic way about potential future relevant public policies; and
- link information about public policies to the objectives and strategies of their organization, system, or group and thus to its performance.

These potential benefits to the leaders of organizations and interest groups are substantial. However, they can be offset by several limitations inherent in any attempt to analyze the complex public policy environments of most entities. These inherent limitations in the ability of individuals, no matter how talented they are or how well supported their endeavors may be, include some of the following truths about people:

- No one can foretell the future through analyses of public policy environments; at best, only informed opinions and guesses about the future can be made.
- People cannot possibly see every aspect of the policymaking process, nor can they even be aware of every detail of the public policies that will have an impact on their organization or interest group.
- Leaders may effectively discern relevant public policies or emergent ones but be unable to interpret correctly the impact of the policies on their organization or group.
- Leaders may effectively discern and interpret the impact of relevant or emergent policies but find their organization or group is unable to respond appropriately.

Although there are limitations to what can be expected from efforts to analyze the public policy environments of health-related organizations and interest groups, their leaders derive enough benefits from doing so to justify committing substantial resources to carry out the analyses. The most important of these resources is the commitment of senior-level leaders to ensuring that effective analysis occurs.

If effective environmental analyses are to be carried out, the senior-level leaders at what Mintzberg (1983) calls the "strategic apex" of their entity must bear responsibility, although they typically rely on the help of others to carry out the functions and specific activities involved in the analysis. These functions extend beyond the obvious one of discerning important information to include organizing the information in useful ways and evaluating the information to determine the issues that are likely to have significant impacts on their entity.

The Procedure of Analyzing Public Policy Environments

The analysis of the public policy environment of an entity such as a healthcare organization or an interest group is part of the larger external environmental analysis through which its leaders seek to determine the externally imposed opportunities and threats facing their organization or, in the case of interest groups, their members. The relevant variables in their external environments include, but are not limited to, the public policy environment. In fact, the external environments of entities include *all* of the factors outside their boundaries that can influence their performance. Public policies are certainly among the factors; however, as noted above, biological, cultural, demographic, ecological, economic, ethical, legal, psychological, social, and technological factors are also relevant and must be routinely analyzed if they are to be taken into account in an entity's efforts to perform well.

An effective analysis of a public policy environment may be conducted using a variety of tools and techniques. Some of the more common ones

include trend identification and extrapolation, expert opinion gathered through the Delphi technique (a means of eliciting opinions and judgments from experts through structured exchange of email, mail, or facsimile that permits successive rounds of interactions) or focus groups, and scenario development. No matter which technique is used, it is most productively applied within the framework of a five-step set of activities that is useful in analyzing any entity's external environment, including its public policy environment. Four of the steps are routinely considered in the general strategic management literature (David 2004) and have been adapted for use specifically in health-related organizations by Swayne, Duncan, and Ginter (2005). A fifth step is added to their list below. The interrelated steps in conducting analyses of public policy environments are as follows:

- *scanning* the environment to identify strategic public policy issues—that is, issues that may be specific public policies or problems, possible solutions to the problems, and political circumstances that might eventually lead to policies—that are relevant and important to the organization, system, or interest group;
- *monitoring* the strategic public policy issues identified;
- *forecasting* or projecting the future direction of strategic public policy issues;
- *assessing* the importance of the strategic public policy issues for the entity; and
- *diffusing* results of the analysis of public policy environments among those in the organization, system, or interest group who can help formulate and implement its response to these issues.

Each of these steps in analyzing public policy environments is examined in turn in the following sections. A more extensive discussion of these steps can be found in Chapter 4 of *Seeking Strategic Advantage Through Health Policy Analysis* (Longest 1997).

Scanning the Environment to Identify Strategic Public Policy Issues

Effective environmental scanning acquires and strategically organizes important information from an entity's external environment. This step properly begins with careful consideration by the leaders of what they believe to be strategic public policy issues. In guiding the focus of scanning, it is useful to remember the definition of public policies given earlier: they are authoritative decisions—made in the legislative, executive, or judicial branches of government—that are intended to direct or influence the actions, behaviors, or decisions of others. When these decisions influence in any way the strategic actions, behaviors, or decisions of an entity's leaders, they can be thought of as strategically important public policy issues.

The set of strategic public policies for any entity constitutes a very large set of decisions. Remember that some of these decisions are codified in the

statutory language of specific public laws. Others are the rules or regulations established to implement public laws or to operate government and its various programs. Still others are the judicial branch's relevant decisions.

The large set of public policies that are of strategic importance, however, represents only part of what must be considered strategic public policy *issues* for an entity. The problems, potential solutions, and political circumstances that might eventually align to lead to strategic policies must also be considered important strategic public policy issues. Thus, effective scanning of the public policy environment involves identifying specific strategic policies *and* identifying emerging problems, possible solutions, and the political circumstances that surround them, which could eventually lead to policies of strategic importance. Together, these form the set of strategic *public policy issues* that should be scanned.

Consideration within any entity about what issues are in fact of strategic importance is largely judgmental, speculative, or conjectural (Klein and Linneman 1984). Obviously, this makes the quality of the judgments, speculations, and conjectures important. For this reason, it is useful to have more than one person decide which of the scanned issues are of strategic significance. One widely used approach in making these judgments is to rely on an ad hoc task force or a committee of people from within the organization or interest group to render their collective opinion.

Another popular approach is to use outside consultants who can provide expert opinions and judgments as to what is strategically important in the environments of health-related organizations and interest groups. It is also possible to utilize any of several more formal expert-based techniques. The most useful among these are the Delphi technique, as well as the nominal group technique (NGT), brainstorming, and focus groups, which are interactive group problem-identification and problem-solving techniques (Swayne, Duncan, and Ginter 2005; Webster, Reif, and Bracker 1989; Jain 1984; Terry 1977; Delbecq, Van de Ven, and Gustafson 1974). The starting point in any scanning activity, no matter who is doing it or which techniques might be employed, is the question of who or what to scan.

Policymakers in federal, state, and local levels of government and those who can influence their decisions—whether through helping shape conceptualization of problems and their potential solutions or through the impact on the political circumstances that help drive the policymaking process—are the appropriate focus of scanning activities. The focus can be refined for particular situations by limiting it to strategically important policies and the problems, potential solutions, and political circumstances that might eventually lead to policies that affect the specific entity doing the scanning.

Another way of identifying who or what should be scanned in a public policy environment is to think of the suppliers of relevant public policies, and those who can influence them, as forming the appropriate focus. As

discussed in Chapter 3, members of each branch of government play a role as supplier of policies in the political market, although the role of each branch is different. Each should receive attention in the scanning activity. Because policies are made in all three branches of government, the list of potential suppliers of public policies—the policymakers—is lengthy, and adding those who can influence the suppliers makes the list even longer.

Effectively scanning an entity's public policy environment identifies specific public policies that are of strategic importance. *Very* effective scanning also identifies the emerging problems, possible solutions to them, and the political circumstances that surround them that could eventually lead to strategically important policies. But scanning, even when very effectively done, is only the first step in the overall set of interrelated activities involved in analyzing a public policy environment.

Monitoring Strategic Public Policy Issues

Monitoring is more than scanning. It is the tracking, or following, of strategically important public policy issues over time. Public policy issues are monitored because the leaders of organizations, systems, or interest groups, or their support staff who may be doing the actual monitoring, believe the issues are of strategic importance. Monitoring them, especially when the issues are not well structured or are ambiguous as to strategic importance, permits more information to be assembled so that issues can be clarified and the degree to which they are, or the rate at which they are becoming, strategically important can be determined (Thomas and McDaniel 1990).

The monitoring step has a much narrower focus than scanning (Swayne, Duncan, and Ginter 2005). The purpose of monitoring is to build a base of data and information around the set of strategically important public policy issues that are identified through scanning or are verified through earlier monitoring. Fewer, usually far fewer, issues will be monitored than will be scanned as part of analyzing public policy environments.

Monitoring is extremely important because it is so often difficult to determine whether public policy issues are strategically important. Under conditions of certainty, the leaders of entities analyzing their environments would fully understand strategic issues and all consequential implications for their decisions and actions. However, uncertainty characterizes much about the strategically important issues faced by most health-related organizations, systems, and groups. Monitoring will not remove uncertainty, but it will likely reduce it significantly as more detailed and sustained information is acquired. As with scanning, techniques that feature the acquisition of multiple perspectives and expert opinions can help the leaders determine what should be monitored; experts in the form of consultants can also be used for the actual monitoring if this is beyond the capacity of the entity's regular staff.

Monitoring the strategic public policy issues for most organizations and interest groups in the health domain will affirm for their leaders that the vast majority of contemporary policies spring from a relatively few earlier policies. The strategically important public policies for most entities result from the modification of prior policies, not from a constant stream of new policies. Monitoring reveals that public policies have histories and, in fact, are frequently "living" history. Many of them continually, although incrementally, evolve through the modification phase of policymaking. As people monitor these changes, they tend to become intimately familiar with the evolutionary paths of the public policies they monitor. Such knowledge can be valuable as a background for the next step in analyzing public policy environments, forecasting changes.

Forecasting Changes in Strategic Public Policy Issues

Effective scanning and monitoring cannot, by themselves, provide all the information about the strategic public policy issues in an entity's environment that its leaders would like. Often, if the response to strategic issues is to be made effectively, reliable forecasts of future conditions or states is necessary. That is, information about issues and their potential effects before they occur is needed. This may give leaders time to formulate and implement successful responses to the issues.

Scanning and monitoring the public policy environment involves searching this environment for signals, sometimes distant and faint signals, that may be the forerunners of strategically important issues. Forecasting involves extending the issues and their impacts beyond their current state. For some public policy issues (e.g., the impact on patient demand of a change in public policy that redefines the eligibility requirements in the Medicaid program), adequate forecasts can be made by extending past trends or by applying a formula. In other situations, forecasting must rely on conjecture, speculation, and judgment, although these can be systematically compiled through such means as Delphi panels or focus groups. Sometimes, even sophisticated simulations can be conducted to forecast the future.

However, some degree of uncertainty characterizes the results of all of these forecasting techniques. It is especially difficult to incorporate in the utilization of any of them because strategically important public policy issues never exist in a vacuum and typically involve many issues at work simultaneously. Existing forecasting techniques and models do not fully account for this condition.

Trend Extrapolation

The most widely used technique for forecasting changes in public policy issues is trend extrapolation (Evans 2002). This technique, when properly used, can be remarkably effective and is relatively simple to use. Trend extrapolation is nothing more than tracking a particular issue and then using the information

to predict future changes. Public policies do not emerge de novo. Instead, they result from linked trains of activities that can and typically do span many years. This feature of the policymaking process makes its results more predictable than some might believe (Molitar 1977).

Even so, trend extrapolation as a technique in environmental analysis must be handled very carefully. It works best under highly stable conditions; under all other conditions it has significant limitations. When used to forecast changes in public policy, it usually permits the prediction of some general trend—such as directional trends in the number of people served by a program or in funding streams—rather than quantification of the trend with great specificity.

Significant policy changes, as well as changes in technology, demographics, or other variables, can render the extrapolation of a trend meaningless or misleading. In spite of this, however, predictions about trends through extrapolation can be quite useful to the leaders of organizations, systems, and interest groups as they seek to predict the paths of their strategically important policy issues. For those who exercise caution in its use and who factor in the effect of changes such as the introduction of a new or modified policy, trend extrapolation can be a very useful technique in forecasting certain aspects of the public policy environments of their health-related organizations, systems, or interest groups.

Scenario Development

Another technique for forecasting the public policy environment is the development, usually in writing, of scenarios of the future (Leemhuis 1985; Shoemaker 1993). A scenario is simply a plausible story about the future. This technique is especially appropriate for analyzing environments that include many uncertainties and imponderables. Such features generally characterize the public policy environments of health-related organizations and interest groups.

The essence of scenario development is to define several alternative future scenarios, or states of affairs. These can be used as the basis for developing contingent responses to the predictions; alternatively, the set of scenarios can be used to select what the organization, system, or interest group leaders consider the most likely future, the one to which they will prepare to respond.

Scenarios of the future can pertain to a single policy issue (e.g., the federal government's policy regarding approval procedures for new medical technology) or to broader-based sets of policy issues (e.g., the federal government's policies regarding regulation of health plans, funding for medical education or research, or a preventive approach to improved health). Scenarios can, and in practice do, vary considerably in scope and depth (Venable et al. 1994).

As a general rule, when using the scenario development technique in forecasting public policy environments, it is useful to develop several scenarios. Multiple scenarios permit the breadth of future possibilities to be explored. After the full range of possibilities has been reflected in a set of scenarios, one can be chosen as the most likely scenario. However, the most common mistake made in using scenario development is to envision too early in the process one particular scenario and base planning on it. The leaders who think they know which scenario will prevail and who prepare only for the one they select may find that the price of guessing incorrectly can be very high indeed.

Assessing the Strategic Importance of Public Policy Issues

Scanning and monitoring strategic public policy issues, and forecasting future changes in them, are important steps in a good environmental analysis. However, the leaders of organizations and interest groups must also concern themselves with the specific and relative strategic importance of the issues they are analyzing. That is, they must be concerned with an assessment or interpretation of the strategic importance and implications of public policy issues for their entities.

Frequently, this assessment involves characterizing issues as opportunities for or threats to their entity (see Figure 2.1). However, such assessments are far from exact. It may well be that sound human judgment is the best technique for making these determinations, although the strategic importance of public policy issues can be considered on several bases.

Experience with similar issues is frequently a useful basis for assessing the strategic importance of a public policy issue. The experience may have been acquired firsthand within the particular organization or interest group where an assessment is being made, or it may come from contact with colleagues in other organizations or groups that have experienced similar public policy issues and who are willing to share their experiences. Great variety exists among the states regarding their public policies that affect the pursuit of health; this variety can be instructive. Similarly, the experiences in other countries with various public policies affecting health and its pursuit can be drawn on for insight. Other bases for assessments include intuition or best guesses about what particular public policy issues might mean to an entity, as well as advice from well-informed and experienced others. When possible, quantification, modeling, and simulation of the potential impacts of public policy issues being assessed can be useful.

Making the appropriate determination is rarely a simple task, even when all of the bases suggested above are considered. Aside from the difficulties encountered in collecting and properly analyzing enough information to inform the assessment fully, there sometimes are problems that derive from the influence of the personal prejudices and biases of those conducting the

environmental assessment. Such problems can force assessments that fit some preconceived notions about what is strategically important rather than reflecting the realities of a particular situation (Thomas and McDaniel 1990).

Diffusing the Results of Environmental Analysis into Organizations and Interest Groups

The final step in analyzing public policy environments is the sometimes difficult one of diffusing or spreading the results of the effort to all of those in the entity who require the information to carry out their own responsibilities. For example, the identification of a shift in a funding stream for certain services may be of strategic importance to several managers in an organization. Each of them needs this information, and it should be effectively diffused in such a way that it reaches all of them. This step is frequently undervalued and may even be overlooked in some situations. Unless it is effectively carried out, however, it really does not matter how well the other steps in environmental analysis are performed.

Leaders can diffuse relevant information about the public policy environment of an entity throughout the organization or to the members served by an interest group in the following three basic ways:

1. use their *power* to dictate diffusion and use of the information (this approach works best in entities whose leaders can, if they choose, use coercion or sanctions to see that the information is diffused and used in all the appropriate places);
2. use *reason* to persuade all of those who are affected by the information to use it (this works as well as or better than relying on power, if the leaders are persuasive); or
3. perhaps best of all in most situations, use *education* of participants in the entity to emphasize and convince those who need to be convinced of the importance and usefulness of the information as a way of improving the chances that the information will be properly used.

However it is done, diffusion of strategically important information about public policy issues among the relevant participants in organizations or interest groups brings the steps in analyzing public policy environments to completion. Given the vital link between entities and the public policies that affect them, no contemporary health-related organization or interest group can expect to succeed in the absence of a reasonably effective set of activities through which its leaders discern and, ultimately, respond to strategically important public policy issues. However, this is only half of the task facing these contemporary leaders regarding their public policy environments. They are also responsible for influencing these environments to the strategic advantage of their organization or system or to the members of their interest group. This complex activity—which is the other half of policy competency—is explored in the next section.

Influencing Public Policy Environments

Leaders of health-related organizations and interest groups typically develop strong operational commitments to devising ways to exert influence in their public policy environments. There is nothing innately wrong with a leader establishing an operational objective of being influential in the entity's public policy environment. However, it almost goes without saying that activities directed to this objective can easily be tainted by overzealous attempts to influence the policymaking process for self-serving purposes. This is an area of activity where adherence to the ethical principles of respect for the autonomy of other people, justice, beneficence, and nonmaleficence are especially important. (It may be useful to review the "Ethics in the Political Marketplace" section of Chapter 3.)

Influence: A Matter of Power and Focus

The effective exercise of influence in the public policy environments of organizations and interest groups, either individually or in collaboration, depends on having a basis for their influence and on knowing where and when to focus their efforts. Power is the potential to exert influence. It is the basis of influence in a public policy environment. Much like the sources of interpersonal power discussed in Chapter 3, the power that entities use to exert influence in their public policy environments derives from three sources: positional power, reward or coercive power, or expert power.

Positional power is based on an entity's place or role in the larger society. Organizations and groups have certain power, or potential to exert influence, simply because they exist and are recognized as legitimate participants in the marketplace for policies. Policymakers entertain the opinions and consider the preferences of the leaders of health-related organizations such as Baxter Worldwide (www.baxter.com), a global medical products and services company, or health-related interest groups such as America's Health Insurance Plans (www.ahip.org), a national association representing nearly 1,300 member companies providing health insurance to more than 200 million people, in part simply because they recognize these people, in their roles as leaders of important entities, as legitimate participants in the policymaking arena. An important aspect of positional power is the recognition given by courts to organizations and interest groups to bring legal actions as part of their efforts to exert influence. Positional power alone may gain a hearing for particular views or preferences. The exertion of influence, however, usually requires more and different power.

Reward or *coercive power* is based on the entity's capacity to reward compliance or to punish noncompliance with its preferred decisions, actions, and behaviors by policymakers. The rewards that can be provided or withheld by organizations, systems, and groups include money in the form of campaign

contributions, as well as other forms of political support by participants in organizations and groups. Political support includes votes, but it also includes the ability to organize and mobilize grassroots activities designed to persuade other people on particular issues.

Expert power is based on an entity's possession of expertise or information that is valued by others. When seeking to exert influence in public policy environments, useful information and expertise may pertain to the definition or clarification of problems or to the development of solutions. Expert power also may consist of expertise in the intricacies of the public policymaking process.

Organizations and interest groups that can marshal these bases of power, especially when they can be integrated, can be very influential. The degree of influence, of course, varies from one entity to another. The relative amount of power each has is important in determining relative influence, but so too are reputations for being able to exert influence ethically and effectively and the strength of ideological convictions held by those who seek to influence. Whatever its bases, however, power is only one part of the complex equation that determines influence.

Leaders of organizations and interest groups must also be concerned about the *focus* of their efforts to influence their public policy environments. Typically, their focus is guided by the identification of policies that are of strategic importance to their entity in the scanning efforts described above, as well as by identification of problems, potential solutions, and political circumstances that might eventually lead to such policies. By focusing in this way, they will seek to influence strategically relevant policymakers in all three branches and in federal, state, and local levels of government. Furthermore, they will extend their efforts to those who have influence with these policymakers.

If leaders of entities are to influence the policymaking process effectively, they must, in addition to influencing policymakers directly, concern themselves with helping to shape the conceptualizations of problems, the development of potential solutions to the problems, and the political circumstances that help drive the policymaking process. The suppliers of relevant public policies, and those who can influence them, form the appropriate focus for organizations and groups seeking to influence their public policy environments.

A Map Can Sharpen Focus

The model of the policymaking process shown in Figure 3.2 can serve as a map to direct influencing efforts where they can be most useful. Depending on the circumstances of a particular situation, the proper focus may be one or more of the various component phases, or stages within them, of the policymaking process as shown in Figure 4.1.

Figure 4.1
Places to Influence Policymaking

Influencing Policy Formulation
- At Agenda Setting
  - *By* *defining and documenting problems*
    developing and evaluating solutions
    shaping political circumstances through lobbying and the courts
- At Legislation Development
  - *By* *participating in drafting legislation*
    testifying at legislative hearings

Influencing Policy Implementation
- At Rulemaking
  - *By* *providing formal comments on draft rules*
    serving on and providing input to rulemaking advisory bodies
- At Policy Operation
  - *By* *interactions with policy implementers*

Influencing Policy Modification
- *By* *documenting the case for modification through operational experience and formal evaluations*

Using the map to determine where to exert influence in their public policy environments, leaders of organizations and groups may focus on those areas where the health policy agenda is shaped by the interaction of problems, possible solutions to the problems, and political circumstances. They can exert influence on policymaking by helping to define the problems that eventually become the focus of public policymaking, by participating in the design of possible solutions to these problems, and by helping to create the political circumstances necessary to convert potential solutions into actual policies. In short, influencing the factors that establish the policy agenda itself can influence policies.

Once issues achieve a prominent place on the policy agenda, they can, but do not always, proceed to the next stage of the policy formulation phase, development of legislation. At this stage, as will be discussed extensively in Chapter 6, specific legislative proposals go through a process involving a carefully prescribed set of steps that can, but do not always, lead to policies in the form of new legislation, or, as is more often the case, amendments to previously enacted legislation.

Although the path for legislation is long and arduous, it is replete with opportunities for leaders of organizations or groups to influence legislation development. Both as individuals and through the interest groups to which they belong, leaders of health-related organizations participate directly in the actual drafting of legislative proposals and frequently participate in the hearings associated with the development of legislation.

As will be discussed in Chapter 7, enacted legislation rarely contains the explicit language to fully guide its implementation. Rather, laws are often vague on implementation details, leaving to the implementing agencies and organizations the establishment of the rules needed to fully operationalize the legislation.

As a formal part of the implementation phase of policymaking, the promulgation of rules is one of the most active points of involvement for the leaders of entities and others who have a stake in a particular policy in the entire policymaking process because it invites those affected by the rules to comment on proposals. The exertion of influence at this point of involvement can produce significant results.

In addition to exerting influence directly by commenting on the rules that will guide the implementation of policies, leaders can exert influence indirectly. This opportunity is occasioned by the fact that when the development of rules is anticipated to be unusually difficult or contentious or when rules are anticipated to be subject to continual revision, special provisions may be made. In particular, advisory bodies or commissions may be established to help shape the development of rules.

The Medicare Payment Advisory Commission (MedPAC) (www.medpac.gov) is one such body. Operationally, MedPAC meets publicly to discuss policy issues and formulate its recommendations to Congress. In the course of these meetings, commissioners consider the results of staff research, presentations by policy experts, and comments from interested parties such as staff from congressional committees and the Centers for Medicare & Medicaid Services (CMS), health services researchers, health services providers, and beneficiary advocates.

Although the opportunities for direct service on such commissions are limited to a very few people, others can influence their thinking. Leaders of health-related organizations and interest groups can and do influence the thinking of commission members, and thus the advice that commission members ultimately provide about formulating and implementing Medicare policy.

As discussed more fully in Chapter 7, influence can be exerted in the operation of policies. The policy operation stage of implementing policies involves the actual running of programs and activities embedded in or stimulated by enacted legislation. Operation is the domain of the appointees and civil servants who staff the government. These people influence policies by their operational decisions and actions. Thus, policies can be influenced by interactions with those who have operational responsibility. This form of influence arises from the working relationships—sometimes close working relationships—that can develop between those responsible for implementing policies and those on whom their decisions and activities impact directly, including health-related organizations and groups.

The opportunities to build these relationships are supported by a prominent feature of the careers of bureaucrats: longevity (Kingdon 1995). Elected policymakers come and go, but the bureaucracy endures. Leaders of entities can, and many do, build long-standing working relationships with some of the people responsible for implementing the public policies that are of strategic importance to their organization or group.

The most solid base for these working relationships is the exchange of useful information and expertise. A leader, speaking from an authoritative position based on actual operational experience with the implementation of a policy, can influence the policy's further implementation with relevant information. If the information supports change, especially if it is buttressed with similar information from others who are experiencing the impact of a particular policy, reasonable implementers may well be influenced to make needed changes. This is especially likely if a well-established working relationship exists that is based on mutual respect for the roles of and the challenges facing each party.

An obvious, and very limiting, problem for those wishing to influence the policymaking process though influencing either the rulemaking or policy operation stages of policy implementation is the enormity of the bureaucracy with which they might need to interact. Consider how many components of the federal government are involved in rulemaking and policy operation that is directly relevant to health-related organizations and groups. Add to this the relevant units of state and local government and the challenge of keeping track of where working relationships might be useful as a means of influencing policymaking, to say nothing of the challenge of actually developing and maintaining the relationships. Obviously, selectivity is required in determining which of these relationships might be of greater strategic importance.

Although some health policies are developed de novo, as has been noted, the vast majority of them result from the modification of existing policies in rather modest, incremental steps. Policy modification occurs when the outcomes, perceptions, and consequences of existing policies feed back into the agenda-setting and legislation-development stages of the formulation phase and into the rulemaking and policy operation stages of the implementation phase and stimulate changes in legislation, rules, or operations (see the feedback loop running along the bottom of Figure 3.2). Opportunities to influence policies continually arise as their outcomes and consequences trigger policy modification. Those who would influence policies have an opportunity to do so in the initial iteration of the policymaking process in regard to any particular policy, but they also get additional opportunities to exert their influence through the subsequent modification of existing policies.

Following the feedback loop in Figure 3.2, it can be seen that because agenda setting involves the confluence of problems, possible solutions, and political circumstances, leaders of health-related entities can be influential in

policy modification by making certain that problems become more sharply defined and better understood through the actual experiences of those who are affected by the policies. Leaders of organizations or groups are often the best sources of feedback on the consequences of policies, including the effects of policies on the individuals and populations they serve. Similarly, possible new solutions to problems can be conceived and assessed through the entities' operational experiences with particular policies, especially when the results of demonstrations and evaluations provide concrete evidence of their performance and impact. Finally, leaders—guided by their experiences and interactions with ongoing policies—become important components of the political circumstances surrounding the amendment of these policies.

Experience with the impact of the implementation of policies that affect their entity help leaders to routinely identify needed modifications in previously formulated legislation. The history of Medicare legislation is a good example of this phenomenon. Over the program's life, services have been added and deleted; premiums and copayment provisions have been changed; reimbursement mechanisms have been changed; features to ensure quality and medical necessity of services have been added, changed, and deleted; and so on. The inputs from entities directly affected by these changes played a role in each of these amendments to the original legislation, although other influences also helped guide these changes.

Leaders of health-related entities also have extensive opportunities to influence the modification of policies in their implementation phases, in both the rulemaking and policy operation stages. The modification of rules, as well as changes in the operations undertaken to implement policies, often reflect the actual reported or documented experiences of those affected by the rules and operations. Leaders can provide this feedback directly to those with rulemaking or operational responsibilities. They can also take their views on the rules and operational practices that affect their organizations, systems, and groups to the courts or to the legislative branch. Both can also be pathways to modifications.

The Real World of Health Policy: Influencing the Policy Environment of an Academic Medical Center provides an example of how the sources of power, combined with the map to potential focus points provided by Figure 3.2, can be used to undertake a broad strategy for exerting influence in the public policy environment of an academic medical center.

The Real World of Health Policy

Influencing the Policy Environment of an Academic Medical Center

As discussed in this chapter, health-related organizations and interest groups have three bases of power available to them in their influencing efforts (i.e.,

positional, capacity to reward or coerce, and expertise), and they have a number of places in the policymaking process to focus their efforts. Some of the experiences of the leaders of Academic Medical Center (AMC), a part of a state university system but whose identity is otherwise disguised, richly illustrate the variety of opportunities typically available to the leaders of health-related entities who wish to influence their public policy environments.

The leaders of Academic Medical Center (AMC) can and do approach the challenges of influencing AMC's public policy environment in a variety of ways. The cells in the grid shown in Exhibit 1, each identified by an alpha character, represent the specific combinations of focus and power available to AMC's leaders.

Exhibit 1 Opportunities to Exert Influence in Public Policy Environments

	Problem Definition	*Solutions Identification*	*Political Circumstances*	*Legislation Development*	*Rule-making*	*Operation*
Power Based on Position	cell (a)	(b)	(c)	(d)	(e)	(f)
Power to Reward/ Coerce	(g)	(h)	(i)	(j)	(k)	(l)
Power Based on Expertise	(m)	(n)	(o)	(p)	(q)	(r)

In cell a, for example, the leaders focus on the ways their *positional power* could be used to help *define and document problems* that could be addressed through public policy. For example, as leaders of AMC they are positioned to help policymakers understand the magnitude of the problem of the lack of health insurance among the state's citizens. These leaders are in a position to document the extent and some of the implications of the problems for policymakers. They may use their membership in the Council of Teaching Hospitals and Health Systems (COTH) (www.aamc.org/members/coth/start.htm) or the Alliance of Independent Academic Medical Centers (AIAMC) (www.aiamc.org) to help with examples from across the nation.

Furthermore, their positions as leaders of a major health organization permit them to call on others for assistance in this effort. Obviously, they can call on other members of the staff at AMC. They can also solicit the help of their counterparts in other health organizations in the state to buttress their documentation of the problem. In addition, they can utilize interest groups to which they belong, such as the State Hospital Association, to help in this process.

In cell j, AMC's leaders focus on the ways in which their ability to *reward* or to *coerce* policymakers could be used to exert influence in the *development of legislation* that would be to the center's strategic advantage. Legislation to support a major expansion of the center's research facilities, for example, might be sponsored and championed by a legislator who receives campaign support from the center's leaders. This legislative champion of AMC's preferred policy on the issue of support for the new research facility could also be supported in a more intangible form by the leaders working with the legislator to accomplish something of importance to the legislator's district, in terms of its economy and its healthcare services, by opening an ambulatory AMC-staffed primary care center in the district.

In cell n, the center's leaders focus on their opportunities to use the power to exert influence that derives from *expertise* to help *identify and implement policy solutions to problems*. For example, when the state legislature granted $50 million to AMC in 2005 to help establish and operate the state's only program in tissue engineering, it did so in response to the AMC's development of a proposal for the initiative as an important advance in the state's medical care and in its economic base. The proposal reflected the center's considerable expertise in tissue engineering.

In cell q, AMC's leaders focus on their opportunities to use *expertise* within the center's staff to influence the final wording on *rules or regulations* that affect the center's organizational performance. For example, there is expertise within the center's staff that would be relevant to the promulgation of federal rules pertaining to funding and operation of graduate medical education programs such as the family practice residency, Medicare reimbursement formulae and practices, and the award of National Institutes of Health research grants, as well as in many other areas. It is routine for leaders at AMC to use their expertise as a mechanism through which to influence the formulation and implementation of rules that affect their organization.

In cell c, AMC's leaders think of ways in which their power to influence based on *position* could be used to change the *political circumstances* surrounding an issue. For example, the members of the State Board of Regents, who are part of AMC's strategic apex, by virtue of their board positions, can and do exert influence on the members of the state legislature. This influence helps determine the state's funding for the state university system, including AMC's state funding.

The examples given above are not exhaustive. Each of the cells discussed contains many other examples of the nexus of focus and power that permit influence to be exerted in AMC's public policy environment. The examples are intended only to stimulate thinking about the range of possibilities to exert influence in public policy environments illustrated in this grid. It should be noted, in this regard, that the real world is not fully captured by this model. In particular, any suggestion that the cells formed by combinations of source of power and focus in the grid in Exhibit 1 can be considered one at the time or in isolation

from each other is an obvious oversimplification of reality. More realistically, the leaders of organizations and interest groups operate in several cells simultaneously even when they are trying to influence single issues in their policy environments. Moreover, they typically focus on many issues at any point in time. This complicates things considerably.

However, the grid does illustrate a very important point for those who would influence an entity's public policy environment. They have many places in the policymaking process where their influence can be legitimately and effectively focused, and they have more than one base of power upon which to seek to exert influence in each of these places.

The Human Element in Analyzing and Influencing Public Policy Environments

A significant challenge—even for those with a high level of policy competency—in successfully analyzing or influencing public policy environments lies in the fact that these environments are largely controlled by humans. The diverse preferences, objectives, priorities, levels of understanding of issues, and other foibles of the people in an entity's public policy environment make accurate analysis or successful influence difficult. The widely divergent positions of policymakers in regard to funding and operating the Medicare program illustrate the nature of this challenge.

Perspectives on the Medicare Program

Medicare has from its inception been the focus of contentious infighting among policymakers, including legislators responsible for laws pertaining to the Medicare program, and executive branch members, including staff at CMS, which is responsible for implementing the program (Longest 2003). Constant and sometimes intense pressure from groups with vested interests in the program—especially advocates for the program's beneficiaries and for hospitals and physicians—fuel the policy battles over the program's funding and operation.

The fight regarding Medicare's funding is heavily influenced by assessments of the political implications of the amounts of money that must be raised from the public to support the program. Regarding the program's operations, always played out against the backdrop of the budgetary implications of their decisions, policymakers have long sought to juggle the interests of providers whose services are reimbursed under the program—especially hospitals and physicians—on the one hand and the program's beneficiaries on the other hand.

Medicare Program Beneficiary Perspective

Although individual beneficiaries may be unhappy with some aspects of the program, Medicare's beneficiaries overwhelmingly view the program positively (Longest 2003). Not only is Medicare the principal source of health benefits for the nation's elderly and people with disabilities but it also protects their families from expenses they might otherwise bear for the medical care of relatives. The program also serves younger Americans with its promise of future protection as they plan their retirement. Its beneficiaries view Medicare favorably in spite of the fact that, on average, they must spend approximately 22 percent of their income for out-of-pocket Medicare and other healthcare expenses (Maxwell, Storeygard, and Moon 2002).

Evidence of the high level of beneficiary satisfaction with the Medicare program comes from the Commonwealth Fund's Survey of Health Insurance (Davis et al. 2002). This national survey compares how well the Medicare program works for its beneficiaries against the experiences of those under age 65 who are covered by private employer—sponsored insurance. The survey is specifically designed to examine the achievement of two central goals of insurance: that those covered are protected against financial hardship resulting from medical expenses and that they are able to obtain healthcare services when needed.

The survey results reveal that Medicare beneficiaries are generally more satisfied with their healthcare than are privately insured persons under age 65. Beneficiaries report fewer access problems and greater confidence about their access to needed services. They also report fewer instances of financial hardship caused by medical expenses. The bottom-line results of the survey indicate that elderly Medicare beneficiaries are 2.7 times more likely than those covered under employer-sponsored plans to rate their health insurance as excellent, and they are only one-third as likely to report negative experiences with their insurance coverage (Davis et al. 2002). Perhaps reflecting the wisdom of age, Medicare beneficiaries appear simultaneously able to value the benefits provided them through the program and to be legitimately concerned about the gaps in these benefits, as well as whether the gaps can be filled, at what cost, and who will bear that cost.

Hospital Executive Perspective

Many hospitals depend heavily on Medicare for revenue, and the magnitude of the dependence for some hospitals is very large. On average, hospitals derive approximately 38 percent of their revenues from Medicare (AHA 2002). However, depending on the demographics of a hospital's service area, this fraction can be much larger. In Pennsylvania, for example, a state that has a population older than the nation's population as a whole, the proportion of net patient revenue derived from Medicare is more than 48 percent on average, and it is as high as 60 to 70 percent for some hospitals (Pennsylvania Health Care Cost Containment Council 2005).

The high level of revenue dependence sharply focuses the attention of hospital executives on the Medicare program and shapes their view of the program to a great extent. A widely held perspective among hospitals is that Medicare is too parsimonious in its reimbursement rates to hospitals. The American Hospital Association argues that the Medicare program does not adequately cover the cost of treating beneficiaries, with hospitals on average experiencing Medicare margins of –1.9 percent (AHA 2005). In one analysis, the association puts the proportion of hospitals experiencing negative margins—hospitals losing money on Medicare patients—at almost 65 percent (AHA 2002).

Balancing Perspectives

Policymakers' perspectives on Medicare are affected by the program's massive size. Current Medicare benefit payments total approximately $297 billion, accounting for 19 percent of total spending for personal health services in the United States (Kaiser Family Foundation 2004). As they look ahead to the retirement of the baby boomer generation, policymakers see a widening gap between program revenues and program expenditures in the years ahead. They know this creates a looming financial crisis for government.

In their March 2004 annual report, trustees of the Medicare trust funds projected that the Medicare Health Insurance (HI) component of the program, which funds Part A of Medicare and pays for acute hospital care, limited skilled nursing home care, and hospice care, will remain solvent only through 2019 (Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds 2004). This projection is based on the intermediate (between the low and high) cost assumptions used in projecting the financial condition of the HI trust fund, as illustrated in Figure 4.2.

As the comptroller general of the United States notes (Walker 2002, 11),

> Unlike private trust funds that can set aside money for the future by investing in financial assets, the Medicare HI trust fund is essentially an accounting device. It allows the government to track the extent to which earmarked payroll taxes cover Medicare's HI outlays. While the U.S. Treasury securities in the HI trust fund are backed by the full faith and credit of the U.S. government, they essentially represent an unfunded promise to pay, which will require tough fiscal choices in future years.

Policymakers, especially those who stand for periodic reelection, detest difficult fiscal choices because of the political consequences such choices impose.

Policymakers find themselves attempting to balance the preferences of hospitals and other providers for generous reimbursements against the understandable desires of beneficiaries for expanding benefits, all the while

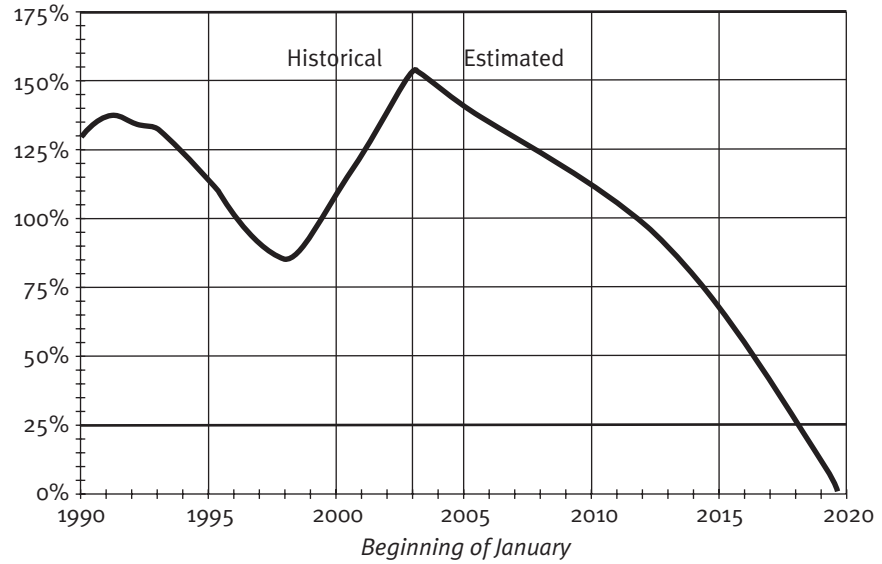

Figure 4.2 Medicare Health Insurance (HI) Trust Fund Balance at Beginning of Year as Percentage of Annual Expenditures

SOURCE: Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds (2004).

keeping a lid on escalating program costs and seeking new revenues. They have options in this balancing act, but none of them are politically palatable.

Proposed Medicare program reforms include a range of ideas. Some involve large changes, such as a proposal to operate the program along the lines of the Federal Employees Health Benefits Program (FEHBP) or a proposal to change the program from a defined-benefit to a defined-contribution plan. Other ideas for reform are more incremental. These include increasing the program's eligibility age, as already has been done for Social Security; further slowing the rate of growth in provider payments—this solution risks eroding provider participation in the program and curtailing access for beneficiaries—and increasing Medicare's Part A taxes and its Parts B and D premiums.

Policymakers have considered these ideas, and others, especially as intense attention has focused on the program since the Balanced Budget Act of 1997 established the National Bipartisan Commission on the Future of Medicare. Reflecting the difficulties inherent in reforming this huge and complex program, the commission could not reach agreement on what to do, even though its members readily agreed that the program was consuming and will continue to consume an increasing share of the federal budget and the nation's economic resources as the baby boomers swell the ranks of program beneficiaries (National Bipartisan Commission on the Future of Medicare 1999).

Not only are policymakers faced with multiple, often competing, demands on their decision making regarding the Medicare program but they

also come to their decision-making tasks with different mind-sets, which affect their approach to the decisions they face. Sometimes these mind-sets are cast in terms of fiscally or socially conservative or liberal perspectives. However, this oversimplifies the fact that when attempting to analyze or influence those in an entity's public policy environment, one faces very different mind-sets among policymakers, which significantly affects attempts to both analyze and exert influence.

The Mind-Sets of Policymakers

Until the present, the nation's health policy history has shown that ignoring or downplaying the reality of the fiscal problem with the Medicare program—or at least postponing a significant resolution of the problem—is not only possible but is the preferred course of action. Four different mind-sets, or what might be called "world views," among policymakers seem to have impeded their willingness or ability to address the issue.

One group of policymakers can be labeled *true romantics*. This group includes policymakers who apparently do not recognize the pending imbalance between Medicare's revenues and expenses as a problem and who are unconcerned about including in decision making any appreciable consideration of the notion that society's resources are limited and that this limitation should be reflected in health policy.

Another group, different from the true romantics because they do understand the issue but choose nevertheless to behave like true romantics in their decision making, can be labeled *pseudo romantics*. This group understands the pending revenue/expenditure gap, but this recognition is apparently tempered or even overridden by other objectives. Because their concerns about Medicare's fiscal flaw, if acted on, might interfere with achieving some other desirable end, they simply ignore the issue. Such policymakers may be relying on the possibility that new resources will suddenly be found and the problem will resolve itself.

A third mind-set that stands in stark contrast to the romantics and pseudo romantics is held by a group of policymakers that can be labeled, derogatorily, the *truly self-serving*. Policymakers with this mind-set may know very well about the necessity to fix the fiscal flaw in the Medicare program but are so intent on making certain that their own interests are well served in the policymaking process that they choose not to do so. The truly self-serving take such pains to make sure that their own interests are addressed that other issues become secondary.

The fourth mind-set, which is very well represented in policymaking and which impedes resolving the Medicare fiscal imbalance, is held by policymakers who can be labeled the *procrastinators*. This very large group includes policymakers who accept the ultimate necessity to resolve the problem but who also believe that the fateful day when difficult decisions must be made can be postponed still further. For the procrastinators, the difficult decisions

necessary to correct the fiscal imbalance in the Medicare program can be left to future policymakers and the consequences to future generations.

There may be other mind-sets that impede resolution of difficult issues like the impending gap in revenues and expenses in the Medicare program, but these four illustrate the point that successfully analyzing or influencing the policymaking process is made more difficult by the existence of various mind-sets among policymakers. It would be easier to analyze or influence if all policymakers had a consistent world view, but they do not. The human element in public policy environments is perhaps the greatest challenge to policy competency.

To this point in the book, we have defined health and health policy and considered the relationship between them. We have also modeled the policymaking process and explored the concept of policy competency, which comprise the dual capabilities more effectively analyzing and influencing the policymaking process. In the remaining chapters, each of the three phases of policymaking—formulation, implementation, and modification—is discussed in more depth. It will be useful to the reader to keep the concept of policy competency in mind as more detail about the policymaking process is discussed.

Summary

Health policies, once formulated and implemented, have consequences for individuals and populations as well as for health-related organizations and interest groups. Those who are affected by policies—those who feel their positive or negative effects—share two fundamental concerns about the policymaking process. They are concerned with analyzing their public policy environments so that they can discern in advance the potential impact of policies on themselves, and they are concerned with influencing the formulation and implementation of these public policies. Successfully addressing these dual concerns requires a degree of *policy competency*, defined in this chapter as the knowledge, skills, and abilities that permit one to successfully analyze the public policymaking process to the point of accurately assessing its impact on his or her domain of interest or responsibility on the one hand and to successfully exert influence in the public policymaking process on the other hand.

Effective analysis of public policy environments and, even more so, the capacity to exert influence in these environments are enhanced by the pooling of resources that can be devoted to the tasks by organizations and interest groups. The leaders of groups and organizations can best analyze their public policy environments through five steps: scanning, monitoring, forecasting, assessing, and diffusing information about their public policy environments into the organization or group.

Health-related organizations and interest groups seek to exert influence in their public policy environments so that the consequences for them will be more favorable—or at least less unfavorable. Success at influencing these environments is a function of *power* bases on which to mount the efforts and the *focus* of the efforts.

Discussion Questions

1. Discuss the concept of policy competency.
2. What two major areas of concern do individuals share with health-related organizations and interest groups regarding policies and the process through which they are produced? Why are these concerns more easily addressed by organizations and groups than by individuals?
3. Discuss the benefits and limitations facing organizations and interest groups that undertake to analyze their public policy environments.
4. Who is responsible for the analysis of the public policy environment of an organization or interest group? Who helps in the process?
5. Discuss the recommended steps in conducting an effective analysis of the public policy environment of an organization or group.
6. Who is responsible for efforts to exert influence in an organization's or interest group's public policy environment on behalf of the organization or group? Who helps in the process?
7. Discuss the fact that influence in public policy environments is a matter of power and focus.

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CHAPTER

5

POLICY FORMULATION: AGENDA SETTING

The three distinct phases of the health policymaking process modeled in Chapter 3 (see Figure 3.2) are examined in greater detail in this chapter, as well as in Chapters 6, 7, and 8. This chapter focuses on the agenda setting that occurs in the policy formulation phase of the policymaking process. Chapter 6 focuses on the development of legislation that also occurs in that phase. Chapter 7 describes the policy implementation phase, and Chapter 8 discusses the policy modification phase. These four chapters address the model's application to health policymaking almost exclusively at the national level of government. However, much that is said about the process of public policymaking applies to the process as it plays out at state or local levels of government as well. The contexts, participants, and specific mechanisms and procedures used in policymaking obviously differ among the three levels of government, but the core process of policymaking is similar (Figure 5.1).

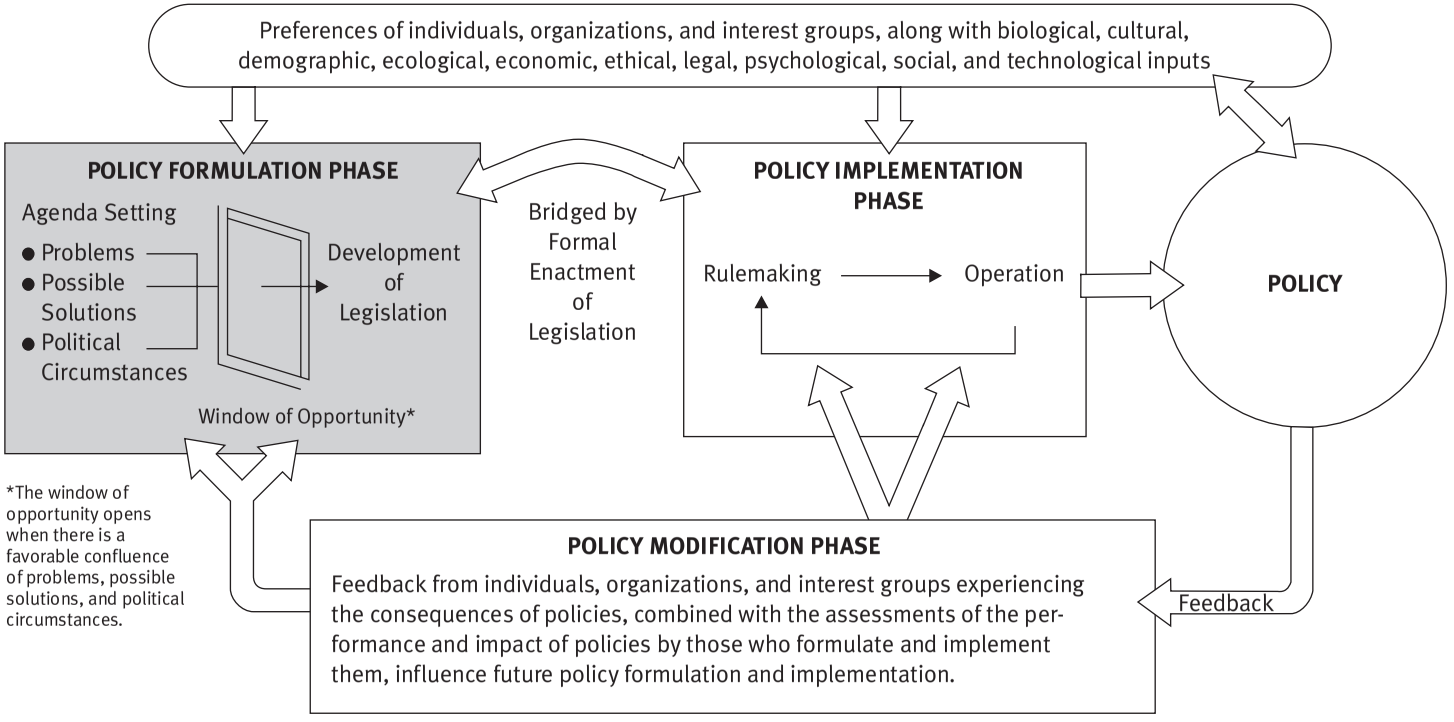
Overview of the Policy Formulation Phase

The formulation phase of health policymaking includes two distinct and sequentially related parts: agenda setting and legislation development (see the shaded portion of Figure 5.1). Each part comprises complex sets of activities in which policymakers, as well as those who would influence their decisions and actions, engage.

The result of the formulation phase of policymaking is policy in the form of new public laws or amendments to existing laws. The public laws or amendments pertaining to health that eventually emerge from the formulation phase are initiated by the interactions of a diverse array of health-related problems, possible solutions to the problems, and dynamic political circumstances that relate both to the problems and to their potential solutions. Before anything else can happen in the sequential policymaking process, some mechanism must initiate the emergence and subsequent movement of certain problem/solution combinations through the process in which public laws are developed as potential policy solutions to the problems.

A useful way to think about how this aspect of the policymaking process unfolds is to consider the following: At any particular time, there are a great many problems or issues related to health. Many of them have possible solutions that are apparent to policymakers. Often these problems have

FIGURE 5.1 A Model of the Public Policymaking Process in the United States: Agenda Setting in the Policy Formulation Phase



alternative solutions, each of which has its supporters and detractors. Diverse political interests that pertain to the problems and to their potential solutions overlay the existence of problems and potential solutions. *Agenda setting*, a crucial initial step in the policymaking process, describes the ways in which particular problems emerge and advance to the next stage.

Once a problem that might be addressed through public policy rises to a prominent place on the political agenda—through the confluence of the problem's identification, the existence of possible policy solutions to the problem, and the political circumstances surrounding both the problem and its potential solutions—it can, but does not necessarily, proceed to the next point in the policy formulation phase, development of legislation. Kingdon (1995) equates the movement of certain problems, along with their associated potential solutions, to the point at which legislation might be developed to address the problems with their passing through a window of opportunity (see Figure 5.1).

At this second point in policy formulation, policymakers put forth specific legislative proposals: One can think of these as hypothetical or unproved potential solutions to the problems they are intended to address. These proposals then go through a process involving carefully prescribed steps that can, but do not always, lead to policies in the form of new public laws or, more likely, policies in the form of amendments to previously enacted laws.

Only a small fraction of the potential universe of problems that might be addressed through public policy ever emerge from agenda setting with sufficient impetus to advance them to the point of having specific legislative proposals developed as a means of addressing them. And even when they do, only some of the attempts to enact legislation are successful. The path of legislation—that is, of policy in the form of public laws—can be long and arduous (Hacker 1997). The details of this path that pertain to agenda setting are described in this chapter and, in regard to the development of legislation, in Chapter 6.

Agenda Setting

Kingdon (1995) describes agenda setting in public policymaking as a function of the confluence of three streams of activity: problems, possible solutions to the problems, and political circumstances. Some people prefer the term "issue" to Kingdon's choice of "problem" to refer to something that might trigger policymaking (Gormley and Boccuti 2001). It really does not matter which term is used; we will use "problem" to be consistent with Kingdon's terminology. In his conceptualization, when problems/possible solutions/political circumstances flow together in a favorable alignment, a "policy window" (Kingdon 1995, 166) or "window of opportunity" opens. When this happens, a problem/potential solution combination that might lead to a

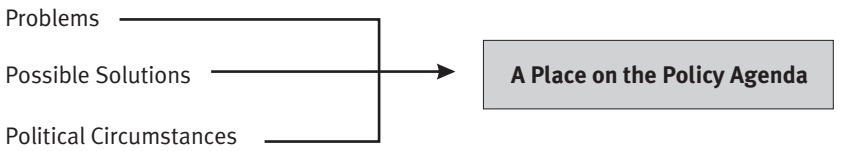


Figure 5.2 Agenda Setting as the Confluence of Problems, Possible Solutions, and Political Circumstances

new public law or an amendment to an existing one emerges from the set of competing problem/possible solution combinations and moves along in the policymaking process (see Figure 5.2).

Current health policies in the form of public laws, such as those pertaining to environmental protection, licensure of health-related practitioners and organizations, funding for AIDS research or for women's health, and regulation of pharmaceuticals, exist because problems or issues emerged from agenda setting and triggered changes in policy in the form of changes in public law. However, the mere existence of problems in these areas was not sufficient to trigger the development of legislation intended to address them.

The existence of health-related problems, even very serious ones such as millions of people without adequate health insurance coverage or the continuing widespread use of tobacco products, does not invariably lead to the establishment of policies intended to solve or ameliorate these problems. There also must be potential solutions to the problems as well as the political will to enact specific legislation intended to solve or ameliorate the problems. Obviously, agenda setting is crucial to the nature of the nation's health policies. Agenda setting is best understood in the context of its three key variables: problems, possible solutions, and political circumstances.

Problems

The breadth of this initiating variable in agenda setting can be seen in the range of possible public policies that have the potential to affect the pursuit of health. Chapters 1 and 2 discussed health as a function of several determinants: the physical environments in which people live and work; their behaviors and biology; social factors; and the type, quality, and timing of health services that they receive.

Beyond these determinants, as shown overarching Figure 5.1, the preferences of individuals, organizations, and interest groups as well as the biological, cultural, demographic, ecological, economic, ethical, legal, psychological, social, and technological aspects of American life also affect the policymaking process as much at the point of agenda setting as anywhere in the process. These inputs join with the consequences of the policies produced through the ongoing policymaking cycle (see the feedback loop from the policies that result from the process shown in Figure 5.1) to continually supply those

responsible for setting the nation's policy agenda with a massive pool of contenders for a place on that agenda. But, from among the contenders, how do certain problems find a place on the agenda while others do not?

Problems that Drive Policy Formulation

Only some problems or issues trigger policy formulation. Generally, the problems that eventually lead to the development of legislation are those broadly identified by policymakers as important and urgent. Problems that do not meet these criteria tend to languish at the bottom of the agenda or never find a place on the agenda at all. Price (1978) argues that whether a problem receives aggressive congressional intervention in the form of policymaking depends on its public salience and the degree of group conflict surrounding it. He defines a publicly salient problem or issue as one with a high actual or potential level of public interest. He defines conflictive problems or issues as those that stimulate intense disagreements between or among interest groups or those that pit the interests of groups against the larger public interest. Price contends that the incentives for legislators to intervene in problems or issues are highest when salience is high and conflict is low. Conversely, incentives are lowest when salience is low and conflict is high. The Real World of Health Policy: Reducing Medical Errors illustrates the difficulty of legislative intervention when conflict is high regarding how to address a problem.

The Real World of Health Policy

Reducing Medical Errors

Between 44,000 and 98,000 Americans die each year in U.S. hospitals due to preventable medical errors, making hospital errors between the fifth and eighth leading cause of death, killing more Americans than breast cancer, traffic accidents or AIDS. Serious medication errors occur in the cases of five to 10 percent of patients admitted to hospitals. These numbers may understate the problem because they do not include preventable deaths due to medical treatments outside of hospitals.

Public attention to this issue fluctuates, tending to rise with well-publicized cases. This occurred in early 2003 with the death of 17-year-old Jesica Santillan who died after a second heart-lung transplant, following an initial transplant in which she was given organs from a donor with the wrong blood type. Quality experts agree that the most common cause of errors is the medical system itself, not the individuals functioning within the system. Publication of the Institute of Medicine's reports, *To Err Is Human* (Committee on Quality of Health Care in America, Institute of Medicine 1999) and *Crossing the Quality Chasm: A New Health System for the 21st Century* (Committee on Quality of Health Care in

America, Institute of Medicine 1999) triggered substantial public and private sector activity, including the formation of the National Patient Safety Foundation by the American Medical Association, the creation of a non-punitive sentinel events reporting system by the Joint Commission for the Accreditation of Healthcare Organizations, and the establishment of new public private partnerships by the Veterans Health Administration and others.

Still, many experts see more talk than progress. For example, fewer than 3 percent of hospitals have implemented computerized drug ordering systems which one study found to reduce medication errors by 86 percent. In a December 2002 Kaiser Family Foundation survey, only 5 percent of physicians identified medical errors as a top healthcare concern. Shortly after the release of the 1999 IOM report, Congress gave $50 million to the U.S. Agency for Healthcare Research and Quality for research into the causes and prevention of medical errors. Beyond that, a flurry of legislative proposals in the 106th and 107th Congress resulted in stalemate over issues such as whether error reporting should be mandatory or voluntary and confidential or publicly released. Meanwhile, the controversy over the Santillan case has entered into the controversy over federal legislation backed by President Bush to limit non-economic damage awards in medical malpractice cases. States have also been a part of this debate as 18 now have mandatory error reporting rules and statutes with a patchwork of differing requirements.

As federal and state policymakers debate the issues related to reducing medical errors, discussion will likely focus on several key issues, including:

- What kind of standardized national reporting of medical errors should be established? Should it be voluntary or mandatory? Should it be confidential or publicly reported? In which cases?
- What agency should be designated to receive error reports? What authority should the agency have to act on reports?
- What kind of reporting may or should be required for “near miss” events? What protections should be provided to reporters of errors and near misses? What effect should this new reporting system have on existing state reporting systems?
- Should Congress set national standards for mandatory overtime by nurses and limitations on work hours for medical interns and residents, both of which have been tied to increased medical errors? These have also become state issues.
- Should Congress mandate hospitals to install computerized drug order entry systems and other technologies with proven ability to reduce errors? If so, should the federal government provide financial support to some or all hospitals to install these systems?
- Should the federal government set clear goals for the reduction of errors over a period of years, particularly for Medicare and Medicaid patients?

Should penalties and/or incentives be created for providers to reduce errors?

- What steps can Congress and state legislatures take to alleviate a serious national shortage of nurses—because many medical errors have been linked with understaffing of nurses and use of temporary nurses?
- How should national reform on medical errors relate to quasi-government regulatory agencies such as the Joint Commission on the Accreditation of Healthcare Organizations and the National Committee on Quality Assurance?
- Should any reports submitted under a medical errors reporting system be admissible as evidence in medical malpractice cases?

SOURCE: Henry J. Kaiser Family Foundation. 2004. "Reducing Medical Errors: Background Brief." [Online brief; retrieved 3/14/05.] http://www.kaiseredu.org/IssueModules/Reducing/index.cfm. This information was reprinted with permission of The Henry J. Kaiser Family Foundation. The Kaiser Family Foundation, based in Menlo Park, California, is a nonprofit, independent national healthcare philanthropy and is not associated with Kaiser Permanente or Kaiser Industries. The brief was prepared by John McDonough, executive director, Health Care for All, March 2004.

Problems that lead to attempted policy solutions in the form of changes in public law find their place on the agenda along any of several paths. Some problems emerge because the trends in certain variables eventually reach unacceptable levels—at least, levels unacceptable to some policymakers. Growth in the number of people with AIDS, the number of people who are uninsured, and costs in the Medicare program are examples of trends that eventually reached levels at which policymakers felt compelled to address the underlying problems through legislation.

An example of a problem that emerged in this way and led to specific legislation was the growing recognition that large numbers of people felt locked into their jobs because they feared that they might not be able to obtain health insurance if they changed jobs. Preexisting health problems or conditions could be cited as a basis for rejecting their applications for insurance benefits in the new job. In response to this problem, the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (P.L. 104-191) significantly limits the use of preexisting-condition exclusions and enhances the portability of health insurance coverage when people change jobs. Other provisions in this law guarantee availability and renewability of health insurance coverage for certain employees and individuals and an increase in the tax deduction for health insurance purchased by the self-employed.

Problems also can be spotlighted by their widespread applicability to many people (e.g., the high cost of prescription medications to millions of Americans) or by their sharply focused impact on a small but powerful group whose members are directly affected (e.g., the high cost of medical education).

Some problems gain their place on the agenda or strengthen their hold on a place because they are closely linked to other problems that already occupy secure places on the policy agenda. Efforts by the legislative and executive branches of the federal government to address the nation's budget deficit problem, at least in part through reduced expenditures on the Medicare program, has been a recurring example of the linkage of one problem (cost increases in the Medicare program) to another (growth of the federal deficit). Linking the control of growth in Medicare expenditures to the reduction of the federal deficit significantly strengthened political prospects for the development of legislation intended to curtail Medicare program expenditures, as was demonstrated in the Balanced Budget Act of 1997 (P.L. 105-33). This legislation called for reductions in the growth of Medicare expenditures of $385 billion from 1998 through 2007.

Problems also can emerge more or less simultaneously along several paths. Typically, problems that emerge this way occupy places of considerable prominence on the policy agenda. For example, the problem of the high cost of health services, both for the private and the public sectors, has received attention by policymakers over many years. This problem emerged along a number of mutually reinforcing paths. In part, the cost problem has been prominent on the health policy agenda at times because the cost trend data disturbs many people. The data contribute to and reinforce a widespread acknowledgment of the problem of health costs in public poll after public poll and has focused intense attention from some of those who pay directly for health services through the provision of health insurance benefits, especially the politically powerful business community. Finally, the health cost problem, as it relates to public expenditures—for the Medicare and Medicaid programs especially—has been linked at times to another significant item on the nation's policy agenda, the need to control the federal budget.

The *combination* of these circumstances regarding the health cost problem reinforces each circumstance and helps explain why this problem perennially occupies a prominent place in the mind of many policymakers. The fact that this problem persists has more to do with the nature of potential solutions than whether health costs have been identified as a problem.

Possible Solutions

The second variable in agenda setting is the existence of possible solutions to problems. The existence of problems—even serious, fully acknowledged ones with widespread implications, such as high costs and uneven access to needed health services—does not invariably lead to policies that attempt to address or solve them. Potential solutions to the problems must also exist. The availability of possible solutions depends on the generation of ideas for solving problems and, usually, on a period of idea testing and refinement. As The Real World of Health Policy: Possible Solutions to the High Cost of Health Care

suggests, numerous ideas typically arise that might serve as possible solutions to problems.

The Real World of Health Policy

Possible Solutions to the High Cost of Health Care

Consumer-driven healthcare, the major private-sector strategy for addressing rising costs, is unlikely to address the fundamental causes of rising healthcare costs. In fact, it is likely to have adverse consequences for patients.

- Consumer-driven healthcare contributes to excessive financial burdens on patients, particularly lower-income and sicker patients. If all Americans had a $1,000 deductible plan, one-third would spend more than 10 percent of their income on healthcare if they were hospitalized, with even higher rates at the lowest end of the income scale. High deductibles would lead to a major increase in the number of underinsured individuals.
- Patient costs are already unacceptably high. Indeed, they are a major reason why public opinion polls show that the affordability of healthcare is Americans' second-leading concern.
- Patient cost-sharing is a blunt instrument for reducing utilization of services. It reduces use of effective services that are already underutilized. Studies have documented that drug-tiering and higher copayments are leading patients to skip filling essential prescriptions, increasing adverse medical events, and raising emergency room use.

There are better alternatives for achieving economies in healthcare than shifting costs to patients. Costs are higher in the United States than in other countries because we pay higher prices for the same services; our administrative costs are higher; and physicians prescribe specialized services that are not clinically justified. If we as a nation were to adopt fundamental reforms—such as an integrated public-private strategy to purchase health services efficiently, demand quality performance, and streamline administrative costs—substantial savings could be achieved.

Short of fundamental reforms, practical steps that could be taken in the near term include:

- **Reducing medical errors and improving care coordination.** A major investment in health information technology, with shared public-private funding, is needed to accelerate the adoption of life-saving and efficiency-enhancing technology.
- **Public reporting of cost and quality data.** Costs incurred over an episode of care and quality vary enormously from hospital to hospital, physician

to physician, and area to area. If we are serious about doing better, we need to know where we stand. Much more extensive efforts are required to achieve comprehensive public reporting of cost and quality data on physicians, hospitals, nursing homes, other healthcare providers, and health plans.

- **Paying for provider performance on quality and efficiency.** Medicare needs to become a leader in "pay for performance" payment methods. While the demonstrations under way are important, Medicare needs to move much more quickly to reward those providers who are both high-quality and low-cost over the course of a patient's treatment. Doing so would spur the development of information about best practices and provide guidance to private insurers looking for effective ways to promote high-performance care.
- **Development and promulgation of clinical guidelines and quality standards.** Public programs and private insurers would benefit from a federal agency charged with establishing the scientific basis for effectiveness not just of new drugs but of specialty consultations, procedures, and tests. A national institute on clinical excellence and effectiveness has shown results in other countries and is a model we should adopt. We also need a substantial investment in research and demonstrations, far in excess of resources currently devoted to the Agency for Healthcare Research and Quality.
- **Better management of high-cost patients.** Public programs and private insurance need to be willing to pay for services of non-physician personnel that are needed for high-cost care management, such as advanced practice nurses, pharmacist medication monitoring, and home "telemonitoring" of conditions such as asthma and congestive heart failure.
- **Improved administrative efficiency.** The U.S. has an extraordinarily complex and fragmented system of health insurance. Ultimately, solutions that would simplify eligibility for insurance and improve the stability of health insurance coverage are needed to cut the administrative costs in our system. Testing statewide electronic insurance clearinghouses to pool insurance eligibility and, potentially, claims payment in a single place should be a priority.
- **Automatic and affordable health insurance for all.** Employers, federal and state governments, and individuals must all share responsibility for achieving automatic and affordable health insurance for all. The most realistic strategy is a combination of group insurance options including: employer coverage for those who are working; a new Congressional Health Plan, modeled on the Federal Employees Health Benefits Program, for small businesses and individuals; an expansion of the State Children's Health Insurance Program to low-income families and individuals with incomes below 150 percent of poverty; and an option for uninsured older adults

and disabled adults to obtain early coverage under Medicare (e.g., by eliminating the two-year waiting period for the disabled, covering spouses of Medicare beneficiaries, and permitting older adults to "buy in" to Medicare). Premium assistance based on income is required to make premiums affordable for all enrollees.

Together, these steps would take us a long way toward ensuring that this country has a high-performing health system worthy of the 21st century.

SOURCE: Davis, K. 2004. "Making Health Care Affordable for All Americans." Invited testimony before the Senate Committee on Health, Education, Labor, and Pensions Hearing on "What's Driving Health Care Costs and the Uninsured?" January 28. Excerpted and reprinted with permission.

While the menus of alternative solutions to the problems that face policymakers vary in size and quality, there are almost always alternative possible solutions. Many alternatives, each with its opponents and proponents, can slow advancement through the policymaking process as the relative merits of the competing alternatives are considered. Without at least one solution that is viewed as having the potential to actually solve the problem, however, issues do not advance in the policymaking process except in some spurious effort to create the illusion that a problem is being addressed.

When alternatives exist, choices must be made about whether the potential solutions under consideration are worth developing into legislative proposals. Frequently, in response to a particular problem, multiple ideas will be considered worthy of such action, resulting in the simultaneous development of several competing proposals, each intended to solve the same problem. This tends to make agenda setting rather chaotic, although, as discussed below, rigorous research and analysis can sometimes help provide more clarity about the choices that policymakers face.

The Role of Research and Analysis in Defining Problems and Assessing Alternatives

Health services research, as well as much biomedical research, contributes to problem identification and specification and to the development of possible solutions. Thus, research can support establishing the health policy agenda by clarifying both the problems and potential solutions to them. Health services research addresses issues of (Eisenberg 1998, 100)

> organization, delivery, financing, utilization, patient and provider behavior, quality, outcomes, effectiveness, and cost. It evaluates both clinical services and the system in which these services are provided. It provides information about the cost of care, as well as its effectiveness, outcomes, efficiency, and quality. It includes studies of the structure, process, and effects of health services for individuals and populations. It addresses both basic and applied research questions, including

fundamental aspects of both individual and system behavior and the application of interventions in practice settings.

Health services research assists policymakers to understand as fully as possible some of the facts that might affect their decisions.

Policymakers value the input of the research community sufficiently to fund much of its work through the National Institutes of Health (NIH) (www.nih.gov), the Agency for Healthcare Research and Quality (AHRQ) (www.ahrq.gov or www.ahcpr.gov), and other agencies. AHRQ, the health services research arm of the Department of Health and Human Services (DHHS), complements the biomedical research mission of its sister agency, NIH. AHRQ is the federal government's focal point for research to enhance the quality, appropriateness, and effectiveness of health services and access to those services.

Research plays an important documentation role by gathering, cataloging, and correlating facts that depict the state of health problems. For example, researchers have documented the dangers of tobacco smoke; the presence of HIV; the numbers of people living with AIDS and with a variety of cancers, heart disease, and other disease; the impact of poverty on health; the number of people who lack health insurance coverage; the existence of disparities in health among population segments; and the dangers imposed by exposure to various toxins in the physical environments, among many other threats to health. The quantification and documentation of health-related problems give these problems some chance of emerging on the policy agenda.

The second way in which research informs, and thus influences, the health policy agenda is through analyses that help determine which policy solutions may work. The fundamental contribution of biomedical research to the development of ever-advancing medical and health technology in the United States is well established. This research has made possible the diagnosis and treatment of previously untreatable diseases. Along different avenues of inquiry, health services research has revealed much of value to policymakers as they propose, consider, and prioritize alternative solutions to problems.

Often taking the form of demonstration projects intended to provide a basis in fact for determining the feasibility, efficacy, or basic workability of a possible policy intervention, research-based recommendations to policymakers can play an important role in policy agenda setting. Potential problem solutions that might lead to public policies—even if the policies themselves are formulated mainly on political grounds—must stand the test of plausibility. Research that supports a particular course of action being contemplated by policymakers or that helps attest to its likelihood of success—or at least to the probability that the course of action will not embarrass them—can make a significant contribution to policymaking by helping to shape the policy agenda.

What research cannot do for policymakers, however, is make their decisions for them. Every difficult decision regarding the health policy agenda—indeed, all policy decisions—ultimately rests with policymakers.

Decision Making Regarding Alternative Possible Solutions

The existence of problems that require decisions and alternative possible solutions to them are two prerequisites for use of the classical, rational model of decision making outlined in Figure 5.3. This decision-making model reflects the basic pattern of the organizational decision-making process typically followed in both the private and public sectors in the United States. However, differences in the use of this model in the two sectors typically arise when the *criteria* to be used in evaluating alternative solutions to problems are introduced.

Some of the criteria used in evaluating and comparing alternative solutions in both the private and public sectors are, of course, the same or similar. For example, the criteria set in both sectors usually includes consideration of whether a particular solution will actually solve the problem; whether it can be implemented within available resources and technologies; its costs and benefits relative to other possible solutions; and the results of an advantage-to-disadvantage analysis of the alternatives.

In both private and public sectors, high-level decisions have scientific or technical, political, and economic dimensions. The scientific or technical aspects can be made more difficult to factor into decisions when the evidence is in dispute, as it often is (Atkins, Siegel, and Slutsky 2005; Steinberg and Luce

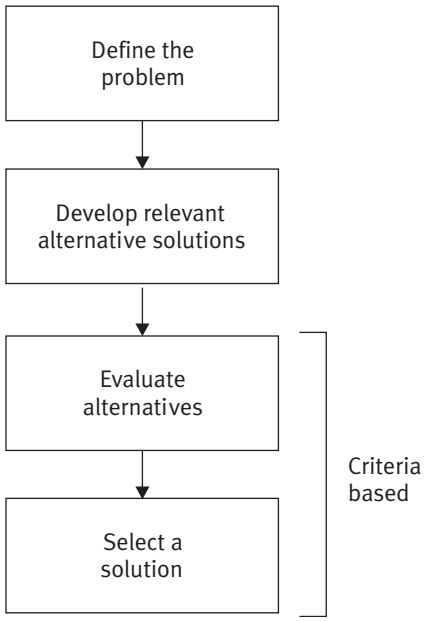


Figure 5.3 The Rational Model of Decision Making

2005). The most pervasive difference between the criteria sets used in the two sectors, however, is the variation in the roles played by political concerns and considerations. Decisions made by policymakers in the public sector must reflect much greater political sensitivity to the public at large as well as to the preferences of relevant individuals, organizations, and interest groups than most decisions made in the private sector. This helps explain the considerable importance of the third variable in agenda setting in the health policymaking process, political circumstances.

Political Circumstances

The existence of a problem that might be solved or lessened by a change in policy, even in combination with a possible solution to that problem, is not of itself sufficient to move the problem/solution combination forward in the policymaking process. A political force, or what is sometimes called political will, is also necessary to advance a problem/potential solution combination.

Thus, the political circumstances surrounding each problem/potential solution in the policymaking process form the crucial third variable in creating a window of opportunity through which problems/potential solutions move toward actual development of legislation. This variable is at least as important as the other two variables in this complex equation (see Figure 5.2). In fact, the establishment of a political thrust forceful enough to move policymakers to attempt to do something substantive about a health-related problem is often the most challenging variable in the problem's emergence from among the set of competing issues vying for places on the policy agenda. The Real World of Health Policy: Public's Agenda Differs from President's illustrates how public opinion can form around problems and potential solutions to them and how these can differ from the preferences of policymakers.

The Real World of Health Policy

Public's Agenda Differs from President's

George W. Bush begins his second term with considerably less popular support than other recent incumbent presidents after their reelection. He also is proposing a second-term policy agenda that differs in several key respects from the public's. Healthcare, aid for the poor, and the growing budget deficit are all increasingly important public priorities, while limiting lawsuit awards, making recent tax cuts permanent and tax simplification rank near the bottom of the public's agenda.

Social Security, which the White House has targeted as a major issue, ranks near the top of the public's policy agenda, with 70 percent identifying it as a top priority. But the public believes that the healthcare system currently is in greater

need of repair than Social Security, the tax system or the legal system all of which are expected to be the subject of administration initiatives.

Nearly half of Americans (47 percent) believe the Social Security system now works pretty well and needs only minor changes, with comparable percentages of Republicans and Democrats in agreement on that point. That compares with just 27 percent who believe that the healthcare system works fairly well and 36 percent who say the same about the education system.

In principle, Americans are open to the idea of introducing private accounts into the Social Security system. But in practice, the public believes it is more important to retain a guaranteed monthly Social Security benefit than it is to let younger workers invest in private accounts whose value would rise or fall depending on how their investments perform. The preference for a guaranteed Social Security benefit has grown since the end of the 1990s stock market boom—65 percent prefer retaining a guaranteed monthly benefit, compared with 54 percent in October 2000.

The latest survey by the Pew Research Center for the People & the Press, conducted January 5–9, 2005 among 1,503 Americans, finds a yawning partisan gap in public policy priorities and in perceptions of President Bush. Overall, half of Americans approve of the president's job performance while 43 percent disapprove. This is well below the approval ratings enjoyed by Presidents Eisenhower, Nixon, Reagan and Clinton as they began their second term.

Bush's lower ranking results from greater disapproval among members of the opposing party than was the case for his reelected predecessors. However, Bush continues to draw an extremely high level of support from the GOP base. Bush's approval rating among his own party (89 percent) is just as high as his predecessors at the start of their second terms.

Looking ahead, the public believes that the military, business corporations and conservative Christians will gain influence in Bush's second term. Among those expected to lose influence in Washington, poor people clearly stand out; 49 percent believe the influence of poor people will decline, compared with 40 percent who expressed that view at the start of Bush's first term. Environmentalists, union leaders, and, significantly, older people also are expected to lose influence. In addition, about a third of Americans (34 percent) say that people like them will have less influence, up from 26 percent who said that four years ago.

Pew's annual assessment of the public's policy priorities reflects the continuing re-emergence of several domestic objectives particularly the need to provide health insurance for the uninsured and deal with the problems of the poor which had faded in importance after the 9/11 terrorism attacks. The deficit also is a growing concern; 56 percent cite reducing the budget deficit as a top policy priority, up from 40 percent just two years ago.

SOURCE: The Pew Research Center for the People & the Press. 2005. *Public's Agenda Differs From President's.* Survey Report, January 13. Washington, DC: The Pew Research Center for the People & the Press. Excerpted and reprinted with permission.

Whether the political circumstances attendant to any particular problem/potential solution combination are sufficient to actually open the window of opportunity for its advancement in the policymaking process depends very much on the nature of other competing entries on the policy agenda. The array of competing problems is always an important variable in agenda setting. When the nation is involved in serious threats to its national security or its civil order, for example, or when a state is in the midst of a sustained recession, health policy will be treated differently from when policymakers are less preoccupied with other, perhaps more urgent, concerns. In fact, health policy can be pushed almost entirely to a secondary position at times. For example, recent polls demonstrate that health issues and policies were "second tier" in the 2004 presidential election, behind "moral values," the state of the economy, terrorism, and the war in Iraq (Blendon et al. 2005).

The political circumstances surrounding any particular problem/potential solution combination include such factors as the relevant public attitudes, concerns, and opinions; the preferences and relative ability to influence political decisions of various groups interested in the problem or in the way in which it is addressed; and the positions and views of involved key policymakers in the executive and legislative branches of government. Each of these factors can exert a powerful influence on whether a problem is addressed through policy, as well as on the nature of the way the problem is addressed, that is, on the shape and scope of any policy developed to address the problem.

Two factors in particular exert great influence in establishing the policy agenda. These are interest groups and the chief executive (president, governor, or mayor), who can be powerful in setting the policy agenda. The role of each in agenda setting is discussed in the next two sections.

Interest Group Involvement in Agenda Setting

To appreciate fully the role of interest groups in helping to set the policy agenda, it is useful to first consider the role of individual members of American society in health policy agenda setting. In a representative form of government, such as that of the United States, individual members of society, unless they are among the elected representatives, usually do not have the opportunity to vote directly on policies. They do, however, have opportunities to vote on policymakers. Thus, policymakers are interested in what the individual members of society want, even when what they want is not easy to discern.

However, one of the great myths of a democratic society is that its members, when confronted with tough problems such as the high cost of healthcare for everyone, the lack of health insurance for many, or the existence of widespread disparities in health among segments of the society, ponder the problems carefully and express their preferences to their elected officials,

who then factor these opinions into their decisions about how to address the problems through policy.

Sometimes these steps take place, but even when the public expresses its opinions about an issue, as illustrated in The Real World of Health Policy: Public's Agenda Differs from President's (see page 174), the result is clouded by the fact that the American people are heterogeneous in their views. Opinions are invariably mixed on just about all health-related problems and their solutions. Public opinion polls can help sort out conflicting opinions, but polls are not always straightforward undertakings. Complicating their use is the fact that on many issues, individuals' opinions are subject to evolutionary change.

Yankelovich (1992) points out that the public's thinking on difficult problems that might be addressed through public policies evolves through predictable stages, beginning with awareness of the problem and ending with judgments about its solution. In between, people explore the problem and alternative solutions, with varying degrees of success. The progress of individuals along this continuum of stages has a great deal to do with their views on both problems and solutions.

The diversity among members of society, together with the fact that their individual views on important problems and potential solutions to the problems evolve and change over time, explains in large part the tendency of organizations and interest groups to be more influential than individuals in establishing the policy agenda. Interest groups in particular can exert extraordinary power and influence in the political marketplace for health policies, as was discussed in Chapter 3.

Whether their membership comprises individuals or organizations, interest groups are able to present a unified position to policymakers on their preferences regarding a particular problem or its solution by organizing and focusing the opinions of their members. A unified position is far easier for policymakers to assess and respond to than the diverse opinions and preferences of many individuals acting alone. Although individuals tend to be keenly interested in their own health, as well as in the health of those they care about, their interests in specific health policies tend to be diffuse. This stands in contrast to the highly concentrated interests of those who earn their livelihood in this domain or who stand to gain other benefits within the health domain. This phenomenon is not unique to health. Indeed, in general, the interests of those who earn their livelihood in any industry or economic sector are more concentrated than the interests of those who merely use its outputs; these interests are far more concentrated than those of individuals who only incidentally or occasionally interact with the domain.

One result of the existence of concentrated interests is the formation of organized interest groups that seek to influence the formulation, implementation, and modification of policies to some advantage for the group's members. Because all interest groups seek policies that favor their members, their own

agendas and behaviors, as well as their preferences regarding the larger public policy agenda, are often predictable.

Feldstein (2001) argues, for example, that all interest groups representing health services providers seek through legislation to increase the demand for members' services, limit competitors, permit members to charge the highest possible prices for their services, and lower their members' costs of operating as much as possible. Likewise, an interest group representing health services consumers logically seeks policies that minimize the costs of the services to the members, ease their access to the services, increase the availability of the services, and so on. Essentially, this is human nature at work.

Interest groups frequently play powerful roles in setting the nation's health policy agenda, as they do subsequently in the development of legislation and in the implementation and modification of health policies. These groups sometimes play their role proactively by seeking to stimulate new policies that serve the interests of their members. Alternatively, they sometimes play their role reactively by seeking to block changes in public policies that they believe do not serve their members' best interests.

Opportunities to join interest groups are widely available for those who are interested in the policy agenda. As Chapter 3 discussed, individual physicians can join and have some of their interests represented by the American Medical Association (AMA) (www.ama-assn.org). Nurses can join the American Nurses Association (ANA) (www.ana.org). Not only can hospitals join the American Hospital Association (AHA) (www.aha.org), but teaching hospitals can join the Association of American Medical Colleges' (AAMC) (www.aamc.org) Council of Teaching Hospitals and Health Systems; children's hospitals can join the National Association of Children's Hospitals (NACH) (www.childrenshospitals.net); and investor-owned hospitals can join the Federation of American Hospitals (FAHS) (www.fahs.com). Health insurers can join America's Health Insurance Plans (AHIP) (www.ahip.org).

Even subsets of the general population can join a group that seeks to serve their health-related interests. For example, the American Association of Retired Persons (AARP) (www.aarp.org) is a powerful interest group representing the interests of many of the nation's older citizens. Other consumer-oriented interest groups include the Alliance for Retired Americans (www.retiredamericans.org); Families U.S.A. (www.familiesusa.org), which describes itself as the "voice of health care consumers"; and the Consortium for Citizens with Disabilities (www.c-c-d.org).

Tactics of Interest Groups in Agenda Setting

As influential participants in public policymaking, interest groups are integral to the process in the United States. And they are especially ubiquitous in the health domain. But how do they exert their influence on agenda setting and at other points in the health policymaking process? The answer to this question

involves four tactics that interest groups rely on heavily as their means of influencing the process: lobbying; electioneering; litigation; and, especially more recently, shaping public opinion in order that it might in turn influence the policymaking process to the groups' advantage (Kingdon 1995; Edwards, Wattenberg, and Lineberry 2003). Each of these tactics is described in the following sections.

Lobbying

This widely used influencing tactic has deep roots in American public policymaking. "Lobbying is as old as legislation and pressure groups are as old as politics" (Schriftgeisser 1951, 3). The tactic is still widely used, as illustrated in The Real World of Health Policy: Medicare Bill Represents Success for Pharmaceutical Lobby. In the mind of many people, lobbying conjures a negative image of money exchanging hands for political favors and backroom deals, but ideally it is nothing more than communicating with public policymakers for the purpose of influencing their decisions to be more favorable to, or at least consistent with, the preferences of those doing the lobbying (Buchholz 1994; Milbrath 1976).

The Real World of Health Policy

Medicare Bill Represents Success for Pharmaceutical Lobby

Ceci Connolly
The Washington Post
November 21, 2003

No industry in negotiations over the $400 billion Medicare prescription drug bill headed to the House floor today outpaced the pharmaceutical lobby in securing a favorable program design and defeating proposals most likely to cut into profits, according to analysts in and out of the industry.

If the legislation passes as Republican leaders predict, it will generate millions of new customers who currently lack drug coverage. At the same time, drug-manufacturing lobbyists overcame efforts to legalize the importation of lower-cost medicines from Canada and Europe and instead inserted language that explicitly prohibits the federal government from negotiating prices on behalf of Medicare recipients.

"It couldn't be clearer there is going to be a positive effect overall," said Dan Mendelson, president of Health Strategies Consultancy, which bills itself as a think tank and consulting firm. "The volume will definitely go up. There will be a lot of people who didn't have coverage before who will have it now and a lot of people getting an upgrade in terms of coverage."

Democrats and consumer advocates complain that the Republican-crafted compromise does little to contain soaring drug costs. They say that by handing

the Medicare drug program's administration to private insurers, Congress missed a chance to exert pressure on pharmaceutical companies to reduce prices.

But Republicans and some industry analysts say that adopting a drug-purchasing mechanism similar to those in corporate health plans is the best way to extract discounts from drugmakers.

If Medicare negotiated on behalf of its 40 million beneficiaries, "I wouldn't be negotiating; I'd just be fixing the price," said Thomas Scully, the program's administrator. "Let's get seniors organized into big purchasing pools that get bulk discounts and see how they fare."

Representatives of the industry's main lobbying arm, the Pharmaceutical Research and Manufacturers of America (PhRMA), declined yesterday to discuss the legislation. But the clearest indication that the bill offers a brighter future for the industry came from Wall Street, where pharmaceutical stock prices have steadily risen over the past week as the legislation's prospects for passage improved. Analysts at Goldman Sachs & Co. project the new Medicare benefit could increase industry revenue by 9 percent, or about $13 billion a year.

After objecting for years to proposals to add prescription drug coverage to Medicare, the pharmaceutical lobby recently shifted positions and poured enormous resources into shaping the legislation. Since the 2000 election cycle, the industry has contributed $60 million in political donations and spent $37.7 million in lobbying in the first six months of this year.

The lobbying continued in earnest this week with a television and print advertising campaign urging passage of the bill. In one series of witty commercials sponsored by the industry-backed Alliance to Improve Medicare, elderly citizens look into the camera and demand: "When ya gonna get it done?"

One Republican with ties to the industry said drugmakers eluded the three things they feared most: legalized importation of lower-cost medicines, many of them patented or made in the United States; government price controls; and easier market access for generic drugs that cost considerably less than brand-name drugs. "In their view, by improving access for all seniors, we will ameliorate any pressure on the industry toward price controls or reimportation," the source said.

About 24 percent of Medicare beneficiaries—nearly 10 million senior citizens—do not have any prescription benefits. Some of them buy medicine at the highest retail prices. Academic studies and anecdotal evidence suggest, however, that many go without prescription medicines and would become new customers for drugmakers if the bill becomes law. The remaining 30 million Medicare recipients buy some supplemental drug coverage, according to the most recent government figures.

Even those with some drug coverage are expected to spend more with the new benefit, said Fredric E. Russell, whose investment management company owns several drug stocks. Whenever a new health benefit is offered, he said, patients and doctors jump at the chance to take advantage of it.

Under the bill, beginning in 2006, all Medicare beneficiaries would have the option of buying a drug plan for about $35 a month, plus a $275 annual deductible. Insurance companies and pharmacy benefit managers (PBMs) would administer the programs for the government.

The great unknown is what sort of prices those insurers will ultimately negotiate on behalf of their Medicare clients, said Kristine Bryan, senior healthcare analyst at Brown Brothers Harriman & Co. "Generally, when you have a large purchaser, you have the ability to demand better pricing," she said.

Republican congressional staffers also point out that because the bill waives a requirement that state Medicaid programs receive the "best price" available, the new private insurers could save Medicare $18 billion. It would, however, likely increase states' drug costs.

Many Democrats say private purchasers have not been as successful at bargaining as have government programs such as the Veterans Administration and Medicaid, which secure some of the steepest drug discounts available.

"We've been going through PBMs for 10 years and nothing's happened except the price of drugs has gone up," said Democratic presidential candidate Howard Dean, a physician.

Perhaps the most striking political victory for the pharmaceutical industry was the decision to reject provisions that would have allowed Americans to legally import drugs from Canada and Europe, where medications retail for as much as 75 percent less than in the United States. Polls show that an overwhelming majority supports the change, and the House approved the provision, 243 to 186. But the Bush administration and pharmaceutical lobby said the move was dangerous and would cut into future research and development.

The provision was dropped from the bill's final version.

SOURCE: Connolly, C. 2003. "Drugmakers Protect Their Turf: Medicare Bill Represents Success for Pharmaceutical Lobby." *The Washington Post*, November 21, A04. **© 2003, The Washington Post, reprinted with permission.**

"Lobbying," the word for these influencing activities, and "lobbyists," the word for people who do this work, arose in reference to the place where such activities first took place. In early Washington, DC, before members of Congress had either offices or telephones, certain people who sought to influence their thinking waited for the legislators and talked to them in the lobbies of the buildings they frequented. The original practitioners of this influencing tactic spent so much time in lobbies that they came, naturally enough, to be called lobbyists and their work lobbying.

Like many other groups of people, lobbyists come in a great variety. The vast majority of them operate in an ethical and professional manner, effectively representing the legitimate interests of the groups they serve. The

few, however, who behave in a heavy-handed, even illegal, manner have to some extent tarnished the reputations of all who do this work. Their image is further affected by the fact that their work, if properly done, is essentially selfish in nature. Lobbyists seek to persuade others that their position—the position of the interests they represent—is the correct one. Lobbyists' whole professional purpose is to persuade others to make decisions that are in the best interests of those who employ or retain them.

Results of studies as well as opinions on the effectiveness of the lobbying tactic as a means of influencing the public policymaking process are mixed at best (Milbrath 1976; Kingdon 1995). Some ambivalence over the role of lobbying in influencing policymaking derives from the difficulty inherent in isolating its effect from the other influencing tactics discussed later. There is no doubt that lobbying has an impact on the policymaking process, but it seems to work best when applied to policymakers who are already committed, or at least sympathetic, to the lobbyist's position on a public policy issue (Edwards, Wattenberg, and Lineberry 2003). Lobbyists certainly played a prominent role in the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (P.L. 108-173) and in a great deal of other health policymaking (Carpenter 2004). The Real World of Health Policy: Lobbying CMS to Make Administrative Changes to the Sustainable Growth Rate (SGR) Formula for Updating the Medicare Physician Fee Schedule provides an example of highly focused and cooperative lobbying. Additional background information on the SGR formula for updating the Medicare physician fee schedule can be found in *Medicare Physician Payments: Concerns About Spending Target Prompt Interest in Considering Reform* (GAO 2004) and in *Medicare Physician Payments: Considerations for Reforming the Sustainable Growth Rate System* (Steinwald 2005).

The Real World of Health Policy

Lobbying CMS to Make Administrative Changes to the Sustainable Growth Rate (SGR) Formula for Updating the Medicare Physician Fee Schedule

July 14, 2004
The Honorable Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, SW
Room 314-G
Washington, DC 20201

Dear Dr. McClellan:

All of the undersigned organizations believe that Medicare's formula for paying physicians and other health professionals is broken. Beginning in 2006, the Sustainable Growth Rate (SGR), which is part of this formula, will cut reimbursements by five percent a year for seven consecutive years, with additional cuts for several years thereafter. Without changes, 2014 payment levels for these practitioners are projected to be about 30 percent less than in 2005. Such an enormous reduction defies logic and would be debilitating for medical practices.

We appreciate that you have spoken positively about the need to correct this situation before it greatly impedes beneficiary access to high quality care. Although a complete solution likely will require congressional action, there are a number of steps that CMS could take administratively to improve the current formula and facilitate legislation in this area. In particular, we believe that it is within your authority to remove physician-administered drugs from the SGR calculation and include the full costs of new benefits and coverage decisions in the SGR target.

Removal of the Cost of Prescription Drugs

Congress intended the SGR to account for Medicare spending on physician/practitioner services. However, even though drugs are products and not "physician services" as defined in the law, the Centers for Medicare & Medicaid Services (CMS) includes the cost of drugs in the SGR. Due to increasing technology and growing demand, spending on these drugs is rising far more rapidly than spending on physicians' and other practitioners' services. Combining the two creates an inaccurate picture of growth in services. Removing drugs from the SGR formula thus is a logical step towards improving the accuracy of the current formula.

Inclusion of the Full Impact of Law and Regulations

The current SGR calculation fails to adequately capture the impact of changes to laws and regulations. For example, although Medicare has new screening benefits, the SGR targets do not appear to account for the downstream services that result when screenings reveal health problems. The same is true of the Medicare prescription drug benefit, which will unquestionably lead to more medical visits, thus generating additional tests and care. The SGR calculations also need to account for this inevitable spending. Additionally, the impact of CMS coverage decisions is excluded from the SGR entirely, even though those decisions significantly influence patient demand. Such changes in law and regulation are likely very beneficial for patient care, but inappropriately result in negative payment updates through the SGR calculation.

These suggested adjustments represent clear and decisive steps in the right direction, even if they will not solve all of the problems associated with

Medicare's reimbursement formula. We urge you to make these improvements now in order to facilitate congressional efforts to reform this broken system before 2006. Please let us know how we can assist, and thank you for your continuing efforts to ensure beneficiary access to high quality care.

Sincerely,

American Academy of Audiology
American Academy of Child and Adolescent Psychiatry
American Academy of Dermatology Association
American Academy of Facial, Plastic and Reconstructive Surgery
American Academy of Family Physicians
American Academy of Neurology
American Academy of Nurse Practitioners
American Academy of Ophthalmology
American Academy of Otolaryngology—Head and Neck Surgery
American Academy of Pediatrics
American Academy of Physical Medicine and Rehabilitation
American Academy of Physician Assistants
American Academy of Sleep Medicine
American Association for Thoracic Surgery
American Association of Clinical Endocrinologists
American Association of Clinical Urologists
American Association of Electrodiagnostic Medicine
American Association of Neurological Surgeons
American Association of Nurse Anesthetists
American Association of Orthopaedic Surgeons
American College of Cardiology
American College of Chest Physicians
American College of Emergency Physicians
American College of Gastroenterology
American College of Nurse-Midwives
American College of Nurse Practitioners
American College of Obstetricians and Gynecologists
American College of Osteopathic Family Physicians
American College of Osteopathic Surgeons
American College of Physicians
American College of Radiology Association
American College of Rheumatology
American College of Surgeons
American Gastroenterological Association
American Geriatrics Society
American Medical Association
American Medical Directors Association
American Medical Group Association
American Nurses Association
American Occupational Therapy Association
American Optometric Association
American Osteopathic Academy of Orthopedics
American Osteopathic Association
American Physical Therapy Association
American Podiatric Medical Association
American Psychiatric Association
American Psychological Association
American Society for Clinical Pathology
American Society for Gastrointestinal Endoscopy
American Society for Reproductive Medicine
American Society for Therapeutic Radiology and Oncology
American Society of Addiction Medicine
American Society of Anesthesiologists
American Society of Cataract and Refractive Surgery
American Society of Clinical Oncology
American Society of General Surgeons
American Society of Hematology
American Society of Nephrology
American Society of Neuroradiology
American Society of Plastic Surgeons
American Speech-Language-Hearing Association
American Thoracic Society
American Urogynecologic Society
American Urological Association
Association of American Medical Colleges
Association of Women's Health, Obstetric and Neonatal Nurses
Cleveland Clinic Foundation
College of American Pathologists
Congress of Neurological Surgeons
Emergency Department Practice Management Association
Heart Rhythm Society
Infectious Diseases Society of America
Joint Council of Allergy, Asthma and Immunology
Marshfield Clinic
Mayo Clinic
Medical Group Management Association
National Association for Medical Direction of Respiratory Care
National Association of Social Workers
National Medical Association
National Organization of Nurse Practitioner Faculties
National Rural Health Association
North American Spine Society
Renal Physicians Association
Society for Cardiovascular Angiography and Interventions
Society for Vascular Surgery
Society of Critical Care Medicine
Society of General Internal Medicine
Society of Gynecologic Oncologists
Society of Hospital Medicine
Society of Interventional Radiology
Society of Thoracic Surgeons
The Endocrine Society

SOURCE: American College of Physicians (ACP). 2004. [Online information; retrieved 6/16/05.] http://acponline.org/hpp/mcclellan04.htm. Reprinted with permission of ACP.

The degree of influence lobbyists exert on agenda setting and other aspects of policymaking is facilitated by several well-recognized sources of their influence with policymakers (Ornstein and Elder 1978; Herrnson, Shaiko, and Wilcox 2004).

- Lobbyists are an important source of information for policymakers. Although most policymakers must be concerned with many policy issues simultaneously, most lobbyists can focus and specialize. They can become expert, and can draw on the insight of other experts, in the areas they represent.
- Lobbyists can assist policymakers with the development and execution of political strategy. Lobbyists typically are politically savvy and can provide what amounts to free consulting to the policymakers they choose to assist.
- Lobbyists can assist elected policymakers in their reelection efforts. (More is said about this in the next section, on electioneering.) This assistance can take several forms, including campaign contributions, votes, and workers for campaigns.
- Lobbyists can be important sources of innovative ideas for policymakers. Policymakers are judged on the quality of their ideas as well as on their abilities to have those ideas translated into effective policies. For most policymakers, few gifts are as valued as a really good idea, especially when they can turn that idea into a bill that bears their name.
- Finally, lobbyists can be friends with policymakers. Lobbyists often are gregarious and interesting people in their own right. They entertain, sometimes lavishly, and they are socially engaging. Many of them have social and educational backgrounds similar to those of policymakers. In fact, many lobbyists have been policymakers earlier in their career. It is neither unusual nor surprising for lobbyists and policymakers to become friends.

Electioneering

The effective use of the electioneering tactic in influencing the policymaking process is based on the simple fact that policymakers who are sympathetic to a group's interests are far more likely to be influenced than are policymakers who are not sympathetic. Thus, interest groups seek to help elect to office—and help keep in office—policymakers whom they view as sympathetic to the interests of the group's members. Electioneering, or using the resources at their disposal to aid candidates for political office, is a common means through which interest groups seek to exert their influence on the policymaking process. Many groups have considerable resources to devote to this tactic.

Interest groups have, to varying degrees, a set of resources that involve electoral advantages or disadvantages for political candidates. "Some groups—because of their geographical dispersion in congressional districts throughout

TABLE 5.1 Money Raised in the 2004 Election Cycle

House:

Party	*No. of Candidates*	*Total Raised*	*Total Spent*	*Total Cash on Hand*	*Total from PACs*	*Total from Individuals*
All	1214	$692,482,733	$632,081,349	$173,597,705	$232,945,633	$393,546,925
Democrats	555	$300,037,245	$274,933,346	$80,094,253	$102,859,223	$175,862,110
Republicans	608	$390,666,710	$355,426,359	$92,858,075	$129,916,253	$216,484,016

Senate:

Party	*No. of Candidates*	*Total Raised*	*Total Spent*	*Total Cash on Hand*	*Total from PACs*	*Total from Individuals*
All	188	$486,254,101	$481,262,666	$63,333,320	$68,217,656	$324,584,361
Democrats	77	$247,164,203	$247,202,890	$33,932,648	$30,670,459	$169,165,050
Republicans	93	$237,745,629	$233,406,918	$28,715,110	$37,531,645	$154,971,547

President:

Party	*No. of Candidates*	*Total Raised*	*Total Spent*	*Total Cash on Hand*	*Total from PACs*	*Total from Individuals*
All	15	$863,046,722	$810,972,725	$49,847,980	$3,688,379	$627,494,380
Democrats	10	$489,873,804	$465,241,779	$25,078,825	$782,112	$351,768,911
Republicans	1	$366,554,535	$339,280,603	$24,595,515	$2,903,767	$271,634,244

SOURCE: Center for Responsive Politics (2005). Reprinted with permission.

the country; their ability to mobilize their members and sympathizers; and their numbers, status, or wealth—are thought to have an ability to affect election outcomes" (Kingdon 1995, 51).

One of the most visible aspects of the electioneering tactic is the channeling of money into campaign finances. Table 5.1 shows the extent of this activity in the 2004 election cycle. Health-related interest groups participate heavily in this form of electioneering.

In 1975 Congress created the Federal Election Commission (FEC) (www.fec.gov) to administer and enforce the Federal Election Campaign Act (FECA)—the law that governs the financing of federal elections. The duties of FEC, which is an independent regulatory agency, are to disclose campaign finance information, enforce the provisions of the law such as the limits and prohibitions on contributions, and oversee the public funding of presidential elections. The Real World of Health Policy: Types of Groups Involved in Financing Political Campaigns describes groups permitted to engage in political activity.

The Real World of Health Policy

Types of Groups Involved in Financing Political Campaigns

501(c) groups—Nonprofit, tax-exempt groups organized under section 501(c) of the Internal Revenue Code that can engage in varying amounts of political

activity, depending on the type of group. For example, 501(c)(3) groups operate for religious, charitable, scientific or educational purposes. These groups are not supposed to engage in any political activities, though some voter registration activities are permitted. 501(c)(4) groups are commonly called "social welfare" organizations that may engage in political activities, as long as these activities do not become their primary purpose. Similar restrictions apply to Section 501(c)(5) labor and agricultural groups, and to Section 501(c)(6) business leagues, chambers of commerce, real estate boards and boards of trade.

527 group—A tax-exempt group organized under section 527 of the Internal Revenue Code to raise money for political activities including voter mobilization efforts, issue advocacy and the like. Currently, the FEC only requires a 527 group to file regular disclosure reports if it is a political party or political action committee (PAC) that engages in either activities expressly advocating the election or defeat of a federal candidate, or in electioneering communications. Otherwise, it must file either with the government of the state in which it is located or the Internal Revenue Service. Many 527s run by special interest groups raise unlimited "soft money," which they use for voter mobilization and certain types of issue advocacy, but not for efforts that expressly advocate the election or defeat of a federal candidate or amount to electioneering communications.

Nonfederal group—A group set up to raise unlimited contributions called "soft money," which it spends on voter mobilization efforts and so-called issue ads that often criticize or tout a candidate's record just before an election in a not-so-subtle effort to influence the election's outcome. 501(c) groups and 527 groups may raise non-federal funds.

Political action committee (PAC)—A political committee that raises and spends limited "hard" money contributions for the express purpose of electing or defeating candidates. Organizations that raise soft money for issue advocacy may also set up a PAC. Most PACs represent business, such as the Microsoft PAC; labor, such as the Teamsters PAC; or ideological interests, such as the EMILY's List PAC or the National Rifle Association PAC. An organization's PAC will collect money from the group's employees or members and make contributions in the name of the PAC to candidates and political parties. Individuals contributing to a PAC may also contribute directly to candidates and political parties, even those also supported by the PAC. A PAC can give $5,000 to a candidate per election (primary, general or special) and up to $15,000 annually to a national political party. PACs may receive up to $5,000 each from individuals, other PACs and party committees per year. A PAC must register with the Federal Election Commission within 10 days of its formation, providing the name and address of the PAC, its treasurer and any affiliated organizations.

SOURCE: Center for Responsive Politics. n.d. "Types of Advocacy Groups." [Online information; retrieved2/11/05.] www.opensecrets.org/527s/types.asp. Reprinted with permission.

The Center for Responsive Politics, a nonpartisan, not-for-profit research group based in Washington, DC, is a rich source of information on the flow of money in politics and its effect on elections and public policymaking. The center's web site (www.opensecrets.org) provides extensive, detailed information on the flow of money into the political process.

Although participating in campaign financing is an important source of influence for interest groups, the most influential among groups are those with multiple ways of exerting their influence through lobbying and electioneering activities. The hospital industry is a notable example. The American Hospital Association is a leading campaign contributor through its political action committee (PAC). Furthermore, it has many additional other resources at its disposal. As Kingdon (1995) points out, every congressional district has hospitals whose trustees are community leaders and whose managers and physicians are typically articulate and respected in their community. These spokespersons can be mobilized to support sympathetic candidates or to contact their representatives directly regarding any policy decision.

As Ornstein and Elder (1978, 74) observe, "The ability of a group to mobilize its membership strength for political action is a highly valuable resource; a small group that is politically active and cohesive can have more political impact than a large, politically apathetic, and unorganized group." The ability to mobilize people and other resources at the grassroots level helps explain the relative capabilities of various groups to influence policymakers and, through them, the policymaking process. The most influential health interest groups, including AHA and AMA, have particularly strong grassroots organizations to call into play in the exercise of their lobbying and electioneering tactics.

Litigation

A third tactic available to interest groups in their efforts to influence the policymaking process is litigation. Interest groups, acting on behalf of their members, seek to influence the policy agenda and the larger policymaking process through litigation in which they challenge existing policies, seek to stimulate new policies, or try to alter certain aspects of the implementation of policies. Use of the litigation tactic, in both state and federal courts, is widespread and increasingly employed by interest groups to influence policymaking in the health domain. The Real World of Health Policy: Interest Groups in the Judicial Process describes how some interest groups have found the judicial branch to be receptive to their efforts and relatively easy for the groups to use as a means of influencing policymaking.

The Real World of Health Policy

Interest Groups in the Judicial Process

Although interest groups are probably better known for their attempts to influence legislative and executive branch decisions, they also pursue their policy

goals in the courts. Some groups have found the judicial branch to be more receptive to their efforts than either of the other two branches of government. Interest groups that do not have the economic resources to mount an intensive lobbying effort in Congress or a state legislature may find it much easier to hire a lawyer and find some constitutional or statutory provision upon which to base a court case. Likewise, a small group with few registered voters among its members may lack the political clout to exert much influence on legislators and executive branch officials. Large memberships and political clout are not prerequisites for filing suits in the courts, however.

Interest groups may also turn to the courts because they find the judicial branch more sympathetic to their policy goals than the other two branches. Throughout the 1960s interest groups with liberal policy goals fared especially well in the federal courts. In addition, the public interest law firm concept gained prominence during this period. The public interest law firms pursue cases that serve the public interest in general—including cases in the areas of consumer rights, employment discrimination, occupational safety, civil liberties, and environmental concerns.

In the 1970s and 1980s conservative interest groups turned to the federal courts more frequently than they had before. This was in part a reaction to the successes of liberal interest groups. It was also due to the increasingly favorable forum that the federal courts provided for conservative viewpoints.

Interest group involvement in the judicial process may take several different forms depending upon the goals of the particular group. However, two principal tactics stand out: involvement in test cases and presentation of information before the courts through *amicus curiae* (Latin, meaning "friend of the court") briefs.

Test Cases

Because the judiciary engages in policy making only by rendering decisions in specific cases, one tactic of interest groups is to make sure that a case appropriate for obtaining its policy goals is brought before the court. In some instances this means that the interest group will initiate and sponsor the case by providing all the necessary resources. . . . Interest groups may also provide assistance in a case initiated by someone else, but which nonetheless raises issues of importance to the group. . . .

Amicus Curiae Briefs

Submission of amicus curiae briefs is the easiest method by which interest groups can become involved in cases. This method allows a group to get its message before the court even though it does not control the case. Provided it has the permission of the parties to the case or the permission of the court, an interest group may submit an amicus brief to supplement the arguments of the parties. The filing of *amicus* briefs is a tactic used in appellate rather than trial courts, at both the federal and the state levels.

* * *

Sometimes friend-of-the-court briefs are used not to strengthen the arguments of one of the parties but to suggest to the court the group's own view of how the case should be resolved. *Amicus curiae* briefs are often filed in an attempt to persuade an appellate court to either grant or deny review of a lower-court decision. A study of the U.S. Supreme Court found that the presence of *amicus* briefs significantly increased the chances that the Court would give full treatment to a case.

Unlike private interest groups, all levels of the government can submit *amicus* briefs without obtaining permission. The solicitor general of the United States is especially important in this regard, and in some instances the Supreme Court may invite the solicitor general to present an *amicus* brief.

SOURCE: U. S. Department of State. 2004. *Outline of the U. S. Legal System*. [Online document (excerpted); retrieved 2/12/05.] The entire document can be read at http://usinfo.state.gov/products/pubs/legalotln/index.htm.

Several examples of the role of the courts in health policymaking were described in Chapter 3. In one of the cases cited there, a group of commercial insurers and HMOs and New York City challenged the State of New York's practice of adding a surcharge to certain hospital bills to raise money to help fund health services for indigent people (Green 1995). The U.S. Supreme Court heard this case. Because its outcome was of considerable importance to their members, a number of health interest groups filed *amicus curiae* (friend-of-the-court briefs) as a means of seeking to influence the court's decision. Through such written depositions, groups state their collective position on issues and describe how the decision in the case will affect their members. This practice is widely used by health-related interest groups as well as by groups in other domains. Through the practice, the Supreme Court has been accessible to these groups who, in expressing their views, have helped determine which cases the court will hear as well as how it will rule on them (Caldeira and Wright 1990). This practice also is frequently and effectively used by interest groups in lower courts to help shape the health policy agenda.

The use of the litigation tactic is not limited to attempts to help shape the policy agenda, however. One particularly effective use of this tactic is to turn to the courts to help fill in specific details of the actual implementation of vague pieces of legislation. This practice provides opportunities for interest groups to exert enormous influence on policymaking overall by influencing the rules, regulations, and administrative practices that guide the implementation of public statutes or laws. More will be said about this in the next chapter, where the discussion turns specifically to rulemaking in the overall

public policymaking process. For now, recall from Chapter 1 that the rules and regulations established to implement laws and programs are themselves authoritative decisions that fit the definition of public policies.

Shaping Public Opinion

Because policymakers are influenced by the opinions held by the electorate, many interest groups seek to shape public opinion as another tactical means through which they might ultimately influence the policymaking process. For example, this tactic is reflected in AMA's establishment of the Fund for America's Liability Reform. Through this effort, AMA is attempting to raise $15 million from its membership to mount a national campaign to promote liability reform. The campaign features "mobilizing grassroots activities, galvanizing public support, and targeted media activity" (AMA 2005).

This tactic is, of course, not new. It was used extensively, for example, in the congressional debate over national health reform in 1993 and 1995. Estimates indicate that interest groups spent more than $50 million seeking to shape public opinion on the issues involved in that debate. For example, the health insurance industry's "Harry and Louise" ads were ubiquitous and thought by many to be effective during the debate (Hacker 1997). The extensive health reform debate of the early 1990s was not the first use of this public opinion tactic by healthcare interest groups, however.

Intense opposition in some quarters to the legislation, especially by AMA, fueled the congressional debate over the Medicare legislation in the 1960s. The American public had rarely if ever been exposed to so feverish a campaign to shape opinions as it experienced in the period leading up to its enactment in 1965.

Among the many activities undertaken in that campaign to influence public opinion (and through it, policymakers), perhaps none is more entertaining in hindsight—certainly few are more representative of the campaign's tone and intensity—than one action taken by AMA. As part of its campaign to influence public opinion on Medicare, AMA sent every physician's spouse a recording and advised him or her to host friends and neighbors and play the recording for them. The idea was to encourage these people to write letters to their representatives in Congress in opposition to the legislation. Near the end of the recording, narrated by Ronald Reagan, the following words can be heard (as quoted in Skidmore 1970, 138):

> Write those letters now; call your friends and tell them to write them. If you don't, this program, I promise you, will pass just as surely as the sun will come up tomorrow. And behind it will come other federal programs that will invade every area of freedom as we have known it in this country. Until one day . . . will awake to find that we have socialism. And if you don't do this, and I don't do it, one of these days you and I are going to spend our sunset years telling our children and our children's children what it was like in America when men were free.

Although the impact on policymaking of the appeals to public opinion made by interest groups is debatable, the extent and persistence of the practice suggests that interest groups believe that it does make a difference. One factor clearly mitigates the usefulness of this tactic and makes difficult its use by interest groups: the heterogeneity of the American population's perceptions of problems and preferences for solutions to them. For example, in the congressional debate over major health reform in the 1990s, the majority viewpoint at the beginning of the debate was that health reform was needed. However, at no time during the debate was a public consensus achieved on the nature of the reform that should be undertaken. No feasible alternative for reform ever received majority support in any public opinion poll. During most of the debate, in fact, public opinion was approximately evenly divided among the possible reform options (Brodie and Blendon 1995).

Interest Group Resources and Success in Influencing the Policy Agenda

Using lobbying, electioneering, litigation, and efforts to shape public opinion as tactics, interest groups seek to influence the policy agenda and the larger public policymaking process to the strategic advantage of their members. The degree of success they achieve is highly dependent on the resources at their disposal. Ornstein and Elder (1978) categorize the resources of interest groups into the following categories:

- physical resources, especially money and the number of members;
- organizational resources such as the quality of a group's leadership, the degree of unity or cohesion among its members, and the group's ability to mobilize its membership for political purposes;
- political resources such as expertise in the intricacies of the public policymaking process and a political reputation for being able to influence the process ethically and effectively;
- motivational resources such as the strength of ideological conviction among the membership; and
- intangible resources such as the overall status or prestige of a group.

An especially important physical resource is the size of a group's membership and the relative proportion of its potential members who are actual members. "Part of a group's stock in trade in affecting all phases of policymaking—agendas, decisions, or implementation—is its ability to convince government officials that it speaks with one voice and truly represents the preferences of its members" (Kingdon 1995, 52). Large numbers of members can obviously result in more financial resources, but perhaps even more importantly, it might provide an advantage simply because the group's membership

is spread through every legislative district. However, the costs of organizing a large group, especially if their interests are not extremely concordant and focused, can be high.

The particular mix of these physical, organizational, political, motivational, and intangible resources available to an interest group, as well as the effectiveness with which the group uses them, helps determine the group's performance in influencing the policy agenda and other aspects of the policymaking process. A particular group's performance also is affected by its level of resources compared to those of other groups that may be pursuing competing or conflicting outcomes from the policymaking process (Feldstein 2001; Kingdon 1995; Edwards, Wattenberg, and Lineberry 2003). The political marketplace, as discussed in Chapter 3, is a place where many people and groups seek to have their policy preferences prevail.

The Influential Role of Chief Executives in Agenda Setting

A second especially influential participant in setting the policy agenda, including that for policy in the health domain, is the chief executive—the president, governor, or mayor. In cases where these individuals enjoy popularity, they can easily play preeminent roles in agenda setting. Kingdon (1995) attributes the influential role in agenda setting of presidents (and his point also applies to other chief executives) to certain institutional resources inherent in the executive office.

Political advantages routinely available to chief executives include the ability to present a unified administration position on issues, which stands in stark contrast to the legislative branch, where opinions and views tend to be heterogeneous, and executives' ability to command public attention. Properly managed, this latter ability can stimulate substantial public pressure on legislators in support of executives' preferences and viewpoints. Chief executives can even rival powerful interest groups in their ability to shape public opinion around the public policy agenda.

Lammers (1997) emphasizes the ability of chief executives to perform "issue-raising activities" as crucial to their ability to influence agenda setting. He notes that the development of legislation is "generally preceded by a variety of actions that first create a widespread sense that a problem exists that needs to be addressed" (Lammers 1997, 112). Problems and preferred solutions can be emphasized by chief executives in a number of ways, including press conferences, speeches, and addresses. This may be especially potent in such highly visible contexts as state of the union or state of the state addresses, as is illustrated in the excerpts in The Real World of

Health Policy: Health Policy in Recent State of the Union Addresses by George W. Bush.

The Real World of Health Policy

Health Policy in Recent State of the Union Addresses by George W. Bush

January 28, 2003—State of the Union

Following his opening remarks, the President noted, "Our first goal is clear: We must have an economy that grows fast enough to employ every man and woman who seeks a job." (Applause.) This goal was briefly discussed, then the president moved to the second goal as follows.

Our second goal is high quality, affordable healthcare for all Americans. (Applause.) The American system of medicine is a model of skill and innovation, with a pace of discovery that is adding good years to our lives. Yet for many people, medical care costs too much—and many have no coverage at all. These problems will not be solved with a nationalized healthcare system that dictates coverage and rations care. (Applause.)

Instead, we must work toward a system in which all Americans have a good insurance policy, choose their own doctors, and seniors and low-income Americans receive the help they need. (Applause.) Instead of bureaucrats and trial lawyers and HMOs, we must put doctors and nurses and patients back in charge of American medicine. (Applause.)

Health care reform must begin with Medicare; Medicare is the binding commitment of a caring society. (Applause.) We must renew that commitment by giving seniors access to preventive medicine and new drugs that are transforming health care in America.

Seniors happy with the current Medicare system should be able to keep their coverage just the way it is. (Applause.) And just like you—the members of Congress, and your staffs, and other federal employees—all seniors should have the choice of a health care plan that provides prescription drugs. (Applause.)

My budget will commit an additional $400 billion over the next decade to reform and strengthen Medicare. Leaders of both political parties have talked for years about strengthening Medicare. I urge the members of this new Congress to act this year. (Applause.)

To improve our health care system, we must address one of the prime causes of higher cost, the constant threat that physicians and hospitals will be unfairly sued. (Applause.) Because of excessive litigation, everybody pays more for health care, and many parts of America are losing fine doctors. No one has ever been healed by a frivolous lawsuit. I urge the Congress to pass medical liability reform. (Applause.)

* * *

January 20, 2004—State of the Union

* * *

Our nation's health care system, like our economy, is also in a time of change. Amazing medical technologies are improving and saving lives. This dramatic progress has brought its own challenge, in the rising costs of medical care and health insurance. Members of Congress, we must work together to help control those costs and extend the benefits of modern medicine throughout our country. (Applause.)

Meeting these goals requires bipartisan effort, and two months ago, you showed the way. By strengthening Medicare and adding a prescription drug benefit, you kept a basic commitment to our seniors: You are giving them the modern medicine they deserve. (Applause.)

Starting this year, under the law you passed, seniors can choose to receive a drug discount card, saving them 10 to 25 percent off the retail price of most prescription drugs—and millions of low-income seniors can get an additional $600 to buy medicine. Beginning next year, seniors will have new coverage for preventive screenings against diabetes and heart disease, and seniors just entering Medicare can receive wellness exams.

In January of 2006, seniors can get prescription drug coverage under Medicare. For a monthly premium of about $35, most seniors who do not have that coverage today can expect to see their drug bills cut roughly in half. Under this reform, senior citizens will be able to keep their Medicare just as it is, or they can choose a Medicare plan that fits them best—just as you, as members of Congress, can choose an insurance plan that meets your needs. And starting this year, millions of Americans will be able to save money tax-free for their medical expenses in a health savings account. (Applause.)

I signed this measure proudly, and any attempt to limit the choices of our seniors, or to take away their prescription drug coverage under Medicare, will meet my veto. (Applause.)

On the critical issue of health care, our goal is to ensure that Americans can choose and afford private health care coverage that best fits their individual needs. To make insurance more affordable, Congress must act to address rapidly rising health care costs. Small businesses should be able to band together and negotiate for lower insurance rates, so they can cover more workers with health insurance. I urge you to pass association health plans. (Applause.) I ask you to give lower-income Americans a refundable tax credit that would allow millions to buy their own basic health insurance. (Applause.)

By computerizing health records, we can avoid dangerous medical mistakes, reduce costs, and improve care. To protect the doctor-patient relationship, and keep good doctors doing good work, we must eliminate wasteful and frivolous medical lawsuits. (Applause.) And tonight I propose that individuals who buy catastrophic health care coverage, as part of our new health savings accounts, be allowed to deduct 100 percent of the premiums from their taxes. (Applause.)

A government-run health care system is the wrong prescription. (Applause.) By keeping costs under control, expanding access, and helping more Americans afford coverage, we will preserve the system of private medicine that makes America's health care the best in the world. (Applause.)

* * *

February 2, 2005—State of the Union

* * *

To make our economy stronger and more productive, we must make health care more affordable, and give families greater access to good coverage—(applause)—and more control over their health decisions. (Applause.) I ask Congress to move forward on a comprehensive health care agenda with tax credits to help low-income workers buy insurance, a community health center in every poor county, improved information technology to prevent medical error and needless costs, association health plans for small businesses and their employees—(applause)—expanded health savings accounts—(applause)—and medical liability reform that will reduce health care costs and make sure patients have the doctors and care they need. (Applause.)

* * *

Because a society is measured by how it treats the weak and vulnerable, we must strive to build a culture of life. Medical research can help us reach that goal, by developing treatments and cures that save lives and help people overcome disabilities—and I thank the Congress for doubling the funding of the National Institutes of Health. (Applause.) To build a culture of life, we must also ensure that scientific advances always serve human dignity, not take advantage of some lives for the benefit of others. We should all be able to agree—(applause)—we should all be able to agree on some clear standards. I will work with Congress to ensure that human embryos are not created for experimentation or grown for body parts, and that human life is never bought and sold as a commodity. (Applause.) America will continue to lead the world in medical research that is ambitious, aggressive, and always ethical.

* * *

Because HIV/AIDS brings suffering and fear into so many lives, I ask you to reauthorize the Ryan White Act to encourage prevention, and provide care and treatment to the victims of that disease. (Applause.) And as we update this important law, we must focus our efforts on fellow citizens with the highest rates of new cases, African American men and women. (Applause.)

* * *

SOURCE: Excerpted from state of the union addresses on January 28, 2003; January 20, 2004; and February 2, 2005. Each address can be read in its entirety at www.whitehouse.gov.

Candidates for the presidency are often specific in their campaigns on various health policy issues, sometimes even to the point of endorsing specific legislative proposals (Fishel 1985). Examples include the emphasis given to enactment of the Medicare program by presidents Kennedy and Johnson in their campaigns and President Clinton's highly visible commitment to fundamental health reform as a central theme of his 1992 campaign. President Bush made enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 a priority as he entered the campaign for his second term in 2004. Another issue-raising mechanism favored by some chief executives is the appointment of special commissions or task forces (Linowes 1998). President Clinton used this tactic in the 1993 appointment of the President's Task Force on Health Care Reform (Johnson and Broder 1996), as did President Bush in the creation of the President's Commission to Strengthen Social Security (www.csss.gov) in 2001.

Governors can also use commissions and task forces to elevate issues on the policy agenda. For example, Massachusetts made history when its Gay and Lesbian Student Rights Law was signed by Governor William F. Weld. He established the nation's first Governor's Commission on Gay and Lesbian Youth, which helped lead the state legislature to enact the law. This law prohibits discrimination in public schools on the basis of sexual orientation. Gay students are guaranteed redress if they suffer name-calling, threats of violence, and unfair treatment in school. Governor Robert Ehrlich of Maryland appointed the Governor's Task Force on Medical Malpractice and Health Care Access in June 2004 to address the crisis created by the cost of malpractice insurance.

Chief executives occupy a position that permits them to be very influential in each phase of the policymaking process. In addition to their issue-raising role in agenda setting, they are well positioned to help focus the legislative branch on the development of legislation and to prod legislators to continue their work on favored issues even when facing enormous competing demands on their time and attention. In addition, chief executives are central to the implementation of policies by virtue of their position atop the executive (or implementing) branch of government, as discussed in Chapter 7, and they play a crucial role in modifying previously established policies, as discussed in Chapter 8.

The Nature of the Health Policy Agenda

The confluence of problems and potential solutions and political circumstances that surround them invariably shapes a health policy agenda. This agenda, however, is extraordinarily dynamic, changing literally on a day-to-day basis. In addition, the nation's health policy agenda does not exist in a

vacuum. Instead, it coexists with policy agendas in other domains such as defense, welfare, education, and homeland securuity. This is further complicated by the fact that in a pluralistic society where difficult problems exist and where clear-cut solutions are rare, there are likely to be a number of different "sides" to any particular problem or potential solution to it, each with its supporters and detractors. The number, ratio, and intensity of these supporters and detractors are determined by the impact of the problem and its solution on those who take positions. One consequence of this phenomenon is severely crowding and confounding the health policy agenda. It is impossible, in fact, for anyone to actually describe this agenda in its full form at any point in time.

As policymakers seek to accommodate the needs and preferences of different interests in particular problem/potential solution combinations over time within the health policy agenda, the inevitable result is a set—a very large and diverse set—of policies that are riddled with incompatibilities and inconsistencies. American health policy offers many examples of this result. The mix of policies regarding the production and consumption of tobacco products—a mix that simultaneously facilitates and discourages tobacco use—provides a good example of the coexistence of public policies at cross-purposes.

Another example can be seen in the health policy agenda, and in the eventual pattern of public policies, related to medical technology. Policymakers have sought to serve the goal of spreading the benefits of new medical technology and at the same time to serve such goals as protecting the public from unsafe technologies and attempting to slow the growth in overall health costs through controlling the explosive growth of new technologies. The result is a large group of technology-related policies that seek to foster (e.g., NIH, National Science Foundation, other biomedical funding, tax credits for biomedical research in the private sector), to inhibit (e.g., state-run certificate-of-need programs that restrain the diffusion of technology), and to control (e.g., Food and Drug Administration regulation and product liability laws) the development and use of medical technology in the United States.

Its complexity and inconsistency aside, the most important aspect of the health policy agenda is that when the existence of a problem is widely acknowledged, when possible solutions have been identified and refined, and when favorable political circumstances exist, a window of opportunity opens, albeit sometimes only briefly. Through this window, problem/potential solution combinations move forward to a new and different set of activities: development of legislation (see Figure 5.1). As described next, in Chapter 6, it is through the development of legislation that policymakers seek to convert some of their ideas, hopes, and hypotheses about addressing problems into concrete policies in the form of new public laws or amendments to existing ones.

Summary

The policy formulation phase of policymaking involves agenda setting and the development of legislation, as shown in Figure 5.1. Agenda setting is the central topic of this chapter. The development of legislation is discussed in Chapter 6.

Following the conceptualization of Kingdon (1995), agenda setting in public policymaking is described as a function of the confluence of three streams of activity: problems, possible solutions to the problems, and political circumstances. When all three streams flow together in a favorable alignment, a window of opportunity opens (see Figure 5.1), allowing a problem/potential solution combination, which might be developed into a new public law or an amendment to an existing one, to advance to the next point in the policymaking process: development of legislation.

Discussion Questions

1. Discuss the formulation phase of policymaking in general terms.
2. Discuss agenda setting as the confluence of three streams of activities. Include the concept of a "window of opportunity" for legislation development in your answer.
3. Describe the nature of problems that drive policy formulation.
5. Discuss the role of research in health policy agenda setting.
5. Contrast decision making in the public and private sectors as it relates to selecting from among alternative solutions to problems.
6. Discuss the involvement of interest groups in the political circumstances that affect agenda setting. Incorporate the specific ways in which they exert their influence on agenda setting in your response.
7. Discuss the role of chief executives in agenda setting at the federal level.
8. Discuss the nature of the health policy agenda that results from agenda setting at the federal level.

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CHAPTER

6

POLICY FORMULATION: DEVELOPMENT OF LEGISLATION

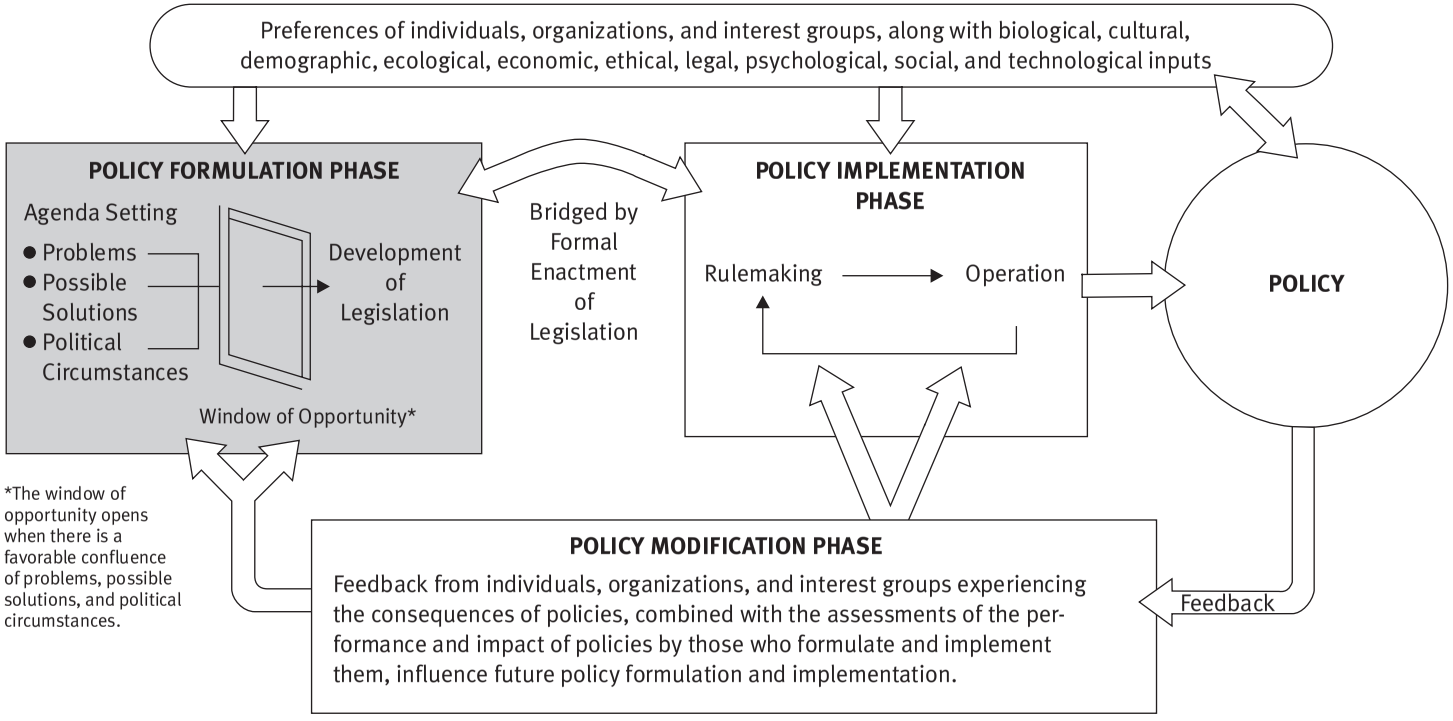
As noted in the previous chapter, the formulation phase of health policymaking includes two distinct and sequentially related parts: agenda setting and legislation development. This chapter, which focuses on the development of legislation, is a companion to the previous chapter in which the agenda-setting aspect of policy formulation was the focus. Policy formulation can be fully appreciated only through the combination of the various activities associated with agenda setting and legislation development.

As in the discussion of agenda setting in Chapter 5, this discussion of legislation development is confined almost exclusively to its occurrence at the federal level of government. However, state and local governments develop legislation of their own, and in general this is done in a manner similar to the federal approach. The problems that legislation is developed to address differ at each level, as do the contexts, many of the participants, and specific mechanisms and procedures used in developing legislation.

The result of the entire formulation phase of policymaking is public policy in the form of new public laws or amendments to existing laws. New health-related laws or amendments that eventually emerge from the activities associated with the development of legislation originate from the policy agenda. Recall that the health policy agenda is established through the interactions of a diverse array of problems, possible solutions to those problems, and dynamic political circumstances that relate both to the problems and to their potential solutions. Combinations of problems, potential solutions, and political circumstances that achieve priority on the policy agenda move on in the overall policymaking process to the next component of policy formulation—legislation development (see the shaded portion of Figure 6.1).

The laws and amendments to existing laws that result from the formulation phase of policymaking are quite tangible, and purposely so. They can be seen and read in a number of places. The U.S. Constitution prohibits the enactment of laws that are not specifically and directly made known to the people who are to be bound by them. In practice, federal laws are published for the citizenry immediately upon enactment. Of course, it is incumbent on persons who might be affected by laws to know of them and to be certain that they understand their impact. In the world of professionals who are involved in

FIGURE 6.1 A Model of the Public Policymaking Process in the United States: Policy Formulation Phase



the pursuit of health, a great deal of attention is paid to the task of ascertaining the impact of laws.

At the federal level, enacted laws are first printed in pamphlet form called *slip law*. Later, laws are published in the *United States Statutes at Large* and eventually incorporated into the *United States Code*. The *Statutes at Large*, published annually, contain the laws enacted during each session of Congress. In effect, they are compilations of all laws enacted in a particular year. The *United States Code* is a complete compilation of all of the nation's laws. A new edition of the code is published every six years, with cumulative supplements published annually. Federal public laws can be read at http://thomas.loc.gov.

The Choreography of Legislation Development

Development of legislation is the point in policy formulation where specific legislative proposals, which are characterized in the previous chapter as hypothetical or unproved potential solutions to the problems they are intended to address, advance through a series of steps that can end in new or amended public laws. These steps, not unlike those of a dance, are specified or choreographed. Only when all of the steps in the legislation development process are completed (recall that this happens for only a fraction of the legislative proposals that begin the steps) does a change in policy result, either in the form of new public laws or, far more typically, in the form of amendments to previously enacted laws. The steps that make up legislation development provide the framework for most of the discussion in this chapter.

Legislation development comprises the series of steps through which laws are made and amended, beginning with the origination of ideas for legislation and extending through the enactment of some of those ideas into law or the amendment of existing laws. The steps apply equally whether the resulting legislation is completely new or, as is so often the case, it represents the amendment of prior legislation. An excellent and extensive description of the steps through which federal legislation is developed can be found by accessing "How Congress Makes Laws" at http://thomas.loc.gov (Library of Congress 2003). Similarly, most states include descriptions of their legislative processes on their web sites. For example, Pennsylvania publishes "The Biography of a Law" at http://www.legis.state.pa.us/WU01/VC/visitor_info/making_law/part_2.htm (Pennsylvania House of Representatives 1992).

The pathway formed by the steps through which legislation is developed extends from the origination of ideas for proposed legislation, which actually emerge in the agenda-setting stage, to formal drafting of legislative proposals and then through several other steps, eventually culminating in the enactment of laws derived from some of the proposals. Remember, however,

that only a small fraction of the legislative proposals that are formally introduced in a Congress—the two annual sessions spanning the term of office of members of the House of Representatives—are actually enacted into law. Proposals that are not enacted by the end of the congressional session in which they were introduced die and must be reintroduced in the next Congress if they are to be considered further.

Only a small fraction of the problem/potential solution combinations that might be addressed through legislation are addressed in this way. When they are, the tangible final product is an enacted law, which can be an entirely new law or one or more amendments to previously enacted laws. As the bridge between the policy formulation and implementation phases (shown in Figure 6.1), formal enactment of proposed legislation into law represents a significant transition between these two phases of the overall public policymaking process. The focus in this chapter is on ways in which public laws are developed and enacted in the policymaking process; their implementation is discussed in Chapter 7.

It is important to remember, as described in Chapter 5, that individuals and health-related organizations, and especially the interest groups to which they belong, are instrumental in the agenda setting that precedes legislation development. They also actively participate in the development itself: Once health policy issues achieve a prominent place on the policy agenda and move to the next stage of policy formulation—development of legislation—those with concerns and preferences about policy in a particular area often actively continue to participate in support of its formulation.

Individuals and health-related organizations and interest groups can participate directly in originating ideas for legislation, help with the actual drafting of legislative proposals, and participate in the hearings sponsored by legislative committees as they undertake the development of legislation. When there are competing bills seeking to address a problem, those with interests in the problems align themselves with favored legislative solutions and oppose those they do not favor. In the following sections, the steps in legislation development are discussed in detail.

Originating and Drafting Legislative Proposals

The development of legislation begins with the conversion of the ideas, hopes, and hypotheses about how problems might be addressed through changes in policy—ideas that emerge from agenda setting—into concrete legislative proposals called *bills.* Proposed legislation can also be introduced as a resolution. As a practical matter, there is little difference between a bill and a resolution, and they are not differentiated operationally here.

Origins of Ideas for Public Policy

Ideas for public policy in the form of law, which are expressed in bills, originate in many places. They obviously come from the members of Congress, whether from the House of Representatives or the Senate. In fact, many legislators are elected to Congress, at least in part, on the basis of the legislative ideas they expressed in their election campaigns. Promises to introduce certain legislative proposals, made during campaigns specifically to the constituents whom candidates seek to represent, are core aspects of the American form of government and are frequent sources of eventual legislative proposals. Once in office, legislators are well positioned to become even more aware of and knowledgeable about the need for amendment or repeal of existing laws or for the enactment of entirely new laws through their evolving understanding of the problems and potential solutions that face their constituents or the larger society.

But the source of ideas for laws is not limited to legislators. Individual citizens, health-related organizations, or, far more likely, interest groups representing many individuals or organizations may avail themselves of their right to petition government—a right guaranteed by the First Amendment—and to propose ideas for the development of legislation. In effect, this process results directly from the participation of individuals, organizations, and groups in the agenda-setting aspect of policy formulation. The ideas behind many of the nation's public laws originate in this way because certain individuals, organizations, or interest groups have considerable knowledge of the problem/potential solution combinations that affect them or their members.

Interest groups tend to be very influential in legislation development, as they are in agenda setting, because of their pooled resources. Well-staffed interest groups, for example, also can draw on the services of legislative draftspersons to help draft the preferred ideas and concepts into appropriate legislative language.

An increasingly important source of ideas for legislative proposals, which also plays a role in agenda setting, is "executive communication" from members of the executive branch to members of the legislative branch. Such communications are usually in the form of a letter from a senior member of the executive branch, such as a member of the president's cabinet; from the head of an independent agency; or even from the president. Through these communications, the executive branch serves as a direct source of ideas for policy in the form of laws, and these communications typically include comprehensive drafts of proposed bills. They are sent to the speaker of the House of Representatives and simultaneously to the president of the Senate, who can then insert them into the legislation development procedures at appropriate places.

The executive branch's role as a source of ideas for policy in the form of laws is based in the U.S. Constitution. Although the Constitution establishes

a government characterized by the separation of powers, in Article II, Section 3, it imposes an obligation on the president to report to Congress from time to time on the "State of the Union" and to recommend for consideration such policies in the form of laws as the president considers necessary, useful, or expedient. Many of the executive communications to Congress follow up on ideas first aired in the president's annual State of the Union address to Congress.

Executive communications that pertain to proposed legislation are referred by the legislative leaders who receive them to the appropriate standing committee or committees having jurisdiction in the areas incorporated in the executive branch proposals. The chairperson of that standing committee usually introduces the bill promptly either in the form in which it was received or with any changes the chairperson considers necessary or desirable. Only members of Congress can actually introduce proposed legislation, no matter who originates the idea or drafts the proposal.

The practice of having committee chairpersons introduce legislative proposals that arise through executive communication is followed even when the majority of the House or the Senate and the president are not of the same political party, although there is no constitutional or statutory requirement that a bill be introduced to put the executive branch's recommendations into effect. When the chairperson of the committee with jurisdiction does not introduce a bill that is based on executive communication, the proposed legislation is considered by the committee or one of its subcommittees to determine whether the bill should be introduced.

The most important of the regular executive communications is the one through which the president annually transmits a proposed federal budget to Congress (Oleszek 2001). The most recently prepared budget and related supporting documents can be read at www.whitehouse.gov/omb/budget/fy2006/budget.html (OMB 2005). More is said about the budget process later in this chapter; here, suffice it to say that the president's budget proposal, together with supportive testimony by officials of the various executive branch departments and agencies and testimony from individuals, organizations, and interest groups concerned about the budget—before 1 of the 13 subcommittees of the Appropriations Committees of the House and Senate—is the basis of the appropriation bills that are eventually drafted by these committees.

Drafting Legislative Proposals

The drafting of legislative proposals is something of an art in itself, one requiring considerable skill, knowledge, and experience. Any member of the Senate or House of Representatives can draft bills, and these legislators' staffs are usually instrumental in drafting legislation, often with assistance from the Legislative Counsel's Office in the Senate or House of Representatives. Information about how the Legislative Counsel's Office for the House and

the Senate works can be seen at http://legcoun.house.gov/public.htm and http://slc.senate.gov/index.htm, respectively.

Sandra Strokoff, senior counsel in the Office of the Legislative Counsel, U.S. House of Representatives, describes the work of the attorneys who work in the counsel's office as follows (Strokoff 2005):

> Frequently, on the floor of the House of Representatives, one will hear a Member refer to another as the "author" of a bill who has "carefully crafted" the language of the proposed legislation. Statements like these make me smile, because if the Members are the authors, then I and my colleagues in the Office of the Legislative Counsel of the House of Representatives are the ghost writers.
>
> The Office of the Legislative Counsel, created by statute originally in 1918, is currently composed of 30-plus attorneys who generally toil in anonymity, at least as far as those outside the legislative process are concerned. Attorneys are charged with taking the idea of any Member or committee of the House of Representatives requesting the services of the Office and transforming it into legislative language or, as one of my clients used to say, "the magic words." We participate in all stages of the legislative process, be it preparing a bill for introduction, drafting amendments, participating in any conference of the two Houses of Congress to resolve differences between the two versions of the bill, or incorporating changes in the bill at each stage for publication and ultimately for presentation to the President. Frequently, we draft while debate is going on—both during committee consideration and on the House Floor, and may be asked to explain the meaning or effect of legislative language.

When bills are drafted in the executive branch, the services of trained legislative counsels are typically involved. These legislative counsels work in several executive branch departments, and their work includes the drafting of bills to be forwarded to Congress. Similarly, proposed legislation that arises in the private sector, typically from interest groups, is drafted by people with expertise in this intricate task.

On occasion, as was the case in the drafting the Clinton health reform proposal in 1993, legislation drafting is undertaken as a public/private partnership (Hacker 1996, 1997). In late 1993, after many months of feverish drafting by a team including some of the nation's foremost health policy experts, President Clinton presented his proposal for legislation that would fundamentally reform the American healthcare system. The document, 1,431 pages in length, outlined the president's vision of the way in which health services should be provided and financed in the United States. The proposal was in the form of a comprehensive draft of a bill (to be called the Health Security Act) that could be enacted into law. However, the proposal faced a long and difficult path of legislation development to possible enactment. Hacker and Skocpol (1997, 315–16) note that "President Clinton sought to enact comprehensive federal rules that would, in theory, simultaneously control medical

costs and ensure universal insurance coverage. The bold Health Security initiative was meant to give everyone what they wanted, delicately balancing competing ideas and claimants, deftly maneuvering between major factions in Congress, and helping to revive the political prospects of the Democratic Party in the process." However, the bill failed miserably (Skocpol 1996; Johnson and Broder 1996).

The failure of this legislative proposal to make it successfully through the remaining steps to enactment into law has been characterized as a matter in which "the bold gambit of comprehensive reform had once again succumbed to the power of antagonistic stakeholders, a public paralyzed by the fears of disrupting what it already had, and the challenge of coalition building engendered by the highly decentralized character of American government" (Peterson 1997, 291).

No matter who drafts legislation, however, because only members of Congress can officially sponsor proposed legislation, the legislative sponsors are ultimately responsible for the language in their bills. Commonly, a bill will have multiple sponsors and may have many cosponsors. Once ideas for solving problems through policy are drafted in legislative language, they are ready for the next step, introduction for formal consideration by Congress. Although the Health Security proposal drafted by the Clinton administration was not enacted into law, it did make it through the next step in the intricate dance of legislation development, formal introduction.

Introducing and Referring Proposed Legislation to Committees

Members of the Senate or the House of Representatives who have chosen to sponsor or cosponsor legislation introduce their proposals in the form of bills. On occasion, identical bills are introduced in both the Senate and the House for simultaneous consideration. When bills are introduced in either chamber of Congress, they are assigned a sequential number (e.g., H.R. 1, H.R. 2, H.R. 3, etc.; S. 1, S. 2, S. 3, etc.) based on the order of introduction by the presiding officer, and are referred to the appropriate standing committee or committees—that is, to the committees that have jurisdiction in the area of the bill—for further study and consideration.

Legislative Committees and Subcommittees

Both the Senate and the House of Representatives are organized into committees and subcommittees. The committee structure of Congress is a fundamental feature of the activities involved in the development of legislation and is crucial to the actual development of legislation. Committee and subcommittee

deliberations provide the settings for intensive and thorough consideration of legislative proposals.

At present, there are 20 standing committees in the House and 17 in the Senate. Each of the standing committees has jurisdiction over certain areas of legislation, and all bills that pertain to a particular area are referred to its committee. Information about the committees is available on their web site home pages, which can be accessed through http://thomas.loc.gov. Committees are divided into subcommittees to facilitate work. For example, the Ways and Means Committee of the House of Representatives has six subcommittees: Trade, Oversight, Health, Social Security, Human Resources, and Select Revenue Measures.

Sometimes, the content of a bill makes appropriate the assignment to more than one committee; in this case, the bill is assigned to more than one committee either jointly or, more commonly, sequentially. For example, the Clinton administration's Health Security plan was introduced simultaneously in the House and the Senate as H.R. 3600 and S. 1757. Because of its scope and complexity, the bill was then referred jointly to ten House committees and two Senate committees for consideration and debate.

Membership on the various congressional committees is divided between the two major political parties. The proportion of the members from each party is determined by the majority party, except that one-half of the members on the Committee on Standards of Official Conduct are from the majority party and one-half from the minority party. Legislators typically seek membership on committees that have jurisdiction in areas in which the policymakers have particular interests and expertise. The interests of their constituencies typically exert significant influence on the interests of policymakers. For example, members of the House of Representatives from agricultural districts or financial centers are often influenced by these areas in their preferences for committee memberships, as are senators in terms of whether they hail from primarily rural or highly urbanized states or from the industrialized northeast or the more agrarian west. The members of a committee rank in seniority in accordance with the order of their appointment to the committee.

The majority party in each chamber also controls the appointment of committee and subcommittee chairpersons. The chairpersons of congressional committees and subcommittees exert great power in the development of legislation because they determine the order and the pace that legislative proposals are considered by the committees or subcommittees they lead.

Each committee has a professional staff to assist with administrative details involved in its consideration of bills. In addition, under certain conditions, a standing committee may appoint consultants on a temporary or intermittent basis to assist the committee in its work. By virtue of expert knowledge, the professional staff who serve committees and subcommittees are key participants in legislation development.

Committees with Health Policy Jurisdiction

Although no congressional committee is devoted exclusively to the health policy domain, several committees and subcommittees have jurisdiction in health-related legislation development. The Real World of Health Policy: Inside a Congressional Committee describes the history and structure of an important committee with extensive health jurisdiction, the Committee on Energy and Commerce of the House of Representatives. Similar information on the operation of committees in the Senate is contained in "Senate Legislative Process," which can be read at http://www.senate.gov/legislative/common/briefing/Senate_legislative_process.htm.

The Real World of Health Policy

Inside a Congressional Committee

For 208 years, the Committee on Energy and Commerce, the oldest legislative standing committee in the U.S. House of Representatives, has served as the principal guide for the House in matters relating to the promotion of commerce and to the public's health and marketplace interests.

In performing this historic function, the Committee has developed what is arguably the broadest (non-tax-oriented) jurisdiction of any Congressional committee. Today, it maintains principal responsibility for legislative oversight relating to telecommunications, consumer protection, food and drug safety, public health, air quality and environmental health, the supply and delivery of energy, and interstate and foreign commerce in general. This jurisdiction extends over five Cabinet-level departments and seven independent agencies—from the Energy Department, Health and Human Services, the Transportation Department to the Federal Trade Commission, Food and Drug Administration, and Federal Communications Commission—and sundry quasi-governmental organizations.

To manage the wide variety of issues it encounters, the Committee relies on the front-line work of six subcommittees: the Subcommittee on Commerce, Trade and Consumer Protection, the Subcommittee on Energy and Air Quality, the Subcommittee on Environment and Hazardous Materials, the Subcommittee on Health, the Subcommittee on Oversight and Investigations, and the Subcommittee on Telecommunications and the Internet.

These subcommittees provide the full Committee with enormous flexibility to keep pace with American enterprise. Indeed, the history of the Committee on Energy and Commerce reflects the history of Congress as it has worked over the past 200 years to assure the prosperity of the nation's dynamic economy and its citizens.

The Committee was originally formed as the Committee on Commerce and Manufactures on December 14, 1795. Prior to this, legislation was drafted in the

Committee of the Whole or in special ad hoc committees, appointed for specific limited purposes. However the growing demands of the new nation required that Congress establish a permanent committee to manage its Constitutional authority to "regulate Commerce with foreign Nations, and among the several States."

From this time forward, as the nation grew and Congress dealt with new public policy concerns and created new committees, the Energy and Commerce Committee has maintained its dominant and central position as Congress's monitor of our nation's commercial progress—a focus reflected in its changing jurisdiction, both in name and practice.

In 1819, the Committee's name was changed to the Committee on Commerce, reflecting the creation of a separate Manufacturers Committee and also the increasing scope of and complexity of American commercial activity, which was expanding the Committee's jurisdiction from navigational aids and the nascent Federal health service to foreign trade and tarrifs. Thomas J. Bliley, who chaired the Committee from 1995 to 2000, chose to use this traditional name, which underscores the Committee's role for Congress on this front.

In 1891, in emphasis of the Committee's evolving activities, the name was again changed to the Committee on Interstate and Foreign Commerce—a title it maintained until 1981, when, under incoming Chairman John D. Dingell, the Committee first assumed what is now its present name to emphasize its lead role in guiding our nation's energy policy, which is essential for assuring commercial prosperity.

In practice, the wide-ranging work of the Committee on Energy and Commerce today builds upon a long record of achievement, which has tracked the dynamic growth of the nation from the early days of the Republic. The Committee's initial achievements overseeing the Federal health service for sick and disabled seaman developed, eventually, into its oversight now of the Public Health Service and National Institutes of Health. Its historic jurisdiction over health, safety, and commerce generally also can be traced in the evolution of and continued oversight through such landmark legislation as the Food, Drug and Cosmetic Act and the Clean Air Act, as well as the Federal Trade Commission Act, and the U.S. Code's Motor Vehicle Safety provisions. Today, when the public reads about the auto safety goals of the TREAD Act or about national energy policy, it can trace these measures back to the seminal legislation produced by the Committee over the years.

From a broader perspective, the Committee's place in Congress can be can observed in how it has kept pace overseeing the changing avenues of commerce in the nation—and the world—over the past two centuries. The Committee's role in assuring a vibrant economy has evolved with changing times—underscored recently by its groundbreaking work on legislation that provides for innovation in and expanded access to high speed Internet services. From the chiefly maritime-oriented nature of interstate and foreign trade of the early years of

the Republic to the railroads and then air of the 19th and 20th Centuries to the telecommunications and digital avenues developing so quickly and essentially for continued prosperity in the 21st Century, the Committee continues to look forward, determined to assure the prosperity of our great nation.

SOURCE: Reprinted from the Committee on Energy and Commerce, U. S. House of Representatives. 2005. "About the Committee." [Online information; retrieved 2/15/05.] http://energycommerce.house.gov/aboutCommittee.htm.

In one analysis of the period from 1980 to 1991, Baumgartner and Talbert (1995) show that the distribution of congressional committee hearings on health-related issues was divided among more committees than hearings in any other policy domain. The authors of this analysis conclude that no other policy area is characterized by this degree of jurisdictional fragmentation.

There is, in fact, some overlap in the jurisdictions of the committees with important health-related legislative responsibilities. Most general health bills are referred to the House Committee on Energy and Commerce and to the Senate Committee on Health, Education, Labor, and Pensions. However, any bills involving taxes and revenues must be referred to the House Committee on Ways and Means and to the Senate Committee on Finance. These two committees have substantial health policy jurisdiction because so much health policy involves taxes as a source of funding. The main health policy interests of these committees are outlined here, beginning with those in the Senate.

- *Committee on Finance* (http://finance.senate.gov), *with its Subcommittee on Health Care.* This Senate committee has jurisdiction over all bills that relate to health programs under the Social Security Act and to health programs financed by a specific tax or trust fund. This gives the committee jurisdiction over matters related to Medicare and Medicaid.
- *Committee on Health, Education, Labor, and Pensions* (http://help.senate.gov), *with its Subcommittee on Retirement Security and Aging, Subcommittee on Education and Early Childhood Development, Subcommittee on Employment and Workplace Safety, and Subcommittee on Bioterrorism and Public Health.* This Senate committee has jurisdiction over bills that relate to biomedical research and development; health personnel; the Public Health Service Act; the Federal Food, Drug, and Cosmetic Act; and the Developmental Disabilities Assistance and Bill of Rights Act.
- *Committee on Ways and Means* (http://waysandmeans.house.gov) *with its Subcommittee on Health.* This House committee has jurisdiction over bills that pertain to providing payments from any source for healthcare, health delivery systems, or health research. The jurisdiction

of the Subcommittee on Health includes bills related to the healthcare programs of the Social Security Act (including Titles XVIII and XIX, which are the Medicare and Medicaid programs) and tax credit and deduction provisions of the Internal Revenue Code dealing with health insurance premiums and healthcare costs.

- *Committee on Energy and Commerce* (http://energycommerce.house.gov), *with its Subcommittee on Health, Subcommittee on Energy and Air Quality, and Subcommittee on Environment and Hazardous Materials.* This House committee has jurisdiction over all bills related to Medicaid; Medicare Part B; public health; health personnel; mental health and research; biomedical research and development programs; health maintenance organizations; food and drugs; drug abuse; and the Clean Air Act and environmental protection in general, including the Safe Drinking Water Act.

Committee and Subcommittee Operations

Depending on whether the chairperson of a committee has assigned a bill to a subcommittee, either the full committee or the subcommittee can, if it chooses, hold hearings on bills. At these public hearings, members of the executive branch, representatives of health-related organizations and interest groups, and other individuals are permitted to present their views and recommendations on the legislation under consideration. The Real World of Health Policy: Testimony on the Anabolic Steroid Control Act of 2004 is an example of testimony offered as a House subcommittee considered a bill, H.R. 3866. Both the House and Senate passed a version of this bill, which became P.L. 108-358. The legislation amended the Controlled Substances Act to clarify the definition of anabolic steroids and to provide for research and education activities relating to steroids and steroid precursors.

The Real World of Health Policy

Testimony on the Anabolic Steroid Control Act of 2004

Statement of Ralph W. Hale M.D.
Chairman of the Board, United States Anti-Doping Agency
Before the House Subcommittee on Crime, Terrorism and Homeland Security of the House Judiciary Committee
Legislative Hearing on H.R. 3866, the "Anabolic Steroid Control Act of 2004."
March 16, 2004

Mr. Chairman, members of the committee, good morning. My name is Dr. Ralph Hale. Thank you for the opportunity to testify regarding this important health issue. Today, I am here as the Chairman of the Board of Directors of the

United States Anti-Doping Agency. I am also a physician who has been practicing medicine for more than 40 years. USADA has been recognized by Congress as the independent, national anti-doping agency for Olympic and Paralympic sport in the United States. Our mission is to protect and preserve the health of athletes, the integrity of competition, and the well-being of sport through the elimination of doping.

Recently USADA has received increased media attention for its role in the investigation into the existence and use by elite athletes of the designer steroid, THG. Designer steroids are an important concern for USADA. However, USADA is equally concerned about a class of anabolic substances that are readily available in the United States on the shelves of supermarkets and nutrition stores, as well available for order on thousands of internet sites. These products, marketed and sold as allegedly "safe" dietary supplements, contain substances, such as androstenedione and norandrostenedione and are one chemical step away from anabolic steroids. Once ingested these products are converted within the body into anabolic steroids. The availability of these products is a significant public health issue that transcends sport and places American consumers at risk.

The perils of anabolic steroid use are well known. In Olympic sport, the most notable, systematic state-supported program of doping with anabolic steroids was conducted by the East Germans from 1974 until the Berlin Wall fell. One of the anabolic substances developed by the East Germans as part of their doping program was androstenedione. In the body, androstenedione metabolizes into the anabolic steroid, testosterone. The documented side effects of the East German steroid program, particularly for women athletes, were tragic. These side effects include damage to the liver and reproductive system, susceptibility to cancers, and permanent masculinization of women. It is also well known that men who abuse steroids and steroid precursors risk serious health consequences including gynecomastia, baldness, shrunken testicles, infertility and susceptibility to aggressive behavior or rage. For adolescents who use steroids the side effects can include all of the above, as well as a strong likelihood that natural growth will be arrested or otherwise detrimentally affected.

Despite all of these well-known health consequences, for approximately the last eight years, American consumers have been able to walk into their corner nutrition store and buy products containing androstenedione. In 1998, after certain popular professional athletes acknowledged using androstenedione, sales of these supplements in the United States, particularly among teenagers, dramatically increased. The popular demand for androstenedione gave birth to an entire industry. Now the nutrition store shelves, and the internet, are flooded with products containing various steroid precursors. For example, 19-norandrostenedione, which metabolizes in the body into the steroid nandrolone, another controlled substance, is present in hundreds of over-the-counter products.

Last Thursday, the Food and Drug Administration took action against androstenedione and acknowledged that there is a "serious and substantial concern" about the safety of products containing androstenedione. USADA fully supports this important action and encourages the FDA to immediately take action against the remaining steroid precursor products on the market. Currently the introduction of these products is governed by the Dietary Supplement Health and Education Act. Under DSHEA a supplement manufacturer is not required to prove to the government that its precursor product is safe prior to putting it on the shelf. Instead, DSHEA places the burden on the government to take action against unsafe products after they reach the shelves.

The androstenedione example makes clear, that by the time the agencies are able to take action against a specific steroid precursor; unscrupulous manufacturers will already have made minor chemical changes to the product and reintroduced it into the marketplace. For example, while the FDA sent letters to 23 companies selling products containing androstenedione, last week's action does not yet reach the companies that are now selling the more popular next-generation androstenedione products such as 1-AD and 4-Androstenediol. While we hope the FDA will promptly address those other products, legislative action needs to be taken to discourage the continued introduction of new steroid precursor products.

Significantly, steroid precursor manufacturers fully exploit the protection offered by DSHEA and actively tout precursor products as "natural" and "legal" in order to raise the false implication that they offer a safe alternative to controlled anabolic steroids. At the same time, the marketers of these products glorify the muscle-building qualities of these substances and reinforce the association between these products and those very same controlled anabolic steroids. These products are marketed under names that reinforce their connection to anabolic steroids, including "Cycloroid," "Masterbolan," "Anabol-X," "Paradrol," and "Animal Stak." These products are advertised as equal to or better than the "real steroids" and promise the user huge gains in muscle mass.

While I believe these products raise a health concern for all American consumers who are duped into taking them, I am particularly concerned about the susceptibility of adolescents to the advertising message of steroid precursors. In a society where high school athletes can sign multi-million dollar endorsement contracts, we cannot expect teenagers to ignore advertisements claiming that these products are "safe alternatives" to steroids and will make them "ripped," "huge," improve their athletic performance and give them the body of their dreams. The manufacturers certainly have no motivation to reveal the serious health consequences associated with their products to the adolescents who are buying them, and unfortunately, there is no law requiring disclosure of those health consequences.

For Olympic athletes, who know to avoid these products, there remains another concern. In increasing numbers, athletes are failing doping tests after

taking mislabeled dietary supplements. Studies have shown that an alarmingly high percentage of dietary supplements contain doping substances that are not disclosed on the label. For example, a recent study of 624 dietary supplements by the International Olympic Committee found that 41 percent of the products from American companies contained a steroid precursor or banned substance not disclosed on the label.

USADA believes that the current effectively unregulated availability of products containing steroid precursors in the United States is a health crisis that affects not just elite athletes, but every American teenager who dreams of athletic success, and every consumer who takes one of these products without being informed of the risks. Additionally, because of the risk of contamination, American consumers who believe they are taking perfectly safe nutritional products may unknowingly be ingesting steroid precursors.

There is simply no credible argument supporting the over-the-counter availability of products containing steroid precursors. The time has come to put a stop to the proliferation of these dangerous products. I appreciate this Committee's attention to this problem, as well as the actions of numerous Senators and Congressmen who have joined USADA in the fight to remove these dangerous products from America's stores. On behalf of USADA, I would like to specifically thank Congressmen Sensenbrenner, Conyers, Sweeney, Osborne, and Berman for introducing the Anabolic Steroid Control Act of 2004. I would also like to thank Senators Biden, Hatch, Grassley and Harkin for their attention to this matter and commend their introduction of the Senate version of this bill.

These bills amend the Controlled Substances Act by scheduling the substances I have discussed here today and by making it easier to schedule any anabolic steroid precursors introduced by manufacturers in the future. USADA believes that these bills are the appropriate solution to the steroid precursor problem. We urge full support for these bills and we are hopeful that they will be rapidly passed by Congress.

I would like to thank this Committee for its time and its interest in this important public health issue and for inviting me to share my thoughts on the dangers posed to American consumers by products containing steroid precursors. Thank you.

SOURCE: Hale, R. W. 2004. "U. S. Anti-Doping Agency. Testimony before the House Subcommittee on Crime, Terrorism and Homeland Security of the House Judiciary Hearing on "Anabolic Steroid Control Act of 2004." March 16. [Online information; retrieved 6/17/05.] http://judiciary.house.gov/HearingTestimony.aspx?ID=69. Reprinted with permission of the United States Anti-Doping Agency.

Following such hearings, the members of committees or subcommittees "mark up" the bills they are considering. This term comes from the procedure of going through bills line by line and making changes to the original bill. Sometimes, when similar bills or bills addressing the same issue

have been introduced, they are combined in the markup process. In cases of subcommittee involvement, when the subcommittee has completed its markup and a vote to approve the bill has occurred, the subcommittee reports out the bill to the full committee with jurisdiction. When no subcommittee is involved, or in a case in which a full committee has reviewed the work of a subcommittee and the full committee has voted to approve the bill, the full committee reports out the bill for a vote, this time to the floor of the Senate or the House. At this point, the administration can formally weigh in with support for or opposition to a bill. This input is issued through a Statement of Administration Policy (SAP), examples of which are found at www.whitehouse.gov/omb/legislative/sap/index.html.

If a committee has voted to report a bill favorably, a member of the committee staff, in the name of a committee member, writes the committee report. This is an extremely important document. The committee report describes the purposes and scope of the bill and the reasons why the committee recommends its approval by the entire Senate or House. Committee reports are very useful and informative documents in recording the legislative history of a public law. They are used by courts in considering matters related to particular laws that have been enacted and by executive branch departments and agencies as guidance for implementing enacted laws. These documents provide a rich source of information regarding legislative proposals that have reached this stage of legislation development for those who are interested in the history, purpose, and meaning of the enacted laws.

Generally, a committee report contains a section-by-section analysis in which the purpose of each section of a bill is described. All changes in existing law that the bill would require are indicated in the report, and the text of laws being repealed by the bill are set out. Committee amendments to a bill as it was originally referred to the committee are described at the beginning of the report, and explanations of the amendments are included. Executive communications pertaining to the bill usually are quoted in full in the report.

House or Senate Floor Action on Proposed Legislation

Following approval of a bill by the full committee with jurisdiction, the bill is discharged from the committee along with its bill report. The House or the Senate, depending on where the bill is being considered, receives it from the relevant committee and places it on the legislative calendar for floor action.

Bills can be further amended in debate on the floor of the House or the Senate. However, because such great reliance is placed on the committee process in both chambers, amendments to bills proposed from the floor require considerable support.

Once passed in either the House or the Senate, bills are sent to the other chamber, where the step of referral to a committee with jurisdiction, and perhaps then to a subcommittee, is repeated and where another round of hearings, markup, and eventual action may take place. If the bill is again reported out of committee, it goes to the involved chamber's floor for a final vote. If passed in the second chamber, any differences in the House and Senate versions of a bill must be resolved before the bill is sent to the White House for action by the president.

Conference Committee Actions on Proposed Legislation

To resolve differences in a bill that both chambers of the Congress have passed, a conference committee may be established (Van Beck 1994). Conferees usually are the ranking members of the committees that reported out the bill in each chamber. If they can reach agreement on resolving the differences, a conference report is written, which is then voted on by both houses of Congress. If the conferees cannot reach agreement, or if either chamber does not accept the report, the bill dies; however, if both chambers accept the conference report, the bill is sent to the president for action. This process is described more fully in The Real World of Health Policy: Conference Committees.

The Real World of Health Policy

Conference Committees

If the Senate does not accept the House's position (or the House does not agree to the Senate's position), one of the chambers may propose creation of a conference committee to negotiate and resolve the matters in disagreement between the two chambers. Typically, the Senate gets to conference with the House by adopting this standard motion: "Mr. President, I move that the Senate insist on its amendments (or "disagree to the House amendments" to the Senate-passed measure), request a conference with the House on the disagreeing votes thereon, and that the Chair be authorized to appoint conferees." This triple motion rolled into one—to insist (or disagree), request, and appoint—is commonly agreed to by unanimous consent. The presiding officer formally appoints the Senate's conferees. (The Speaker names the House conferees.) Conferees are traditionally drawn from the committee of jurisdiction, but conferees representing other Senate interests may also be appointed.

There are no formal rules that outline how conference meetings are to be organized. Routinely, the principals from each chamber or their respective staffs conduct pre-conference meetings so as to expedite the bargaining process when

the conference formally convenes. Informal practice also determines who will be the overall conference chair (each chamber has its own leader in conference). Rotation of the chairmanship between the chambers is usually the practice when matched pairs of panels (the tax or appropriations panels, for example) convene in conference regularly. For standing committees that seldom meet in conference, the choice of who will chair the conference is generally resolved by the conference leaders from each chamber. The decision on when and where to meet and for how long are a few prerogatives of the chair, who consults on these matters with his or her counterpart from the other body.

Once the two chambers go to conference, the respective House and Senate conferees bargain and negotiate to resolve the matters in bicameral disagreement. Resolution is embodied in a conference report, signed by a majority of Senate conferees and House conferees. The conference report must be agreed to by both chambers before it is cleared for presidential consideration. In the Senate, conference reports are usually brought up by unanimous consent at a time agreed to by the party leaders and floor managers. Because conference reports are privileged, if any Senator objects to the unanimous consent request, a nondebatable motion can be made to take up the conference report. Approval of the conference report itself is subject to extended debate, but conference reports are not open to amendment.

Almost all of the most important measures are sent to conference, but these are only a minority of the bills that the two houses pass each year.

Exchange of Amendments Between the Houses

Differences between versions of most noncontroversial bills and some major bills that must be passed quickly are reconciled through the exchange of amendments between the houses. The two chambers may send measures back and forth, amending each other's amendments until they agree to identical language on all provisions of the legislation. Generally, the provisions of an amendment between the houses are the subject of informal negotiations, so extended exchanges of amendments are rare. But there is also a parliamentary limit on the number of times a measure may shuttle between the chambers. In general, each chamber has only two opportunities to amend the amendments of the other body because both chambers prohibit third-degree amendments. In rare instances, however, the two chambers waive or disregard the parliamentary limit and exchange amendments more than twice. The current record is nine exchanges.

At any stage of this process a chamber may accept the position of the other body, insist on its most recent position, request a conference to resolve the remaining differences, or refuse to take further action and allow the measure to die.

The Senate normally takes action on an amendment of the House only when there is an expectation that the amendment may be disposed of readily, typically by unanimous consent. In the absence of such an expectation, the Senate will

generally proceed to conference in order to negotiate a resolution to any serious disagreements within the Senate or with the House rather than attempt to resolve them on the floor.

SOURCE: Excerpted and reprinted from U.S. Senate. n.d. "Senate Legislative Process." [Online information; excerpt retrieved 2/15/05.] http://www.senate.gov/legislative/common/briefing/Senate_legislative_process.htm#4.

Presidential Action on Proposed Legislation

The president has several options regarding proposed legislation that has been approved by both the House and the Senate. The bill can be signed, in which case it immediately becomes law. The president can veto the bill, in which case it must be returned to Congress along with an explanation of the basis for rejection. A two-thirds vote in both houses of the Congress can override a presidential veto. The president's third option is neither to veto the bill nor to sign it. In this case, the bill becomes law in ten days, but the president has made a political statement of disfavor regarding the legislation. A fourth option may apply when the president receives proposed legislation near the close of a Congressional session; the bill can be pocket vetoed if the president does nothing about it until the Congress is adjourned. In this case, the bill dies.

Legislation Development for the Federal Budget

Because enactment of legislation related to the federal government's annual budget is so crucial to the performance of government and to the well-being of the American people, special procedures have been developed to guide this process. The Congressional Budget and Impoundment Control Act of 1974 (P.L. 93-344) and its subsequent amendments provide Congress with the process through which it establishes target levels for revenues, expenditures, and the overall deficit for the coming fiscal year.

The development of legislation for the federal budget is similar to the process through which all legislation is developed, but it differs in several important ways. First, because the Constitution requires that any bill raising revenue must originate in the House of Representatives, the House traditionally takes the lead in the budget process.

The second distinctive feature of the budget process is that the president's role in developing budget legislation is more formalized. The president is required by statute to submit a budget to Congress each year. By doing so, the president establishes the starting point and the framework of the annual process of legislation development for the federal budget.

The third difference between the budget process and the normal legislative process is that federal budget making is made up of three distinct stages. First, Congress drafts and approves a budget resolution that provides the framework for overall federal government taxation and spending for various programs and purposes for the upcoming year. Second, the programs and purposes are authorized by way of establishment, extension, or modification. This must take place before any money can be appropriated for a particular program or purpose, the third stage of federal budget making. The amount

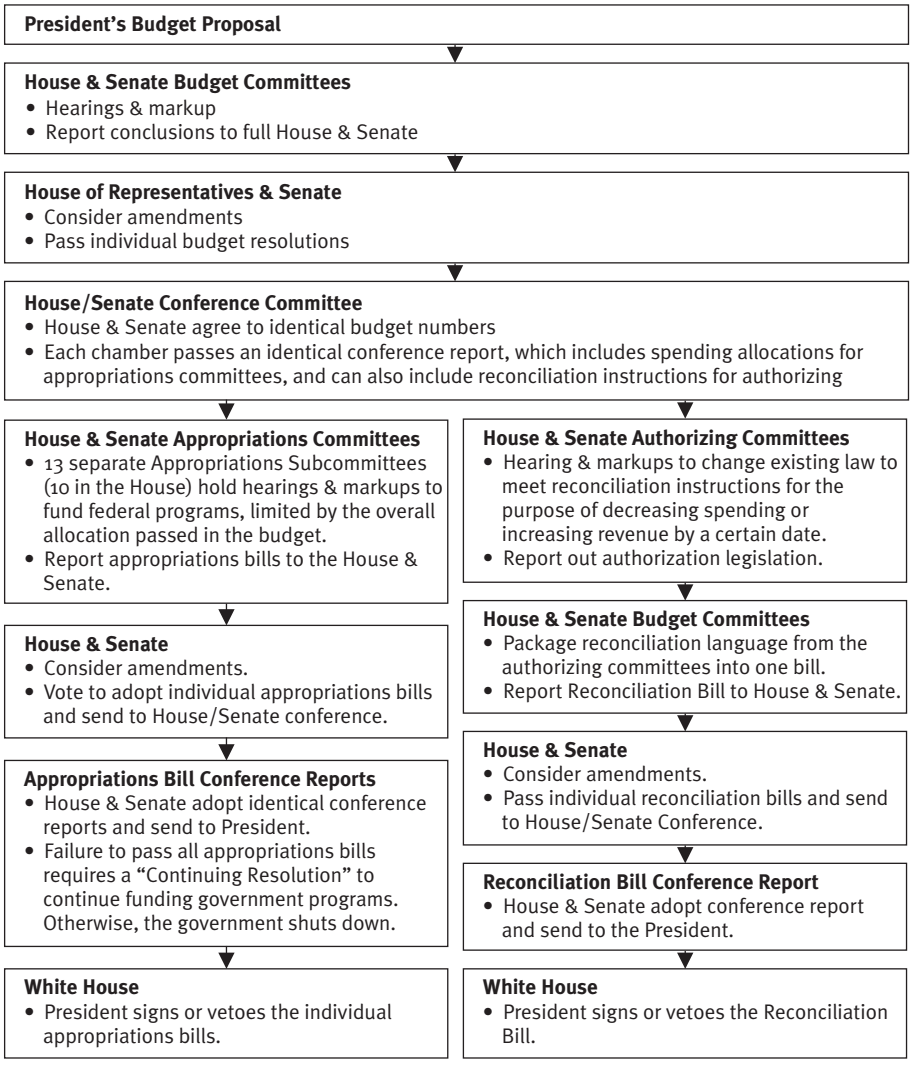


FIGURE 6.2 Steps in the Federal Budget Process

SOURCE: American Public Health Association (2005). Copyright by the American Public Health Association and reprinted with their permission.

of money authorized for a program or purpose is generally less than the actual amount appropriated for it.

The budget process is designed to coordinate decisions on sources and levels of federal revenues and on the objectives and levels of federal expenditures. Such decisions have a substantial impact on other policy decisions, including those that pertain to the health policy domain. Figure 6.2 shows, step by step, the process through which the annual federal budget is developed. The schedule begins when the president submits a proposed budget to Congress (see the first box in Figure 6.2). The Real World of Health Policy: The Federal Budget Process describes these steps in more detail.

The Real World of Health Policy

The Federal Budget Process

The way in which Congress develops tax and spending legislation is guided by a set of specific procedures laid out in the Congressional Budget Act of 1974. The centerpiece of the Budget Act is the requirement that Congress each year develop a "budget resolution" setting overarching limits on spending and on tax cuts. These limits apply to legislation developed by individual congressional committees as well as to any amendments offered to such legislation on the House or Senate floor.

The following is a brief overview of the federal budget process, including:

- the President's budget request, which kicks off the budget process each year;
- the congressional budget resolution—how it is developed and what it contains;
- how the terms of the budget resolution are enforced on the House and Senate floor; and
- budget "reconciliation," a special procedure used in some years to facilitate the passage of spending and tax legislation.

Step One: The President's Budget Request

On or before the first Monday in February, the President submits to Congress a detailed budget request for the next federal fiscal year, which begins on October 1. This budget request, developed by the President's Office of Management and Budget (OMB), plays three important roles. First, it tells Congress what the President believes overall federal fiscal policy should be, as established by three main components: (1) how much money the federal government should devote to public purposes; (2) how much it should take in as tax revenues; and (3) how much of a deficit (or surplus) the federal government should run, which is simply the difference between (1) and (2).

Second, the budget request lays out the President's relative priorities for federal programs—how much he believes should be spent on defense, agriculture, education, health, and so on. The President's budget is very specific, and lists a recommended funding level for individual federal programs or small groups of programs called "budget accounts." The budget typically sketches out fiscal policy and budget priorities not only for the coming year but for the next five years or more; it is accompanied by historical tables that set out past budget figures.

The third role that the President's budget plays is to signal to Congress what spending and tax policy changes the President recommends. The President does not need to propose legislative change for those parts of the budget that are governed by permanent law if he feels none is necessary. Nearly all of the federal tax code is set in permanent law, and will not expire; almost two-thirds of spending—including the three largest entitlement programs (Medicare, Medicaid, and Social Security)—is also permanently enacted. Similarly, interest paid on the national debt is set automatically, with no need for specific legislation. (There is, however, a separate "debt ceiling" which limits how much the U. S. can borrow. The debt ceiling is periodically raised through separate legislation.)

The one type of spending the President *does* have to ask for each year is:

- **Funding for annual "discretionary" or "appropriated" programs**, which are programs spending that fall under the jurisdiction of the House and Senate Appropriations Committees. Any discretionary program must have its funding renewed each year in order to continue operating. Most defense spending is discretionary, as are the budgets for education, health research, and housing, to name just a few examples. Altogether, discretionary programs make up about one-third of all federal spending. The President's budget spells out how much funding he recommends for each specific discretionary program.

The President's budget can also include:

- **Changes to "mandatory" or "entitlement" programs**, such as Social Security, Medicare, Medicaid, and certain other programs (including food stamps, federal civilian and military retirement benefits, veterans' benefits, and unemployment insurance) that are not controlled by annual appropriations. For example, when the President proposed adding a prescription drug benefit to Medicare, he had to show a corresponding increase in Medicare costs in his budget, relative to what Medicare would otherwise have cost under existing law. Similarly, the President could propose a reduction in Medicaid payments to states, which would lead to lower costs than projected under current law.
- **Changes to the tax code.** Any increase or decrease in taxes would affect the amount of federal revenue expected to be collected in that year or in future years.

In sum, the President's budget requests a specified funding level for appropriated programs and may request changes in tax and entitlement law.

Step Two: The Congressional Budget Resolution

After receiving the President's budget request, Congress generally holds hearings to question Administration officials about the budget and then develops its own budget resolution. This work is done by the House and Senate Budget Committees, whose sole function is to draft the budget resolution. Once the committees are done, their budget resolution goes to the House and Senate floor, where it can be amended (by a majority vote).[1] It then goes to a House-Senate conference to resolve any differences, and a conference report is passed by both houses.

The budget resolution is a "concurrent" congressional resolution, not an ordinary bill, and does not go to the President for his signature or veto. It also requires only a majority vote to pass, and is one of the few pieces of legislation that cannot be filibustered in the Senate. The budget resolution is supposed to be passed by April 15, but it often takes longer. Occasionally, Congress does not pass a budget resolution. If that happens, the previous year's resolution stays in effect.

- **What is in the budget resolution?** The congressional budget resolution is a very simple document. It consists of a set of numbers that state how much Congress is allowed to spend in each of 20 spending categories (known as budget "functions") and how much total revenue the government will collect, for each of the next five or more years. (The Congressional Budget Act requires that the resolution cover a minimum of five years; Congress often chooses to develop a 10-year budget.) The difference between the two totals for each year—the spending ceiling and the revenue floor—represents the deficit (or surplus) expected for that year.
- **How spending is defined: budget authority vs. outlays.** The spending totals in the budget resolution are stated in two different ways: the total amount of "budget authority" that is to be provided, and the estimated level of expenditures, or "outlays." Budget authority is how much money Congress allows a federal agency to commit to spend; outlays are how much money actually flows out of the federal Treasury in a given year. For example, a bill that appropriated $50 million for building a bridge would provide $50 million in budget authority in the same year, but the bill might not result in $50 million in outlays until the following year, when the bridge actually is built.

  Budget authority and outlays thus serve different purposes. Budget authority represents a limit on how much funding Congress will provide; it is generally what Congress focuses on in making most budgetary decisions. Outlays, because they represent actual cash flow, help determine the size of the overall deficit or surplus.

- **How committee spending limits get set: 302(a) allocations.** The report that accompanies the budget resolution includes a table called the "302(a) allocation." This table takes the total spending figures that are laid out by budget function in the budget resolution and distributes these totals by congressional committee. The House and Senate tables are slightly different from one another, since committee jurisdictions vary somewhat between the two chambers.

The Appropriations Committee receives a single 302(a) allocation for all of its programs; it then decides on its own how to divide up this funding among its 13 subcommittees, into what are known as 302(b) sub-allocations. The various committees with jurisdiction over mandatory programs each get an allocation that represents a total dollar ceiling for all of the legislation they produce that year.

The spending totals in the budget resolution do *not* apply to the "authorizing" legislation produced by most congressional committees. Authorizing legislation typically either changes the rules for a federal program or provides a limit on how much money can be appropriated for it. Unless it involves changes to a mandatory program (such as Social Security or Medicare), authorizing legislation does not actually have a budgetary impact. For example, the Education Committees could produce legislation that authorizes a certain amount to be spent on Title I reading and math programs for disadvantaged children. However, none of that money can be spent until the annual Labor-HHS *appropriations* bill—which includes education spending—sets the actual dollar level for Title I funding for the year.

Often the report accompanying the budget resolution contains language describing the assumptions behind it, including how much it envisions certain programs being cut or increased. These assumptions generally serve only as guidance to the other committees and are not binding on them. Sometimes, the budget resolution includes more complicated devices intended to ensure that particular programs receive a certain amount of funding. For example, the budget resolution could create a "reserve fund" that could be used only for a specific purpose.

The budget resolution can also include temporary or permanent changes to the federal budget process. For example, the fiscal year 2004 budget resolution contained a provision limiting the amount of money that the 2005 budget resolution could allocate to the Appropriations Committees, and created a point of order—waiveable only by the vote of 60 Senators—to enforce that limit.

How Are the Terms of the Budget Resolution Enforced?

The main enforcement mechanism that prevents Congress from passing legislation that is not in keeping with the budget resolution is the ability of a single member of the House or the Senate to raise a "point of order" on the floor to block such legislation. In recent years, this point of order has not been

particularly important in the House because it can be waived there by a simple majority vote on a resolution developed by the leadership-appointed Rules Committee, which sets the conditions under which a bill will be considered on the floor. However, the budget point of order is very important in the Senate, where any legislation that exceeds a committee's spending allocation—or cuts taxes below the level allowed in the budget resolution—is vulnerable to a budget point of order on the floor that order requires *60 votes* to waive.

Appropriations bills (or amendments to them) must fit within the 302(a) allocation given to the Appropriations Committee (and the 13 sub-allocations) for the coming fiscal year. Tax or entitlement bills (or any amendments offered to them) must fit within the budget resolution's spending limit for the relevant committee or fit within the revenue floor, both in the first year *and* over the total multi-year period covered by the budget resolution. The cost of a tax or entitlement bill is determined (or "scored") by the nonpartisan Congressional Budget Office, which measures it against a budgetary "baseline" that projects entitlement spending or tax receipts under current law.

The Budget "Reconciliation" Process

From time to time, Congress has chosen to make use of a special procedure outlined in the Congressional Budget Act known as "reconciliation."[2] This procedure was originally designed to facilitate the passage of deficit-reduction legislation and was created because procedural points of order could not compel Congress to pass spending cuts or tax increases called for in the budget resolution. While the reconciliation process was intended as a deficit-reduction mechanism, it has been used twice during the Bush Administration (in 2001 and 2003) to pass tax-cutting legislation as well.

- **What is a reconciliation bill?** A reconciliation bill is a single piece of legislation that typically includes multiple provisions (generally developed by several committees) all of which affect the federal budget—whether on the spending side, the tax side, or both. Like the budget resolution, a reconciliation bill cannot be filibustered on the Senate floor, so it can pass by a majority vote.
- **How does the reconciliation procedure work?** If Congress decides to use the reconciliation procedure, language known as a "reconciliation directive" must be included in the budget resolution. The reconciliation directive instructs various committees to produce legislation by a specific date that meets certain spending or tax targets. (If they fail to produce this legislation, the Budget Committee Chair can write amendments to meet the reconciliation targets for them, which is enough of a threat that committees generally comply with a reconciliation directive.) The Budget Committees then package all of these bills together and present them on the floor for an up-or-down vote, with only limited opportunity for amendments. After

the House and Senate resolve the differences between their two bills, a final conference report is considered on the floor of each house and then goes to the President for his signature or veto.

- **Constraints on reconciliation: the "Byrd rule."** While reconciliation enables Congress to bundle together several different provisions affecting a broad range of programs, it faces one major constraint: the "Byrd rule," named after Senator Byrd of West Virginia. This Senate rule makes any provision of (or amendment to) the reconciliation bill that is deemed "extraneous" to the purpose of amending entitlement or tax law vulnerable to a point of order. If a point of order is raised under the Byrd rule, the offending provision is automatically stripped from the bill unless at least 60 senators vote to waive the rule. This makes it difficult, for example, to include any policy changes in the reconciliation bill unless they have direct fiscal implications. Under this rule, authorizations of discretionary appropriations are not allowed, nor are changes to civil rights or employment law, for example. Changes to Social Security also are not permitted under the Byrd rule.

  In addition, the Byrd rule bars any entitlement increases or tax cuts that cost money beyond the five (or more) years covered by the reconciliation directive, unless these "out-year" costs are fully offset by other provisions in the bill. This is a central reason why Congress made the 2001 tax cuts expire by 2010, rather than making them permanent.

NOTES:
1. For more than two decades, the House leadership has not allowed the budget resolution to be amended freely on the floor. Instead, the Rules Committee—an arm of the leadership whose role is to develop resolutions that restrict floor debate—has generally allowed the consideration of only a few "substitute" amendments. These are alternative budgets, typically developed by the minority party and/or caucuses within the House that have a particular interest in budget policy.
2. In this context, the term "reconciliation" does not have its ordinary meaning of two parties working out their differences (for example, the House and Senate are often described as going to conference to "reconcile" competing versions of a bill). Rather, it refers to the process by which congressional committees adjust, or "reconcile," existing tax or entitlement law with the new tax or entitlement spending targets called for in the budget resolution.

SOURCE: Coven, M., and R. Kogan. 2004. "Introduction to the Federal Budget Process." [Online information; retrieved 2/16/05.] http://www.cbpp.org/3–7-03bud.htm. Reprinted with permission of the Center for Budget and Policy Priorities.

The appropriations process is a key element in the development of annual federal budget legislation. A useful source of information about this process is the *Appropriations Primer* (http://appropriations.house.gov/_files/Primer2004.pdf) produced by the Appropriations Committee of the U.S. House of Representatives.

Legislation Development for State Budgets

The states also develop budget legislation, although the process varies considerably from state to state. In all states, however, the budget is among the most—if not the most—important mechanisms for establishing policy priorities. Pennsylvania uses a process that includes three key steps (IssuesPA 2005):*

Step 1: Budget preparation

The Governor is clearly in control of the first phase of building a budget. Preparing for the next year's budget begins in the Governor's Office a full year in advance. The Governor establishes initial direction for the budget in August and agencies must take these priorities into account in developing their requests for funding.

It is at this point that outside forces begin to influence the process. State agency heads (appointed by the Governor) must balance the wants and needs of their constituencies with the administration's policy priorities and guidelines on total spending.

The Budget Office (with a director reporting directly to the Governor) exerts considerable influence at this point through its evaluation of agency requests and its ability to formulate preliminary spending and revenue recommendations. Agency heads have the opportunity to meet with the Governor to make their case for changes to those recommendations. The Governor makes his final recommendations based on this input.

Step 2: Legislative review and enactment

The Governor transmits his budget recommendations each year via a speech to the General Assembly. In the following month, the Appropriations' Committees of both chambers hold hearings and gather information from cabinet secretaries and others. At the same time legislative staff analyze the details of the proposals. It is at this point that interest groups have the greatest opportunity to influence the outcome in specific areas by interacting with the legislature.

In Pennsylvania the Governor has the power of "line-item veto". This means that the Governor can reduce or eliminate, but not increase, specific items in the budget legislation. This gives the Governor the ability to draw a firm line on some items in the budget and exert additional influence over the legislative process before the legislation reaches his desk. In addition, Pennsylvania's Constitution requires a balanced budget. The Governor must veto spending levels that exceed the estimated available revenues.

Step 3: Budget execution and auditing

After signing the budget the Governor assumes responsibility for implementation. This includes approving spending plans of the agencies within the broad discretion

* *Source*: Reprinted with permission of the Pennsylvania Economy League, Inc.

of the appropriations and authorizing staffing levels. The executive branch also must periodically report the progress of spending to the General Assembly.

At the close of the fiscal year, the Budget Office informally reviews program and financial performance and performs formal evaluations of selected programs. In addition, the Auditor General performs a financial post audit.

A complete description of one state's budget process can be seen in The Real World of Health Policy: Michigan's Budget Process. Most states include descriptions of their budget process on state web sites. For example, California's process can be seen at http://www.dof.ca.gov/fisa/bag/process.htm; New York's at http://www.budget.state.ny.us/citizen/process/process.html; North Carolina's at http://www.osbm.state.nc.us/files/pdf_files/2003_budget_manual.pdf; and Texas's at http://www.senate.state.tx.us/SRC/pdf/Budget101_2005.pdf.

The Real World of Health Policy

Michigan's Budget Process

Introduction

The Michigan Constitution requires the Governor to propose an Executive Budget for state activities on an annual basis. By law the Executive Budget must be submitted to the Legislature within thirty days after the Legislature convenes in regular session on the second Wednesday in January. However, when a newly elected Governor is inaugurated into office, sixty days are allowed to prepare the proposal. The Executive Budget is more than a statutory requirement. It represents a statement of priorities for the policy activities of state government. Therefore, a detailed budget preparation process is necessary to provide information that will help the Governor and the Legislature allocate state resources most effectively. The budget process can be broken down into four stages:

- Development of the Governor's Executive Budget
- Enactment by the Legislature
- Budget Revisions
- Closing the Books

Development of the Governor's Executive Budget

Department Requests

The development of each new fiscal year budget begins in August approximately thirteen to fourteen months prior to the beginning of the new fiscal year. The process starts with the State Budget Office issuing program policy guidelines to the departments. The guidelines and directions include assumptions regarding

revenue changes, federal funds information, and economic adjustments. The guidelines also include instructions for the preparation of different levels of expenditures for each department. By October, departments submit their budget proposals to the State Budget Office. The State Budget Director makes preliminary budget recommendations to the Governor based on staff evaluations and funding proposals.

First Revenue Estimating Conference

These recommendations are fine-tuned during the next few months. The Revenue Estimating Conference held each January is a major part of the budget process. During the conference, national and state economic indicators are used to formulate an accurate prediction of revenue available for appropriation in the upcoming fiscal year. This conference first convened in 1992, pursuant to Act No. 72 of the Public Acts of 1991. The principal participants in the conference are the State Treasurer and the Directors of the Senate and House Fiscal Agencies or their respective designees. Other participants may include the Governor and senior officials from the Department of Treasury.

Governor's Budget Decisions

Before and after the Revenue Estimating Conference, the State Budget Office, the Executive Office and the state departments hold briefings and hearings in order to review requests and prepare recommendations. The Governor makes final budget decisions in December prior to the presentation to the Legislature.

Executive Budget Presentation

As indicated above, Act No. 431 of Public Acts of 1984, the Management and Budget Act, requires the budget to be submitted within thirty days after the Legislature convenes in regular session on the second Wednesday in January. When a new governor is elected sixty days are allowed.

During the budget presentation, the State Budget Director on behalf of the Governor presents the budget and accompanying explanations, recommendations, and legislation to the Legislature. This generally takes place in early February during a joint session of the House and Senate Appropriations Committees.

Legislative Action

By custom, all the appropriation bills are introduced in both houses of the Legislature and are divided between the houses for consideration. The bills usually receive more detailed hearings in the house of origin. Generally, all the appropriation bills are introduced by each appropriations committee chair or the ranking member of the Governor's party. Traditionally, only half of the bills are considered in each house initially. Currently, the practice is to alternate the house of origin each year. This practice allows both appropriations committees to work simultaneously on the appropriations bills.

The Appropriations Committees assign the budgets to specific subcommittees. These subcommittees then conduct a series of hearings. State department directors and their staff present an overview of the Governor's proposed budget, followed by briefings from House Fiscal Agency and Senate Fiscal Agency staff. The subcommittees may also hold public hearings in locations across the state. Finally, the subcommittee composes recommendations that are reported to the full Appropriations Committee.

During full House and Senate Committee meetings, state department directors and their staff are expected to provide explanations when their agency's appropriations are considered. A legislative fiscal analyst assigned to that bill is also present. This analyst may prepare a report or series of reports on the bill. The chair of the related subcommittee asks the legislative analyst to summarize the bill. The committee members are then free to ask questions regarding the bill. The appropriations committee may amend the bill or adopt a substitute version. Following approval, the bill is reported to the floor.

Prior to floor consideration, the Democratic and Republican members will discuss the bill during a caucus meeting. In addition to developing a party position, the caucus provides individual legislators with an opportunity to become better informed regarding policy issues incorporated in the budget.

The legislative procedure for consideration of the appropriation bills is basically the same as for other bills except that appropriation measures receive priority on the legislative calendars. In many instances, members who are going to offer amendments will propose the changes to the appropriations committees before floor debate. Floor consideration varies considerably depending on the particular subject matter, issues, and other factors. There may be minimal debate or it may take a whole day or more for a given bill. Fiscal analysts prepare floor sheets summarizing the appropriation bill, the difference in funding from the prior year, the Governor's recommendation, or between house recommendations, new, expanded or eliminated programs, and total FTEs (full-time equated positions) authorized.

Second Revenue Estimating Conference

A second Revenue Estimating Conference takes place in May of each year. Its purpose is to provide an updated consensus forecast of anticipated revenues for the Executive Budget. Upon completion of the revised consensus revenue estimate, legislative leadership meets with the Governor and the State Budget Director in an attempt to establish final spending targets for each state department. The process of target setting also involves discussion and attempts for agreement on other overall budget issues including boilerplate language, revenue bills, and other statutory changes to be included in the final budget. Reports of the agreements reached during target setting are then provided to the Legislature.

Conference Committees

Differences between the two houses on each appropriations bill are resolved by a conference committee. The committee consists of six members, three members from the Senate and three members from the House. Traditionally, when differences on any of the appropriation bills necessitate a conference committee, the conferees are usually members of the respective House and Senate appropriations subcommittees. Rule 7 of the Joint Rules of the Senate and the House of Representatives provides:

> The conference committee shall not consider any matters other than matters of difference between the two Houses. When the agreement arrived at by the conferees is such that it affects other parts of the bill, the conferees may recommend amendments to conform with the agreement. The conferees may also recommend corrections to any errors in the bill or title.

Conference committees are expected to ensure that the final levels of appropriations in the conference reports are equal to the appropriations targets established by legislative leadership. This process helps ensure that the enacted appropriations bills do not exceed the consensus estimate of available revenues.

If the conference committee report is approved by both houses, the bill is enrolled and printed (final copy of a bill in the form as passed by both houses) and presented to the Governor. If the conference committee does not reach a compromise and reports that the committee cannot reach an agreement, or if the Legislature does not accept the conference report, a second conference committee may be appointed.

While there is no specific legal time requirement for passage of the budget bills, this task is accomplished prior to the beginning of the new fiscal year. Appropriations bills are usually considered and passed in April by the first house, in early June by the second house, and usually final action is completed in July.

Governor Signs Bills and/or Vetoes

The same procedures related to gubernatorial approval of other legislation also apply to appropriation bills. However, the Governor has additional authority to veto any distinct item or items appropriating money in any appropriation bill. The parts approved become law. Vetoed items are void unless the Legislature overrules the veto by a 2/3 vote of the members elected to and serving in each house. An appropriation line item vetoed by the Governor and not subsequently overridden by the Legislature is not funded unless another appropriation for that line item is approved.

Budget Revisions

According to the Michigan Constitution, no appropriation is a mandate to spend. The Governor, by Executive Order and with the approval of the appropriations committees, can reduce expenditures whenever it appears that actual revenues

for a fiscal period will fall below the revenue estimates on which the appropriations for that period are based. By statute, any recommendation for the reduction of expenditures must be approved or disapproved by both of the Appropriations Committees within ten days after the recommendation is made. A reduction cannot be made without approval from both committees; not later than thirty days after a proposed order is disapproved, the Governor may submit alternative recommendations for expenditure reductions to the committees for their approval or disapproval.

Since 1970, the Governor has issued twenty-seven Executive Orders to reduce expenditures, but on eleven occasions the Executive Orders did not receive approval of the Appropriations Committees. Subsequently, the Governor issued other Executive Orders that were approved. The Governor may not reduce expenditures for the legislative or judicial branches or expenditures from funds constitutionally dedicated for specific purposes.

Each department prepares the allotment of appropriations and may request revisions, legislative or administrative transfers, or supplemental appropriations. The State Budget Office must approve revisions to allotments. Transfer of funds other than administrative transfers within a department must be submitted by State Budget Office to the House and Senate Appropriations Committees.

Expenditure increases for a new program or for the expansion of an existing program cannot be made until the availability of money has been determined and the program has been approved and appropriated by the Legislature. The Governor and the Legislature act on supplemental appropriation bills in a manner similar to original appropriations.

Closing the Books

The fiscal year runs from October 1 to September 30 of the following year. The following January, the State Budget Office releases its initial estimates of the actual year-end balances in the General Fund and School Aid Fund. These estimates are contained in a report referred to as the Preliminary Book Closing Report.

Final book closing occurs in March. The State Budget Office releases the final accounting for the previous fiscal year revenues, expenditures, and year-end balances. These data are contained in the State of Michigan Comprehensive Annual Financial Report (CAFR).

SOURCE: Reprinted from Office of the State Budget, Michigan. n.d. "Budget Process." [Online information; retrieved 2/17/05.] http://www.michigan.gov/budget/0,1607,7-157-11462-34950- -,00.html.

From Formulation to Implementation

When a legislature, whether the U.S. Congress or a state legislature, approves proposed legislation, and the chief executive, whether the president or a governor, then signs it, the policymaking process crosses an important

threshold. The point at which proposed legislation is formally enacted into law is the point of transition from policy formulation to policy implementation. As shown in Figure 6.1, the formal enactment of legislation serves to bridge the formulation and implementation phases of the policymaking process and triggers the implementation phase of the process. Policy implementation is considered in the next chapter.

Summary

The policy formulation phase of policymaking involves agenda setting and the development of legislation. Agenda setting, discussed in Chapter 5, entails the confluence of problems, possible solutions to those problems, and political circumstances that permit certain problem/possible solution combinations to progress along to the point of legislation development.

Legislation development, the other component of policy formulation and the central topic of this chapter, follows a carefully prescribed choreography that includes the drafting and introduction of legislative proposals, their referral to appropriate committees and subcommittees, House and Senate floor action on proposed legislation, conference committee action when necessary, and presidential action on legislation voted on favorably by the legislature. These steps apply whether the legislation is new or, as is often the case, the amendment of prior legislation.

The tangible final products of legislation development are public laws or amendments to existing ones, or budgets in the case of legislation development in the budget process. At the federal level, laws are first printed in pamphlet form called *slip law*. Subsequently, laws are published in the *Statutes at Large* and then incorporated into the *United States Code*. They can be read on the Internet at http://thomas.loc.gov.

Discussion Questions

1. Discuss the link between agenda setting and the development of legislation.
2. Describe the steps in legislation development.
3. Discuss the various sources of ideas for legislative proposals.
4. What are the most important congressional committees regarding health policy? Briefly describe their roles.
5. Describe the federal budget process. Include the relationship between the federal budget and health policy in your response.

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CHAPTER

7

POLICY IMPLEMENTATION: RULEMAKING

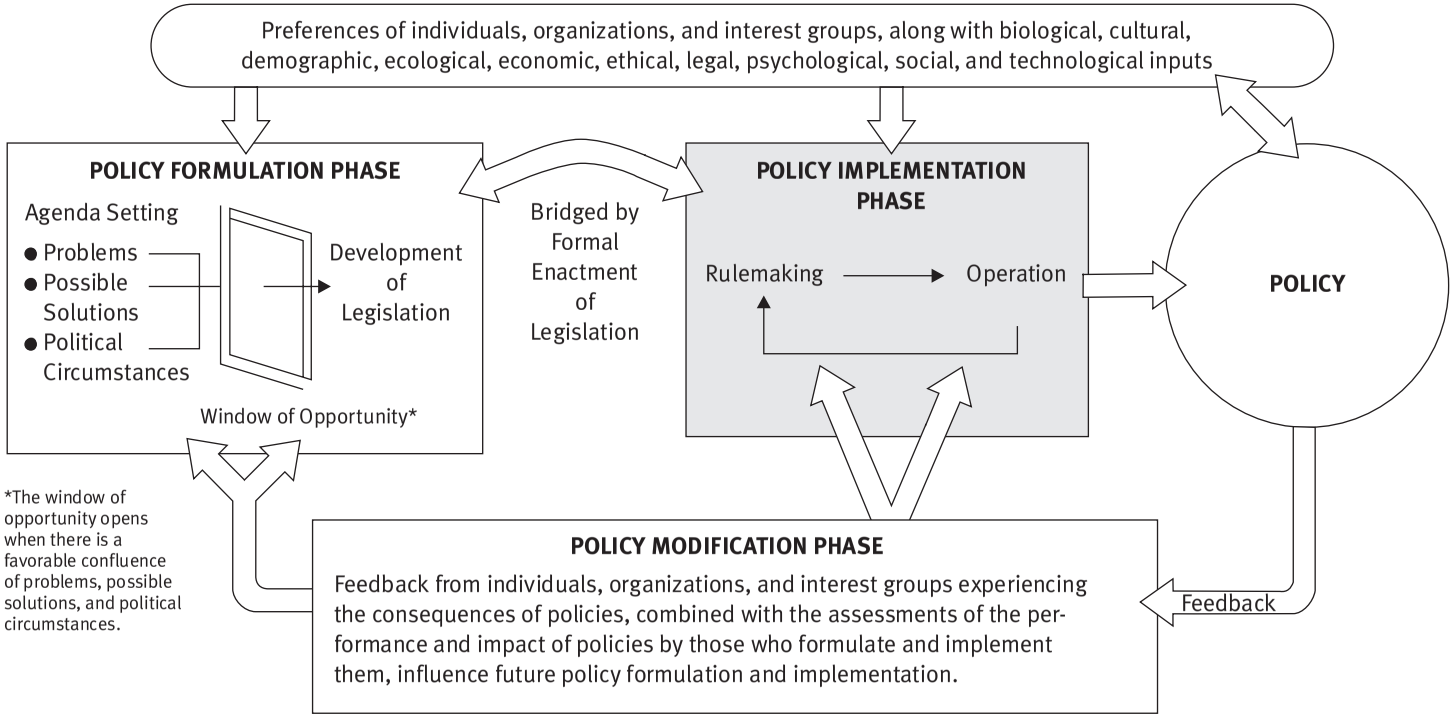
Policy formulation, as a phase of the overall public policymaking process, is described in Chapters 5 and 6 as two sets of interrelated activities—agenda setting and the development of legislation. Sometimes, these formulation activities lead to policies in the form of new or amended public laws, such as the enactment of P.L. 108-173—the Medicare Prescription Drug, Improvement, and Modernization Act of 2003—which amends Title XVIII of the Social Security Act to provide for a voluntary program of prescription drug coverage under the Medicare program. Enactment of laws demarcates the transition between policy formulation and policy implementation, although the boundary between the two phases of policymaking is porous. The bridge connecting policy formulation and policy implementation in the center of Figure 7.1 is intentionally shown as a two-way connector between the two phases of policymaking.

Implementing organizations, primarily the departments and agencies in the executive branch of government, are established and maintained and the people within them employed to carry out the intent of public laws as enacted by the legislative branch. Legislators rely on the implementers to bring their legislation to life. Thus, the relationship between those who formulate and those who implement policies is highly symbiotic.

In short, health policies in the form of changes in public law must be implemented effectively if they are to exert their intended impact on the determinants of health. Otherwise, policies are only so much paper and rhetoric. When implemented, however, laws can change the physical or social environment in which people live and work, affect their behavior and even their biology, and influence tremendously the availability and accessibility of health services.

This chapter focuses on the rulemaking stage of the implementation phase of public policymaking. As can be seen in the shaded portion of Figure 7.1, policy implementation begins with *rulemaking*, which is the establishment of the formal rules (the term "regulations" is used interchangeably with the term "rules" in this context) necessary to fully operationalize the intent embedded in public laws. The second set of activities in policy implementation is associated with the *operation* of public laws, and this stage of implementation is covered in Chapter 8. As will be discussed in that chapter, if a policy in the form of a public law is intended to protect people from exposure to toxic substances in their environments, for example, its operation entails

FIGURE 7.1 A Model of the Public Policymaking Process in the United States: Policy Implementation Phase



the activities involved in providing that protection. Such operational activities might include measuring and assessing dangers from substances in the environment or imposing fines as a means to prevent or restrict environmental pollution.

The implementation phase of public policymaking involves managing human, financial, and other resources in ways that make the goals and objectives embodied in enacted legislation achievable by those responsible for its implementation. The most important point in understanding policy implementation, as part of the larger process of policymaking, is that it is primarily a *management* undertaking. That is, policy implementation in its essence is the utilization of human and other resources in pursuing the objectives embedded in public laws.

Depending on the scope of policies being implemented, the managerial tasks involved can be fairly simple and straightforward, or they can require massive effort. President Lyndon B. Johnson once observed that the preparations made for implementing the Medicare program represented "the largest managerial effort the nation [had] undertaken since the Normandy invasion" (Iglehart 1992, p. 1468). No matter what the scale, however, the implementation of public laws always includes two separate but interrelated sets of activities—rulemaking and operation.

It is important to note the cyclical relationship between rulemaking and the operational activities involved with implementation of a law. As shown in the shaded portion of Figure 7.1, rulemaking precedes operation in the sequence of these activities, but the operational activities feed back into rulemaking. This cyclical relationship means that experience gained with the operation of policies can influence the modification of rules or regulations used in the implementation phase. In a practical sense, this means that the rules promulgated to implement policies undergo revision—sometimes extensive and continual revision—and that new rules can be adopted as experience dictates. This characteristic of policymaking tends to make the process much more dynamic than it would be otherwise.

Another characteristic vital to a comprehensive understanding of policymaking is that *authoritative* decisions made within the executive branch organizations to implement public laws are themselves policies. Recall from Chapter 1 that authoritative decisions refer to decisions that are made anywhere within the three branches of government that are under the legitimate purview (i.e., within the official roles, responsibilities, and authorities) of those making the decisions. For example, rules promulgated to implement a law are just as much policies as are the laws they support. Similarly, operational decisions made by implementing organizations, to the extent that they require or influence particular behaviors, actions, or decisions by others, are policies. Furthermore, decisions made in the judicial branch regarding the applicability of laws to specific situations or regarding the appropriateness of the actions of

implementing organizations are policies. Recall the definition of public policy, given in Chapter 1, as authoritative decisions made in the legislative, executive, or judicial branches of government that are intended to direct or influence the actions, behaviors, or decisions of others. By definition, policies are established within both the policy formulation and the policy implementation phases of the policymaking process.

Responsibility for Policy Implementation

In the implementation phase, much of the responsibility for policymaking shifts from the legislative branch of government to the executive branch. However, the legislative branch retains oversight responsibility for implementation, and there is a judicial dimension to implementation of policies as well. Each branch's responsibility is described below, beginning with the executive branch agencies.

Executive Agencies' Implementation Responsibilities

Agencies such as the Department of Health and Human Services (DHHS) (www.dhhs.gov) and the Department of Justice (DOJ) (www.usdoj.gov) (as well as subdivisions of those departments) and a number of independent federal agencies such as the Environmental Protection Agency (EPA) (www.epa.gov), the Consumer Product Safety Commission (CPSC) (www.cpsc.gov), and the Food and Drug Administration (FDA) (fda.gov) bear direct responsibility for implementing laws enacted by the legislative branch. These and many other executive branch organizations exist to implement the laws formulated by the legislative branch.

The Centers for Medicare & Medicaid Services (CMS) (www.cms.gov) is a good example of an implementing organization. CMS is a federal agency located organizationally within DHHS, as shown in Figure 7.2. It was created in 1977 specifically to administer the Medicare and Medicaid programs and is the primary federal implementing agent for the public laws that established and now continue these programs. Figure 7.3 is an organization chart of CMS. The agency is organized around the following three centers to support its key functions:

1. The Center for Medicare Management focuses on management of the traditional fee-for-service Medicare program. This includes development of payment policy and management of the Medicare fee-for-service contractors.
2. The Center for Beneficiary Choices focuses on the management of the Medicare Advantage and Medicare Prescription Drug plans and the support and coordination of beneficiary services. This center also

FIGURE 7.2 Organization Chart of the Department of Health and Human Services

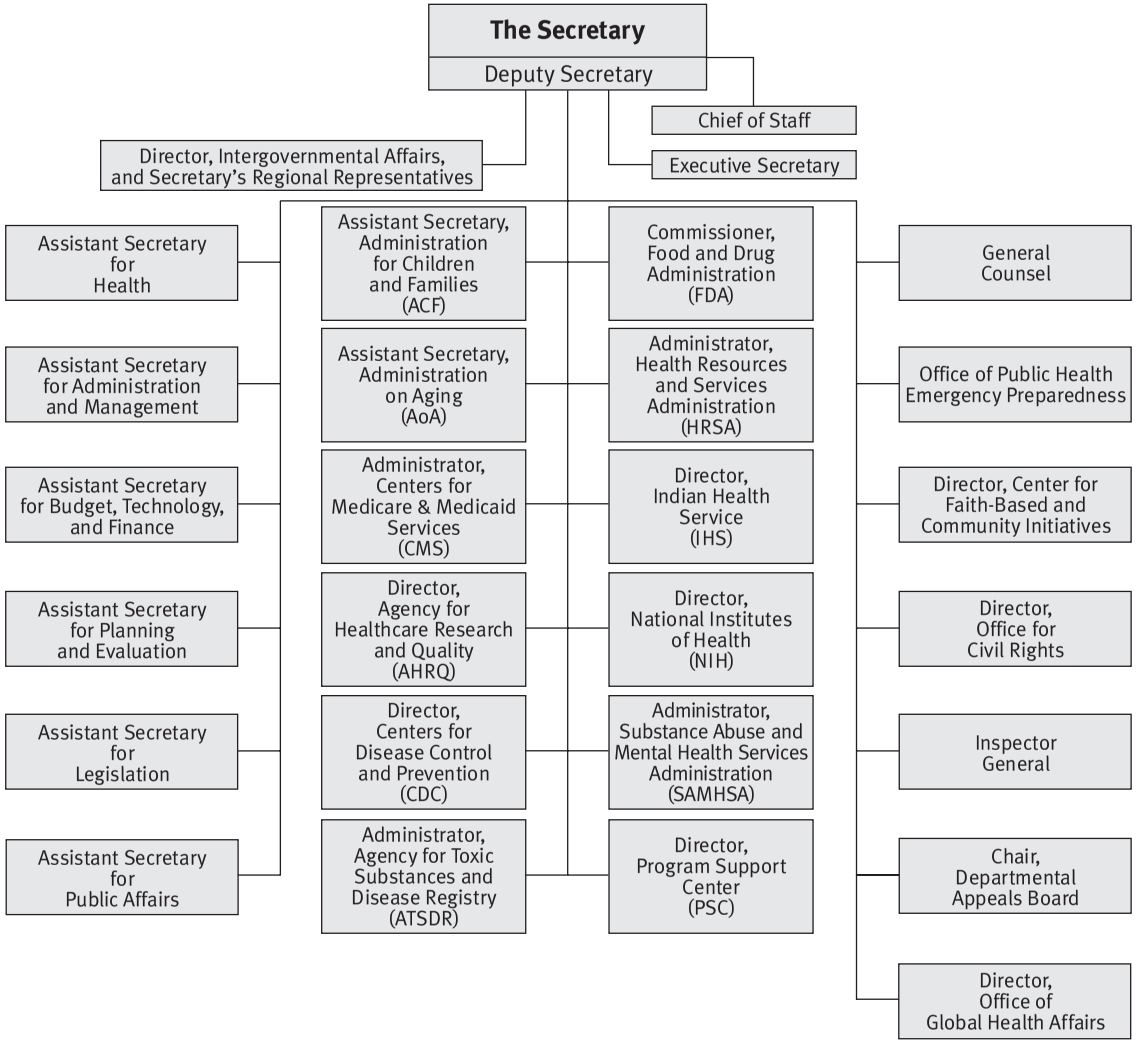
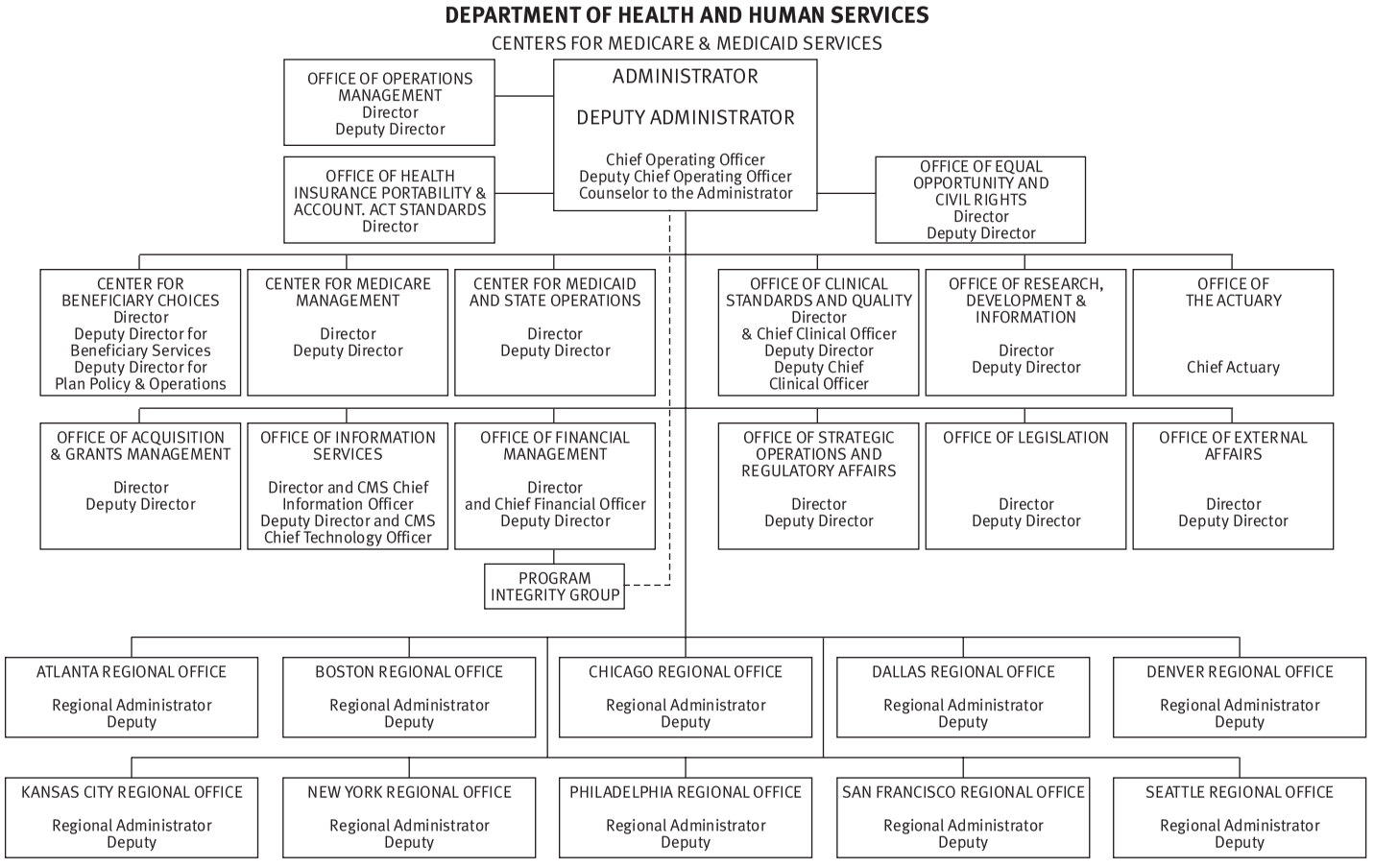


FIGURE 7.3 Organization Chart of the Centers for Medicare & Medicaid Services



responds to the information and assistance needs of Medicare beneficiaries and their families, handles appeals, develops and publishes reference materials for beneficiaries, conducts consumer research, and ensures that CMS protects the privacy of individuals and the confidentiality of health records under the Health Insurance Portability and Accountability Act (HIPAA) and the Privacy Act.

3. The Center for Medicaid and State Operations focuses on programs administered by states. This includes Medicaid, the State Children's Health Insurance Program (SCHIP), insurance regulation functions, survey and certification, and the Clinical Laboratory Improvements Act (CLIA).

CMS staff works in the organization's Baltimore headquarters and in ten regional offices nationwide. The regional offices provide a more decentralized presence, which can contribute to customer service and program oversight. Information about the mission and activities of the agency can be seen at http://www.cms.hhs.gov/about/mission.asp.

Legislative Oversight of Implementation

Although organizations in the executive branch bear most of the responsibility for implementing policies, the legislative branch maintains a very important oversight responsibility in the implementation phase. Oversight of the executive branch's implementation of the policies enacted by the legislative branch is actually mandated in the Legislative Reorganization Act of 1946. Generally, legislative oversight is intended to accomplish the following:

- ensure that implementing organizations adhere to congressional intent;
- improve the efficiency, effectiveness, and economy of government's operations;
- assess the ability of implementing organizations and individuals to manage and accomplish implementation, including investigation of alleged instances of inadequate management, waste, fraud, dishonesty, or arbitrary action; and
- ensure that implementation of policies reflects the public interest.

Effective legislative oversight is accomplished through several means. One powerful oversight technique occurs within the context of the funding appropriations that Congress must make for the continuing implementation of many of the laws it enacts. Although some health policies, such as the Medicare program, are entitlements, many others require annual funding through appropriations acts. Examples include the research programs of the National Institutes of Health (NIH) (www.nih.gov), health activities of the Department of Veterans Affairs (VA) (www.va.gov), and the activities of the U.S. Public Health Service (USPHS) (www.usphs.gov) and the FDA. Review by

the appropriations committees of the House and Senate is an important means of overseeing the performance of these and similar organizations in carrying out their implementation responsibilities. Implementation inadequacies—real or perceived—may be reflected in the budgets appropriated by Congress for implementing organizations.

Other means of oversight include direct contact between members of Congress and their staffs and executive branch personnel who are involved in implementing policies and the use of oversight agencies specifically created by Congress to help with that task (Nadel 1995), including the Congressional Budget Office (CBO) (www.cbo.gov) and the Government Accountability Office (GAO) (www.gao.gov).

Legislative oversight responsibility goes beyond the appropriations procedure. Each standing committee of the House and Senate has certain oversight responsibilities; those for the standing committees in the House of Representatives are spelled out in Clause 2(d)(1) of Rule X of the Rules of the House for the 109th Congress (www.house.gov/rules/10RX.htm). (A parallel rule exists in the Senate.) Rule X requires that "Not later than February 15 of the first session of a Congress, each standing committee shall, in a meeting that is open to the public and with a quorum present, adopt its oversight plan for that Congress. Such plan shall be submitted simultaneously to the Committee on Government Reform and to the Committee on House Administration." Clause 2(b)(1) of Rule X states,

> In order to determine whether laws and programs addressing subjects within the jurisdiction of a committee are being implemented and carried out in accordance with the intent of Congress and whether they should be continued, curtailed, or eliminated, each standing committee (other than the Committee on Appropriations) shall review and study on a continuing basis:
>
> - the application, administration, execution, and effectiveness of laws and programs addressing subjects within its jurisdiction;
> - the organization and operation of Federal agencies and entities having responsibilities for the administration and execution of laws and programs addressing subjects within its jurisdiction;
> - any conditions or circumstances that may indicate the necessity or desirability of enacting new or additional legislation addressing subjects within its jurisdiction (whether or not a bill or resolution has been introduced with respect thereto); and
> - future research and forecasting on subjects within its jurisdiction.

The Real World of Health Policy: Oversight Plan of the Committee on Ways and Means, 109th Congress shows a typical oversight plan, in this instance of a committee with important oversight responsibilities for health policy.

The Real World of Health Policy

Oversight Plan of the Committee on Ways and Means, 109th Congress

February 2, 2005
The Honorable Tom Davis
Chairman
Committee on Government Reform
2157 Rayburn HOB
Washington, D.C. 20515

The Honorable Robert W. Ney
Chairman
Committee on House Administration
1309 Longworth HOB
Washington, D.C. 20515

Dear Chairman Davis and Chairman Ney:

In accordance with the requirements of Clause 2 of Rule X of the rules of the House of Representatives, the following is a list of oversight hearings and other oversight-related activities, which the Committee on Ways and Means and its Subcommittees plan to conduct during the 109th Congress.

Full Committee

Tax Reform. The full Committee intends to hold hearings to examine proposals to reform Federal taxation.

Fiscal Year 2006 and 2007 Budget Initiatives Regarding Taxes. The full Committee intends to hold hearings to receive information regarding tax legislation proposed in the President's 2006 and 2007 budgets.

Strengthening Social Security. The full Committee intends to hold hearings to examine various issues affecting the well-being of individual recipients, the financial challenges facing Social Security, and options to address those challenges.

* * *

Subcommittee on Health

Medicare Program Oversight. The Subcommittee intends to hold a hearing to evaluate the management of the Medicare program by the Centers for Medicare and Medicaid Services (CMS). The Subcommittee will explore changes that could be made to improve CMS's efficiency and its interactions with beneficiaries and the providers who serve them. The Subcommittee will examine CMS's progress on implementing the changes required by the Medicare Modernization Act (MMA) (P.L. 108-173).

Medicare Payments for Physician Services. The Subcommittee intends to hold hearings to examine Medicare reimbursement for physician services, including problems associated with the Sustainable Growth Rate formula and will explore alternative payment structures. In addition, the Subcommittee will examine creating incentives to promote physician performance and efficiency and will look at issues surrounding physician resource use. Geographic variations in payments to physicians will also be scrutinized. Finally, the Subcommittee will continue its oversight of payment adequacy for oncology related services, drugs, and biologics, including the changes made by the MMA.

Medicare Payment for Hospital Services. The Subcommittee intends to examine pricing transparency for hospital services. In addition, the Subcommittee will conduct oversight of the current reimbursement structure under Medicare, including potential hearings on operation of the wage index and differences between specialty and community based institutions. The Subcommittee intends to hold a hearing on paying for performance and physician resource use in the hospital setting. The Subcommittee intends to hold a hearing on financial reporting for hospitals, including instruments to better reflect costs and to promote the timeliness of data reporting.

Medicare Payments for Post-Acute Care. The Subcommittee intends to hold a hearing on payments to post-acute care providers in the Medicare program to determine whether the payment structures create incentives to inappropriately shift site of care to more lucrative settings. In addition, the Subcommittee will study proposals that provide financial security to individuals for long term care costs outside of the traditional Medicare structure.

Retiree Health Coverage and Interaction with Medicare. The MMA required the U.S. Government Accountability Office (GAO) to conduct initial and final reports on the trends in retiree health coverage, new options available to employers to subsidize coverage included in the MMA and what impact, if any, these subsidies had on retiree coverage. The Subcommittee will examine implementation of the MMA subsidies as they relate to retiree health coverage.

Medicare Waste, Fraud and Abuse. The Subcommittee will examine enforcement of laws to combat waste, fraud and abuse in the Medicare program and what steps might be taken to improve their application. The Subcommittee will also examine the issue of Medicare program solvency.

Medically Uninsured. The Subcommittee intends to hold a hearing on options to reduce the number of individuals and families without health insurance. The hearing will include an examination of tax credits, reinsurance of risk and purchasing pools, among other solutions.

New Technologies in the Medicare Program. The Subcommittee intends to hold a hearing on CMS policies that foster or hinder the adoption of new technologies in the Medicare program, including coverage and reimbursement policies and national and local coverage determinations.

Other Medicare Payments. The Subcommittee intends to hold a hearing on the appropriateness of payments to other Medicare providers, including home

health agencies, skilled nursing facilities, end stage renal disease providers, durable medical equipment suppliers and others. Such an examination will include proposals to make Medicare more efficient and responsive.

Health Savings Accounts. The Subcommittee intends to hold hearings and conduct other oversight activities on Health Savings Accounts.

Medicare Advantage Program. The Subcommittee intends to hold hearings and conduct other oversight activities on the Medicare Advantage program. The Subcommittee intends to examine payment and structural changes to Medicare Advantage plans enacted as a result of the MMA.

Other Issues. Further hearings will be scheduled as time permits to examine certain additional aspects of Medicare program management. Matters to be considered may include healthcare information technology, healthcare quality issues, Medigap reform, medical liability reform, especially as it affects the Medicare program and patient safety issues.

Subcommittee on Human Resources

Welfare Reform. Reauthorizing the Temporary Assistance for Needy Families (TANF) and related programs to amend and improve the 1996 welfare reform law continues to be a priority for the Subcommittee. Issues of particular interest to the Subcommittee include how TANF block grant funds and other HHS efforts to communicate with the public are used to develop strong families and encourage healthy marriage and how welfare reform policies can be strengthened to better promote increased work, reduced poverty, enhanced program integrity, and improved child well-being.

Child Support and Fatherhood. The Subcommittee intends to hold hearings on the nation's Federal-State child support system, review the results of program changes made in 1996 and 1998 law, and consider proposals for further improvements. The Subcommittee also will review proposals to encourage responsible fatherhood and closer involvement between fathers, children and families, both as a result of child support and other program policies.

Supplemental Security Income. The Supplemental Security Income (SSI) program provides over $30 billion in benefit payments to 7 million disabled needy individuals each year. The Subcommittee will review proposals to reduce fraud and abuse in the program, and examine options for improving program outcomes such as enhancing the ability of individuals to return to work.

Child Protection. The Subcommittee held a number of child protection oversight hearings during the 108th Congress, examining the purposes and outcomes of current child protection programs. The Subcommittee will review program improvement proposals for child protection programs broadly, as well as involving distinct issues such as the handling of interstate placements. The Subcommittee also will review the operation of the Promoting Safe and Stable Families program in anticipation of the expected reauthorization of this program prior to the end of fiscal year 2006.

Unemployment Compensation. The Subcommittee intends to hold hearings on the Nation's unemployment compensation system. Issues of interest include a more detailed understanding of the characteristics of unemployment benefit recipients over time, and improving the program to better promote work, savings, and program integrity. The Subcommittee also will review reemployment services provided to unemployment benefit recipients, and consider whether better return-to-work outcomes can be achieved through reforms.

Subcommittee on Social Security

Strengthening Social Security. The Subcommittee intends to hold hearings to examine the degree to which Social Security programs are meeting the needs of today's and tomorrow's beneficiaries, along with the financial challenges facing the program and proposals to strengthen Social Security.

Use of the Social Security Number. The Subcommittee will continue their examination of the integrity of Social Security numbers (SSNs) and Social Security cards as identifiers, including their role in identity theft and other fraud.

Disability Program Reform and Oversight. The Subcommittee intends to hold hearings on the Social Security Disability Insurance (DI) program, including: the Social Security Administration's (SSA's) implementation of the Ticket to Work and Work Incentives Improvement Act (P.L. 160-170); oversight of SSA's disability program management, including efforts to improve workload processing at both the initial application and appeals levels.

Stewardship of the Social Security Programs. The Subcommittee intends to hold oversight hearings to examine the management of the Social Security programs, including international agreements, to assess their potential vulnerability to waste, fraud, and abuse, and to explore necessary legislative remedies.

Service Delivery. The Subcommittee intends to hold oversight hearings to examine SSA's service delivery to the public, including efforts to modernize service delivery to meet the changing expectations of today's customers, and SSA's efforts to communicate with the public about the financing challenges facing Social Security and possible changes to the program.

* * *

This list is not intended to be exclusive. The Committee anticipates that additional oversight activities will be scheduled as issues arise and/or as time permits.

Sincerely,

Bill Thomas
Chairman

SOURCE: Excerpted from Oversight Plan of the House Committee on Ways and Means. 2005. "About the Committee: Oversight Plan." [Online document; retrieved 2/20/05.] http://waysandmeans.house.gov/About.asp?section=6.

Judicial Dimension of Implementation

Legislation, as well as the rules made by those responsible for its implementation, can be challenged in the courts. Administrative law judges in the implementing agencies hear the appeals of people or organizations who are dissatisfied with the way the implementation of a policy affects them. For example, the Office of Administrative Law Judges (OALJ) (www.epa.gov/oalj) is an independent office in the Office of the Administrator of EPA. These administrative law judges conduct hearings and render decisions in proceedings between EPA and people, businesses, government entities, and other organizations that are regulated under environmental laws. Administrative law judges preside in enforcement and permit proceedings under the Administrative Procedure Act and also conduct other proceedings involving alleged violations of environmental laws, including the following:

- Clean Air Act (CAA)
- Clean Water Act (CWA)
- Comprehensive Environmental Response, Compensation and Liability Act (CERCLA)
- Emergency Planning and Community Right-to-Know Act (EPCRA)
- Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)
- Marine Protection, Research, and Sanctuaries Act (MPRSA)
- Safe Drinking Water Act (SDWA)
- Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act (RCRA)
- Toxic Substances Control Act (TSCA)
- Subchapter II of TSCA, known as the Asbestos Hazard Emergency Response Act (AHERA)

Federal administrative law judges are certified by the Office of Personnel Management and assured decisional independence. Decisions issued by administrative law judges at EPA are subject to review by the Environmental Appeals Board (EAB). The initial decision of these judges—unless a party appeals to EAB, or EAB on its own initiative elects to review the initial decision—becomes EPA's final order.

Rulemaking: The Beginning of Implementation

Enacted laws seldom contain enough explicit language to guide their implementation completely. Rather, they are often vague on implementation details, leaving it to the implementing organizations to specify, publish, and circulate the rules or regulations (remember, these terms have the same meaning in the policy context) subsequently used to guide the law's actual operation. For this reason, implementation typically begins with rulemaking. Figure 7.4 contrasts laws and rules.

FIGURE 7.4
Laws and Rules

Congress Passes Laws	*Executive Agencies Issue Rules*
Publish in Slip Law/Statutes at Large Codified in U.S. Code	Publish in *Federal Register* Codified in *CFS*
Power comes from Constitution	Power delegated by Congress
Courts review for constitutionality	Courts review for constitutionality and limits of delegated authority, arbitrary and capricious actions, and Administrative Procedure Act requirements
Representative Democracy: Congress acts collectively to represent the will of the people	Participatory Democracy: Agencies must seek and consider public comment on benefits of rules vs. burdens and costs
Set broad social and economic goals and legal requirements	Prescribe specific legal requirements to meet goals

SOURCE: Medicare Learning Network (2005).

Usually the link is fairly direct between the enactment of a new or amended law and the promulgation of the rules necessary for its full implementation. The development of rules follows a prescribed process consisting of the following five steps (Medicare Learning Network 2005):

1. Grant of rulemaking authority
   - Congress delegates authority directly to agencies
   - President may delegate constitutional authority to subordinates
   - President or an agency head may redelegate authority to subordinates
2. Proposed rule stage
   - Office of Management and Budget (OMB) reviews under Executive Order 12866
   - Agencies publish proposed rule in *Federal Register* (*FR*) for public comment
3. Final rule stage
   - OMB reviews again under Executive Order 12866
   - Agencies publish final rule in *FR*
   - Agencies respond to comments, amend the *Code of Federal Regulations* (*CFR*), set effective date
4. Congressional review
   - Agencies submit rules to Congress and to GAO, which has the ability to nullify rules
5. Effective date
   - Rules go into effect after a 30-day minimum; a 60-day minimum applies for major rules
   - Agencies may delay or withdraw rules before they become effective

Rulemaking typically takes place in a timely way so that implementation can proceed smoothly, but this is not always the case. Laws are formulated in the legislative branch and implemented primarily in the executive branch, after all, and sometimes this separation has significant implications. For example, in 1946, Congress enacted the Hospital Survey and Construction Act (P.L. 79-725), also known as the Hill-Burton Act, after its sponsors, Senators Lester Hill and Harold Burton. This law provided grants to build, expand, or modernize hospitals and contained provisions that required grantees to provide "a reasonable volume of services to those unable to pay" and to make their facilities "available to all persons residing in their service areas." However, it was not until significant court action took place in the 1970s that the Department of Health, Education, and Welfare (DHEW), now DHHS, issued effective rules governing these free-care obligations. For 30 years, those responsible for implementing the law simply avoided issuing final rules that required hospitals to meet these obligations, probably because they wished to avoid anticipated conflict with the hospital industry over the enforcement of these provisions of the law.

In addition to rulemaking triggered by new or amended laws, other factors can trigger rulemaking. These include congressional hearings/reports, executive orders, OMB circulars, court orders, agencies acting on their own initiative to carry out their mission, petitions for rulemaking from affected parties, and advisory committee recommendations (Medicare Learning Network 2005). No matter what triggers the rulemaking, rules established by executive departments and agencies through formal rulemaking have legal effect. As authoritative decisions made within government for the purpose of guiding the decisions, actions, and behaviors of others, rules or regulations are by definition policies. These policies are codified in *CFR*, which can be read at www.gpoaccess.gov/cfr.

Rules of Rulemaking

The promulgation of rules, as a formal part of the implementation phase of policymaking, is itself guided by certain rules and protocols, primarily contained in the Federal Register Act of 1935 and the Administrative Procedure Act of 1946. Key among these is the requirement that implementing agencies publish *proposed* rules. The purpose of publishing proposed rules is to give those with interests in the issue an opportunity to participate in the rulemaking prior to the adoption of a *final* rule. Proposed and final rules are published in *FR* (www.gpoaccess.gov/fr/index.html), which is a daily publication that provides a uniform system for publishing presidential and federal agency documents. It includes the following major sections: Presidential Documents, Rules and Regulations, Proposed Rules, and Notices. *FR*, along with numerous other documents, can be read on a web site maintained by the Government Printing Office (GPO) called GPO Access (www.gpoaccess.gov/index.html).

The Real World of Health Policy: Proposed and Final Rules contains examples of a proposed rule and a final rule—in this instance, the rules to implement the Medicare Prescription Drug Benefit enacted as Title I of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (P.L. 108-173). Another example can be seen in the section on Rules and Regulations in Chapter 1. As can be seen in the example, each proposed rule begins with a heading that includes the name of the issuing agency; the *CFR* title and part(s) affected; and a brief description of the specific subject of the document, and in some cases an agency docket number, which identifies the document within the agency's internal filing system. A regulation identifier number (RIN) may also be included. Instructions for filing comments and the date by which comments must be filed are also provided. The Proposed Rules section of *FR* also contains documents relating to previously published proposed rules, extending comment periods, announcing public hearings, making available supplemental information, withdrawing proposed rules, or correcting previously published proposed rules. This section also includes advanced notices of proposed rulemaking. An advanced notice describes a problem or situation and the anticipated regulatory action of the agency and seeks public response concerning the necessity for regulation as well as the adequacy of the agency's anticipated regulatory action.

The Real World of Health Policy

Proposed and Final Rules

A Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services

42 CFR Parts 403, 411, 417, and 423
[CMS-4068-P]
RIN 0938-AN08

Medicare Program; Medicare Prescription Drug Benefit

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would implement the new Medicare Prescription Drug Benefit. This new voluntary prescription drug benefit program was enacted into law on December 8, 2003, in section 101 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). The addition of a prescription drug benefit to Medicare represents a landmark change to the Medicare program that will significantly improve the healthcare coverage available to millions of Medicare beneficiaries. The MMA specifies that the

prescription drug benefit program will become available to beneficiaries beginning on January 1, 2006. Please see the executive summary in the SUPPLEMENTARY INFORMATION section for further synopsis of this rule.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on October 4, 2004.

ADDRESSES: In commenting, please refer to file code CMS-4068-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of three ways (no duplicates, please):

1. Electronically. You may submit electronic comments to http://www.cms.hhs.gov/regulations/ecomments (attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word).
2. By mail. You may mail written comments (one original and two copies) to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-4068-P, P.O. Box 8014, Baltimore, MD 21244-8014.

   Please allow sufficient time for mailed comments to be received before the close of the comment period.
3. By hand or courier. If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-7197 in advance to schedule your arrival with one of our staff members.

   (Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by mailing your comments to the addresses provided at the end of the "Collection of Information Requirements" section in this document.

For information on viewing public comments, see the beginning of the SUPPLEMENTARY INFORMATION section.

FOR FURTHER INFORMATION CONTACT: Lynn Orlosky (410) 786-9064 or Randy Brauer (410)786-1618 (for issues related to eligibility, elections, enrollment, including auto-enrollment of dual eligible beneficiaries, and creditable coverage).

Wendy Burger (410) 786-1566 (for issues related to marketing and user fees).

Vanessa Duran-Scirri (214) 767-6435 (for issues related to benefits and beneficiary protections, including Part D benefit packages, Part D covered drugs, coordination of benefits in claims processing and tracking of true-out-of-pocket costs, pharmacy network access standards, plan information dissemination requirements, and privacy of records).

Craig Miner, RPh. (410) 786-1889 or Tony Hausner (410) 786-1093 (for issues of pharmacy benefit cost and utilization management, formulary development, quality assurance, medication therapy management, and electronic prescribing).

Mark Newsom (410) 786-3198 (for issues of submission, review, negotiation, and approval of risk and limited risk bids for PDPs [prescription drug plans] and MA-PD [Medicare Advantage prescription drug] plans; the calculation of the national average bid amount; determination and collection of enrollee premiums; calculation and payment of direct and reinsurance subsidies and risk-sharing; and retroactive adjustments and reconciliations.)

Jim Owens (410) 786-1582 (for issues of licensing and waiver of licensure, the assumption of financial risk for unsubsidized coverage, and solvency requirements for unlicensed sponsors or sponsors who are not licensed in all States in the region in which it wants to offer a PDP.)

Terese Klitenic (410) 786-5942 (for issues of coordination of Part D plans with providers of other prescription drug coverage including Medicare Advantage plans, state pharmaceutical assistance programs (SPAPs), Medicaid, and other retiree prescription drug plans; also for issues related to eligibility for and payment of subsidies for assistance with premium and cost-sharing amounts for Part D eligible individuals with lower income and resources; for rules for states on eligibility determinations for low-income subsidies and general state payment provisions including the phased-down state contribution to drug benefit costs assumed by Medicare).

Frank Szeflinski (303) 844-7119 (for issues related to conditions necessary to contract with Medicare as a PDP sponsor, as well as contract requirements, intermediate sanctions, termination procedures and change of ownership requirements; employer group waivers and options; also for issues related to cost-based HMOs and CMPS offering Part D coverage.)

John Scott (410) 786-3636 (for issues related to the procedures PDP sponsors must follow with regard to grievances, coverage determinations, and appeals.)

Tracey McCutcheon (410) 786-6715 (for issues related to solicitation, review and approval of fallback prescription drug plan proposals; fallback contract requirements; and enrollee premiums and plan payments specific to fallback plans.)

Jim Mayhew (410) 786-9244 (for issues related to the alternative retiree drug subsidy.)

Joanne Sinsheimer (410) 786-4620 (for issues related to physician self-referral prohibitions.)

Brenda Hudson (410) 786-4085 (for issues related to PACE organizations offering Part D coverage.)

Julie Walton (410) 786-4622 or Kathryn McCann (410) 786-7623 (for issues related to provisions on Medicare supplemental (Medigap) policies.)

For general questions: Please call (410) 786-1296.

SUPPLEMENTARY INFORMATION:

Executive Summary. Generally, coverage for the prescription drug benefit will be provided under private prescription drug plans (PDPs), which will offer only prescription drug coverage, or through Medicare Advantage prescription drug plans (MA-PDs), which will offer prescription drug coverage that is integrated with the healthcare coverage they provide to Medicare beneficiaries under Part C of Medicare. PDPs must offer a basic prescription drug benefit. MA-PDs must offer either a basic benefit or broader coverage for no additional cost. If this required level of coverage is offered, the PDP or MA-PD plan may also offer supplemental benefits through enhanced alternative coverage for an additional premium. All organizations offering drug plans will have flexibility in the design of the prescription drug benefit. Consistent with the MMA, this proposed rule provides for subsidy payments to sponsors of qualified retiree prescription drug plans.

We intend to implement the drug benefit to permit and encourage a range of options for Medicare beneficiaries to augment the standard Medicare coverage for drug costs above the initial coverage limit ($2250 in 2006) and below the annual out-of-pocket threshold ($5100 in 2006). In addition to the coverage established by the statute for low-income beneficiaries, we seek comments on the best way to support options for expanding beneficiaries' drug coverage. Potential options include facilitating coverage through employer plans, MA-PD plans and/or high-option PDPs, as well as through charity organizations and State pharmaceutical assistance programs. We specifically seek comments on ways to maximize the continued use of non-Medicare resources (private contributions, employer/union contributions, state contributions, health plan contributions, and other sources) that currently provide at least partial coverage for three-fourths of Medicare beneficiaries. See sections II.C, II.J, and II.P, and II R of this preamble for further details on these issues. We are also considering establishing a CMS demonstration to evaluate possible ways of achieving such extended coverage, and we welcome all suggestions in this regard.

Throughout the preamble, we identify options and alternatives to the provisions we propose. We strongly encourage comments and ideas on our approach and on alternatives to help us design the Medicare Prescription Drug Benefit Program to operate as effectively and efficiently as possible in meeting the needs of Medicare beneficiaries.

Although this proposed rule specifies most of the requirements for implementing the new prescription drug program, readers should note that we are also issuing a closely related proposed rule that concerns Medicare Advantage plans, which will usually combine medical and prescription drug

coverage. In addition, although this proposed rule specifies requirements related to PDP regions it does not designate those regions. Regional boundary decisions will be made through a separate process. Additional non-regulatory guidance on this and other topics will also be forthcoming.

We have considered and, in some places, have identified how this proposed rule intersects with other Federal laws, such as the Health Insurance Portability and Accountability Act (HIPAA) of 1996 Certification of Creditable Coverage and the HIPAA Privacy Rule. We are interested in learning how this proposed rule may interact with other legal obligations to which the PDP sponsors and MA-PD plans may be subject and intend to make appropriate changes in the final rule to address such issues.

Submitting Comments: We welcome comments from the public on all issues set forth in this rule to assist us in fully considering issues and developing policies. Comments will be most useful if they are organized by the section of the proposed rule to which they apply. You can assist us by referencing the file code [CMS-4068-P] and the specific "issue identifier" that precedes the section on which you choose to comment.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. After the close of the comment period, CMS posts all electronic comments received before the close of the comment period on its public Web site. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone (410) 786-7197.

Copies: To order copies of the Federal Register containing this document, send your request to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250-7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 512-1800 (or toll-free at 1-888-293-6498) or by faxing to (202) 512-2250. The cost for each copy is $10. As an alternative, you can view and photocopy the Federal Register document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the Federal Register. This Federal Register document is also available from the Federal Register online database through GPO Access, a service of the U.S. Government Printing Office. The Web site address is: http://www.access.gpo.gov/fr/index.html.

SOURCE: Excerpted from *Federal Register*. 2004. "Proposed Rules." *Federal Register* 69 (148): 46631–46680.

A Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services

42 CFR Parts 400, 403, 411, 417, and 423
[CMS-4068-F]
RIN 0938-AN08

Medicare Program; Medicare Prescription Drug Benefit

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule implements the provisions of the Social Security Act (the Act) establishing and regulating the Medicare Prescription Drug Benefit. The new voluntary prescription drug benefit program was enacted into law on December 8, 2003 in section 101 of Title I of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173). Although this final rule specifies most of the requirements for implementing the new prescription drug program, readers should note that we are also issuing a closely related rule that concerns Medicare Advantage organizations, which, if they offer coordinated care plans, must offer at least one plan that combines medical coverage under Parts A and B with prescription drug coverage. Readers should also note that separate CMS guidance on many operational details appears or will soon appear on the CMS website, such as materials on formulary review criteria, risk plan and fallback plan solicitations, bid instructions, solvency standards and pricing tools, plan benefit packages.

The addition of a prescription drug benefit to Medicare represents a landmark change to the Medicare program that will significantly improve the healthcare coverage available to millions of Medicare beneficiaries. The MMA specifies that the prescription drug benefit program will become available to beneficiaries beginning on January 1, 2006.

Generally, coverage for the prescription drug benefit will be provided under private prescription drug plans (PDPs), which will offer only prescription drug coverage, or through Medicare Advantage prescription drug plans (MA PDs), which will offer prescription drug coverage that is integrated with the healthcare coverage they provide to Medicare beneficiaries under Part C of Medicare. PDPs must offer a basic prescription drug benefit. MA-PDs must offer either a basic benefit or broader coverage for no additional cost. If this required level of coverage is offered, MA-PDs or PDPs, but not fallback PDPs may also offer supplemental benefits through enhanced alternative coverage for an additional premium. All organizations offering drug plans will have flexibility in the design of the prescription drug benefit. Consistent with the MMA, this final rule also provides for subsidy payments to sponsors of qualified retiree prescription drug plans to encourage retention of employer-sponsored benefits.

We are implementing the drug benefit in a way that permits and encourages a range of options for Medicare beneficiaries to augment the standard Medicare coverage. These options include facilitating additional coverage through employer plans, MA-PD plans and high-option PDPs, and through charity organizations and State pharmaceutical assistance programs. See sections II.C, II.J, and II.P, and II.R of this preamble for further details on these issues.

The proposed rule identified options and alternatives to the provisions we proposed and we strongly encouraged comments and ideas on our approach and on alternatives to help us design the Medicare Prescription Drug Benefit Program to operate as effectively and efficiently as possible in meeting the needs of Medicare beneficiaries.

DATES: These regulations are effective on March 22, 2005.

FOR FURTHER INFORMATION CONTACT: *[This Final Rule contains a long list of contacts similar to the one shown above for the Proposed Rule; the list is omitted here.]*

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V. Regulatory Impact Analysis

SOURCE: Excerpted from *Federal Register*. 2005. "Rules and Regulations." *Federal Register* 70 (18): 4193–4242.

A proposed rule is effectively a *draft* of a rule or set of rules that will be used to guide the implementation of a law while the final rules are still under development. Rules can be added, deleted, or modified over the life of a public law; thus rulemaking is an ongoing component in the life of any public law. Publication of a proposed rule is an open invitation for all parties with an interest in the rule to react before it becomes final. For example, in 1989, Congress amended the Medicare policy to change the way physicians who treat Medicare patients are paid for their services. This procedure—which used resource-based relative value scales (RBRVS)—sought to base payment on the actual demands of professional work involved in various physician-provided services and to capture for each service the relevant physician practice expenses, liability insurance costs, and regional norms. The net effect of this change in policy was to decrease the amount of payment for many procedure-based services, such as surgery, and to increase payment for many primary care services. Publication in *FR* of the proposed rules to implement this change literally served as an invitation to physicians who would be affected by this change, and their interest groups, to bargain and negotiate the new levels of payment for their services (Moon 1993). As might be expected, many accepted the invitation.

Changes in proposed rules often result from the interactions between officials of implementing organizations and those whom the rules will affect directly. In fact, these interactions, triggered by the publication of a proposed rule, are among the most active points of involvement in the entire policymaking process for individuals, health-related organizations, and interest groups with a stake in how a particular public law is implemented. The role of interest groups is especially potent at this point in the process.

The Role of Interest Groups in Rulemaking

Implementation of any complex health-related law readily provides examples of what Thompson (1997) calls the "strategic interaction" that occurs during

rulemaking between implementing organizations and affected interest groups. For example, among the numerous rules proposed in implementing the 1974 National Health Planning and Resources Development Act (P.L. 93-641) were some that sought to reduce obstetrical capacity in the nation's hospitals. One rule proposed in 1977 called for hospitals to perform at least 500 deliveries annually or close their obstetrical units. Notice of this proposed rule elicited immediate objections, especially from hospitals in rural areas where compliance would be extremely difficult or impossible. The implementing organization (DHEW, now DHHS) received more than 55,000 written reactions to the proposed rule, almost all of them negative (Zwick 1978). As a result, the final rule was far less restrictive and made no reference to a specific number of deliveries necessary to keep rural obstetrics units open.

All policies affect one or more interest groups. Because the individual and organizational members of interest groups are so often the targets of rules established to implement health-related public laws, these groups routinely seek to influence rulemaking. Regulatory policies are implemented to prescribe and control the actions, behaviors, and decisions of certain individuals or organizations. Allocative policies work to provide income, services, or other benefits to certain individuals or organizations at the expense of others. Thus, interest groups that represent the individuals and organizations so directly affected by public policies can be expected to be actively interested in all aspects of policymaking, including rulemaking. As the discussion in Chapter 3 of interest groups in the political marketplace shows, these groups tend not to be passive about what they want to accomplish on behalf of their members. Many are well organized and aggressive in pursuit of their preferences, seeking to influence both the formulation and the implementation of policies that affect them.

Lobbying and other forms of influence become especially intense when some interest groups strongly support, while others oppose, the formulation of a particular law or the manner in which it is to be implemented. The preferences of particular interest groups may well come in conflict with the preferences of other groups. Policymakers almost always face this dilemma when they confront important choices in the formulation and implementation of policies. As noted in Chapter 3, legislators in such situations can be expected to seek to maximize their net political support through their decisions and actions. The same can be said for those responsible for the management of implementing agencies and organizations. This means that rulemaking is often influenced by interest group preferences, with the more politically powerful groups exerting the greatest influence.

The potential of conflicting interests among various groups concerned with health policy can be seen in the general preferences of several categories of individuals and organizations shown in Figure 7.5. Although some similarities exist among the preferences of the various categories, there are also

Federal Government
- Deficit reduction/Increased surpluses
- Control over growth of Medicare and Medicaid expenditures
- Fewer uninsured citizens
- Slower growth in healthcare costs

Employers
- Slower growth in healthcare costs
- Simplified benefit administration
- Elimination of cost-shifting
- No mandates

Insurers
- Administrative simplification
- Elimination of cost-shifting
- Slower growth in healthcare costs
- No mandates

Individual Practitioners
- Income maintenance/growth
- Professional autonomy
- Malpractice reform

Suppliers
- Continued demand
- Sustained profitability
- Favorable tax treatment

State Government
- Medicaid funding relief
- More Medicaid flexibility
- Fewer uninsured citizens
- More federal funds and slower growth in healthcare costs

Consumers
- Insurance availability
- Access to care (with choices)
- Lower deductibles and copayments

Technology Producers
- Continued demand
- Sustained research funding
- Favorable tax treatment

Provider Organizations
- Improved financial condition
- Administrative simplification
- Less uncompensated care

Professional Schools
- Continued demand
- Student subsidies

Figure 7.5
Typical Policy Preferences of Selected Health-Related Individuals and Organizations

some important differences. Policymakers generally can anticipate that these individuals and organizations, working through their interest groups to a great extent, will seek to have their preferences reflected in any policies that are enacted and to have their preferences influence the subsequent implementation of such policies as well.

Health policy is replete with examples of the influence of interest groups on rulemaking. One such example can be seen in the rulemaking that stemmed from enactment of the Medicare program. In part to improve its chances for passage, the Medicare legislation (P.L. 89-97) was written so that the Social Security Administration (www.ssa.gov) (the original implementing agency, subsequently replaced by the Health Care Financing Administration, which became the Centers for Medicare & Medicaid Services) would reimburse hospitals and physicians in their customary manner. This meant that they would be paid on a fee-for-service basis, with the fees established by the providers. Each time providers gave services to Medicare program beneficiaries, they were paid their "usual and customary" fees for doing so.

However, unlike the physicians and hospitals, some prepaid providers, such as health maintenance organizations (HMOs), had a different method of charging for their services. Their approach was to charge an annual fee per patient no matter how many times the patient might see a physician or use a hospital. In this situation, the hospitals and fee-for-service physicians had an obvious preference for having the Social Security Administration reimburse them according to their customary payment pattern. But they could also see an advantage in not permitting the competing prepaid organizations to be paid in their customary manner—that is, in making them subject to the fee-for-service payment rules. Their preferences, vigorously made known to the Social Security Administration through the powerful American Medical Association and to a somewhat lesser extent through the American Hospital Association, resulted in the prepaid organizations being forced to operate under fee-for-service payment rules until the rules were finally changed in 1985 (Feldstein 2001).

The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) was signed into law in December 2003. Title I of MMA established Part D of Medicare to provide an outpatient prescription drug benefit beginning in 2006. On August 3, 2004, CMS published a proposed rule in *FR* to implement the benefit provided in Title I. Comments about the proposed rule were due by October 4, 2004. More than 7,000 comments were received, including many from health-related interest groups. The comments helped shape the final rule, which was published on January 28, 2005. (See The Real World of Health Policy: Proposed and Final Rules above.)

Other Interactions Between Rulemakers and Those Affected by the Rules

In certain instances, especially when the development of rules is anticipated to be unusually difficult, when such development seems likely to attract severe disagreement and conflict, or when rules are likely to be subject to continual revision, special provisions may be made regarding their development. For example, after passage of the Health Maintenance Organization Act (P.L. 93-222) in 1973, DHEW (now DHHS) organized a series of task forces, with some members drawn from outside the implementing organization, to help develop the proposed rules for implementing the law. This strategy produced rules that were much more acceptable to those who would be affected by them.

Another strategy used to support rulemaking is the creation of advisory commissions. For example, following enactment of the 1983 Amendments to the Social Security Act (P.L. 98-21), which established the prospective payment system (PPS) for reimbursing hospitals for the care of Medicare beneficiaries, Congress established the Prospective Payment Assessment Commission

(ProPAC) to provide nonbinding advice to the Health Care Financing Administration (now CMS) in carrying out its responsibilities in implementing the reimbursement system. A second commission, the Physician Payment Review Commission (PPRC), was established later to advise Congress and CMS regarding payment for physicians' services under the Medicare program. These commissions proved useful in helping CMS make required annual decisions regarding reimbursement rates, fees, and other variables involved in operating the Medicare program. The Balanced Budget Act of 1997 (P.L. 105-33) replaced both commissions with a new commission—the Medicare Payment Advisory Commission (MedPAC) (www.medpac.gov)—which incorporates and expands the roles of ProPAC and PPRC. The Real World of Health Policy: MedPAC briefly describes MedPAC's role.

The Real World of Health Policy

MedPAC

The Medicare Payment Advisory Commission (MedPAC) is an independent federal body established by the Balanced Budget Act of 1997 (P.L. 105-33) to advise the U.S. Congress on issues affecting the Medicare program. The Commission's statutory mandate is quite broad: In addition to advising the Congress on payments to private health plans participating in the Medicare and providers in Medicare's traditional fee-for-service program, MedPAC is also tasked with analyzing access to care, quality of care, and other issues affecting Medicare.

The Commission's 17 members bring diverse expertise in the financing and delivery of healthcare services. Commissioners are appointed to three-year terms (subject to renewal) by the Comptroller General and serve part time. Appointments are staggered; the terms of five or six Commissioners expire each year. The Commission is supported by an executive director and a staff of analysts, who typically have backgrounds in economics, health policy, public health, or medicine.

MedPAC meets publicly to discuss policy issues and formulate its recommendations to the Congress. In the course of these meetings, Commissioners consider the results of staff research, presentations by policy experts, and comments from interested parties. Commission members and staff also seek input on Medicare issues through frequent meetings with individuals interested in the program, including staff from congressional committees and the Centers for Medicare and Medicaid Services (CMS), healthcare researchers, healthcare providers and beneficiary advocates.

Two reports, issued in March and June each year, are the primary outlet for Commission recommendations. In 2004, the Commission's March report addressed a variety of payment policy issues. The June 2004 report was devoted

to the subject of new approaches in Medicare. In addition to these reports and additional reports on subjects requested by the Congress, MedPAC advises the Congress through other avenues, including comments on reports and proposed regulations issued by the Secretary of the Department of Health and Human Services, testimony, and briefings for congressional staff.

SOURCE: Excerpted from Medicare Payment Advisory Commission (MedPAC). n.d. "About MedPAC." [Online information; retrieved 2/22/05.] http://www.medpac.gov/about_medpac/index.cfm?section=about_medpac.

After laws have been enacted and initial rules necessary for implementing them have been promulgated, the implementation phase enters an operational stage (see Figure 7.1), which will be discussed in Chapter 8. At the point of operation, those involved in policy implementation are required to fulfill the mandates inherent in the laws they are responsible for implementing by following the rules promulgated to guide the implementation. Ideally, this is exactly what happens as policy implementation unfolds. However, the possibility always exists that implementation will not go smoothly. It is even possible that some individuals with implementing responsibilities will disagree with the purposes of the enacted laws and may seek to stall, alter, or even subvert the laws in their implementation phases.

The power of those with implementation responsibilities to affect the final outcomes and consequences of policies should not be underestimated. It is a power similar to that possessed by those in private-sector organizations with operational responsibilities for the achievement of organizational missions, goals, and objectives.

Summary

The implementation phase of the policymaking process includes rulemaking in support of implementation, which is the focus of this chapter, as well as the actual operation of policies, which is the focus of Chapter 8. Rulemaking is a necessary part of policymaking because enacted laws seldom contain enough explicit and directive language concerning the steps necessary to guide their implementation adequately.

Implementing organizations routinely promulgate rules to help guide the operation of enacted laws. The drafting and issuing of rules are themselves guided by certain rules and established procedures. These rules and procedures help to ensure that those who will be affected by the implementation of a policy will have ample opportunity to participate in the rulemaking associated with its implementation.

Discussion Questions

1. Describe in general terms the implementation phase of the public policymaking process.
2. Who is responsible for policy implementation?
3. Discuss legislative oversight of policy implementation.
4. Discuss rulemaking. Include the role of interest groups in rulemaking in your response.

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CHAPTER

8

POLICY IMPLEMENTATION: OPERATION

This chapter continues our focus on the implementation phase of public policymaking—a phase that involves two interrelated sets of activities. The shaded portion of Figure 7.1 shows that policy implementation begins with *rulemaking*, which was the focus of Chapter 7. The second stage in policy implementation, also shown in the shaded portion of Figure 7.1, is the *operation* of public laws, and that stage is the focus of this chapter. If a policy in the form of a public law is intended to protect people from exposure to toxic substances in their environments, for example, its operation entails the activities involved in actually providing such protection. Operational activities in this situation might include measuring and assessing dangers from substances in the environment, or imposing fines as a means to prevent or restrict environmental pollution.

As was noted in the previous chapter, implementation involves those responsible for implementation in managing human, financial, and other resources in ways that permit attainment of the goals and objectives embodied in enacted legislation. The most important point in understanding policy implementation as part of the larger process of policymaking is that it is primarily a *management* undertaking. The operation stage of implementation involves the actual conduct or running of the programs and processes embedded in enacted public laws. This stage is the domain, although not exclusively, of the appointees and civil servants who staff the government. For any policy, two variables are especially important for a successful operational stage: (1) the policy itself in terms of how it is designed or constructed and (2) certain characteristics of the organization(s) charged with a policy's implementation, including the capability of the managers. Each of these variables is examined in this chapter.

The Impact of a Policy's Design or Construction on Its Own Operation

As with any writing intended to influence the actions, behaviors, or decisions of others (e.g., legal contracts, procedure manuals), the language and construction of a policy—especially a policy in the form of a public law—play a crucial role in the course and success of its operationalization. The impact of the design of a public law can be felt both in the rulemaking associated with its

implementation and in its operation. The design or construction of a policy includes its goals and objectives, the hypothesis or the causal relationships embedded within it, and the degree of flexibility about how to implement the policy left to those responsible for its implementation.

Policy Goals and Objectives

Well-written laws always include clearly articulated goals and objectives that the law is intended to achieve, although clear goals and objectives are only part of the makeup of a good policy. When those with implementation responsibility know what the law is really intended to accomplish—what its goals and objectives are—it is easier to operate the programs and procedures embedded within it. In contrast, when the goals and objectives of a policy are not clear or when they are multiple or conflicting, successful operation is made more difficult, if not impossible, to achieve, even before the effort begins.

An example of the problem of multiple, conflicting goals and objectives within a single law can be found in the National Health Planning and Resources Development Act of 1974 (P.L. 93-641). Congress hoped this massive policy would fulfill many of the goals and objectives it had previously attempted to attain through a wide variety of earlier, more focused policies. As outlined in Section 1513 of P.L. 93-641, its multiple goals included the following:

- improving the health of people;
- increasing the accessibility (including overcoming geographic, architectural, and transportation barriers), acceptability, continuity, and quality of health services; and
- restraining increases in the cost of providing health services.

As has been noted regarding the multiple goals embedded in P.L. 93-641, "the legislation proposed every health system desideratum its authors could imagine" (Morone 1990, 272). This expansive set of inherently contradictory goals eventually doomed the policy; Congress repealed it in 1986.

Multiple goals and objectives embedded in a single policy can make its implementation extremely difficult, especially if they conflict or are not mutually supportive. In one study, managers of the Medicare program report that they are often torn by the competing demands imposed by the multiple goals and objectives established for the program (Gluck and Sorian 2004). This study notes that these managers are simultaneously required under Medicare policy to do the following:

- serve Medicare beneficiaries' healthcare needs;
- protect the financial integrity of the program and preserve the solvency of the Medicare trust funds;

- make sure payments to providers are adequate to ensure their participation in the program;
- ensure the quality of services provided to program beneficiaries
- guard against fraud and abuse in the program's operation;
- work with numerous private contractors, ensuring their quality and keeping them satisfied with the relationship; and
- work with states, respond to congressional oversight, and serve the political and policy priorities of the executive branch.

This means, for example, that "Medicare managers must ensure adequate participation in Medicare by healthcare providers, but also see to it that providers meet performance and quality standards" (Gluck and Sorian 2004, 65).

Hypothesis of the Policy

Vague or conflicting goals and objectives are not the only potentially serious problems with the construction of policies—problems that can make their operational stage very difficult, if not impossible. The procedural paradigm set forth in a public law can also be flawed. Embedded in every policy is a theory, or *hypothesis*, about the effect of operationalizing the policy: if someone does A, then B will result. As Thompson (1997) has noted, however, only in a perfect world would policymakers always base their laws on entirely plausible hypotheses. He points out that "Limits to their knowledge and the political dynamics of policy formulation often impede this development" (Thompson 1997, 158).

Because an underlying rationale or logic—flawed though it may be—is implicit in a policy, another useful way to think about the hypothesis embedded in a policy is to think of the policy as a *logic model* (W. K. Kellogg Foundation 2001). Policies are not written as logic models, but there is invariably a logic model inherent in any policy in the form of a public law. The logic model of a public law can be expressed in terms of how resources are supposed to be processed to achieve the policy's goals and objectives.

If the hypothesis underpinning a policy is wrong, the policy cannot be successfully implemented because its operational stage will not solve the problem the policy is intended to address. It will not matter that its goals and objectives are appropriate, or even that they are noble. In formulating the National Health Planning and Resources Development Act (P.L. 93-641), for example, Congress patched together an oddly matched pair of strategies: voluntary, community-based planning on the one hand and heavy-handed regulation, at least of capital expansion in the health sector, on the other. To no one's surprise, at least in hindsight, the combination did not work very well. The core hypothesis of the policy was seriously flawed.

Degree of Flexibility in Implementing the Policy

Another aspect of the construction of policies that can have significant impact on their implementation is the nature and extent of decisions left to the implementing organizations. These decisions arise by virtue of the explicitly directive language in the law, by what is not said in the law, or by confusing or vague language in the law. For example, although a degree of flexibility in developing the rules to be used in policy implementation can be advantageous, vague policy directives can create all sorts of problems for those with implementation responsibilities.

The Occupational Safety and Health Act of 1970 (P.L. 91-596), for example, contained a number of vague directives and phrases that created significant problems for its implementers. In Section 2 of the law, the language stressed the importance of fostering healthful working conditions "in so far as possible." This language was in lieu of specific objectives or targets for achieving reductions in occupational injuries or diseases. In Section 6, the statute authorized the Secretary of Labor, in implementing the law, to issue standards dealing with toxic substances in the workplace "to the extent feasible." In attempting to operationalize this complex law, considerable time and energy were expended in attempting to decide if this phrase meant that implementers could take the economic costs of their actions to employers into account in establishing standards dealing with workplace toxic substances. In these instances, effective implementation was impeded by some of the policy's vague and imprecise language.

In contrast, language that is too restrictive can also impede the implementation of a policy. In combination with the very imprecise language noted in the Occupational Safety and Health Act, Congress was precise and extremely restrictive in writing into the law the range of fines that could be assessed against firms that violated standards. For less serious violations, the fine would be $1,000. For serious, willful violations, the fine could be up to $10,000. Most analysts considered the limits of these fines to be far too low to be effective deterrents, especially for large, profitable enterprises. In this instance, effective operation of the law was impeded by some of its very specific language.

The way in which laws are written—that is, the way in which policies are designed—has substantial impact on how they are subsequently implemented. The impact is felt both in rulemaking and in operation. In general, in recent decades, Congress has tended to enact longer and much more detailed laws in attempting to enhance their implementation (Melnick 1994). For example, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 is 416 pages long. But no matter how a law is written, its implementation is also directly affected by the organization or agency charged with the task, including the competence of its managers.

The Impact of Implementing Organizations and Their Managers on Implementation

The essence of the implementation phase of policymaking is that one or more organizations or agencies undertake to operationalize enacted legislation, ideally in a manner that permits realization of the legislative intent behind the legislation. This involves promulgating the rules under which implementation will proceed as well as actually putting the laws into operation.

As noted earlier, one important constant in the dynamic circumstances involved in rulemaking and in operationalizing public laws is that the bulk of these implementation responsibilities rests with executive branch organizations. For example, the Centers for Medicare & Medicaid Services (CMS) is primarily responsible for implementing the Medicare program, the Food and Drug Administration (FDA) is primarily responsible for implementing many of the nation's food and drug policies, and the Administration on Aging (AoA) (www.aoa.gov) is responsible for implementing the Older Americans Act. State insurance departments are responsible for implementing the states' policies regarding health insurance, and so on. Consideration of the operation of policies thus must include attention to the characteristics and attributes of implementing organizations that contribute to their organizational success at policy implementation, including the roles of their managers in successful implementation (Trattner and McGinnis 2004).

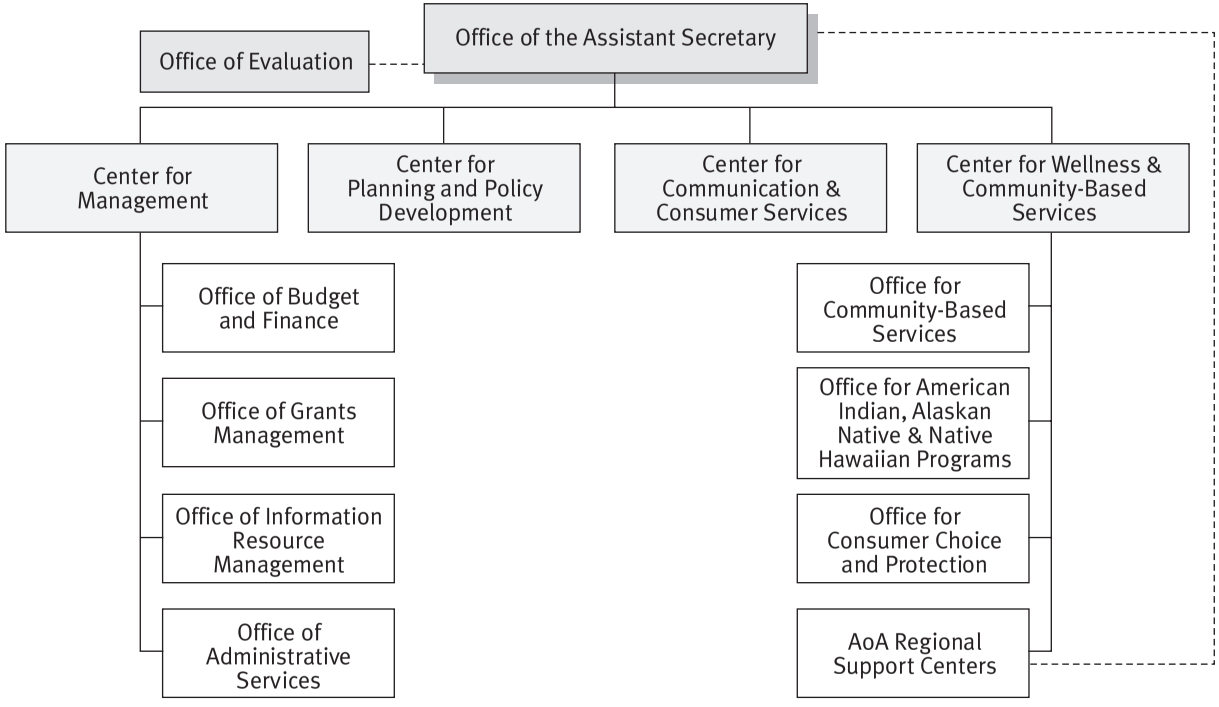
The organizational structure of the Department of Health and Human Services (DHHS), which contains a number of agencies with implementation responsibilities, is shown in the previous chapter in Figure 7.3. One of these agencies, AoA, is described in the next section as an example of the origin, mission, organizational structure, and budget of a "typical" implementing agency or organization.

Administration on Aging

The Older Americans Act of 1965 (P.L. 89-73) (OAA) created AoA as the agency with primary responsibility to implement the law. In addition, OAA authorized grants to states for community planning and services programs, as well as for research, demonstrations, and training projects in the field of aging. Subsequent amendments to OAA added grants to area agencies on aging for local needs identification, planning, and funding of services, including but not limited to nutrition programs in the community as well as for those who are homebound; programs that serve Native American elders; services targeted at low-income minority elders; health promotion and disease prevention activities; in-home services for frail elders; and those services that protect the rights of older persons, such as the long-term-care (LTC) ombudsman program.

In 2000, OAA was amended and reauthorized AoA through 2005. The amendments established the National Family Caregiver Support Program,

FIGURE 8.1 Organization Chart of the Administration on Aging



which is intended to help people who are caring for older family members who are ill or who have disabilities. Family caregivers have always been the mainstay underpinning LTC for older persons in the United States. Among noninstitutionalized persons needing assistance with activities of daily living (ADLs), two-thirds depend solely on family and friends and another one-fourth supplement family care with services from paid providers. Only a little more than 5 percent rely exclusively on paid services (AoA 2005).

Figure 8.1 is an organization chart for AoA. The fiscal year (FY) 2006 budget request for AoA is $1.369 billion, including the following components (AoA 2005):

- $1,250 million for state- and community-based services, the same as the FY 2005 level;
- $32.7 million for services for Native Americans, the same as the FY 2005 level;
- $19.4 million for protection of vulnerable older americans, $72,000 more than the FY 2005 level;
- $48.9 million for innovation and demonstration, $19.4 million less than the FY 2005 level; and
- $17.9 million for program administration, $422,000 less than FY 2005 level.

The Real World of Health Policy: Administration on Aging (AoA) describes the mission and core functions of AoA. As Figure 8.1 shows, AoA is managed by the Assistant Secretary for Aging at DHHS, who is a presidential appointee.

The Real World of Health Policy

The Administration on Aging (AoA)

The Administration on Aging (AoA), an agency in the U.S. Department of Health and Human Services, is one of the nation's largest providers of home- and community-based care for older persons and their caregivers. Its mission is to promote the dignity and independence of older people, and to help society prepare for an aging population.

Created in 1965 with the passage of the Older Americans Act (OAA), AoA is part of a federal, state, tribal and local partnership called the National Network on Aging. This network, serving about 7 million older persons and their caregivers, consists of 56 State Units on Aging; 655 Area Agencies on Aging; 233 Tribal and Native organizations; two organizations that serve Native Hawaiians; 29,000 service providers; and thousands of volunteers. These organizations provide assistance and services to older individuals and their families in urban, suburban, and rural areas throughout the United States.

While all older Americans may receive services, the OAA targets those older individuals who are in greatest economic and social need: the poor, the isolated, and those elders disadvantaged by social or health disparities.

Services Funded By the OAA

There are six core services funded by the OAA including:

Supportive services, which enable communities to provide rides to medical appointments, and grocery and drug stores. Supportive services provide handyman, chore and personal care services so that older persons can stay in their homes. These services extend to community services such as adult day care and information and assistance as well.

Nutrition services, which include more than a meal. Since its creation, the Older Americans Act Nutrition Program has provided nearly 6 billion meals for at-risk older persons. Each day in communities across America, senior citizens come together in senior centers or other group settings to share a meal, as well as comradery and friendship. Nutrition services also provide nutrition education, health screenings, and counseling at senior centers. Homebound seniors are able to remain in their homes largely because of the daily delivery of a hot meal, sometimes by a senior volunteer who is their only visitor. March 2002, marked the 30th anniversary of the OAA Nutrition Program, and AoA will be celebrating this successful community-based service throughout the year.

Preventive health services, which educate and enable older persons to make healthy lifestyle choices. Every year, illness and disability that result from chronic disease affects the quality of life for millions of older adults and their caregivers. Many chronic diseases can be prevented through healthy lifestyles, physical activity, appropriate diet and nutrition, smoking cessation, active and meaningful social engagement, and regular screenings. The ultimate goal of the OAA health promotion and disease prevention services is to increase the quality and years of healthy life.

The National Family Caregiver Support Program (NFCSP), which was funded for the first time in 2000, is a significant addition to the OAA. It was created to help the millions of people who provide the primary care for spouses, parents, older relatives and friends. The program includes information to caregivers about available services; assistance to caregivers in gaining access to services; individual counseling, organization of support groups and caregiver training to assist caregivers in making decisions and solving problems relating to their caregiving roles; and supplemental services to complement care provided by caregivers.

The program also recognizes the needs of grandparents caring for grandchildren and for caregivers of those 18 and under with mental retardation or developmental difficulties and the diverse needs of Native Americans.

Services that protect the rights of vulnerable older persons, which are designed to empower older persons and their family members to detect and prevent

elder abuse and consumer fraud as well as to enhance the physical, mental, emotional and financial well-being of America's elderly. These services include, for example, pension counseling programs that help older Americans access their pensions and make informed insurance and healthcare choices; long-term care ombudsman programs that serve to investigate and resolve complaints made by or for residents of nursing, board and care, and similar adult homes. AoA supports the training of thousands of paid and volunteer long-term care ombudsmen, insurance counselors, and other professionals who assist with reporting waste, fraud, and abuse in nursing homes and other settings; and senior Medicare patrol projects, which operate in 47 states, plus the District of Columbia and Puerto Rico. AoA awards grants to state units on aging, area agencies on aging, and community organizations to train senior volunteers how to educate older Americans to take a more active role in monitoring and understanding their healthcare.

Services to Native Americans, which include nutrition and supportive services designed to meet the unique cultural and social traditions of tribal and native organizations and organizations serving Native Hawaiians. Native American elders are among the most disadvantaged groups in the country.

SOURCE: Excerpted and reprinted from Administration on Aging. 2005. "Welcome: Mission." [Online information; retrieved 2/22/05.] http://www.aoa.gov/about/over/over_mission.asp.

The Fit Between Implementing Organizations and the Goals and Objectives of Policies

No characteristic of an implementing organization is more basic to success than a close fit between the organization and the goals and objectives of the policies it must implement. The keys to such a fit include whether (1) the organization is sympathetic to the policy's goals and objectives and (2) the organization has the necessary resources, in the form of authority, money, personnel, status or prestige, information and expertise, technology, and physical facilities and equipment, to implement the policy effectively.

Central to whether a policy-implementing organization is sympathetic to the goals and objectives of the policy is the attitude and perspective of its senior leaders and managers. They are the people most instrumental in ensuring that necessary support for the implementation task is garnered. In the case of AoA, for example, attitudes and commitments critical to the organization's success include those of the Assistant Secretary for Aging, who manages this organization, as well as his or her key subordinates such as those who manage AoA's Center for Communication and Consumer Services and Center for Wellness and Community-Based Services (see Figure 8.1). If an implementing organization's leaders are not sympathetic to the policies they must implement, they are unlikely to protect them from unwarranted amendments

or intrusions by nonsupporters, especially by legislators hostile to the policy and those who seek to influence those legislators. Strong allies in the legislative branch and among interest groups can be important to this protective task, but much of the responsibility rests with the leaders of the implementing organization.

The connection between any organization's resources and its capacity to fulfill its purposes is straightforward. AoA's budget and staff must be adequate to the implementation challenges facing the organization. Another important aspect of determining whether there is a good fit between an implementing organization and the policies it is supposed to implement is the organization's repertoire of technologies used in carrying out its work. Implementing organizations rely on a variety of methods and technologies to implement policies. Just as policies differ in substantial ways (recall the distinction between allocative and regulatory policies made in Chapter 1), the technologies needed to implement them also differ (Thompson 1997).

Regulatory policies require implementation technologies that prescribe and control the behaviors of whoever is being regulated. Such technologies include capacity for rule promulgation, investigatory capacity, and ability to impose sanctions. Allocative policies, on the other hand, require technologies such as processes through which implementing organizations deliver income, goods, or services. Such technologies include targeting recipients or beneficiaries, determining eligibility for benefits, and managing the supply and quality of goods or services provided through the policy. The Occupational Safety and Health Administration (OSHA), for example, relies heavily on regulatory technologies as it seeks to protect workers from hazards in the workplace. In contrast, AoA relies heavily, although not exclusively, on allocative technologies in the operation of its programs and activities.

Only when the leaders of an implementing organization are fully sympathetic to the goals and objectives of a policy and have adequate resources for the task, including possession of the appropriate technologies to get the job done, can they fully and effectively carry out their implementation duties. Even then, however, other factors play a part in the degree of success achieved, including notably the contributions made by the organization's managers.

The Capability of Managers to Contribute to Implementation

The performance of the managers of implementing organizations, especially those at senior levels, directly affects the performance levels achieved by implementing organizations (White and Newcomer 2005). The type, quality, and extent of the contributions made by managers depend on their managerial capability—that is, how adeptly they carry out a trio of interrelated activities: strategizing, designing, and leading (Zuckerman and Dowling 1997; Longest 2005). These managerial activities are discussed below; later, attention is given to the importance of management competencies in implementing

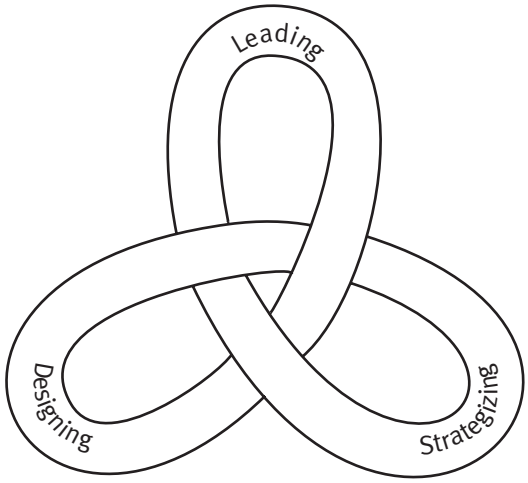


Figure 8.2 The Core Activities in Managing

organizations. Although the activities of managing are discussed here in sequence, in reality they exist as parts of a whole—a mosaic—in which all three activities are undertaken continuously and more or less simultaneously by managers. The relationship among these core activities in managing is depicted in Figure 8.2.

Strategizing

This activity pertains to the efforts of managers to establish suitable organizational missions, goals, and objectives and to develop and carry out plans or strategies that are capable of accomplishing the purposes of their organization. When managers think strategically, they are thinking about how to adapt their organizational domains to the challenges and opportunities presented to them by their environment. Implementing organizations are dynamic, open systems. They exist in the context of an often remarkably complex external environment and frequently have an extensive organizational history.

The managers of an implementing organization routinely engage in ongoing exchanges with others in their organization's external environment and are influenced, sometimes dramatically, by what goes on in that external environment. Imagine, for example, the significance for an implementing organization of being assigned major new responsibilities or of having some of its core responsibilities curtailed. Or consider the operational impact on an implementing organization of a decisive shift in control of Congress, such as occurred in the 1992 congressional election or the midterm defection of Senator James Jeffords in 2001 from the Republican Party—a move that shifted overnight the control of the U. S. Senate from the Republicans to the Democrats because the party split in the Senate at the time was nearly equal.

When managers think and act strategically, they acknowledge the fact that their organization is affected by what goes on outside it, and their decisions and actions reflect this relationship. Thus, a crucial element of effective strategizing is expertise in discerning the significant information in their environment.

Effective managers engage in situational analysis as a means of identifying and assessing pertinent environmental information. Contemporary managers of implementing organizations must analyze enormous amounts of information that could potentially affect their organization. Much of this information pertains to the plans of executive branch administration, but information on the activities occurring in the legislative branch is also relevant. In addition, external biological, cultural, demographic, ecological, economic, ethical, legal, psychological, social, and technological information must also be analyzed for its potential impact on the organization.

In conducting comprehensive situational analyses, managers are required to proceed in four interrelated steps: (1) scanning the environment to identify strategic issues (i.e., trends, developments, opportunities, threats, or possible events) that could affect the organization; (2) monitoring the strategic issues identified; (3) forecasting or projecting the future directions of strategic issues; and (4) assessing the implications of the strategic issues for the organization.

Good situational analysis, however, includes more than external discernment. It adds a comprehensive assessment of the internal strengths and weaknesses of the organization and of the values held by those in the organization.

Armed with the external and internal information garnered from a thorough situational analysis, managers can formulate or refine relevant missions, goals, and objectives for their organization and develop suitable strategic plans for achieving them. The importance of effective strategizing is directly proportional to the nature of the relationship between an organization and its external environment and to the volatility of both its external and internal environments. Most implementation organizations are highly dependent on their external environment, and both their internal and external environments tend to be dynamic and fluid. The Real World of Health Policy: AoA's Strategic Action Plan, 2003–2008 illustrates the tangible result of strategizing in an implementing organization—a strategic plan.

The Real World of Health Policy

AoA's Strategic Action Plan, 2003–2008

The AoA Strategic Action Plan for 2003–2008 was developed at the direction of the Assistant Secretary for Aging to guide the Administration on Aging as it

carries out its statutory mission and provides national leadership on aging issues. The plan establishes five strategic priorities and related goals and objectives that will be used to focus AoA's investment of effort and resources over the five-year period, 2003–2008. The plan is framed by the priorities established by the Assistant Secretary for Aging and supports the HHS Strategic Plan for 2003–2008.

Goal 1: Increase the number of older people who have access to an integrated array of health and social supports.

Objective 1.1 Strengthen AoA's capacity to provide information to older individuals that can help them access health and social supports, and educate the public about the importance of improving older people's access to an integrated array of health and social supports.

Strategies We Will Use to Accomplish Our Objective:

- Educate the public, including policy-makers, about the challenges older people face in trying to access services, and strategies that can be used to address these challenges.
- Disseminate information to older people, including low-income, rural, and limited English speaking older people, to help them access health and social supports.

Objective 1.2 Support the Aging Services Network's role in developing systems of care that provide older people an integrated array of health and social supports.

Strategies We Will Use to Accomplish Our Objective:

- Provide formula grants that support information, outreach, access nutrition and supportive services (Titles IIIB, IIIC, and VI of the OAA), and ensure the effective use of these grant funds in promoting the development of more integrated systems of health and social supports.
- Use the OAA state plan requirements and tribal organization grant applications to help states and tribes document how they are utilizing Titles IIIB, IIIC and Title VI formula grant funds to advance AoA and HHS priorities in this area.
- Identify and disseminate state-of-the art knowledge, information and technical assistance on models and techniques that states, tribes and communities can use to improve older people's access to an integrated array of health and social supports.

- Support the development and testing of new models and techniques that can improve older people's access to an integrated array of health and social supports.
- Conduct analysis of research findings, demographic trends, program data, and other information to identify strategies and approaches to support future program and policy development in this area.

Objective 1.3 Partner with other federal agencies and private sector organizations to promote policies, programs and activities that will increase the number of older people who have access to an integrated array of health and social supports.

Strategies We Will Use to Accomplish Our Objective:

- Partner with other agencies and organizations on joint projects and activities that are designed to increase older people's access to an integrated array of health and social supports.
- Participate in HHS, government-wide and private sector projects and activities that have the potential to improve older people's access an integrated array of health and social supports.

Goal 2: Increase the number of older people who stay active and healthy.

Objective 2.1 Strengthen AoA's capacity to provide information to older people that can help them stay active and healthy, and educate the public about the importance of healthy lifestyle choices, and about health promotion and disease prevention programs that can benefit people as they age.

Strategies We Will Use to Accomplish Our Objective:

- Educate older people and the general public, including policy-makers, about the importance of maintaining active lifestyles and healthy behaviors for successful aging.
- Disseminate information on health promotion and disease prevention programs to older people, including low-income, rural, and limited English speaking older people, and to the general public.

Objective 2.2 Support the Aging Services Network's role in developing programs that help older people adopt and maintain active lifestyles and practice healthy behaviors.

Strategies We Will Use to Accomplish Our Objective:

- Provide formula grants that support health promotion services (Titles C1, C2 and D of the OAA), and ensure the effective use of these grant funds.

- Use the OAA state plan requirements to help states document how they are utilizing Titles C1, C2 and D formula grant funds to advance AoA and HHS priorities in this area.
- Identify and disseminate state-of-the art knowledge, information and technical assistance on models and techniques that can be used by states, tribes and communities to enhance health promotion and disease prevention programs for older people.
- Support the development and testing of new models and techniques that can help older people stay active and healthy, including models targeted at "high risk" populations.
- Conduct analysis of research findings, demographic trends, program data, and other information to identify strategies and approaches to support future program and policy development in this area.

Objective 2.3 Partner with other federal agencies and private sector organizations to promote policies, programs and activities that encourage older people to adopt and maintain active lifestyles and practice healthy behaviors.

Strategies We Will Use to Accomplish Our Objective:

- Partner with other agencies and organizations on joint projects and activities that are designed to help older people stay active and healthy.
- Participate in HHS, government-wide and private sector projects and activities that have the potential to improve the health of older people, including *Healthy People 2010*.

Goal 3: Increase the number of families who are supported in their efforts to care for their loved ones at home and in the community.

Objective 3.1 Strengthen AoA's capacity to provide information to families that will help them in their caregiving roles, and educate the public on family caregiving and the importance of supporting family caregivers.

Strategies We Will Use to Accomplish Our Objective:

- Educate the public, including policy-makers, about family caregiving and the importance of helping families to care for their loved ones at home.
- Disseminate information to families, including low-income, rural and limited English speaking families, to help them care for their older relatives.

Objective 3.2 Support the Aging Services Network's role in helping family caregivers.

Strategies We Will Use to Accomplish Our Objective:

- Provide formula grants for the National Family Caregiver Support Program (Titles IIIE and VIC of the OAA), and ensure the effective use of these grant funds.
- Use the OAA plan requirements to help the states and tribes document how they are utilizing Title IIIE and Title VIC funds to advance AoA and HHS priorities in this area.
- Identify and disseminated state-of-the art knowledge, information and technical assistance on models and techniques that can be used by states, tribes and communities to design and implement programs and services that support caregivers.
- Support the development of new models and techniques that can help family caregivers.
- Conduct analysis of research findings, demographic trends, program data, and other information to identify strategies and approaches to support future program and policy development in this area.

Objective 3.3 Partner with other federal agencies and private sector organizations to promote policies, programs and activities that support family caregivers.

Strategies We Will Use to Accomplish Our Objective:

- Partner with other agencies and organizations on joint projects and activities that will benefit family caregivers.
- Participate in HHS, government-wide and private sector projects and activities that have the potential to benefit family caregivers.

Goal 4: Increase the number of older people who benefit from programs that protect their rights and prevent elder abuse, neglect and exploitation.

Objective 4.1 Strengthen AoA's capacity to provide information to older consumers on elder rights and consumer protection issues and programs, and educate the public on the importance of such programs.

Strategies We Will Use to Accomplish Our Objective:

- Educate the public, including policy-makers, on the importance of protecting the rights of older people and preventing elder abuse, neglect and exploitation.
- Provide information to older people, including low-income, rural, and limited-English speaking older people, on their rights and consumer protection programs, and benefits to which they are entitled.

Objective 4.2 Support the Aging Services Network's role in protecting older consumers and preventing elder abuse, neglect and exploitation.

Strategies We Will Use to Accomplish Our Objective:

- Provide formula grants to support elder abuse prevention, legal services, hotlines and long term care ombudsmen programs (Titles II, IIIB, IV and Title VII of the OAA), and ensure the effective use of these grant funds.
- Use the OAA state plan requirements to help the states document how they are utilizing these formula grant funds to advance AoA and HHS priorities.
- Identify and disseminate state-of-the art knowledge, information and technical assistance on innovative models and techniques that can be used by states and communities to inform the elderly of their rights and prevent elder abuse, neglect and exploitation.
- Support the development of new models and techniques that can make it easier for older people to know their rights and to prevent elder abuse, neglect and exploitation.
- Conduct analysis of research findings, demographic trends, program data, and other information to identify strategies and approaches to support future program and policy development in this area.

Objective 4.3 Partner with other federal agencies and the public and private sectors to promote policies, programs and activities that will help inform the elderly of their rights and prevent elder abuse, neglect and exploitation.

Strategies We Will Use to Accomplish Our Objective:

- Partner with other agencies and organizations on joint projects and activities that will help protect older consumers and prevent elder abuse, neglect and exploitation.
- Participate in HHS, government-wide and private sector projects and activities that have the potential to benefit older consumers and help prevent elder abuse, neglect and exploitation.

Goal 5: Strengthen the effectiveness of AoA's management practices.

Objective 5.1 Improve the strategic management of human capital within AoA

Strategies we will use to accomplish our objective:

- Enhance communication throughout AoA and use employee performance plans to facilitate the contribution of all employees to meeting our goals.
- Maintain and regularly update a workforce plan.

- Use competitive sourcing opportunities to augment and improve the capabilities of the AoA workforce.
- Proactively seek opportunities to gain the support and assistance of other employees and programs within the Department to assist AoA in achieving its goals.

Objective 5.2 Improve and maintain strong financial management practices

Strategies we will use to accomplish our objective:

- Proactively participate in ongoing financial statement audits, and any corrective action, to insure the integrity of AoA financial information.
- Effectively use timely AoA budget/financial information to inform management and program decision making.
- Proactively participate in the HHS Unified Financial Management System (UFMS).

Objective 5.3 Leverage technology for optimal program management and service delivery

Strategies we will use to accomplish our objective:

- Proactively use technology to effectively communicate with and respond to AoA constituents.
- Actively seek opportunities to develop or employ technology that improves our programs and reduces our costs or that of our stakeholders.
- Proactively participate, and where appropriate take a leadership role, in Department-wide and Government-wide E-government initiatives.

Objective 5.4 Achieve integration of budget and performance

Strategies we will use to accomplish our objective:

- Develop a continuous approach that links feedback from GPRA [Government Performance and Results Act] performance measures and State reporting to the budget formulation process for use in shaping budget decisions and developing new program and budget proposals.
- Develop management reports to provide feedback data to AoA senior management on an ongoing basis.
- Develop ongoing vehicles for sharing performance information with budget stakeholders (in HHS, OMB, the Congress) outside of AoA.

SOURCE: Excerpted and reprinted from Administration on Aging. 2002. *U.S. Administration on Aging Strategic Action Plan, FY 2003–2008*, 8–17. [Online document; retrieved 6/14/05.] www.aoa.gov/about/strategic/strategic.asp.

Designing

In the designing activity, managers engage in establishing intentional patterns of relationships between people and other resources in their organization. Managers designate individual positions and aggregate these positions into work groups such as teams, departments, and divisions. In short, they design the structure of their organization.

The designing responsibilities of managers in implementing organizations are a continual challenge. In their volatile environments, organization design is not something managers in typical implementing organizations can do only once before turning their attention elsewhere. Instead, organizing is ongoing and involves not only initial design but also routine redesign. Some of the typical circumstances under which public-sector managers are likely to be involved in making organization design changes include the following:

- A significant change occurs in an implementing organization's external environment that directly influences its operations. Such changes include new or amended public laws for the organization to implement and changes in the rules that affect their operationalizing of public laws. Environmental changes might also include a major reduction in the organization's budget or a reorganization initiative undertaken in the executive branch.
- An organization adapts new technologies in carrying out its work or is given new responsibilities for implementation. An organization design change may be required to infuse necessary resources into the new activities. Conversely, when old technologies are abandoned or when previous responsibilities are shifted elsewhere, new structural arrangements may be necessary to accommodate the changes.
- An organization experiences a change in its management personnel. Leadership changes are a routine matter in the executive branch organizations that carry out policy implementation. People move in and out of public service. Administrations change. Changes at or near the top level of organizations routinely stimulate organizational redesigns. New leadership provides a ripe opportunity to rethink the way in which the affected organization is designed and how it conducts its work. New managers typically view their organization's design from a fresh, and often different, perspective and may wish to have its design reflect their own ideas and preferences to the extent possible.
- Often, large-scale organization design changes involving substantial reorganizing or restructuring occur in the context of larger programs of change initiated by an organization. An example of this is seen in The Real World of Health Policy: CDC Announces New Goals and Organizational Design.

The Real World of Health Policy

CDC Announces New Goals and Organizational Design

Press Release
May 13, 2004
Centers for Disease Control and Prevention (CDC) (www.cdc.gov)

Centers for Disease Control and Prevention (CDC) Director Dr. Julie Gerberding announced today new goals and integrated operations that will allow the federal public health agency to have greater impact on the health of people around the world. Today's announcement evolved from an ongoing strategic development process called the Futures Initiative which began a year ago at CDC and has included hundreds of employees, other agencies, organizations, and the public.

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The integrated organization coordinates the agency's existing operational units into 4 coordinating centers to help the agency leverage its resources to be more nimble in responding to public health threats and emerging issues as well as chronic health conditions.

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The new coordinating centers and their directors are:

Coordinating Center for Infectious Diseases—includes the National Center for Infectious Diseases, the National Immunization Program, and the National Center for STD, TB, and HIV Prevention. Dr. Mitchell Cohen will lead this coordinating center.

Coordinating Center for Health Promotion—includes the National Center for Chronic Disease Prevention and Health Promotion and the National Center for Birth Defects and Developmental Disabilities. Dr. Donna Stroup will lead this coordinating center.

Coordinating Center for Environmental Health, Injury Prevention, and Occupational Health—includes the National Center for Environmental Health, the Agency for Toxic Substances and Disease Registry, the National Center for Injury Prevention and Control, and the National Institute for Occupational Safety and Health. Dr. Henry Falk will lead this coordinating center.

Coordinating Center for Health Information and Services—includes the National Center for Health Statistics, a new National Center for Health Marketing, and a new National Center for Public Health Informatics. Dr. James Marks will lead this coordinating center.

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Dr. Gerberding congratulated and thanked the thousands of employees and partners who have participated in the process and she reminded them all that they really are the cornerstone of CDC's future. She said the time is right to move

forward with these changes. "CDC is very strong and credible agency that has - and will always - base its decisions on the best of science. The time for change to enhance your impact is when you're at your best and for CDC that time is right now."

Dr. Gerberding and executive leaders throughout CDC will be moving forward to implement these changes by October 1, 2004, the start of the next fiscal year.

SOURCE: Excerpted and reprinted from Centers for Disease Control and Prevention. 2004. "CDC Announces New Goals and Organizational Design," [Online press release; retrieved 2/23/05.] http://www.cdc.gov/od/oc/media/pressrel/r040513.htm.

The organizational changes stimulated by changes in the environments of many implementing organizations have made the designer role of their managers increasingly important and challenging. But the designer role is only one of the three roles played by these managers. How they play their other roles in carrying out their implementation responsibilities also affects the performance of their organizations.

Leading

Leading is essential in all purposeful organizations because some people in those organizations determine, initiate, integrate, and oversee the work of others. Some lead, others follow. As leaders, the senior-level managers in implementing organizations are responsible for

- molding a widely shared internal and external agreement on implementing the organization's purposes and priorities;
- building widespread support for the organization's purposes and priorities among internal and external stakeholders, especially among administrative branch superiors, legislators with oversight responsibility for the organization, and relevant interest groups;
- striking a workable balance among the economic and professional interests of the organization's members, the demands and preferences of its external stakeholders, and the public interest the organization is required to serve; and
- negotiating and maintaining effective relationships with people and organizations, regulated by or otherwise affected by the implementing organization, who supply resources to the implementing organization and with other organizations with whom the implementing organization must work closely in carrying out its policy implementation responsibilities.

Leading implementation organizations effectively requires *transformational leadership*. Leadership in transforming or revitalizing implementing organizations is accomplished through decisions about organizational mission and structure, resources, priorities, quality and other performance standards,

and acquisition of new technologies. This is different from *transactional leadership,* through which leaders summon extra motivation and performance from those they lead through transactions with them. In these transactions, leaders help meet certain needs of the followers if they perform to the leader's expectations (Burns 1978). But such transactions are not the main determinants of the success of those who lead policy-implementing organizations. In this role, the focus must be on leadership of the entire organization, and at that level the responsibility is for transformational leadership.

The essence of transformational leadership is the ability to develop and instill in the participants within an organization a common vision of what the organization is to accomplish, to envision how it is to be accomplished, and to stimulate determined and widespread adherence to that vision. The Real World of Health Policy: Dr. Zerhouni Charts a Roadmap for Medical Research provides an example of transformational leadership in action. This example illustrates that successful leaders at the organizational level must focus on the various decisions and activities that affect the entire organization, including those intended to ensure its survival and overall well-being. Successful organizational leaders must establish missions, goals, and objectives; inculcate appropriate values in the organization's participants; manage the culture of the organization; build intra- and interorganizational coalitions; and interpret and respond to various challenges and opportunities presented to the organization from its external environment.

The Real World of Health Policy

Dr. Zerhouni Charts a Roadmap for Medical Research

History and Purpose

Soon after becoming the Director of the National Institutes of Health (NIH), in May 2002, Elias A. Zerhouni, M.D. convened a series of meetings to chart a "roadmap" for medical research in the 21st century. The purpose was to identify major opportunities and gaps in biomedical research that no single institute at NIH could tackle alone but that the agency as a whole must address, to make the biggest impact on the progress of medical research. The opportunities for discoveries have never been greater, but the complexity of biology remains a daunting challenge. NIH is uniquely positioned to catalyze changes that must be made to transform our new scientific knowledge into tangible benefits for people.

Developed with input from meetings with more than 300 nationally recognized leaders in academia, industry, government, and the public, the NIH Roadmap provides a framework of the priorities NIH as a whole must address in order to optimize its entire research portfolio. It lays out a vision for a more efficient and productive system of medical research. The NIH Roadmap identifies

the most compelling opportunities in three main areas: new pathways to discovery, research teams of the future, and re-engineering the clinical research enterprise.

Initiatives under the NIH Roadmap will help enable the agency to sustain its historic record of making cutting-edge contributions that are central to extending the quality of healthy life for people in this country and around the world.

Steps in the Process

The process of crafting the Roadmap—from vision to implementation—is described in the following sections.

The initial step in the Roadmap process involved a series of five meetings in which Dr. Zerhouni and Directors of the various NIH Institutes and Centers led invited participants through lively discussions about the most compelling initiatives that the NIH should pursue over the next 10 years—those that will have the most profound impact on the progress of medical research, both in the United States and worldwide. Participants were asked:

- What are today's scientific challenges?
- What are the roadblocks to progress?
- What do we need to do to overcome roadblocks?
- What can't be accomplished by any single Institute—but is the responsibility of NIH as a whole?

During each meeting, participants were asked to step into the NIH Director's role and to prioritize different research areas.

NIH Leadership Forum Meets to Define Action Plan

The priority areas identified through the Roadmap meetings formed the basis for discussions held at the 2002 NIH Leadership Forum—an annual retreat for NIH Institute and Center Directors. Forum participants were organized into five groups to address the major themes that emerged from the roadmap meetings. Dr. Zerhouni charged the groups with critically assessing the input from the roadmap meetings—What can be done? What can't be done? What needs to be done? When can it be done? What is realistic?

In addition, Dr. Zerhouni asked the groups to consider compelling arguments for each proposed initiative and to assess the impact, feasibility, appeal to a wide constituency, and potential for real advances in medical research. Dr. Zerhouni stressed that he was not looking for "business as usual under another name." Instead, the groups should come up with exciting, enabling ideas and actions that can be clearly articulated to a wide audience. The groups identified short and long-term activities and actions; other activities that should be addressed in the future; and areas of science hindered by specific roadblocks. At the end of the day, each group had identified 3–5 major, trans-NIH themes for further consideration.

Working Groups Develop Initial Blueprints for Action

In the months after the Forum, the new ideas were further refined. Development of proposed Roadmap initiatives required systematic analysis and planning. In the spring of 2003, a series of Institute Director-chaired Working Groups of NIH staff, along with ad hoc outside advisors, were formed. Thus, the action plans developed by the Working Groups served as the initial blueprints for building the medical research enterprise of tomorrow.

Each working group presented their top initiatives at the 2003 NIH Budget Retreat, attended by the NIH Director and Institute and Center Directors. The group examined the initiatives and weighed them in the context of several broad criteria:

- Is the initiative truly transforming—will it dramatically change how or what biomedical research is conducted in the next decade?
- Would the outcomes from the initiative be used by and synergize the work of many NIH Institutes and Centers?
- Can the NIH afford NOT to do it?
- Will the initiative be compelling to our stakeholders, especially the public?
- Does the initiative position the NIH as unique—doing something that no other entity can or will do?

Implementation Groups

The Roadmap working groups were grouped into nine Implementation Groups. These nine groups devised implementation plans for the next stage of the Roadmap. These plans include timelines, milestones, mechanisms for coordination, need for inventories, and staffing needed for program implementation.

Major NIH Roadmap Themes

The NIH Roadmap is an integrated vision to deepen our understanding of biology, stimulate interdisciplinary research teams, and reshape clinical research to accelerate medical discovery and improve people's health. Most of the initiatives begin in FY 2004. Other initiatives will start in FY 2005 and beyond, depending upon the budget and other emerging needs. The three NIH Roadmap themes are as follows:

New Pathways to Discovery

This theme of the NIH Roadmap addresses the need to advance our understanding of the daunting complexity of biological systems. Future progress in medicine will require a quantitative understanding of the many interconnected networks of molecules that comprise our cells and tissues, their interactions, and their regulation. We need to more precisely know the combination of molecular events that lead to disease if we hope to truly revolutionize medicine. New Pathways

to Discovery also sets out to build a better "toolbox" for medical research in the 21st century.

To fully capitalize on the recent completion of the human genome sequence and many recent discoveries in molecular and cell biology, the research community needs wide access to technologies, databases and other scientific resources that are more sensitive, more robust, and more easily adaptable to researchers' individual needs. Among the resources to be established are libraries of chemical molecules that may provide: probes of biological networks; imaging probes for molecular and cellular events; improved computational infrastructure for biomedical research; nanotechnology devices capable of viewing and interacting with basic life processes; and potential targets for new therapies.

These initiatives will provide a solid scientific foundation of new strategies for diagnosing, treating, and preventing disease. The implementation groups in this area are:

- Building Blocks, Biological Pathways, and Networks
- Molecular Libraries & Molecular Imaging
- Structural Biology
- Bioinformatics and Computational Biology
- Nanomedicine

Research Teams of the Future

The scale and complexity of today's biomedical research problems increasingly demands that scientists move beyond the confines of their own discipline and explore new organizational models for team science. For example, imaging research often requires radiologists, physicists, cell biologists, and computer programmers to work together in integrated teams. Many scientists will continue to pursue individual research projects; however, they will be encouraged to make changes in the way they approach the scientific enterprise. NIH wants to stimulate new ways of combining skills and disciplines in both the physical and biological sciences. The Director's Pioneer Award will encourage investigators to take on creative, unexplored avenues of research that carry a relatively high potential for failure, but also possess a greater chance for truly groundbreaking discoveries. In addition, novel partnerships, such as those between the public and private sectors, will be encouraged to accelerate the movement of scientific discoveries from the bench to the bedside.

As part of its theme, Research Teams of the Future, the NIH Roadmap seeks to encourage scientists and scientific institutions to test alternative models for conducting research. The implementation groups in this area are:

- High-Risk Research
- Interdisciplinary Research
- Public-Private Partnerships

Re-engineering the Clinical Research Enterprise

Ideally, basic research discoveries are quickly transformed into drugs, treatments, or methods for prevention. Such translation lies at the very heart of NIH's mission. Although NIH has historically been successful by funding medical research that has helped to transform once acute and lethal diseases into more chronic ones, it has become clear to the scientific community that our country will need to recast its entire system of clinical research if we are to remain as successful as in the past.

Over the years, clinical research that helps discover mechanisms of disease, prevention, diagnosis, or treatment has become more difficult to conduct. Yet the exciting discoveries we are currently making require us to conduct even more efficiently the complex clinical studies needed to make rapid medical progress, and to further inform our basic science efforts. This is undoubtedly the most challenging, but critically important, area identified through the NIH roadmap process.

At the core of this vision is the need to develop new partnerships of research with organized patient communities, community-based healthcare providers, and academic researchers. This also includes the need to build better integrated networks of academic centers linked to a qualified body of community-based healthcare providers who care for sufficiently large groups of patients interested in working with researchers to quickly develop, test, and deliver new interventions. This vision will require new paradigms in how clinical research information is recorded, new standards for clinical research protocols, modern information technology platforms for research, new models of cooperation between NIH and patient advocates, and new strategies to re-energize our clinical research workforce.

Re-engineering the Clinical Research Enterprise is intended to address these pressing needs by promoting the better integration of existing clinical research networks, encouraging the development of technologies to improve the assessment of clinical outcomes, harmonizing regulatory processes, and enhancing training for clinical researchers. A major goal is to more fully involve and empower the public in the research process. The implementation groups in this area are:

- Clinical Research Networks/NECTAR
- Clinical Research Policy Analysis and Coordination
- Clinical Research Workforce Training
- Dynamic Assessment of Patient-Reported Chronic Disease Outcomes
- Translational Research

Taken together, the components of these initiatives are part of a carefully considered national portfolio of research to meet the health demands of the 21st century.

SOURCE: Reprinted from National Institutes of Health. 2005. "NIH Roadmap Overview." [Online information; retrieved 2/24/05.]. http://nihroadmap.nih.gov/overview.asp.

As in all organizations, the leaders of implementing agencies and organizations can benefit from the histories and experiences of their organization. Organizational leadership is invariably facilitated in situations in which

- the existence of long-standing shared values and commonly accepted principles and norms help shape the organization's mission and operating practices and resolve conflicts among competing views;
- a history of success in implementing policies helps legitimize the organization's claims for support from internal and external stakeholders; and
- a history of effective relationships with oversight actors and relevant interest groups and the availability of adequate financial resources provide a sense of organizational pride and stability and an appropriate degree of self-determination and autonomy.

The possession of basic management skills—especially communication, conflict resolution, and motivation skills—also facilitates organizational leadership. Leaders who can effectively articulate and communicate their views and preferences have a distinct advantage in having them considered and thus in providing guidance for the behaviors of their followers. Similarly, successful organizational leaders are likely to be able to minimize conflict among stakeholders, mobilize widespread commitment among stakeholders to their preferences regarding the organization, and motivate stakeholder contributions to the realization of these preferences.

Managerial Competencies Underpin Performance

Successfully carrying out the strategizing, designing, and leading activities necessary to manage implementation organizations requires that managers possess certain competencies. In Chapter 4, a competency was defined as "a cluster of related knowledge, skills, and ability (sometimes referred to by the acronym SKA) that: 1) affect a major part of one's job (a role or responsibility), 2) correlate with performance on the job, 3) can be measured against well accepted standards, and 4) can be improved by training and development" (Lucia and Lepsinger 1999).

The managerial competencies required of managers in the organizations and agencies that implement policy—if they are to be able to do their work well—begin with *policy competency* as defined and discussed in depth in Chapter 4. The other necessary managerial competencies parallel to a great extent the classification developed by Katz (1974) of the competencies appropriate for work in the private sector: *conceptual*, *technical*, and *interpersonal*. Katz's concept of interpersonal skill is expanded to include competence in collaborating between and among organizations, yielding an *interpersonal/collaborative* competency. Each of these competencies is discussed below.

Policy Competency

In Chapter 4, policy competency was defined from the viewpoint of individuals, organizations, and groups affected by policy as the knowledge, skills, and abilities that permit one to successfully analyze the public policymaking process to the point of accurately assessing its impact on their domain of interest or responsibility on the one hand and to successfully exert influence in the public policymaking process on the other hand. With modest differences in focus and application, this definition works equally well for managers in policy implementing organizations.

It is important for managers of implementing organizations to understand the policymaking process in its entirety in order that through analysis they can predict the impact of numerous decisions on their domains of responsibility. For example, decisions that determine an organization's budget and the scope of its implementation responsibilities are obvious policies that affect the organization. Similarly, the essence of managing an implementing organization is to be able to exert influence in the policymaking process, albeit from inside the process rather than as an outsider seeking to influence the process.

Conceptual Competency

In all organizational settings, possession of an adequate cluster of conceptual knowledge and skills is a competency that permits managers to envision the places and roles of their organization or agency in the larger context within which they exist. This competency also allows managers to visualize the complex interrelationships within their workplace—relationships among staff and other resources and among departments or other units. Adequate conceptual competency allows managers to identify, understand, and interact with their organization's or agency's myriad external and internal stakeholders—that is, with the individuals, groups, organizations, and agencies that have an interest or stake in the decisions and actions of the organization or agency. Conceptual competency also enhances managers' abilities to comprehend organizational cultures and historically developed values, beliefs, and norms and to visualize the future of their organization or agency.

Technical Competency

The cluster of knowledge and associated skills that comprise technical competency pertains to competence in managing—in knowing how to effectively strategize, design, and lead—*and* in the actual direct work of a particular agency or organization. For example, managers in FDA must know about managing and about at least some aspects of food or drug safety and efficacy. Managers in the Centers for Disease Control and Prevention (CDC) (www.cdc.gov) must know about managing and about some aspects of developing and applying disease prevention and control, environmental health, or health promotion and education activities designed to help in the pursuit of health.

Interpersonal/ Collaborative Competency

An important ingredient in managerial success in any setting is the cluster of knowledge and skills related to human interactions by which managers direct or lead others in pursuit of objectives. *Interpersonal* competency incorporates knowledge and skills useful in effectively interacting with others. This competency includes the knowledge and related skills that permit managers to develop and instill a common vision and stimulate a determination to pursue the vision and fulfill objectives related to it. The essence of the interpersonal competency of managers is knowledge of and skills in motivating people, communicating their visions and preferences, handling negotiations, and managing conflicts.

The core elements of traditional interpersonal competency expand considerably when organizations or agencies are involved in collaboration or cooperative endeavors involving other organizations or agencies. Interpersonal relationships that occur within organizations differ from those that occur among or between collaborating organizations, agencies, or different levels of government. *Collaborative* competency is the ability to partner with other entities. This requires the ability to create and maintain multiparty organizational arrangements; to negotiate complex agreements, perhaps even contracts, that sustain these arrangements; and to produce mutually beneficial outcomes through such arrangements.

A partnering skill crucial to success in establishing and maintaining effective interorganizational or interagency collaborations is the ability of managers to develop shared cultures, or at least to minimize the differences that exist in the cultures of collaborating entities. In this context, culture is the pattern of shared values and beliefs that become ingrained in organizations or agencies over time and that influence the behaviors and decisions of the people in them. Collaborating organizations and agencies frequently have different cultures, which complicates the relationships between or among them.

Within organizations or agencies, conflict management responsibilities primarily involve managers in issues of intrapersonal conflict (within a person), interpersonal conflict (between or among individuals), intragroup conflict (within a group), or intergroup conflict (between or among groups). In interorganizational or interagency collaborations, managers become involved in managing conflicts between and among the participating organizations or agencies.

When more than one organization or agency is involved in the implementation of a policy, as is frequently the case, the capability of the implementing organizations to work collaboratively to carry out implementation responsibilities is highly important to success. Rarely is a health policy implemented by a single organization, and never when the policy is large in scope. The responsibility for implementing the Medicaid program, for example, does not rest entirely with a single organization. It involves the federal agency CMS working with the Medicaid agencies in each state and with such private-sector

organizations as hospitals, nursing homes, and health plans. The successful implementation of the Medicaid program depends heavily on the quality of the interactions among these and other organizations. Even more likely to call collaborative capabilities into play are situations in which several different implementing organizations are required to coordinate and integrate their implementation responsibilities for a variety of policies, all intended, in one way or another, to address a particular problem. It is not unusual for a chief executive (president or governor) to issue an executive order directing two or more agencies to work collaboratively or to establish a mechanism such as a joint task force to facilitate such collaboration, as is illustrated in The Real World of Health Policy: Governor Establishes Office of Health Care Reform.

The Real World of Health Policy

Governor Establishes Office of Health Care Reform

COMMONWEALTH OF PENNSYLVANIA
GOVERNOR'S OFFICE
EXECUTIVE ORDER

Subject: Commonwealth's Health Care Reform Agenda	Number: 2003-1
Date: January 21, 2003	By Direction of: Edward G. Rendell, Governor

WHEREAS, the citizens of the Commonwealth are entitled to an accessible and affordable health care system of the highest quality; and

WHEREAS, the Commonwealth agencies responsible for administering and delivering health care services have over time been delegated overlapping responsibilities; and

WHEREAS, due to redundant responsibilities, the current health care system is subject to unnecessary duplication, inefficiency, and added costs; and

WHEREAS, it is the responsibility of the Commonwealth to determine how best to reform Pennsylvania's health care system and to develop sound fiscal policy so as to resolve the concerns of the Commonwealth's patients, health care providers, and insurance carriers; and

WHEREAS, the establishment of an Office of Health Care Reform and the establishment of the Governor's Health Care Reform Cabinet will coordinate and implement the Commonwealth's Health Care Reform Agenda.

NOW, THEREFORE, I, Edward G. Rendell, Governor of the Commonwealth of Pennsylvania, by virtue of the authority vested in me by the Constitution of the Commonwealth of Pennsylvania and other laws of the Commonwealth, do hereby establish the **Office of Health Care Reform** and the **Governor's Health Care Reform Cabinet.** By doing so, I invest it with the necessary powers to perform the duties and functions set forth herein and to advise and counsel me in the development and operation of the **Commonwealth's Health Care Reform Agenda.**

1. **Office of Health Care Reform.** The Office of Health Care Reform shall be managed by the Director of the Office of Health Care Reform (hereafter referred to as "Director"), who shall serve at the pleasure of, and report directly to, the Governor. The Director, in consultation with the Office of Administration, shall determine the appropriate staffing levels and associated classifications necessary to support the operation of the Office of Health Care Reform.

   a. **Responsibilities.** The purpose of the Office of Health Care Reform is to coordinate the Commonwealth's Health Care Reform Agenda. In coordinating the Commonwealth's Health Care Reform Agenda, the Office of Health Care Reform shall:

      (1) facilitate the analysis of administrative, fiscal and regulatory policies and practices;

      (2) oversee the redesign of operations and infrastructure; and

      (3) direct the creation and maintenance of a system to assure the accountability of designated agencies for their assigned powers, duties and responsibilities.

   b. **Authority.** The Office of Health Care Reform shall, at the direction of the Governor, direct the restructuring of the Commonwealth's health care system and the implementation of its Health Care Reform Agenda.

   c. **Reporting.** The Office of Health Care Reform shall not have line responsibility for day-to-day operations of the departments, agencies, commissions, and offices with a health care purview or regulatory function. Certain relevant policy and process experts from throughout the government shall be designated "on-loan" or detailed to report to the Director of the Office of Health Care Reform to aid its mission. In addition, members of the Governor's Health Care Reform Cabinet shall report to the Office of Health Care Reform

for any and all accountabilities related to the Commonwealth's Health Care Reform Agenda.

d. **Health Care Reform Advisory Council.** The Office of Health Care Reform shall establish a Health Care Reform Advisory Council (hereinafter referred to as "Advisory Council"), consisting of stakeholder experts recommended by the Director and appointed by the Governor. The Advisory Council shall advise the Director and the Governor's Health Care Reform Cabinet on matters relating to health care. The Director shall chair the Advisory Council.

(1) **Terms.** All members shall serve at the pleasure of the Governor.

(2) **Compensation.** Members of the Advisory Council shall serve without compensation for their services except that such members may be reimbursed the necessary and actual expenses incurred in attending meetings of the Advisory Council and in the performance of their duties in accordance with established Commonwealth policy.

2. **Governor's Health Care Reform Cabinet.**

a. **Responsibilities.** The Governor's Health Care Reform Cabinet shall advise the Director and the Governor on matters related to health care reform and shall direct government resources in the implementation of the Health Care Reform Agenda. The Director shall chair the Governor's Health Care Reform Cabinet.

b. **Composition.** The Governor's Health Care Reform Cabinet shall consist of the following officials and individuals:

(1) Director of the Office of Health Care Reform.

(2) Secretary of Aging.

(3) Adjutant General.

(4) Secretary of Health.

(5) Commissioner of Insurance.

(6) Secretary of Public Welfare.

(7) Director of the Governor's Policy Office.

(8) Additional members as may be recommended by the Director and appointed by the Governor.

3. **Relationship with Other Agencies.** All agencies under the Governor's jurisdiction shall cooperate with and provide assistance and support to the Office of Health Care Reform and the Governor's Health Care Reform Cabinet. The Office of Health Care Reform shall also be directed and appointed by the Governor to participate in certain other commissions, panels, cabinets, and initiatives.

4. **Effective Date.** This *Executive Order* shall take effect immediately.

5. **Termination Date.** This *Executive Order* shall remain in effect unless revised or rescinded by the Governor.

SOURCE: Reprinted from Executive Order #2003-1, Commonwealth's Health Care Reform Agenda. [Online document; retrieved 2/25/05.] www.ohcr.state.pa.us/OHCR_about.htm.

Summary

The implementation phase of the policymaking process includes rulemaking in support of implementation, the focus of Chapter 7, as well as the actual operation of policies, the focus of this chapter. The operation stage of implementation involves the actual running of the programs embedded in enacted legislation. Operational activities are largely the domain of the appointees and civil servants who staff the executive branch of government.

Two variables have a direct impact on policy implementation and are especially important to the successful operation of policies. First is the clarity of the goals and objectives of the policy and the embedded theory or hypothesis concerning how the policy should work. Related to this variable, the level of flexibility permitted the implementing organizations by the construction of a policy directly affects the course of implementation and the outcome for any policy. The second important variable in the implementation experience for any policy consists of the characteristics and attributes of the organizations with implementation responsibilities and the capabilities of the managers of these organizations.

Discussion Questions

1. What does it mean to characterize policy implementation as public management?
2. Describe, in general terms, the operation stage of policy implementation.
3. Discuss the impact of a policy on its own implementation.
4. Discuss the impact of implementing organizations on policy implementation.
5. Discuss managing an implementation organization. What competencies underpin successful management in implementing organizations?

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CHAPTER

9

POLICY MODIFICATION

Policymaking is not a perfect process. Mistakes of omission and commission are routinely made in both the formulation and implemention phases of public policymaking. The model of the policymaking process described throughout this book comes full cycle because of a third phase of the process, modification. This phase is a necessary part of policymaking because perfection eludes policymakers in the formulation and implementation phases. Even when decisions about policies are correct at the time they are made, circumstances change. Suitable policies made in one era may lose some of their usefulness or become totally inadequate with subsequent changes in biological, cultural, demographic, ecological, economic, ethical, legal, psychological, social, and technological variables.

In a policymaking process without a modification phase, policies would be formulated in their original version and then implemented, and that would be the end of the process—except, of course, for consequences of the policies. In practice, however, policymaking does not work this way. The consequences of policies, including consequences for those who formulate and implement the policies as well as for the individuals, organizations, and interest groups outside the process but affected by them cause people to seek to modify existing policies. This occurs continually in the process.

At a minimum, modification of policies that provide benefits to certain individuals, organizations, or interest groups may be sought because modifications that increase, maintain, or do not decrease these benefits over time are desirable to beneficiaries. Similarly, those affected by policies in a negative way will seek to modify them to minimize the negative consequences. In addition, when the policymakers who formulate and implement public policies observe them in operation, they may evaluate a particular policy against their objectives for that policy. When preferences and reality do not match, efforts to modify the policy typically ensue.

Almost all policies have a history. They are formulated in their initial version and then evolve and change over time as they are implemented, either through amendments to the original legislation or through new or revised rules and changes in how they are operated. Some policies eventually die—they are repealed by the legislative branch—but most have long and dynamic lives during which they are continually and routinely modified in various ways. This chapter addresses the policy modification phase of public policymaking

(see the shaded portion of Figure 9.1), beginning with drawing a distinction between policy initiation and policy modification.

Distinguishing Policy Modification from Policy Initiation

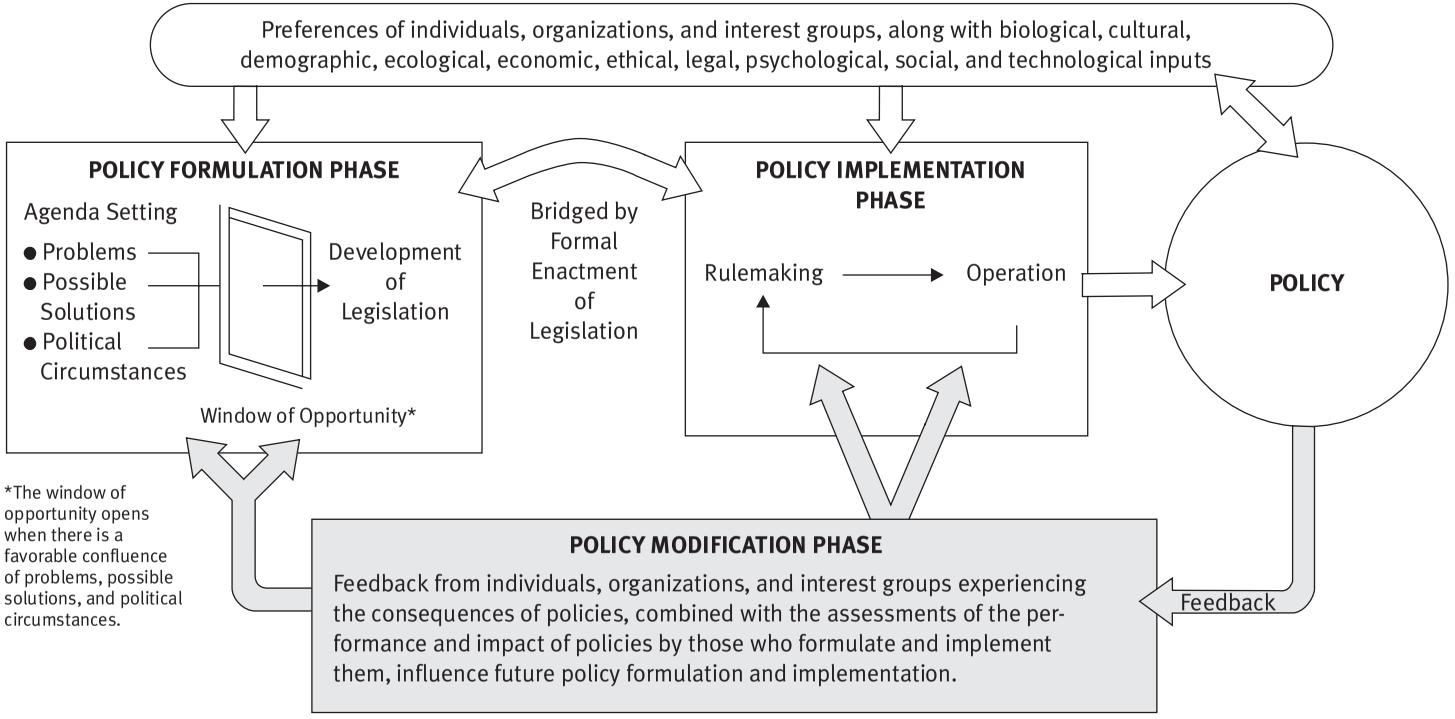
Conceptually, policy *modification* can be differentiated from policy *initiation*, although in reality the two are closely intertwined. Policy initiation—the establishment of an original public law—results when the confluence of problems, possible solutions, and political circumstances leads to the initial development of legislation in the formulation phase (as described in Chapters 5 and 6) and, when enacted into public law, then to subsequent first iterations of rulemaking and operation as the law is implemented, as described in Chapters 7 and 8. In contrast, policy modification results when the consequences of existing policies feed back into the agenda-setting and legislation-development stages of the formulation phase and into the rulemaking and operational stages of the implementation phase and stimulate changes in legislation, rules, or operations. This is shown as the feedback loop in Figure 9.1. Examine the loop closely, noting that it feeds back into the overall process in several places.

The history of American health policy demonstrates clearly that policymakers can, and on occasion do, initiate entirely new policies. For example, in 1798, Congress established the U.S. Marine Hospital Service to provide medical care for sick and disabled seamen. This was the initial policy from which eventually grew the U.S. Public Health Service. In 1921, Congress enacted the initial Maternity and Infancy Act (P.L. 67-97), through which grants were made to states to encourage them to develop health services for mothers and children. This new policy became the prototype for federal grants in aid to the states. In 1935, Congress enacted the Social Security Act (P.L. 74-271), which initiated the major entrance of the federal government into the area of social insurance. This policy, through a long life during which it has been modified many times, now encompasses, among many other things, the Medicare and Medicaid programs.

As these examples illustrate, some health policies are indeed formulated and implemented *de novo*. But a very important feature of health policymaking in the United States is that the vast majority of contemporary health policies spring from relatively few earlier initial policies. *Most health policies are the result of modifying prior policies.* This is why understanding the modification phase of the policymaking process is so important.

A review of the chronology of important American health policies, such as the one contained in Appendix C, readily illustrates just how many contemporary health policies are, in fact, amendments of previously enacted public laws or how frequently they result from changes—often, a string of changes—in the rules and practices that determine how laws are currently

FIGURE 9.1 A Model of the Public Policymaking Process in the United States: Policy Modification Phase



being implemented. In fact, none of the authoritative decisions that have been defined as policies are permanent. Modification of prior policies—whether in the form of decisions representing public laws, implementation rules or regulations, rulings of a court, or operational practices—pervades the entire policymaking process. The likelihood that prior decisions will be revisited and changed is a distinguishing feature of public policymaking in the United States. It is the feature that makes policymaking a cyclical process.

Policymaking Is a Cyclical Process

Careful consideration of the modification phase of policymaking is fundamentally important to understanding the process as a continual cycle of interrelated activity. Efforts to modify existing policies are routinely triggered when their consequences are negative. This is clearly seen in The Real World of Health Policy: AMVETS Seek Higher Funding for VA, for example. In situations where the consequences of existing policies are positive for individuals, organizations, or groups, they may well seek modifications that give them more benefits or that protect existing ones.

The Real World of Health Policy

AMVETS Seek Higher Funding for VA

U.S. House of Representatives Committee on Veterans' Affairs
Hearing on the Department of Veterans Affairs Budget Request for FY 2006
February 16, 2005
Testimony of Richard A. Jones
AMVETS National Legislative Director

Chairman Buyer, Ranking Member Evans, and members of the Committee:

AMVETS is honored to join fellow veterans service organizations at this hearing on the VA's budget request for fiscal year 2006. My name is Richard A. Jones, National Legislative Director, and I am pleased to provide you our best estimates on the resources necessary to carry out a responsible budget for the fiscal year 2006 programs of the Department of Veterans Affairs. AMVETS testifies before you today as a co-author of The Independent Budget.

For over 19 years AMVETS has worked with the Disabled American Veterans, the Paralyzed Veterans of America, and the Veterans of Foreign Wars to produce a working document that sets out our spending recommendations on veterans' programs for the new fiscal year. Indeed, we are proud that over 40 veteran, military, and medical service organizations endorse these recommendations.

In whole, these recommendations provide decision-makers with a rational, rigorous, and sound review of the budget required to support authorized programs for our nation's veterans.

* * *

As we look to fiscal year 2006, we witness a live lesson about the challenges inherent to inadequate funding. VA says that action was taken, due to inadequate resources, to ban healthcare access to tens of thousands of veterans who are eligible to enroll in the very system put in place to serve them. The resource situation reaches the absurd when, after blocking entry to these so-called "high income" veterans, VA directs its workers under VHA [Veterans Health Administration] Directive 2003–003, January 17, 2003, to send banned veterans to Community Social Work for assistance. For those brave men and women who once served to defend America's freedom, welfare has replaced their earned benefit.

Looking at the 2006 budget, released last week, AMVETS notes that the Administration is proposing an $880 million increase in VA health care. More than 85 percent of the administration's proposed increase, $768 million, comes directly from the wallets of veterans using the system, in the form of a new user tax and a doubling of prescription copayments for about 2 million veterans.

When stripped of the proposed new user tax and increased copay, the budget recommendation presents a paltry one-half of one percent increase above last year's funding—$111.2 million—not even enough to cover the president's proposed federal pay raise for the medical staff that delivers veterans' health care. The result of these proposals, according to VA, would push 215,000 former servicemembers out of the very system designed for their care.

To avoid implementation of the proposed exclusion of these veterans, The Independent Budget recommends Congress provide $31.2 billion to fund VA medical care for fiscal year 2005, an increase of $3.5 billion over the Administration's request. We ask Congress to recognize that the VA healthcare system can only bring quality health care if it receives adequate funding. It is an excellent investment for America.

* * *

It is also important to clearly state that AMVETS along with its Independent Budget partners strongly supports shifting VA healthcare funding from discretionary funding to mandatory. We recommend this action because the current discretionary system is not working. Moving to mandatory funding would give certainty to healthcare services. VA facilities would not have to deal with the whimsy of discretionary funding, which has proven inconsistent and inadequate. Mandatory funding would provide a comprehensive solution to the current funding problem. Once healthcare funding matches the actual average cost of care for veterans enrolled in the system, with annual indexing for inflation, the VA can fulfill its mission.

* * *

Mr. Chairman, this concludes my statement. I thank you again for the privilege to present our views, and I would be pleased to answer any questions you might have.

SOURCE: Jones, R. A. 2005. Testimony before the House Committee on Veterans' Affairs Hearing on the Department of Veterans Affairs Budget Request for FY 2006. [Online excerpt; retrieved 6/19/05.] http://veterans.house.gov/hearings/schedule109/feb05/2-16-05/rjones.html. Excerpted and reprinted with permission from AMVETS and Jones, R. A.

In addition to efforts by those affected by existing policies to modify the policies to their advantage, those who formulate and implement policies may seek modifications based on performance and consequences of existing policies. Although there is typically a strong affinity for incremental changes in policies, both among those who formulate and implement them as well as many of those affected by them, there is nevertheless a relentless pressure for the modification of policies.

As described in this chapter, there are many places in the policymaking process where pressure to modify is exerted. The existence of its modification phase makes the public policymaking process dynamic, with continuously evolving results. Decisions within the cycle of the process are always subject to further review and revision. Policy modifications—large and small—emphasize that the separate components of the policymaking process are, in reality, highly interactive and interdependent.

Incrementalism in Policymaking

Not only are most public policies in all domains, including health, modifications of previously established policies but also most of the modifications reflect only modest changes (Hinckley 1983). The combination of a process that is characterized by continual modification of previous decisions with the fact that these changes tend to be modest has led to the apt characterization of the public policymaking process in the United States as a process of *incrementalism* (Lindblom 1969, 1992).

The affinity for modest, incremental change in public policy is not in any way restricted to health policy. The operation of the nation's overall political, social, and economic systems reflect preferences for modest rather than fundamental change. As was noted in the discussion of the subject in Chapter 3, members of the power elite in the United States have a strong preference for incremental changes in public policies. They see incrementalism in policymaking—building on existing policies by modification in small,

incremental steps—as allowing time for the economic and social systems to adjust without these systems being unduly threatened by change. Incremental policymaking permits a minimum of economic dislocation or disruption and causes minimal alteration in the social system's status quo.

In policymaking that is characterized by incrementalism, significant departures from the existing patterns of policies occur only rarely; instead, most of the time, the impacts and consequences of policies play out relatively slowly and with some degree of predictability. This accounts for the fact that the major participants in the policymaking process—policymakers in all three branches of government, leaders in health-related organizations and interest groups, and many individuals who benefit from such policies as the Medicare and Medicaid programs—typically have a strong preference for incrementalism in health policymaking.

The preference rests simply and firmly on the fact that the results and consequences of incrementally made decisions are more predictable and stable than is the case with decisions not made incrementally. Unless a person—whether a policymaker or one affected by policies—is very unhappy with a situation and wishes an immediate and drastic change, the preference for incrementalism will almost always prevail.

Incrementalism in policymaking also provides a mechanism for increasing the likelihood of reaching compromises among the diverse interests within the political marketplace where policymaking occurs. The potential for compromise is an important feature of a smoothly working policymaking process. Words like "incrementalism" and "compromise" used in the context of public policymaking may bring to mind compromised principles, inappropriate influence peddling, and corrupt deals made behind closed doors. However, "In a democracy compromise is not merely unavoidable; it is a source of creative invention, sometimes generating solutions that unexpectedly combine seemingly opposed ideas" (Starr and Zelman 1993, 8).

The health policy domain is replete with examples of patterns of incrementally developed policies. For instance, the history of the evolution of the National Institutes of Health (NIH) (www.nih.gov) vividly reflects incremental policymaking over a span of more than 100 years. Ranging from 1887, when the federal government's expenditures on biomedical research totalled about $300, and extending into the 1930s, when a small federal laboratory conducting biomedical research was initiated, NIH has experienced extensive elaboration (the addition of new institutes as biomedical science evolved); growth (its annual budget is more than $28.5 billion in 2006); and shifts in the emphases of its research agenda (cancer, AIDS, women's health, health disparities, schizophrenia, and pediatric diseases). Every step in NIH's continuing and incremental evolution has been guided by specific changes in policies, each an incremental modification intended to have NIH make carefully measured adjustments in its actions, decisions, and behaviors.

The Mechanics of the Modification Phase

The policymaking process provides abundant opportunities for the consequences that result from the formulation and implementation of public laws to influence the reformulation of future iterations as well as to change the rules and operational practices that guide their implementation. As the feedback arrows in Figure 9.1 illustrate, policies can be modified at four points in the policymaking process: in both the agenda setting and legislation development that occur in the formulation phase and in the rulemaking and operation that occur in the implementation phase. Modification at each of these points in the overall process is discussed in the following sections.

Modification in the Policy Formulation Phase

Modification of policies in the formulation phase—the reformulation of existing policies—occurs in both agenda setting and legislation development. Recall from the discussion in Chapters 5 and 6 that policy formulation—making the decisions that result in public laws—entails these two distinct and sequentially related sets of activities in which policymakers, and those who would influence their decisions and actions, engage. The result of the formulation phase of policymaking for initial versions of policies is new public laws; for subsequent revisions, the result is amendments to existing laws.

Both initial public laws and the subsequent amendments to them that pertain to health stem from the interactions of (1) diverse arrays of health-related problems, (2) possible solutions to the problems, and (3) dynamic political circumstances that relate to both the problems and their potential solutions. The amendment of previously enacted public laws occurs through the process of legislation development, just as does the creation of an entirely new legislative proposal. The only significant difference is that the possibility of amendment implies the existence of a particular prior public law that can now be changed through amendments. This previously enacted legislation already has a developmental history and an implementation experience, both of which can influence its amendment.

Modification at Agenda Setting

Remember that agenda setting involves the confluence of problems, possible solutions, and political circumstances. Policy modification routinely begins in this stage of activity as problems already receiving attention become more sharply defined and better understood within the context of the ongoing implementation of existing policies. Possible solutions to problems can be assessed and clarified within the same context, especially when operational experience and the results of demonstrations and evaluations provide concrete evidence of the performance of particular potential solutions under consideration. In addition, the interactions among the branches of government and the health-related organizations and interest groups involved with and affected by

ongoing policies become important components of the political circumstances surrounding their reformulation, as well as of the initial formulation of future new policies. People learn from their experiences with policies, and those in a position to do so may act on what they learn.

Leaders in health-related organizations and interest groups, by virtue of their keen interest in certain health policies—interest driven by the fact that they, and their organizations and groups, directly experience the consequences of these policies—may be well positioned to serve as sentinels regarding whether particular policies are having the effects envisioned by those who formulated and implemented them. Because of their position, they may be among the first to observe the need to modify a policy, and they can use their experience to help policymakers better define or document problems that led to the original policy. These leaders can gather, catalog, and correlate facts that more accurately depict the actual state of a problem and can then share this information with policymakers.

Similarly, these leaders are well positioned to observe the impact and actual consequences of a hoped-for solution to a problem—a solution in the form of a policy. Leaders can devise and assess possible new solutions or alterations in existing ones through the operational experience of the organizations and groups they lead. Finally, their experiences with ongoing policies may become a basis for their attempts to change the political circumstances involved in a particular situation. When the confluence of problems, possible solutions, and political circumstances that led to an original policy is altered, a new window of opportunity may open, this time permitting the amendment of previously enacted legislation.

Modification at Legislation Development

Health policies in the form of public laws are routinely amended, some of them repeatedly and over a span of many years. Such amendments reflect, among other occurrences, the emergence of new medical technologies, changing federal budgetary conditions, and evolving beneficiary demands. These and other stimuli for change often gain the attention of policymakers through routine activities and reporting mechanisms that occur in the implementation of policies. Pressure to modify policy through changes in existing public laws may also emanate from the leaders of health-related organizations and interest groups—including those that represent individual memberships—who feel the policy consequences. When modifications do occur at the legislation development point in the process, they follow the same set of procedures as the original legislative proposals or bills (steps that were discussed fully in Chapter 6).

In some instances, the impetus to modify an existing law arises from changes in another law. For example, policies intended to reduce the federal budget deficit have typically impinged on other policies, often causing their modification. Implementation of the Deficit Reduction Act of 1984 (P.L. 98-369) required a temporary freeze on physicians' fees paid under the Medicare

program, and implementation of the Emergency Deficit Reduction and Balanced Budget Act of 1985 (P.L. 99-177), also known as the Gramm-Rudman-Hollins Act, required budget cuts in defense and in certain domestic programs, including a number of health programs.

Modification in the Policy Implementation Phase

Modification of policies in the implementation phase occurs in both rulemaking and in the operation of policies. Recall from the discussion in Chapters 7 and 8 that policy implementation entails these two distinct and sequentially related sets of activities in which policymakers, and those who would influence their decisions and actions, engage. Feedback from the consequences of formulated and implemented policies can also stimulate the modification of policies in the implementation phase, at both the rulemaking point in the process and in the operation of policies, and often at both points concurrently.

Modification at Rulemaking

As noted in Chapter 7, rulemaking is a necessary precursor to the operation and full implementation of new public laws because enacted legislation rarely contains enough explicit and directive language to completely guide implementation of the legislation. Newly enacted policies are often vague on implementation details, usually intentionally so, leaving it to the implementing organizations to promulgate the rules needed to guide the operation of the policies. Beyond this, existing policies are modified most frequently through changes in the rules or regulations used to guide their implementation.

The practice of using rulemaking to modify policies by updating or changing features of their implementation pervades policymaking. As discussed in Chapter 7, rules promulgated by executive branch agencies and departments to guide policy implementation possess the force of law. The rules themselves are policies. As implementation occurs, rulemaking becomes a means to modify policies and their implementation over time. In the process, rulemaking creates new policies. Changed rules are modified policies.

Modification in Operation

Policy operation, as discussed in Chapter 8, involves the actual running of the programs embedded in public laws. The operational stage of a policy is primarily a responsibility of the appointees and civil servants who staff the government, particularly those who manage the departments and agencies with policy implementation responsibilities. The managers responsible for operating a public law have significant opportunities to modify the policy—especially in terms of its impact on and consequences for those affected by the law—through the manner in which they manage its operation.

Policies implemented by managers who are committed to the objectives of those policies and who have the talent and resources available to vigorously implement them are qualitatively different from policies operated by managers

who are not committed to their objectives or who lack adequate talent and resources to achieve full and effective implementation. Modification of policies through changes in the way they are implemented is a routine occurrence in the ongoing policymaking process.

Two principal sources of stimulus for modification exist in the operation of policies: one internal and the other external. Internally, the managers responsible for operating policies approach the task in ways that are similar to the ways of managers in all settings; that is, they seek to *control* the results of their operations. To accomplish this, they establish standards or operating objectives (e.g., to serve so many clients per day, to process so many reports in a quarter, to distribute benefits to certain categories of beneficiaries, to assess compliance with certain regulations by so many firms); operations ensue; results are monitored; and changes are made in operations, objectives, or both when results do not measure up to the predetermined standards (Longest 2005). Such routine operational modifications are inherent in the implementation phase of any policy. They are part of the daily work that occurs within organizations that implement health policies.

In addition to the internal pressures to modify policy operation, there are external pressures as well. These pressures for change in the operation of a health policy are exerted by the individuals and especially by health-related organizations and interest groups that experience the consequences of implemented policies. As noted above, all of those who feel the consequences of policies are likely to seek to modify them. One avenue open to them, and one of the key points at which they can exert pressure for the modification of policies in their operational stages, is the opportunity to influence the modification of policies through influencing those who manage their operation.

These opportunities for policy modification arise within the working relationships—sometimes close working relationships—that can be developed between those responsible for implementing public policies and those whom their decisions and activities directly affect. The opportunities to build these relationships are supported by a prominent feature of the careers of bureaucrats: longevity (Kingdon 1995). Elected policymakers come and go, but the bureaucracy endures. Leaders of health-related organizations and interest groups can, and many do, build long-standing working relationships with some of the people responsible for implementing the public policies that are of strategic importance to these organizations and groups.

The most solid base for these working relationships is the exchange of useful information and expertise. The leader of a health-related organization or interest group, speaking from an authoritative position with relevant information based on actual operational experience with the implementation of a policy, can influence the policy's further implementation. If the information supports change, especially if it is buttressed with similar information from others who are experiencing the impact of a particular policy, reasonable

implementers may well be influenced to make needed changes. This is especially likely if there is a well-established working relationship, one based on mutual respect for the roles of and the challenges facing each party.

Sometimes the relationships between those who feel the consequences of policies, usually operating through their interest groups, and those responsible for implementing policies important to them are expanded to include members of the legislative committees or subcommittees with jurisdiction over the policies. This triad of mutual interests forms what has been termed an "iron triangle," so called because the interests of the three parts of the triangle "dovetail nicely and because they are alleged to be impenetrable from the outside and uncontrollable by president, political appointees, or legislators not on the committees in question" (Kingdon 1995, 33). As discussed in Chapter 3, however, the widely divergent interests of so many organizations and groups, coupled with their increasing presence in the policymaking arena, have made the formation of solid triangles more difficult and rarer in the health policy domain.

An obvious, and very limiting, problem for those who wish to modify health policies through influencing their operation, as well as the rulemaking that precedes operation, is the sheer enormity of the bureaucracy with which they might need to interact. Consider the enormous number of components of the federal government with relevance to health policy that are involved in rulemaking and policy operation. The number increases when relevant units of state and local government are added. Taken all together, the huge challenge of simply keeping track of where working relationships might be useful as a means of modifying policy through influencing policymakers in the implementation phase—to say nothing of actually developing and maintaining the relationships—begins to come into focus. Obviously, selectivity is necessary in determining which of these relationships might be most strategically important.

Modification Through the Cyclical Relationship Between Rulemaking and Operation

An important aspect of policy modification within the implementation phase of the process is represented by the feedback loop in Figure 9.1 between rulemaking and operation. As discussed in Chapters 7 and 8, there is a cyclical relationship between rulemaking and the operational activities involved with a public law's implementation. Although rulemaking precedes operation in the sequence of these activities, the experiences gained in operations feed back into rulemaking.

This cyclical relationship is important. It means that experience gained with the operation of policies can influence the modification of rules or regulations subsequently used in their operation. The Real World of Health Policy:

OSHA Proposes and then Withdraws a Rule Based on Operation of the Occupational Health and Safety Act illustrates this situation: the Occupational Safety and Health Administration (OSHA) proposed a rule on occupational exposure to tuberculosis (TB) only to subsequently withdraw it based on the fact that the occupational risk of acquiring TB declined as the incidence of TB in the population as a whole declined. Practically, the cyclical relationship between rulemaking and operation means that rules promulgated to implement policies undergo revision—sometimes the revision is extensive and continual—and that new rules can be adopted or existing ones changed or dropped as experience dictates. This feature of policymaking is an important aspect of the continual modification of policy.

The Real World of Health Policy

OSHA Proposes and then Withdraws a Rule Based on Operation of the Occupational Health and Safety Act

DEPARTMENT OF LABOR
Occupational Safety and Health Administration

29 CFR Part 1910
[Docket No. H-371]
RIN 1218-AB46

Occupational Exposure to Tuberculosis

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Proposed rule; termination of rulemaking.

SUMMARY: OSHA is withdrawing its 1997 proposed standard on Occupational Exposure to Tuberculosis (TB). Because of a broad range of Federal and community initiatives, the rate of TB has declined steadily and dramatically since OSHA began work on the proposal in 1993. Hospitals, which are the settings where workers are likely to have the highest risk of exposure to TB bacteria, have come into substantial compliance with Federal guidelines for preventing the transmission of TB. Overall reductions in TB mean that all workers are much less likely now to encounter infectious TB patients in the course of their jobs.

In addition, an OSHA standard is unlikely to result in a meaningful reduction of disease transmission caused by contact with the most significant remaining source of occupational risk: exposure to individuals with undiagnosed and unsuspected TB. Particularly outside of hospitals, workers often will not identify suspect TB cases quickly enough to implement isolation procedures and other precautions before exposure occurs.

OSHA recognizes, however, that continued vigilance is necessary to maintain the gains achieved so far. OSHA intends to provide guidance to workplaces with less medical expertise and fewer resources than hospitals, and to use cooperative relationships with employers, public health experts and other government agencies to promote TB control. OSHA will also continue to enforce the General Duty Clause of the OSH Act and relevant existing standards in situations where employers' failure to implement available precautions exposes workers to the hazard of TB infection.

DATES: This withdrawal is effective December 31, 2003.

SUPPLEMENTARY INFORMATION:

I. Background

On August 25, 1993, the Coalition to Fight TB in the Workplace petitioned OSHA to promulgate both an Emergency Temporary Standard (ETS) under section 6(c) of the Occupational Safety and Health Act (OSH Act), and a permanent occupational health standard under section 6(b) of the Act to protect workers from occupational exposure to TB (Ex.1). 29 U.S.C. 655(b), 655(c). Citing the resurgence of TB at that time and the emergence and increasing prevalence of multi-drug resistant TB (MDR-TB), the petition argued that a mandatory standard was needed to address the hazards associated with occupational exposure to TB. According to the petition, TB Guidelines developed by the Federal Centers for Disease Control and Prevention (CDC) were not an adequate response to this hazard because the guidelines were not mandatory and were not being implemented fully or rigorously in most workplaces. The petition also requested that, as an interim measure, OSHA immediately issue nationwide enforcement guidelines.

* * *

On January 26, 1994, OSHA responded to the rulemaking petition, saying that it was initiating rulemaking on a permanent standard, but would not issue an ETS. On October 17, 1997, OSHA published a Proposed Rule on Occupational Exposure to Tuberculosis (62 FR 54160). In the proposal, the Agency made a preliminary determination that workers in hospitals, nursing homes, hospices, correctional facilities, homeless shelters, and certain other work settings faced a significant risk of incurring TB infection through occupational exposure. The Agency also made a preliminary conclusion that use of established infection prevention and control measures could reduce or eliminate this significant risk. The protective measures OSHA proposed were based in large part on existing CDC guidelines, and included instituting procedures for the early identification and treatment of TB patients, isolating patients with infectious TB in rooms designed to protect others from contact with disease-causing microorganisms, requiring healthcare workers to use respirators to perform certain high-hazard procedures on infectious patients, training workers in TB recognition and control,

and providing medical follow-up for occupationally exposed workers who become infected and information to their colleagues with similar exposures.

* * *

II. Reasons for Withdrawal of the Proposed Standard

OSHA has decided not to promulgate a standard addressing occupational exposure to TB because it does not believe a standard would substantially reduce the occupational risk of TB infection. Many commenters argued forcefully that the proposed rule was based on an overestimate of this risk. In addition, existing TB control efforts, initiated by the Federal government in concert with other public health agencies, have led to a dramatic decline in TB over the past decade, greatly reducing the risk of occupational exposure to TB. Because of these TB control efforts, effective infection control measures are already in place, particularly in hospitals, which is where the occupational risk of TB exposure would be most severe.

* * *

In summary, OSHA has concluded that the success of existing Federal and community programs to control TB has significantly diminished the need for a standard, and that promulgating a standard will not reduce the remaining occupational risk substantially. Under the leadership of the CDC, community, institutional, and occupational public health efforts, including OSHA's own continuing outreach and enforcement, have increased worker and employer awareness of the factors leading to TB infection and disease and led to an increased implementation of CDC's TB guidelines. OSHA also intends to continue to use its enforcement, outreach, and education resources to ensure that employers' TB control efforts remain effective.

* * *

SOURCE: Excerpted and reprinted from *Federal Register*. 2003. "Occupational Exposure to Tuberculosis." *Federal Register* 68 (250): 75767–75775.

The Medicare Program: A Long History of Policy Modification in Practice

As described in the foregoing sections, modification of previous decisions is possible at many points in the policymaking process. In fact, modification of previous decisions characterizes the process. The role of policy modification can be seen vividly, for example, in the legislative history of the Medicare program. Imbedded in the chronology of Medicare-related legislation are many examples of how the modification phase of public policymaking plays out. The chronology of Medicare begins with the enactment of a new policy, the 1935 Social Security Act (P.L. 74-271), but from that point forward the

establishment and continuation of the Medicare program is largely a matter of modifying previous policies.

The Medicare program emerged on the nation's policy agenda in large part through the operation of the Social Security program over a span of three decades, from the mid-1930s to the mid-1960s. President Franklin D. Roosevelt formed the Committee on Economic Security in 1934 and charged its members to develop a program that could ensure the "economic security" of the nation's citizens. The committee considered the inclusion of health insurance as part of the Social Security program from the outset. There was, in fact, strong sentiment for its inclusion among members of the committee (Starr 1982). But in the end they decided not to recommend the inclusion of health insurance because of the tremendous political burdens associated with such a proposal. The American Medical Association (AMA) in particular strongly opposed the concept (Peterson 1993).

As reflected in the original legislation, the objective embedded in the Social Security Act of 1935 was

> . . . to provide for the general welfare by establishing a system of federal old age benefits, and by enabling the several States to make more adequate provision for aged persons, blind persons, dependent and crippled children, maternal and child welfare, public health, and the administration of their unemployment compensation laws. . . .

Although health insurance was not included among the program's original provisions, its addition was considered from time to time in the ensuing years. President Harry S. Truman considered national health insurance a key part of his legislative agenda (Altmeyer 1968). But AMA's continued powerful opposition and the necessity for the Truman administration to divert its attention to Korea in 1950 meant that President Truman was unable to stimulate the development and enactment of any sort of universal health insurance policy. Faced with dim political prospects for universal health insurance, proponents turned to a much more limited idea—hospital insurance for the aged.

Following a number of modest proposals for such insurance, none of which could muster the necessary political support for enactment, two powerful members of Congress, Senator Robert Kerr (D-Okla.) and Representative Wilbur Mills (D-Ark.), were able to see through to passage a bill that provided federal support for states' programs in welfare medicine. The Amendments to the Social Security Act of 1960 (P.L. 86-778) provided health benefits to the aged, although only to those who were poor. Not until the Democratic margin in Congress was significantly increased in President Lyndon B. Johnson's landslide election in 1964 did a more expansive initiative have much chance of passage. Key events leading up to the enactment of Medicare can be read at http://www.cms.hhs.gov/about/history/corningappa.asp (CMS 2004).

With Medicare's prospects significantly improved by the 1964 election, it received a very high priority among President Johnson's Great Society programs and was enacted as part of the Social Security Amendments of 1965 (P.L. 89-97). Medicare emerged on the nation's policy agenda through a series of attempts to modify the original Social Security Act by expanding the benefits provided to include health insurance. Although these attempts at modifying the original Social Security Act failed more often than not, they set the stage for the eventual modification that resulted in the Medicare program. As Peterson (1997, 292) notes, "The (policy) choices of one period are intimately linked to the choices grasped or missed in a previous era."

Following the original enactment of the legislation establishing the Medicare program, the chronology of related legislation shows a remarkable pattern of the evolutionary, incremental modification of a single, although massive, public policy. In a progression of modifications that continues today, among other changes, services for Medicare beneficiaries have been added and deleted; premiums and copayment provisions have been changed; reimbursement rates and payment mechanisms for service providers have been changed; and features to ensure quality and medical necessity of services have been added, changed, and deleted.

The legislative chronology of the Medicare program reflects significant legislative change from year to year, a pattern likely to continue so long as this complex and expensive program exists. The pattern of modifications exhibited in the Medicare legislation, chronicled in the lists that follow, has been heavily influenced by ongoing experience with the implementation of the original legislation and its subsequent modifications. This list illustrates how Medicare policy has been modified extensively over the course of the program's life and emphasizes the role that the modification phase plays in the overall policymaking process.

- *1935: Social Security Act (P.L. 74-271)*. This landmark legislation, enacted during the Great Depression, initiated the expansion of the federal government's central role in the domain of social insurance. Importantly, for the future of federal health policy, it included provisions through which the federal government made grants in aid to states for the support of programs for the needy elderly, dependent children, and the blind. Over the years, a number of amendments were made to the act, including the amendments of 1960 (P.L. 86-778), known as the Kerr-Mills Act, which established a new program for medical assistance for the aged.
- *1965: Social Security Amendments (P.L. 89-97)*. This legislation provided health insurance for the aged through Title XVIII (Medicare) and provided grants to the states for medical assistance programs for the poor through Title XIX (Medicaid).

Part A of Medicare provided hospital insurance benefits intended to protect beneficiaries against certain costs of hospital and related posthospital services. These benefits were financed by an increase in the Social Security earnings (payroll) tax. Part B of Medicare provided supplemental medical insurance benefits intended to protect beneficiaries from the costs of certain physician services, laboratory tests, supplies, and equipment, as well as certain home health services. These benefits were financed by voluntary premium payments from those who chose to enroll, matched by payments from general revenues.[1]

- *1967: Social Security Amendments (P.L. 90-248)*. The first modifications to the Medicare program, coming two years after its establishment, expanded coverage for such aids as durable medical equipment for use in the home, podiatrist services for nonroutine foot care, and outpatient physical therapy under Part B, and the addition of a lifetime reserve of 60 days of coverage for inpatient hospital care over and above the original coverage for up to 90 days during any spell of illness.

  In addition, certain payment rules were modified in favor of providers. For example, payment of full reasonable charges for radiologists' and pathologists' services provided to inpatients was authorized under one modification.
- *1972: Social Security Amendments (P.L. 92-603)*. Although in part these changes continued the pattern of program expansions started in the 1967 modifications, they marked an important shift to some policy modifications that were intended specifically to help control the growing costs of the Medicare program. Among the most important of the 1972 modifications was the establishment of professional standards review organizations (PSROs), which were to monitor both the quality of services provided to Medicare beneficiaries and the medical necessity for the services.

  Another modification aimed at cost containment was the addition of a provision to limit payments for capital expenditures by hospitals that had been disapproved by state or local planning agencies. Still another was the authorization of grants and contracts to conduct experiments and demonstrations related to achieving increased economy and efficiency in the provision of health services. Some of the specifically targeted areas of these studies included prospective reimbursement, the requirement that patients spend three days in the hospital prior to admission to a skilled nursing home, the potential benefits of ambulatory surgery centers, payment for the services of physician assistants and nurse practitioners, and the use of clinical psychologists.

  At the same time that these and other cost-containment modifications were made in the Medicare policy, a number of cost-increasing changes were also made. Notably, persons who were eligible

for cash benefits under the disability provisions of the Social Security Act for at least 24 months were made eligible for medical benefits under the Medicare program. In addition, those who were insured under Social Security, as well as their dependents, who required hemodialysis or renal transplantation for chronic renal disease were defined as disabled for the purpose of covering them under the Medicare program for the costs of treating their end-stage renal disease (ESRD). The inclusion of coverage for the disabled and ESRD patients in 1972 represented extraordinarily expensive modifications of the Medicare program. In addition, certain less costly but still expensive additional coverages were extended, including chiropractic and speech pathology services.

- *1976–77: A major reorganization of the U.S. Department of Health, Education, and Welfare (now the U.S. Department of Health and Human Services)*. Although not technically a modification of the Medicare policy, this reorganization resulted in the establishment of the Health Care Financing Administration (HCFA), an agency within DHEW (now DHHS) that assumed primary responsibility for implementation of the Medicare and Medicaid programs. This new agency combined functions that had been located in the Bureau of Health Insurance of the Social Security Administration (Medicare) and in the Medical Services Administration of the Social and Rehabilitation Service (Medicaid), among others.
- *1977: Rural Health Clinic Services Amendments (P.L. 95-210)*. This legislation modified the categories of practitioners who could provide reimbursable services to Medicare beneficiaries in rural settings. Under the provisions of this act, rural health clinics that did not routinely have physicians available on site could, if they met certain requirements regarding physician supervision of the clinic and review of services, be reimbursed through the Medicare and Medicaid programs for services provided by nurse practitioners and physician assistants. This act also authorized certain demonstration projects in underserved urban areas for reimbursement of these nonphysician practitioners.
- *1977: Medicare-Medicaid Antifraud and Abuse Amendments (P.L. 95-142)*. These modifications were intended to reduce fraud and abuse in both the Medicare and Medicaid programs and thereby help contain their costs. Specific changes included strengthening criminal and civil penalties for fraud and abuse, modifying the operations of the PSROs, and promulgating uniform reporting systems and formats for hospitals and certain other healthcare organizations participating in the Medicare and Medicaid programs.
- *1978: Medicare End-Stage Renal Disease Amendments (P.L. 95-292)*. Since the addition of coverage for ESRD under the Social Security Amendments of 1972 (P.L. 92-603), the costs to the Medicare program had risen steadily and quickly. These amendments sought to help control

the program's costs. One modification added incentives to encourage the use of home dialysis and renal transplantation in ESRD. Another modification permitted the use of a variety of reimbursement methods for renal dialysis facilities. Still another modification authorized studies of ESRD itself, especially studies incorporating possible cost reductions in treatment for this disease, and authorized the Secretary of DHEW (now DHHS) to establish areawide network coordinating councils to help plan for and review ESRD programs.

- *1980: Omnibus Budget Reconciliation Act, or OBRA '80 (P.L. 96-499).* Extensive modifications of Medicare and Medicaid policy were made in this legislation. Fifty-seven separate sections pertained to one or both of the programs. Many of the changes reflected continuing concern with the growing costs of the programs and were intended to help control these costs. Examples of the changes that were specific to Medicare included removal of the 100-visits-per-year limitation on home health services and the requirement under Part B that patients pay a deductible for home care visits. These changes were intended to encourage home care rather than more expensive institutional care. Another provision permitted small rural hospitals to use their beds as "swing beds" (alternating their use as acute or long-term-care beds as needed) and authorized swing-bed demonstration projects for large and urban hospitals.
- *1981: Omnibus Budget Reconciliation Act, or OBRA '81 (P.L. 97-35).* Just as in 1980, this legislation included extensive changes in the Medicare and Medicaid programs (46 sections pertained to these programs). Enacted in the context of extensive efforts to make reductions in the federal budget, many of the provisions hit Medicaid especially hard, but others were aimed directly at the Medicare program. For example, one provision eliminated the coverage of alcohol detoxification facility services, another removed the use of occupational therapy as a basis for initial entitlement to home health services, and yet another increased the Part B deductible.
- *1982: Tax Equity and Fiscal Responsibility Act, or TEFRA (P.L. 97-248).* A number of important changes with significant impact on the Medicare program were contained in this legislation. For example, one provision added coverage for hospice services provided to Medicare beneficiaries. These benefits were extended later and are now an integral part of the Medicare program. However, the most important provisions, in terms of impact on the Medicare program, were those that sought to control the program's costs by setting limits on how much Medicare would reimburse hospitals on a per-case basis and by limiting the annual rate of increase for Medicare's reasonable costs per discharge. These changes in reimbursement methodology represented fundamental changes in the Medicare program and reflected a dramatic shift in the nation's Medicare

policy. Another provision of TEFRA pertained to replacing PSROs, which had been established by the Social Security Amendments of 1972 (P.L. 92-603), with a new utilization and quality control program called peer review organizations (PROs). The TEFRA changes regarding the operation of the Medicare program were extensive, but they were only the harbinger of the most sweeping legislative changes in the history of the Medicare program the following year.

- *1983: Social Security Amendments (P.L. 98-21)*. This important legislation initiated the Medicare prospective payment system (PPS) and included provisions to base payment for hospital inpatient services on predetermined rates per discharge for diagnosis-related groups (DRGs). PPS was a major departure from the cost-based system of reimbursement that had been used in the Medicare program since its inception in 1965. The dramatic impact of this change on Medicare is best seen in terms of hospital expenditures, which were reduced sharply. An analysis by Russell and Manning (1989) shows that 1990 Medicare expenditures for hospital inpatient care were approximately 20 percent lower than they would have been without implementation of PPS. In this act, Congress directed the Reagan administration to study physician payment reform options.
- *1984: Deficit Reduction Act, or DEFRA (P.L. 98-369)*. Among the provisions of this act was one to temporarily freeze physicians' fees paid under the Medicare program. Another placed a specific limitation on the rate of increase in the DRG payment rates that the secretary of DHHS could permit in the two subsequent years. This act also created two classes of physicians in regard to their relationships to the Medicare program and outlined different reimbursement approaches for them depending on whether they were classified as participating or nonparticipating.
- *1985: Emergency Deficit Reduction and Balanced Budget Act, or the Gramm-Rudman-Hollins Act (P.L. 99-177)*. This legislation established mandatory deficit reduction targets for the five subsequent fiscal years. Under provisions of the law, the required budget cuts would come equally from defense spending and from domestic programs that were not exempted. The Gramm-Rudman-Hollins Act had significant impact on the Medicare program throughout the last half of the 1980s, as well as on other health programs such as community and migrant health centers, programs for veterans and Native Americans, health professions education, and NIH (Rhodes 1992). Among other actions, this legislation led to substantial cuts in Medicare payments to hospitals and physicians.
- *1985: Consolidated Omnibus Budget Reconciliation Act, or COBRA '85 (P.L. 99-272)*. Through a number of provisions of the act that affected Medicare, hospitals that served a disproportionate share of poor patients received an adjustment in their PPS payments; hospice care was made a

permanent part of the program; FY 1986 PPS payment rates were frozen at 1985 levels through May 1, 1986, and increased 0.5 percent for the remainder of the year; payment to hospitals for the indirect costs of medical education were modified; and a schedule to phase out payment of a return on equity to proprietary hospitals was established.

- *1986: Omnibus Budget Reconciliation Act, or OBRA '86 (P.L. 99-509).* This act altered the PPS payment rate for hospitals once again and reduced payment amounts for capital-related costs by 3.5 percent for part of FY 1987, by 7 percent for FY 1988, and by 10 percent for FY 1989. In addition, certain adjustments were made in the manner in which "outlier," or atypical, cases were reimbursed.
- *1987: Omnibus Budget Reconciliation Act, or OBRA '87 (P.L. 100-203).* This legislation required the secretary of DHHS to update the wage index used in calculating hospital PPS payments by October 1, 1990 and to do so at least every three years thereafter. It also required the Secretary to study and report to Congress on the criteria being used by the Medicare program to identify referral hospitals. Deepening the reductions established by OBRA '86, one provision of the act reduced payment amounts for capital-related costs by 12 percent for FY 1988 and 15 percent for FY 1989.
- *1988: Medicare Catastrophic Coverage Act (P.L. 100-360).* This act provided the largest expansion of the benefits covered under the Medicare program since its establishment in 1965. Among other provisions, this act added coverage for outpatient prescription drugs and respite care and placed a cap on out-of-pocket spending by the elderly for copayment costs for covered services. The legislation included provisions that would have the new benefits phased in over a four-year period and paid for by premiums charged to Medicare program enrollees. Thirty-seven percent of the costs were to be covered by a fixed monthly premium paid by all enrollees, and the remainder of the costs were to be covered by an income-related supplemental premium that was, in effect, an income surtax that would apply to fewer than half of the enrollees. Under intense pressure from many of their elderly constituents and their interest groups, who objected to having to pay additional premiums or the income surtax, Congress repealed P.L. 100-360 in 1989 without implementing most of its provisions.
- *1989: Omnibus Budget Reconciliation Act, or OBRA '89 (P.L. 101-239).* The act included provisions for minor, primarily technical, changes in PPS and provisions to extend coverage for mental health benefits and add coverage for Pap smears. Small adjustments were made in the disproportionate share regulations, and the 15 percent capital-related payment reduction established in OBRA '87 was continued in OBRA '89. Another provision required the secretary of DHHS to update the

wage index annually in a budget-neutral manner beginning in FY 1993. The most important provision of OBRA '89 was one through which HCFA was directed to begin implementing a resource-based relative value scale (RBRVS) for reimbursing physicians under the Medicare program on January 1, 1992. The new system was to be phased in over a four-year period beginning in 1992.

- *1990: Omnibus Budget Reconciliation Act, or OBRA '90 (P.L. 101-508).* The act made additional minor changes in PPS, including further adjustments to the wage index calculation and the disproportionate share regulations. Regarding the wage index, one provision required the Prospective Payment Assessment Commission (ProPAC), which was established by the 1983 Amendments to the Social Security Act to help guide Congress and the secretary of DHHS on implementing PPS, to further study the available data on wages by occupational category and to develop recommendations on modifying the wage index to account for occupational mix. It also included a provision that continued the 15 percent capital-related payment reduction that was established in OBRA '87, and continued in OBRA '89, and included another provision that made permanent the reduced teaching adjustment payment established in OBRA '87. One of its more important provisions provided a five-year deficit reduction plan that was to reduce total Medicare outlays by more than $43 billion between FY 1991 and FY 1995.
- *1993: Omnibus Budget Reconciliation Act, or OBRA '93, (P.L. 103-66).* This legislation established an all-time record five-year cut in Medicare funding and included a number of other changes affecting the Medicare program. For example, the legislation included provisions to end return on equity (ROE) payments for capital to proprietary skilled nursing facilities and reduced the previously established rate of increase in payment rates for care provided in hospices. In addition, the legislation cut laboratory fees drastically by changing the reimbursement formula and froze payments for durable medical equipment, parenteral and enteral services, and orthotics and prosthetics in FY 1994 and FY 1995.

It should be noted that the period 1993–96 was a unique time in the legislative history of the Medicare program—indeed, for health policy in general. The intense focus on President Clinton's attempt to reform the American healthcare system through his Health Security Act, which was introduced in late 1993 and died with the 1994 Congress (Hacker and Skocpol 1997; Hacker 1997), meant that little legislative energy was available for other health-related legislation. The hiatus in significant health policy continued following the Health Security bill's demise. Intense efforts in 1995 to enact unprecedented cutbacks in the Medicare and Medicaid programs as part of a far-reaching budget reconciliation bill ended in a veto by President Clinton.

The budget battle grew even worse in 1996. Proposed changes in the Medicare program, changes that were linked to the development of a plan to balance the federal budget over a seven-year span, would have meant massive cuts in the program. But political and philosophical differences over these plans between the Republican-controlled Congress and President Clinton, a Democrat, were so fundamental that they led to a complete impasse in the budget negotiations in 1996, including a brief shutdown of the federal government in the absence of budget authority to operate. Stung by public criticism of the disruptive budget battle of 1996, Congress resumed its normal schedule in developing the budget legislation in 1997. The result continued the significant pattern of modification in the Medicare program.

- *1997: Balanced Budget Act of 1997 (BBA) (P.L. 105-33)*. This legislation contained the most significant changes in the Medicare program since the program's inception in 1965. Overall, it requires a five-year reduction of $115 billion in the Medicare program's expenditure growth and a $13 billion reduction in growth of the Medicaid program. The Medicare+Choice program was created, which gives Medicare beneficiaries the opportunity to choose from a variety of health plan options the one that best suits their needs and preferences. Significant changes were also made in the traditional Medicare program. Among them, hospital annual inflation updates were reduced, as were hospital payments for inpatient capital expenses and bad debts. Other provisions established a cap on the number of medical residents supported by Medicare graduate medical education (GME) payments and provided incentives for reductions in the number of residents.

  An important provision of this act established the State Children's Health Insurance Program (SCHIP) and provided states with $24 billion in federal funds for the period 1998 to 2002 to increase health insurance for children. Other provisions established two new commissions. One of these, the Medicare Payment Advisory Commission (MedPAC) replaced the Physician Payment Review Commission and the Prospective Payment Review Commission. MedPAC was required to submit an annual report to Congress on the status of Medicare reforms and make recommendations on Medicare payment issues. A second new commission, the National Bipartisan Commission on the Future of Medicare, was established by this legislation and charged to develop recommendations for Congress on actions necessary to ensure the long-term fiscal health of the Medicare program. This commission was charged to consider several specific issues that were debated in the development of the BBA of 1997 but rejected. These issues included raising the eligibility age for Medicare, increasing

the Part B premiums, and developing alternative approaches to financing GME.

The National Bipartisan Commission on the Future of Medicare concluded its work and released its final report, *Building a Better Medicare for Today and Tomorrow*, on March 16, 1999. The report contains three sets of recommendations: (1) the design of a premium support system for the Medicare program, (2) improvements to the current Medicare program, and (3) financing and solvency of the Medicare program. The key recommendations of the commission, however, could not gather the bipartisan support necessary for amending the Medicare policy.

As BBA began to be implemented, health interest groups affected by the law, including the American Hospital Association, mounted an intense lobbying campaign to reverse some of BBA's effects. The campaign was made easier because the nation's budget surplus was growing at an unexpected rate. Two important health-related laws were enacted to modify BBA.

- *1999: Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (P.L. 106-113)*. This legislation changed the BBA provisions in a number of ways. For example, hospitals treating a disproportionate share (DSH) of low-income Medicare and Medicaid patients receive additional payments from Medicare. BBRA froze DSH adjustments at 3 percent (the FY 2000 level) through FY 2001, reduced the formula to 4 percent from the BBA-established 5 percent in FY 2002, and mandated a 0 percent level for subsequent years. The law increased hospice payment by 0.5 percent for FY 2001 and by 0.75 percent for FY 2002. Medicare reimburses teaching hospitals for their role in providing GME. Prior to BBA, Medicare's indirect medical education (IME) adjustment payments increased 7.7 percent for each 10 percent increase in a hospital's ratio of interns and residents to beds. BBA decreased the adjustment to 6.5 percent in FY 1999, 6.0 percent in FY 2000, and 5.5 percent in FY 2001 and subsequent years. BBRA froze the IME adjustment at 6.5 percent through FY 2000, reduced it to 6.25 percent in FY 2001, and reduced it to 5.5 percent in FY 2002 and subsequent years.
- *2000: Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (P.L. 106-554)*. This legislation was attached as an amendment to that year's appropriations bill and signed into law by President Clinton on December 21, 2000. It effectively changed a number of provisions previously enacted in BBA and BBRA. Among the important changes were
  - an increase of 3.4 percent for Medicare inpatient payments in FY 2001 and an estimated 3.5 percent in FY 2002;

- an increase of 4.4 percent in Medicare outpatient payments in 2001;
- IME payments at 6.5 percent in FY 2001 and FY 2002;
- elimination of the additional 1 percent cut in Medicare DSH hospital payments in FY 2001 and 2002;
- an increase from 55 to 70 percent in Medicare payments for bad debt;
- an increase for the direct GME payment floor to 85 percent of the national average;
- elimination of BBA's FY 2001 and 2002 Medicaid DSH cut;
- removal of the 2 percent payment reduction for rehabilitation hospitals in FY 2001;
- a 3.2 percent increase in skilled nursing service payments in FY 2001;
- a one-year delay of the 15 percent reduction for home health and the full market basket in FY 2001;
- an increase of 3 percent in incentive payments for psychiatric hospitals/units; and
- expansion of Medicare payment for telehealth services to rural areas.

In the 107th Congress, the Medicare debate centered on the addition of an outpatient prescription drug benefit to the program; legislation providing the benefit was enacted in the 108th Congress. The lack of coverage for more than one in four beneficiaries and continued increases in drug expenditures led to several proposals, culminating in the enactment on December 8, 2003 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. This law contained the most significant changes in the Medicare program since its enactment in 1965. Full implementation of the law was scheduled to take place over several years.

- *2003: Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (P.L. 108-173)*. This law created a new drug benefit as Part D of Medicare. The new benefit begins in 2006, with an interim Medicare-endorsed drug discount card available to beneficiaries. In addition, this law adds certain preventive benefits including an initial routine physical examination for new beneficiaries, cardiovascular blood screening tests, and diabetes screening and services. MMA also renamed Medicare+Choice to Medicare Advantage (MA) and changed some of the enrollment and disenrollment rules for beneficiaries.

  Another fundamental change in the Medicare program resulting from MMA is the Part B premium determination, which has been uniform for all beneficiaries since the program's inception. Beginning in 2007, this premium will be higher for those with an income over $80,000 for a single beneficiary, or over $160,000 per couple. In addition, the Part B deductible, set at $100 since 1991, is increased to $110 and thereafter will increase by the annual percentage increase in Part B expenditures.

- *2005: Final Rule Implementing MMA.* The Centers for Medicare & Medicaid Services (CMS) issued the final rule implementing MMA on January 21, 2005. A comprehensive summary of the final rule to implement the prescription drug benefit can be read at http://www.kff.org/medicare/upload/51141_1.pdf.

In the 109th Congress (2005–06), efforts to modify Medicare policy continue apace. For example, S. 222 seeks to amend Title XVIII of the Social Security Act to stabilize the amount of the Medicare Part B premium; S. 445 seeks to amend Part D of Title XVIII of the Social Security Act, as added by MMA, to provide for negotiation of fair prices for Medicare prescription drugs; and H.R. 868 seeks to amend Title XVIII of the Social Security Act to improve the provision of items and services provided to Medicare beneficiaries residing in rural areas.

Indeed, modification is a ubiquitous component of the overall policymaking process, as the chronology of modification in Medicare policy clearly illustrates. With this as background, attention turns in the next section to two structural aspects of the modification phase of policymaking.

Key Structural Features of Policy Modification

Two structural features drive much of the activity in the modification phase of the policymaking process: oversight actors and the results of formal analyses (also called assessments or evaluations) of how policies perform. The important roles in policy modification played by these two structural features are considered in the next sections.

The Role of Oversight Actors in Policy Modification

Oversight actors in the public policymaking process include participants from each branch of government. Their roles are played differently, but each has important implications for policy modification. In the legislative branch, oversight responsibilities are assigned to committees and subcommittees, which can stimulate modification in policy formulation and implementation. Chief executives (presidents, governors, or mayors, depending on the level of government) and their top appointees monitor implementation and can serve to point out when adjustments and modifications are needed. Courts can also determine when modifications are needed, such as when the results of one policy infringe on or conflict with the desired results of other policies.

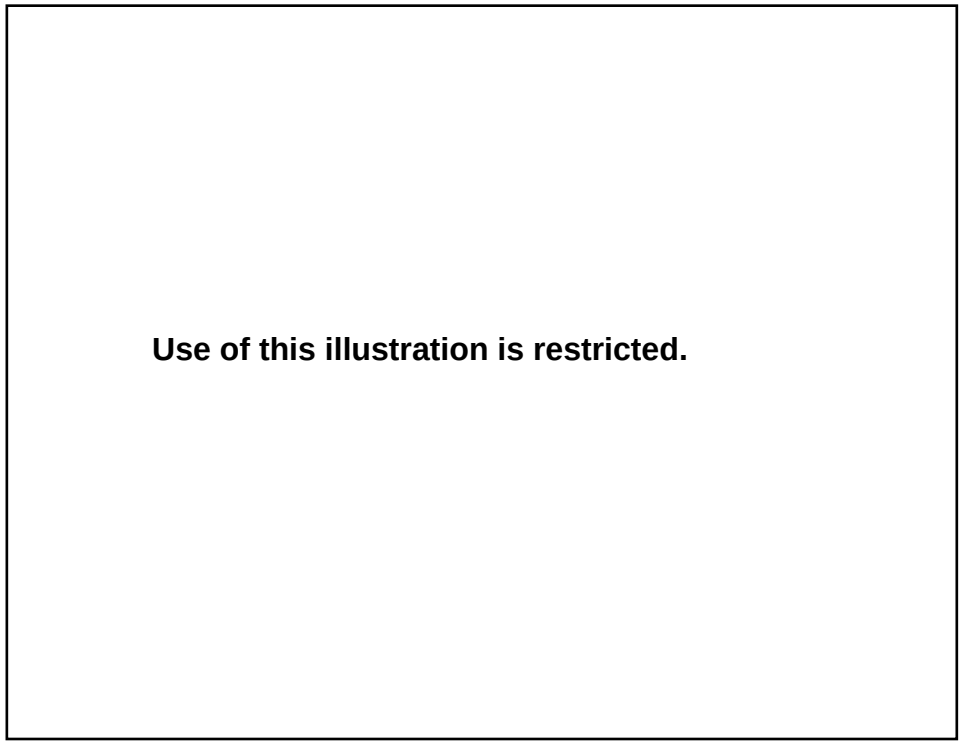
Legislative Branch

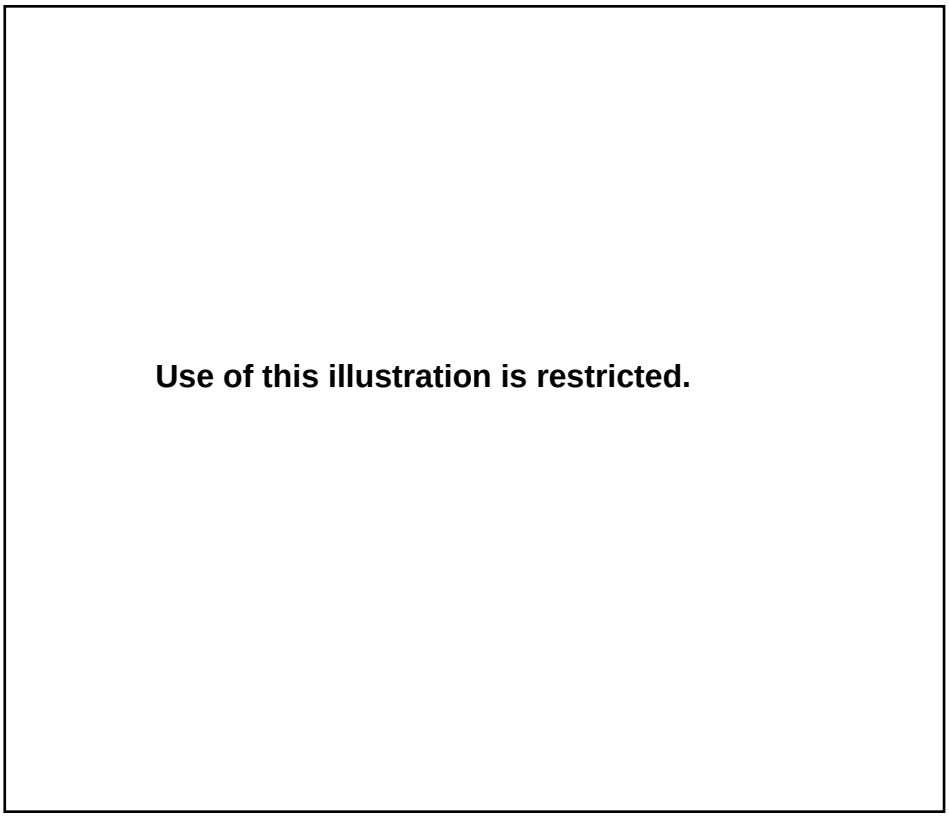
In the case of Congress, and with parallel arrangements in many state legislatures, committees and subcommittees have specific oversight responsibilities. The purpose of oversight in this context "is to analyze and evaluate both

the execution and effectiveness of laws administered by the executive branch, and to determine if there are areas in which additional legislation (including amendment of existing legislation) is necessary or desirable" (National Health Council, Inc. 1993, 10).

While any committee with jurisdiction can hold oversight hearings, the House and Senate appropriations committees (http://appropriations.house.gov and http://appropriations.senate.gov, respectively) have especially important oversight responsibilities inherent in their annual reviews of the budgets of implementing organizations and agencies. Routinely, legislators seeking to influence implementation decisions use the budget review mechanism.

In addition, out of oversight hearings often emerge the first or clarifying indications that existing legislation needs to be amended or that new legislation may be needed in a particular area. For example, over the period of March 1–3, 2005, the Senate Committee on Health, Education, Labor, and Pensions held hearings on the Food and Drug Administration's handling of drug safety and approval processes; hearing testimony can be read at http://help.senate.gov/calendars/all.html. See The Real World of Health Policy: Give and Take in Legislative Oversight to read the newspaper report of one of these hearings. Such hearings provide an opportunity for legislators to gain information that might be helpful in decisions about modifying policy, and they provide an opportunity for officials from implementing organizations to suggest needed modifications.





Executive Branch

Chief executives play very important oversight roles. In the context of managing the implementation of policies, chief executives (presidents, governors, or mayors) exert oversight and control of the implementation phase of policymaking. This provides them with unique power to initiate the modification of policies. Chief executives are supported in oversight activity by staff in the Executive Office as well as the appointees in the various departments and agencies who are responsible to the chief executive.

The Bush administration uses an approach termed the president's management agenda (PMA) (www.whitehouse.gov/omb/budintegration/pma_index.html) to organize its efforts to oversee and improve performance in implementation. The development and use of such approaches is not new. Every administration for the past 40 years had an organized approach to this task. Lyndon Johnson adopted the planning-programming-budgeting system (PPBS), which was based on a model developed in the private sector and Department of Defense. Richard Nixon replaced this with management by objectives (MBO). Zero-based budgeting (ZBO) followed as the approach preferred by Jimmy Carter's administration to rank order public spending options. Bill Clinton's administration used national performance review (NPR) as a means to focus government management and budgeting on achieving

results (Nathan 2005). The Bush administration's PMA approach is organized around the following five broad initiatives (Executive Office of the President 2002):

1. strategic management of human capital;
2. competitive sourcing;
3. improved financial performance;
4. expanded electronic government; and
5. budget and performance integration.

The Real World of Health Policy: The President's Management Agenda (PMA) expands on these strategic initiatives.

The Real World of Health Policy

The President's Management Agenda (PMA)

Launched in August 2001, the President's Management Agenda (PMA) set out to strengthen management practices and foster accountability so that Government managers and their employees could better focus on and produce results. Federal managers now routinely ask themselves if the programs they manage are achieving results at a reasonable cost. If the answer is "no" or "we don't know," managers find out what the problem is and work to fix it. If the answer is "yes," they pursue ways to increase efficiency by replicating their success in new areas. The Administration's efforts to improve Government effectiveness and efficiency will allow Departments and agencies to serve the American people better and with fewer resources. In each area of the PMA, the Administration has established markers of success and goals for future progress.

Strategic Management of Human Capital

The Strategic Management of Human Capital Initiative of the PMA helps agencies ensure they have high-performing employees with the right skills at the right time. Through this initiative, agencies are identifying the critical skills their employees need to fulfill the agency's mission. The agencies then work to close any gaps through directed hiring and training. This effort is driving agencies to improve performance appraisal systems to distinguish accurately among different levels of performance. These updated appraisal systems also make clear how each employee's contributions affect the agency's overall effectiveness. Managers are responsible for making performance expectations clear to each employee.

* * *

Competitive Sourcing

Competitive sourcing through public-private competition is helping agencies become more results-oriented and effective. Through competition with private providers, Federal employees who perform commercial activities are given the opportunity to develop plans for restructuring their organizations to optimize efficiency and eliminate waste. And private contractors have the chance to offer new and innovative solutions to meet the pressing needs of the Federal Government. These efforts have accelerated the implementation of long-overdue reengineering efforts and cost-savings measures, and have produced impressive results.

* * *

Improved Financial Performance

This past November (2004), a record 22 Federal agencies prepared their Performance and Accountability Reports within 45 days of the end of the fiscal year. When the Administration first set this new goal, agencies typically took five months to prepare these financial reports. Of the 24 major Federal agencies, 18 received unqualified audit opinions this past fiscal year. These important achievements demonstrate that agencies were able to maintain the high levels of financial management of previous years while accelerating their financial reporting dramatically. These achievements were possible because of the year-round financial management disciplines that agencies established. They implemented systematic and automated improvements to reconciliation and analysis processes, as well as improved coordination and communication with the agencies' Inspectors General, external auditors, and operating partners. Demonstrating fiscal accountability and achieving unqualified financial statements are good first steps. Ultimately, agency leadership must use this more accurate, precise, and timely financial information in their day-to-day management.

* * *

Electronic Government

The E-Government initiative focuses on ensuring that the Federal Government's $60 billion annual investment in information technology (IT) is well spent. Agencies are working to ensure that all major IT investments are justified with strong business cases that detail cost, schedule, and performance goals, and explain how each investment fits into a larger IT investment strategy. Agencies are working to ensure that all projects are completed within 10 percent of cost, schedule, and performance goals.

Federal agencies are also working to ensure that all IT systems are properly secured and data is appropriately protected. Currently, 77 percent of Government systems have been certified as secure, up from 26 percent three years ago.

The E-Government initiative emphasizes the customer—the general public. In 2001, the Administration proposed 24 solutions for providing E-Government services to the public. Federal agencies work together to implement E-Government projects to improve and streamline services for citizens, businesses, and Federal workers and reduce redundancy of investments. For instance, Federal job applicants can now access a central on-line source for all Federal job postings through *www.usajobs.gov*. Citizens no longer need to submit multiple 20-page applications, but can instead submit a single three to five page resume to apply for Federal jobs. Agencies are also working to place their rulemaking docket contents online, at *www.regulations.gov*, to facilitate effective public review and comment on proposed rules.

Interagency cooperation is also a vehicle for increasing the efficiency of the Government's management practices. The consolidation of 26 Federal payroll systems into two—an initiative this Administration launched in 2001—is expected to save $1.1 billion over 10 years. Building on this experience, agencies are pursuing consolidation opportunities in other areas, such as financial management, grants management, and human resources management. Federal agencies will compete with one another and with private providers to be designated shared service providers that will provide specific administrative services on a Government-wide basis, reducing the need for individual agencies to invest in these administrative systems individually. The Administration will continue to work with the Congress to remove legislative restrictions on E-Government so all Federal agencies can fully implement this important management tool.

Budget and Performance Integration

The overall goal of the Budget and Performance Integration Initiative is to have all programs achieve their expected results and continue to improve performance, which is central to effective Government.

The Administration is systematically assessing every program using the Program Assessment Rating Tool (PART). The PART requires us to ask whether a program has a clear definition of success, uses strong management practices, and produces results. The PART drives improvements in the quality of performance information and makes agencies accountable for the performance of their programs.

A key principle of the PMA is that performance should significantly influence policy-making. The PART provides valuable performance information that informs decisions about how to invest limited budgetary resources. All programs receive close scrutiny. Low priority and low performing programs are generally proposed for reduction or elimination, and the funding is redirected to higher performing alternatives. Programs that are high priorities, but that need improvement are subjected to reforms that will produce better results. For instance, as a result of PART analyses, the (FY 2006) Budget proposes to consolidate the Community

Development Block Grant and the Economic Development Assistance programs into a more targeted, unified program that sets accountability standards in exchange for flexible use of the funds to support communities' economic development and community revitalization efforts.

* * *

The Budget and Performance Integration Initiative is changing the usual debates about budget policy. Instead of asking agencies only "how much" they need, agencies are being asked "how well" they are performing with the dollars they receive. To reinforce this shift in approach, the agencies are preparing performance budgets that display clearly the level of performance expected with the requested funding level.

The Administration has assessed 60 percent of Federal programs, and has plans to assess the remaining 40 percent over the next two years. Because the potential for savings and productivity are great, the Administration is proposing two mechanisms for realizing these opportunities in a systematic and expedited fashion.

First, the Administration is proposing the establishment of a Sunset Commission to provide regular scrutiny of Federal programs. This bipartisan commission would review each Federal program on a schedule established by the Congress to determine whether it is producing results and should continue to exist. Programs would automatically terminate according to the schedule unless the Congress took action to continue them.

The second proposal is to establish Results Commissions to review Administration plans to consolidate or streamline programs that cross departmental or congressional committee jurisdictional lines to improve performance and increase efficiency. Ordinarily, programs that cross such boundaries often are not subject to the usual performance review process, resulting in inefficiencies, lost opportunities, or redundancies. Results Commissions, made up of experts in relevant fields, would be established as needed to review consolidation proposals. The Congress would consider the Commission's recommendation through expedited review authority.

SOURCE: Excerpted from www.whitehouse.gov. 2005. "Managing for Results." [Online document; retrieved 6/14/05.] *Making Government More Effective*, 50–54. http://www.whitehouse.gov/omb/budget/fy2006/pdf/budget/effective.pdf.

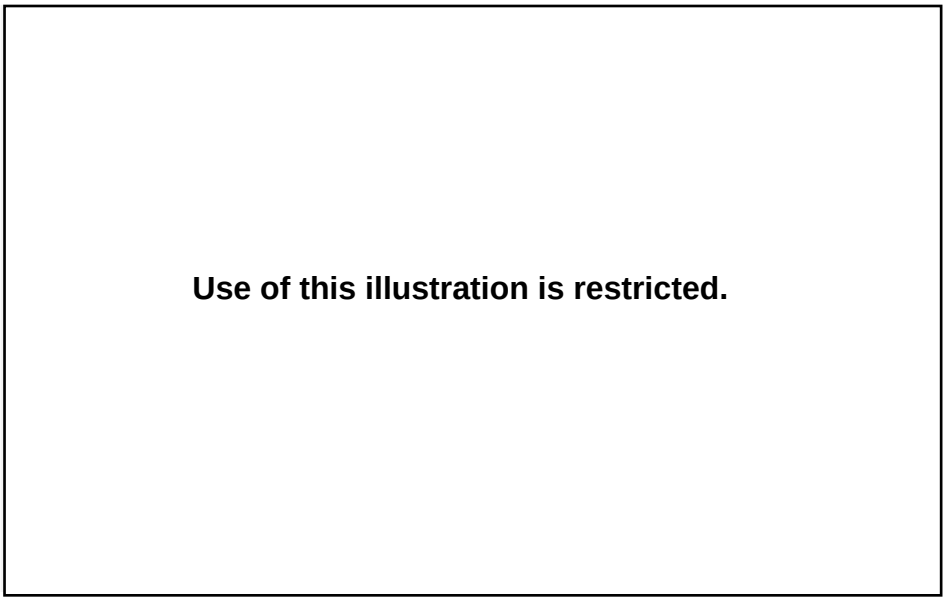
Judicial Branch

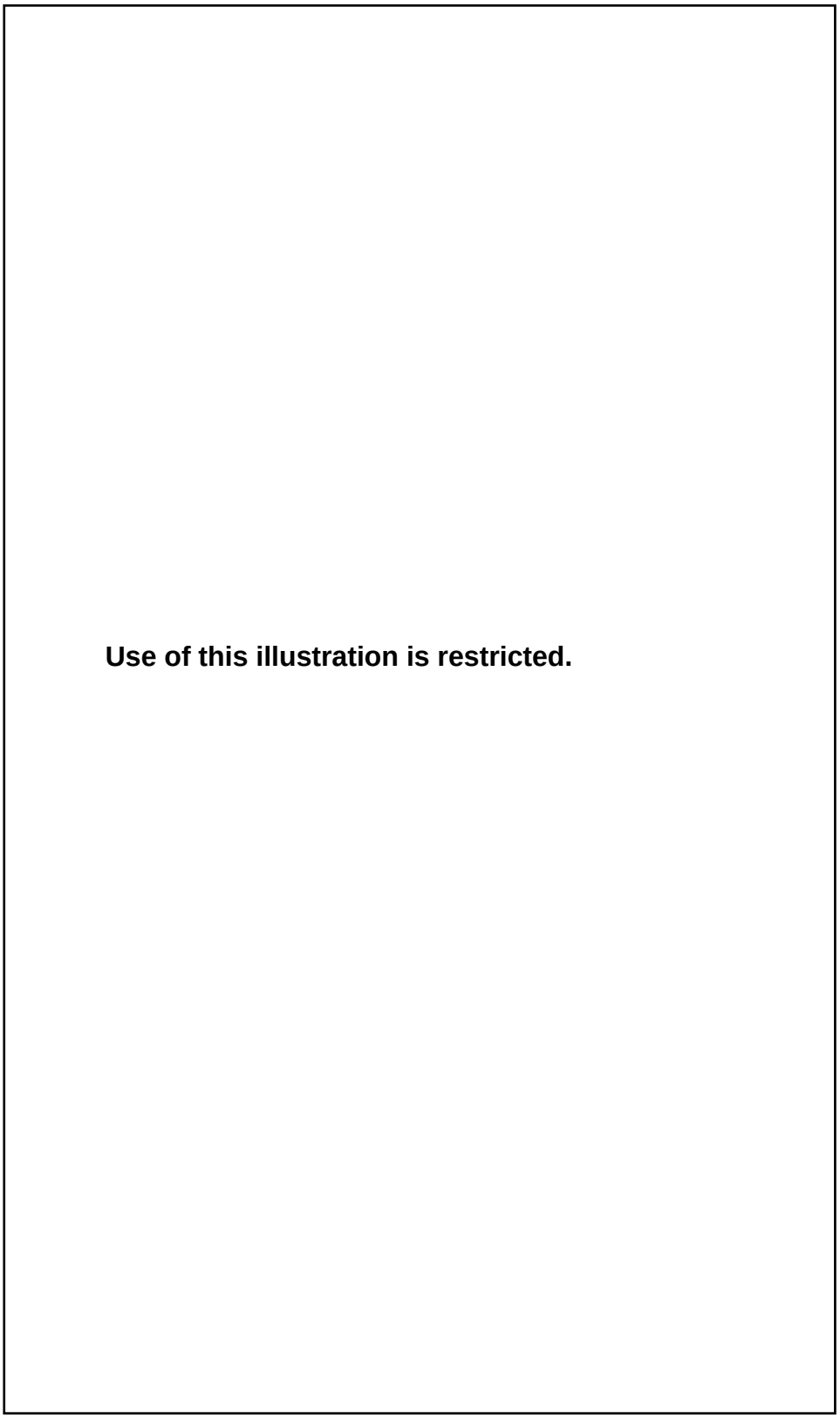
The courts also have a role in modifying health policy. The federal courts play an important oversight role regarding how laws are interpreted and enforced (information on the system of federal courts in the United States can be obtained at the Federal Judiciary's "About the U.S. Courts" web page at www.uscourts.gov/about.html). State courts are involved as well in interpreting and enforcing state laws and other policies within their jurisdictions. Anderson (1992) notes the courts' important roles in the modification of health

policies in areas such as (1) coverage decisions made by public and private health insurers; (2) states' payment rates for hospitals and nursing homes; and (3) antitrust rulings relating to mergers between healthcare organizations.

One of the more important ways that courts have modified policy is through their involvement in many aspects of the implementation of the nation's environmental protection laws and other policies. The Occupational Safety and Health Act (P.L. 91-596) set into motion a massive federal program of standard setting and enforcement that sought to improve safety and health conditions in the nation's workplaces. As Thompson (1981, 24) notes, "Business and labor leaders . . . have repeatedly appealed decisions by the Occupational Safety and Health Administration (OSHA) to the courts. The development of this program in some respects reads like a legal history."

Although enough adverse judicial decisions growing out of a particular policy can lead to its amendment or even to the stimulation of new legislation, the courts have their most direct modifying impact on the implementation of policies, especially in ensuring that laws and supporting rules and provisions are appropriately applied. In 1999, California enacted a nurse staffing ratio law that required a ratio of one registered nurse (RN) per five patients by January 1, 2001. Subsequent legislation moved the deadline to January 1, 2002; eventually, the deadline was set for January 1, 2005. In November 2004, California's governor, Arnold Schwarzenegger, issued an emergency order delaying implementation of the ratio until 2008. This elicited a lawsuit by the California Nurses Association. As The Real World of Health Policy: California Judge Tells Hospitals to Raise Nurse Staff Ratio reflects, a Superior Court judge ruled that the governor acted illegally by delaying implementation of the state law.

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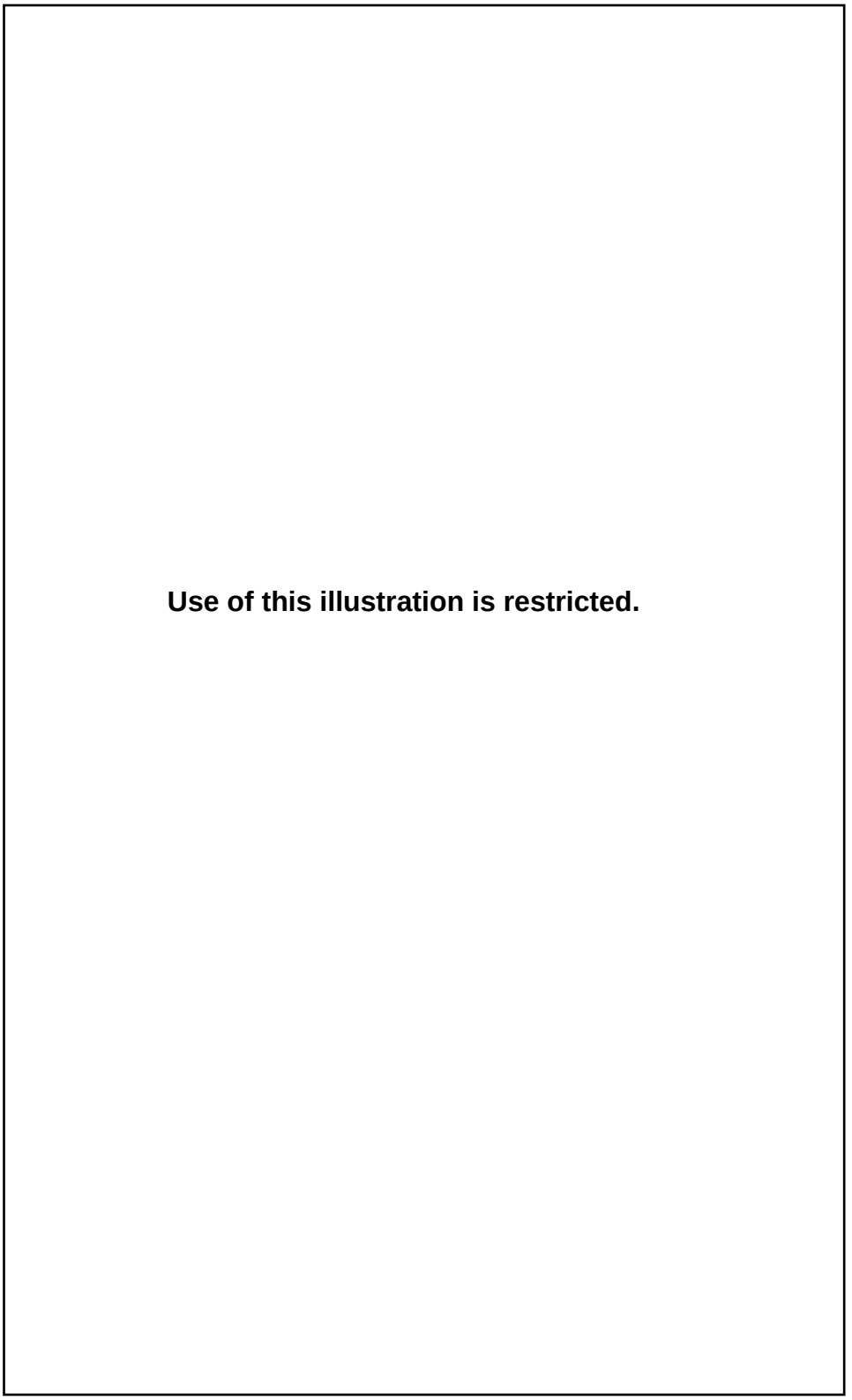
Use of this illustration is restricted.

One aspect of the courts' role that most complicates policy modification arises from the fact that the court system in the United States is highly decentralized. Although court autonomy is an important element in the ability of courts to play their roles in the American system of government, one consequence of this autonomy is the possibility of inconsistency in the treatment of policy-relevant issues. As has been noted, "The structure of the judicial system has made it difficult for the courts to provide consistent guidance about what constitutes acceptable behavior" (Anderson 1992, 106). Limitations of the courts aside, the judicial branch is a vitally important and integral structural feature of the policymaking process and plays an especially significant role in the modification phase of the process.

The Role of Analysis in Policy Modification

A second key structural feature of policy modification is the role played by formal analysis (also called assessments or evaluations) of the performance of policies. The results of these efforts can trigger and guide modification in policies (House 1993). Good policy analysis increases the likelihood of appropriate modifications. The most efficacious modification of policies is generally based on solid information, including information obtained through policy analysis.

To be of most value in guiding policy modification, analysis must consist of more than those activities that occur *after* a policy has been implemented. Effective policy analysis is a continuum of analytical activities that can begin in agenda setting and pervade and support the entire policymaking process. The continuum of these activities can be organized as ex-ante policy analysis, policy maintenance, policy monitoring, and ex-post policy analysis (Patton and Sawicki 1986).

- *Ex-ante policy analysis.* This type of analysis, which is also called "anticipatory" or "prospective" policy analysis, mainly influences agenda setting, whether in the original formulation of a policy or in its subsequent modification. Ex-ante policy analysis helps decision makers clarify the problems they face and identify and assess the various potential solutions to those problems. It may also include analyses of the relative benefits and costs of the various alternatives, thereby providing quantitative information that can help decision makers assess the potential consequences and political implications of their decisions.
- *Policy maintenance.* This type of analysis is typically undertaken to help ensure that policies are implemented as their formulators designed them and intended them to be implemented. Policy maintenance involves analysis that is part of the exercise of both legislative oversight and managerial control in implementation. As such, it can play a powerful role

in identifying when and how to modify a policy, either in reformulating it or by making changes in its implementation.

- *Policy monitoring.* This type of analysis is the relatively straightforward measuring and recording of the ongoing operation of a policy's implementation. Such monitoring is frequently a necessary precursor to the conduct of more formal ex-post policy analyses or evaluations, providing valuable information for the subsequent ex-post analysis. Policy monitoring can play a useful role in the exercise of appropriate managerial control and legislative oversight in the implementation phase, pointing out when and where modifications might be needed, both in rules and in operations.
- *Ex-post policy analysis.* This type of retrospective analysis is a way to determine the real value of a policy. This sometimes very difficult determination depends on an assessment of the degree to which a policy's objectives are achieved through its implementation.

Policy Analysis as a Basis for Policy Modification

Analyzing policies, especially in terms of their impacts and consequences, is a highly technical procedure that can be approached in a variety of ways, although typically one or more of a few basic approaches are used. These include before-and-after comparisons, with-and-without comparisons, actual-versus-planned performance comparisons, experimental and quasi-experimental designs, and cost-oriented analytical approaches (Patton and Sawicki 1986).

Analyses based on *before-and-after comparisons*, as the name suggests, involve comparing conditions or situations before a policy is implemented and after it has had an opportunity to make an impact on affected individuals, organizations, and groups. This is the most widely used approach to analyzing the impact of policies. A variation on this approach, known as *with-and-without comparisons*, involves assessing the consequences for individuals, organizations, or groups with the policy in place and comparing them to situations in which the policy does not exist.

In the health policy domain, analyses based on with-and-without comparisons are prevalent because variation in the nation's states provides something akin to a natural laboratory in which such comparisons are made possible. For example, studies have compared variations in states' use of managed care options for Medicaid populations (Gold 1997). In some situations, states do try policies first and the results do inform the consideration of these policies by other states and at the national level. However, Oliver and Paul-Shaheen (1997) studied policy innovation in states by examining states' enactment of major pieces of health-related legislation in the late 1980s and early 1990s. Their findings cast considerable doubt on the popular proposition that states can invent policies for substantial health system reforms for subsequent use by other states or by the federal government. The authors argue instead that

it is more appropriate to think of states as "specialized political markets" in which, under certain circumstances, unique solutions to unique problems can be addressed through public policy.

Another useful approach to assessing the performance of policies, *actual-versus-planned performance comparisons*, involves comparing policy objectives (e.g., health status improvements, dollars saved, people inoculated, tons of solid waste removed) with actual postimplementation results. Neither this nor the other two approaches to ex-post or retrospective analysis, however, supports the unassailable assignment of causation to the policies being assessed or evaluated. This limitation is a significant weakness of all three approaches to policy analysis. Nevertheless, these approaches are widely used because they tend to be easily implemented and cost relatively little. The results, however, of any of these comparison approaches must be interpreted carefully.

To help offset some of the technical limitations and weaknesses of the comparison approaches, two alternative approaches have been developed and are used in health policy analyses. These *experimental* and *quasi-experimental* analytical designs can permit more meaningful conclusions. In policy analyses that use experimental designs, individuals are randomly assigned to control or experimental groups so that the actual impact of the policy being evaluated can be better assessed. An excellent example of the power of experimental designs to evaluate policies can be found in the health insurance experiment conducted by the Rand Corporation in the 1970s (Newhouse 1974).

At the time, randomized controlled trials had become the standard approach to clinical research, but the approach had been rarely used in policy analysis. This now famous analysis by Rand clearly demonstrated the usefulness of the approach for assessing policy performance. However, this analytical approach is so expensive and difficult to conduct that its impact on modifying policy remains limited.

Considering the fact that experimental designs are expensive and can be difficult to conduct, quasi-experimental designs can serve a useful purpose in the conduct of policy analyses. This approach maintains the logic of full experimentation but without some of its restrictions and expenses (Cook and Campbell 1979; Shadish, Cook, and Campbell 2001). Quasi-experimental designs can provide one of the most useful aspects of assessing or evaluating a policy's performance: the ability to ascribe causality to a particular policy, although typically this is extremely difficult to do. Quasi-experimental designs are frequently used when it is not feasible or ethical to use random assignment of subjects in a study or an evaluation.

A final type of approach to policy analysis is one based on cost-oriented assessments or evaluations. This approach can be especially important in the context of the search for policies that provide value for public dollars. *Cost-benefit analysis* (CBA) and *cost-effectiveness analysis* (CEA) are the two most widely used forms of cost-oriented policy evaluation. In CBA, an evaluation is

based on the relationship between the benefits and costs of a particular policy, where all costs and benefits are expressed in monetary terms. Such analyses can help answer the fundamentally important question of whether the benefits of a policy are at least worth its costs. Typically, the result of these analyses is a measure of net benefits, which is "the difference between the total monetary input costs of an intervention and the consequences of that intervention, also valued in monetary terms" (Elixhauser et al. 1993, JS2).

In CEA, performance assessment is based on the desire to achieve certain policy objectives in the least costly way. This form of analysis compares alternative policies that might be used to achieve the same or very similar objectives. Typically, the results of CEA determinations are expressed as "the net costs required to produce a certain unit of output measured in terms of health, e.g., lives saved, years of life saved, or quality-adjusted life years" (Elixhauser et al. 1993, JS2–JS3). Much use of these health-related policy analysis techniques has centered on analyses related to variations in utilization and the relative effectiveness of various medical practices and surgical interventions.

Responsibility for Policy Analyses

Both the legislative and executive branches of the federal government are involved in policy analyses because they are interested in the performance of the policies they enact and implement. Several key policy analysis organizations are briefly described in the following sections.

Government Accountability Office (GAO) (www.gao.gov)

GAO is the investigative arm of Congress. It is often called the "congressional watchdog" because it investigates how the federal government spends taxpayer dollars. Its analyses "routinely answer such basic questions as whether government programs are meeting their objectives or providing good service to the public. Ultimately, GAO ensures that government is accountable to the American people. To that end, GAO provides Senators and Representatives with the best information available to help them arrive at informed policy decisions—information that is accurate, timely, and balanced" (GAO 2005).

Its mission permits GAO to analyze a wide range of matters that involve the use of public funds. In carrying out this mission, GAO performs audits and analyses of a host of programs and activities that arise from the implementation of federal policies. Organizationally, GAO is under the direction of the comptroller general of the United States, who is appointed by the president, with the advice and consent of the Senate, to a 15-year term. This gives GAO a level of independence and continuity of leadership that is rare within government. The Budget and Accounting Act of 1921 established the organization for the limited purpose of independently auditing federal agencies. Over the years, however, Congress has expanded GAO's audit authority, added extensive new responsibilities and duties, and strengthened the organization's ability to perform its work independently.

The majority of its analyses are made in response to specific congressional requests. GAO is required to perform work requested by committee chairpersons and assigns equal status to requests from ranking minority members of congressional committees. When possible, GAO also responds to requests for analyses and audits from individual members of Congress. The Real World of Health Policy: GAO Concludes the Selection of Antiretroviral Medications Provided Under the President's Emergency Plan for AIDS Relief Is Limited provides an example of this type of analytical activity. In this instance the analysis was conducted at the request of three senators.

The Real World of Health Policy

GAO Concludes the Selection of Antiretroviral Medications Provided Under the President's Emergency Plan for AIDS Relief Is Limited

This is an abstract of GAO Report (GAO-05-133) on "Global HIV/AIDS Epidemic: Selection of Antiretroviral Medications Provided Under U.S. Emergency Plan Is Limited", issued on January 11, 2005.

In developing countries, only about 7 percent of people with HIV/AIDS receive treatment. In 2003, the Congress authorized the President's Emergency Plan for AIDS Relief, a 5-year, $15 billion initiative under the Office of the U.S. Global AIDS Coordinator. The Emergency Plan focuses on 15 developing countries, with a goal of supporting treatment for 2 million people. Treatment regimens use multiple antiretroviral medications (ARV), which can be original or generic. Fixed-dose combinations (FDC) combine two or three ARVs into one pill. Questions have been raised about whether the plan is providing ARVs preferred by the focus countries at reasonable prices. GAO compared the selection of ARVs provided under the plan with that provided under other major treatment initiatives, compared the prices of those selections, and determined what the Coordinator's Office is doing to expand the plan's selection of quality-assured lower-priced ARVs.

The Emergency Plan provides a smaller selection of recommended first-line ARVs than other major HIV/AIDS treatment initiatives in developing countries. The plan's selection includes six original ARV products—the only ARVs that have met the plan's quality assurance requirement—and does not include some FDCs that are preferred by most of the focus countries because they can simplify treatment. In contrast, the other initiatives provide a selection that in addition to the six original ARVs includes generic ARVs and more of the preferred FDCs. The original ARVs provided under the plan are generally higher in price than the generic ARVs provided under the other initiatives. The differences in the prices, quoted to GAO during June and July 2004 by 13 manufacturers, ranged

from $11 less to $328 more per person per year for original ARVs than for the lowest-priced corresponding generic ARVs provided under the other initiatives. At these prices, three of the four first-line regimens recommended by the World Health Organization could be built for less—from $40 to $368 less depending on the regimen—with the generic ARVs provided under the other initiatives than with the original ARVs provided under the plan. Such differences in price per person per year could translate into hundreds of millions of dollars of additional expense when considered on the scale of the plan's goal of treating 2 million people by the end of 2008. The Coordinator's Office has worked to expand the selection of quality-assured ARVs—including FDCs and lower-priced generics—that it provides to the focus countries under the plan. The selection of ARVs available under the plan is primarily limited by its quality assurance requirement. The Coordinator's Office is working with manufacturers to take the steps necessary for more ARVs to meet this requirement. However, if generic ARVs meet the plan's quality assurance requirement, a statutory prohibition on the purchase of any medication manufactured outside the United States if the manufacture of that medication in the United States would be covered by a valid U.S. patent could become a barrier to expansion because all ARVs are currently under U.S. patents. Unless the patent holders for ARVs that have met the plan's quality requirement give permission or the Coordinator's Office exercises its authority to purchase these products notwithstanding the patent requirement, the selection of ARVs provided under the Emergency Plan may not expand rapidly enough to address the AIDS emergency.

SOURCE: Reprinted from Government Accountability Office. 2005. *Global HIV/AIDS Epidemic: Selection of Antiretroviral Medications Provided Under U.S. Emergency Plan Is Limited.* Report no. GAO-05-133. [Onine report; retrieved 2/22/05.] www.gao.gov/new.items/d05133.pdf.

Because GAO must maintain the ability to conduct a wide range of policy analyses, its staff is drawn from a variety of disciplines, including accounting, law, public and business administration, economics, and the social and physical sciences. Their work is organized so that staff members concentrate on specific subject areas, facilitating the development of expertise and in-depth knowledge. When an analytical assignment requires specialized experience not available within GAO, outside experts can be used to assist the permanent staff. Reflecting the organization's need to attract and maintain a highly capable professional staff, the GAO Human Capital Reform Act of 2004 (P. L. 108-271) made a number of significant changes to how GAO operates (http://www.gao.gov/about/namechange.html).

- It decouples GAO from the federal employee pay system.
- It establishes a compensation system that places greater emphasis on job performance while protecting the purchasing power of employees who are performing acceptably.

- It gives GAO permanent authority to offer voluntary early retirement opportunities and voluntary separation payments (buy-outs).
- It provides greater flexibility for reimbursing employees for relocation benefits.
- It allows certain employees and officers with less than three years of federal service to earn increased amounts of annual leave.
- It authorizes an exchange program with private-sector organizations.

Office of Management and Budget (OMB) (www.whitehouse.gov/omb)

OMB plays a crucial analytical role: Its predominant mission is to assist the president in overseeing the preparation of the federal budget and to supervise its administration in executive branch agencies. In helping to formulate the president's spending plans, OMB evaluates the effectiveness of agency programs, policies, and procedures; assesses competing funding demands among agencies; and sets funding priorities.

In assisting the administration in formulating its annual budget plans, OMB evaluates the effectiveness of executive branch organizations' operating decisions and assesses competing funding demands among these organizations. These assessments help establish the administration's funding priorities, which then guide the development of the budget. See the earlier discussion of budget and performance integration in The Real World of Health Policy: The President's Management Agenda (PMA) for additional information on how this connection between performance and funding occurs in the Bush administration, including the role of the Program Assessment Rating Tool (PART) (See Figure 9.2). PART requires programs to ask whether they have a clear definition of success, use strong management practices, and produce results. This tool drives improvements in the quality of performance information and makes agencies more accountable for the performance of their programs.

A key principle of PMA is that performance should significantly influence policy making. PART provides valuable performance information that informs decisions about how to invest limited budgetary resources. All programs receive close scrutiny. Low-priority and low-performing programs are generally proposed for reduction or elimination, and their funding is redirected to higher-performing alternatives.

In its role of supervising the various executive branch organizations through its administration of the federal budget, OMB ensures that the organizations' reports, rules, testimony, and proposed legislation are consistent with the administration's preferences. In addition, OMB oversees and coordinates the administration's procurement, financial management, and information practices and procedures. In each of these areas, OMB's role is to help improve the management of policy implementation, which, as was discussed in Chapters 7 and 8, is largely the responsibility of executive branch organizations.

Figure 9.2
Program Assessment Rating Tool (PART)

What Is the PART and How Is It Used?

The Program Assessment Rating Tool (PART) is designed to help assess the management and performance of individual programs. The PART evaluates a program's purpose, design, planning, management, results, and accountability to determine its overall effectiveness. Recommendations are then made to improve program results.

To reflect that Federal programs deliver goods and services using different mechanisms, the PART is customized by program category. The seven PART categories are: Direct Federal, Competitive Grant, Block/Formula Grant, Research and Development, Capital Assets and Aquisition, Credit, and Regulatory. The PART types apply to both discretionary and mandatory programs.

Each PART includes 25 basic questions and some additonal questions tailored to the program type all divided up into four sections. The first section of questions gauges whether a program's design and purpose are clear and defensible. The second section involves strategic planning, and weighs whether the agency establishes valid annual and long-term goals for its programs. The third section rates the management of an agency's program, including financial oversight and program improvement efforts. The fourth section of questions focuses on results that programs can report with accuracy and consistency.

The answers to questions in each of the four sections result in a numerical score for each section from 0 to 100 (100 being the best score). Because reporting a single weighted numerical rating could suggest false precision, or draw attention away from the very areas most in need of improvement, numerical scores are translated into qualitative ratings. The bands and associated ratings are as follows:

Rating	Range
Effective	85–100
Moderately Effective	70–84
Adequate	50–69
Ineffective	0–49

Regardless of overall score, programs that do not have acceptable performance measures or have not yet collected performance data generally receive a rating of "Results Not Demonstrated."

PART ratings do not result in automatic decisions about funding. Clearly, over time, funding should be targeted to programs that can prove they achieve measurable results. In some cases, a PART rating of "Ineffective" or "Results Not Demonstrated" may suggest that greater funding is necessary to overcome identified shortcomings, while a program rated "Effective" may be in line for a proposed funding decrease if it is not a priority or has completed its mission. However, most of the time, an "Effective" is an indication that the program is using its funding well and that major changes may not be needed.

SOURCE: OMB (2005).

Congressional Budget Office (CBO) (www.cbo.gov)

CBO was created by the Congressional Budget and Impoundment Control Act of 1974. The agency's mission is to provide Congress with the objective, timely, nonpartisan analyses needed for economic and budget decisions and with the information and estimates required for the congressional budget process. Compared with the missions of Congress's other support agencies—the Congressional Research Service and the Government Accountability Office—CBO's mission is narrow and focused. Even so, given the wide array of activities that the federal budget covers, the agency is involved in wide-ranging health policy activity.

The Budget Act requires CBO to produce a cost estimate for every bill "reported out" (approved) by a Congressional committee. CBO's cost estimates show how the legislation would affect spending or revenues over the subsequent five years or more. Those written estimates provide information about the proposal and explain how CBO prepared the estimate. The Real World of Health Policy: CBO Issues a Cost Estimate is an example of the work CBO does in estimating the cost of a proposed policy. This example is straightforward, as are many of CBO's estimates. However, on occasion, the estimates become extremely complicated, as they did in CBO's estimates of the projected costs of adding a prescription drug benefit to the Medicare program.

The Real World of Health Policy

CBO Issues a Cost Estimate

Congressional Budget Office **February 14, 2005**
Cost Estimate

S. 306
Genetic Information Nondiscrimination Act of 2005
As reported by the Senate Committee on Health, Education, Labor, and Pensions on February 10, 2005

S. 306 would prohibit the use of genetic information (including results of genetic tests and family history of disease) by employers in employment decisions and by health insurers and health plans in making enrollment determinations and setting insurance premiums.

CBO estimates that enacting the bill would increase the number of individuals who obtain insurance by about 1,000 people per year, nearly all of whom would obtain insurance in the individual market. The bill would affect federal revenues because some of the premiums paid by those newly insured individuals would be tax-deductible. CBO estimates that enacting S. 306 would decrease revenues by less than $500,000 in each year from 2006 through 2015.

The bill would require the Secretaries of Health and Human Services (HHS), Labor, and the Treasury to issue regulations to carry out the provisions of this bill, and would require the Secretaries of HHS and Labor to enforce those provisions. In addition, the bill would establish a commission to review the science of genetics and to make recommendations to the Congress on the need to establish a disparate impact standard for genetic discrimination. The bill would authorize the appropriation of such sums as necessary to establish the commission and to carry out the other provisions of the bill. Assuming the appropriation of the necessary amounts, CBO estimates that implementing S. 306 would cost less than $500,000 in 2006 and about $2 million over the 2006–2015 period. We estimate that the bill would have no significant effect on direct spending.

S. 306 would preempt some state laws that establish confidentiality standards for genetic information, and would restrict how state and local governments use such information in employment practices and in the provision of health care to employees. The preemption and the limitations on state and local actions would be intergovernmental mandates as defined in the Unfunded Mandates Reform Act (UMRA), but there is little indication that state, local, or tribal governments currently engage in or are likely to engage in the activities that would be prohibited by the bill. Consequently, CBO estimates that the costs of the mandates would not be significant and would not exceed the threshold established in UMRA ($62 million in 2005, adjusted annually for inflation).

The bill contains private-sector mandates on health insurers, health plans, employers, labor unions, and other organizations. CBO estimates that the direct cost of those requirements would not exceed the annual threshold specified in UMRA ($123 million in 2005, adjusted annually for inflation) in any of the first five years in which the mandates would be effective.

The CBO staff contacts for this estimate are Tom Bradley (for the federal budget impact),Leo Lex (for the state and local impact), and David Auerbach (for the private-sector impact). This estimate was approved by Robert A. Sunshine, Assistant Director for Budget Analysis.

SOURCE: Reprinted from Congressional Budget Office. 2005. "S. 306: Genetic Information Nondiscrimination Act of 2005." [Online document; retrieved 3/6/05.] http://www.cbo.gov/showdoc.cfm?index=6110&sequence=0.

CBO's primary responsibility is to help the congressional budget committees with the matters under their jurisdiction—principally the congressional budget resolution and its enforcement. To help the budget committees enforce the budget resolution, CBO provides estimates of the budgetary costs of legislation approved by the various congressional committees and tracks the progress of spending and revenue legislation.

Overall, CBO's services can be grouped into four categories: helping Congress formulate budget plans, helping it stay within these plans, helping

it assess the impact of federal mandates, and helping it consider the impact of policies on the federal budget. In the last role, for example, the analyses examine current and proposed policies, sometimes suggesting alternative approaches and projecting how the alternatives would affect current programs, the federal budget, and the economy. In line with its nonpartisan mandate, CBO does not offer specific recommendations on policy.

Congressional Research Service (CRS) (www.loc.gov/crsinfo)

CRS is another analytical resource available especially to members of Congress. The agency was established to provide Congress with information and analysis needed to make more informed decisions. CRS operates in many ways as an extension of, or supplement to, the members' own office staff. As a legislative branch organization within the Library of Congress, CRS's work is performed exclusively for Congress on a confidential, nonpartisan basis.

The agency's staff includes people with expertise in a wide range of issues and disciplines, including law, economics, foreign affairs, the physical and behavioral sciences, environmental science, public administration, the social sciences, and information science.

CRS analysts support legislators at all stages of the policymaking process by helping identify problems and possible solutions in the formulation of legislative proposals. CRS also provides policy analysis and legal research. It is organized into six interdisciplinary research divisions, which are clustered around the following public policy issues: American law; domestic social policy; foreign affairs, defense, and trade; government and finance; information research; and resources, science, and industry. Within each division, CRS analysts and specialists are organized into smaller sections that focus on specific areas of public policy such as education, labor, taxes, and health.

Conclusion

As noted at the beginning of this chapter, and as we have seen throughout this book, policymaking is not a perfect process. The decisions made within this process must be reviewed and changed when necessary. Beyond this operational aspect of the need for policy modification lies the fact that policies have huge consequences for individuals and populations, as well as for health-related organizations and interest groups. Because they are so directly affected by the outcomes of the health policymaking process, the leaders of these entities typically devote considerable attention and resources to analyzing this process and the larger public policy environments that face their organization or group. And they seek to exert influence in these environments; one pervasive result is the ongoing participation of the leaders of health-related organizations and interest groups in the policy modification phase of the public policymaking process.

When policies have positive consequences such as more services, higher incomes, less pollution, or more money for biomedical research, those enjoying the benefits will likely seek to increase them through modification of the existing policies that affect these benefits. Similarly, when policies have negative consequences, those experiencing the reductions will likely seek to remedy the negative consequences through modification of the existing policies that cause them. The constant modification of existing policies is indeed an important hallmark of policymaking in the United States. This aspect of policymaking permits the results of the process to be corrected or improved over time—an important attribute given the complexity of the world in which the policymaking process plays out and the human fallibility of the participants in the process.

Summary

The modification phase of the public policymaking process involves the feeding back of the consequences of policies and the actions these consequences stimulate into the other phases of the process. As the feedback loop depicted in Figure 9.1 shows, policy modification occurs in both the agenda setting and legislation development inherent in policy formulation and in the rulemaking and operations that characterize policy implementation.

The modification phase is an extremely important feature of the health policymaking process because it provides continuing opportunities for the performance of policies and the resulting consequences to stimulate modifications. Changes occur through the influence of policy outcomes on agenda setting or through the amendment of previously enacted public laws. In addition, the results of policy implementation routinely lead to modifications in both the rulemaking and the operation of policies.

In a very real sense, as was pointed out in the overview of the policymaking process presented in Chapter 3 and reemphasized in this concluding chapter, the modification phase of policymaking exists because perfection cannot be achieved in the other phases and because policies are established and exist in a dynamic world. Suitable policies made today may become inadequate with biological, cultural, demographic, ecological, economic, ethical, legal, psychological, social, and technological changes in the future.

Discussion Questions

1. Discuss the distinction between policy initiation and policy modification.
2. Discuss the concept of incrementalism in public policymaking.

3. Describe modification in the agenda setting that precedes policy formulation.
4. Discuss how modification occurs in legislation development.
5. Discuss how modification occurs in rulemaking.
6. Discuss how modification occurs at the operational stage of implementing policies.
7. Discuss the cyclical relationship between rulemaking and operation and how this affects modification.
8. Discuss the role of oversight actors in policy modification.
9. Discuss the role of policy analysis in policy modification. Include brief descriptions of three federal agencies that support policymaking through policy analysis.

Note

1. Rich histories of the events leading up to the enactment of these amendments have been written by Marmor (1973) and Feder (1977). Such histories document the often rancorous political debates and philosophical differences that preceded the 1965 legislation. This history is not repeated here because the focus is primarily on the pattern of modifications made in the Medicare policy after its enactment as an example of the modification phase of policymaking.

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APPENDIX

A

OVERVIEW OF MEDICARE

Title XVIII of the Social Security Act, designated "Health Insurance for the Aged and Disabled," is commonly known as Medicare. As part of the Social Security Amendments of 1965, the Medicare legislation established a health insurance program for aged persons to complement the retirement, survivors, and disability insurance benefits under Title II of the Social Security Act.

When first implemented in 1966, Medicare covered most persons age 65 or over. In 1973, the following groups also became eligible for Medicare benefits: persons entitled to Social Security or Railroad Retirement disability cash benefits for at least 24 months, most persons with end-stage renal disease (ESRD), and certain otherwise non-covered aged persons who elect to pay a premium for Medicare coverage. The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (Public Law 106-554) allowed persons with Amyotrophic Lateral Sclerosis (Lou Gehrig's Disease) to waive the 24-month waiting period.

Medicare has traditionally consisted of two parts: Hospital Insurance (HI), also known as Part A, and Supplementary Medical Insurance (SMI), also known as Part B. A third part of Medicare, sometimes known as Part C, is the Medicare Advantage program, which was established as the Medicare+Choice program by the Balanced Budget Act (BBA) of 1997 (Public Law 105-33) and subsequently renamed and modified by the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 (Public Law 108-173). The Medicare Advantage program expands beneficiaries' options for participation in private-sector healthcare plans.

The MMA also established a fourth part of Medicare: a new prescription drug benefit, also known as Part D, beginning in 2004. Part D activities are handled within the SMI trust fund, but in an account separate from Part B. It should thus be noted that the traditional treatment of "SMI" and "Part B" as synonymous is no longer accurate, since SMI now consists of both Parts B and D. The purpose of the two separate accounts within the SMI trust fund is to ensure that funds from one part are not used to finance the other.

When Medicare began on July 1, 1966, approximately 19 million people enrolled. In 2004, almost 42 million people are enrolled in one or both of Parts A and B of the Medicare program, and about 5 million of them have chosen to participate in a Medicare Advantage plan.

Coverage

Part A is generally provided automatically, and free of premiums, to persons age 65 or over who are eligible for Social Security or Railroad Retirement benefits, whether they have claimed these monthly cash benefits or not. Also, workers and their spouses with a sufficient period of Medicare-only coverage in Federal, State, or local government employment are eligible beginning at age 65. Similarly, individuals who have been entitled to Social Security or Railroad Retirement disability benefits for at least 24 months, and government employees with Medicare-only coverage who have been disabled for more than 29 months, are entitled to Part A benefits. Part A coverage is also provided to insured workers with ESRD (and to insured workers' spouses and children with ESRD), as well as to some otherwise ineligible aged and disabled beneficiaries who voluntarily pay a monthly premium for their coverage. In 2003, Part A provided protection against the costs of hospital and specific other medical care to about 41 million people (35 million aged and 6 million disabled enrollees). Part A benefit payments totaled $152.1 billion in 2003.

The following healthcare services are covered under Part A:

- *Inpatient hospital* care coverage includes costs of a semi-private room, meals, regular nursing services, operating and recovery rooms, intensive care, inpatient prescription drugs, laboratory tests, x-rays, psychiatric hospitals, inpatient rehabilitation, and long-term care hospitalization when medically necessary, as well as all other medically necessary services and supplies provided in the hospital. An initial deductible payment is required of beneficiaries who are admitted to a hospital, plus copayments for all hospital days following day 60 within a benefit period (described later).
- *Skilled nursing facility* (SNF) care is covered by Part A only if it follows within 30 days (generally) of a hospitalization of 3 days or more and is certified as medically necessary. Covered services are similar to those for inpatient hospital but also include rehabilitation services and appliances. The number of SNF days provided under Medicare is limited to 100 days per benefit period (described later), with a copayment required for days 21–100. Part A does not cover nursing facility care if the patient does not require skilled nursing or skilled rehabilitation services.
- *Home health agency* (HHA) care is covered by both Parts A and B. The BBA transferred from Part A to Part B those home health services furnished on or after January 1, 1998 that are unassociated with a hospital or SNF stay. Part A will continue to cover the first 100 visits following a 3-day hospital stay or a SNF stay; Part B covers any visits thereafter. Home health care under Part A and Part B has no copayment and no deductible.

HHA care, including care provided by a home health aide, may be furnished part-time by a HHA in the residence of a home-bound beneficiary if intermittent or part-time skilled nursing and/or certain other therapy or rehabilitation care is necessary. Certain medical supplies and durable medical equipment (DME) may also be provided, though beneficiaries must pay a 20-percent coinsurance for DME, as required under Part B of Medicare. There must be a plan of treatment and periodical review by a physician. Full-time nursing care, food, blood, and drugs are not provided as HHA services.

- *Hospice* care is a service provided to terminally ill persons with life expectancies of 6 months or less who elect to forgo the standard Medicare benefits for treatment of their illness and to receive only hospice care for it. Such care includes pain relief, supportive medical and social services, physical therapy, nursing services, and symptom management. However, if a hospice patient requires treatment for a condition that is not related to the terminal illness, Medicare will pay for all covered services necessary for that condition. The Medicare beneficiary pays no deductible for the hospice program, but does pay small coinsurance amounts for drugs and inpatient respite care.

An important Part A component is the benefit period, which starts when the beneficiary first enters a hospital and ends when there has been a break of at least 60 consecutive days since inpatient hospital or skilled nursing care was provided. There is no limit to the number of benefit periods covered by Part A during a beneficiary's lifetime; however, inpatient hospital care is normally limited to 90 days during a benefit period, and copayment requirements (detailed later) apply for days 61–90. If a beneficiary exhausts the 90 days of inpatient hospital care available in a benefit period, he or she can elect to use days of Medicare coverage from a non-renewable "lifetime reserve" of up to 60 (total) additional days of inpatient hospital care. Copayments are also required for such additional days.

All citizens (and certain legal aliens) age 65 or over, and all disabled persons entitled to coverage under Part A, are eligible to enroll in Part B on a voluntary basis by payment of a monthly premium. Almost all persons entitled to Part A choose to enroll in Part B. In 2003, Part B provided protection against the costs of physician and other medical services to about 38 million people (33 million aged and 5 million disabled). Part B benefits totaled $123.8 billion in 2003.

Part B covers the following services and supplies:

- Physicians' and surgeons' services, including some covered services furnished by chiropractors, podiatrists, dentists, and optometrists. Also covered are the services provided by these Medicare-approved practitioners who are not physicians: certified registered nurse

anesthetists, clinical psychologists, clinical social workers (other than in a hospital or SNF), physician assistants, and nurse practitioners and clinical nurse specialists in collaboration with a physician.
- Services in an emergency room or outpatient clinic, including same-day surgery, and ambulance services.
- Home health care not covered under Part A.
- Laboratory tests, x-rays, and other diagnostic radiology services, as well as certain preventive care screening tests.
- Ambulatory surgical center services in a Medicare-approved facility.
- Most physical and occupational therapy and speech pathology services.
- Comprehensive outpatient rehabilitation facility services, and mental health care in a partial hospitalization psychiatric program, if a physician certifies that inpatient treatment would be required without it.
- Radiation therapy, renal (kidney) dialysis and transplants, heart, lung, heart-lung, liver, pancreas, and bone marrow transplants, and, as of April 2001, intestinal transplants.
- Approved DME for home use, such as oxygen equipment and wheelchairs, prosthetic devices, and surgical dressings, splints, and casts.
- Drugs and biologicals that cannot be self-administered, such as hepatitis B vaccines and immunosuppressive drugs (certain self-administered anticancer drugs are covered).

To be covered, all services must be either medically necessary or one of several prescribed preventive benefits. Part B services are generally subject to a deductible and coinsurance (see next section). Certain medical services and related care are subject to special payment rules, including deductibles (for blood), maximum approved amounts (for Medicare-approved physical, speech, or occupational therapy services performed in settings other than hospitals), and higher cost-sharing requirements (such as those for outpatient treatments for mental illness).

Medicare Advantage (Part C) is an expanded set of options for the delivery of healthcare under Medicare. While all Medicare beneficiaries can receive their benefits through the original fee-for-service program, most beneficiaries enrolled in both Part A and Part B can choose to participate in a Medicare Advantage plan instead. Organizations that seek to contract as Medicare Advantage plans must meet specific organizational, financial, and other requirements. Following are the primary Medicare Advantage plans:

- Coordinated care plans, which include health maintenance organizations (HMOs), provider-sponsored organizations (PSOs), preferred provider organizations (PPOs), and other certified coordinated care plans and entities that meet the standards set forth in the law.
- Private, unrestricted fee-for-service plans, which allow beneficiaries to select certain private providers. For those providers who agree to accept

the plan's payment terms and conditions, this option does not place the providers at risk, nor does it vary payment rates based on utilization.

These Medicare Advantage plans are required to provide at least the current Medicare benefit package, excluding hospice services. Plans may offer additional covered services and are required to do so (or return excess payments) if plan costs are lower than the Medicare payments received by the plan.

Beginning in 2006, a new regional Medicare Advantage plan program is established that allows regional coordinated care plans to participate in the Medicare Advantage program. Between 10 and 50 regions will be established, and plans wishing to participate must serve an entire region. There are provisions to encourage plan participation, and a fund will be established that can be used to encourage plan entry and limit plan withdrawals.

For individuals entitled to Part A or enrolled in Part B (except those entitled to Medicaid drug coverage), the new Part D initially provides access to prescription drug discount cards, at a cost of no more than $30 annually. For low-income beneficiaries, Part D initially provides transitional financial assistance (of up to $600 per year) for purchasing prescription drugs, plus a subsidized enrollment fee for the discount cards. This temporary plan began in mid-2004 and will phase out in 2006.

Beginning in 2006, Part D will provide subsidized access to prescription drug insurance coverage on a voluntary basis, upon payment of a premium, to individuals entitled to Part A or enrolled in Part B, with premium and cost-sharing subsidies for low-income enrollees. Beneficiaries may enroll in either a stand-alone prescription drug plan (PDP) or an integrated Medicare Advantage plan that offers Part D coverage. (Late enrollment penalties may apply under certain circumstances.)

Part D coverage includes most [Food and Drug Administration] FDA-approved prescription drugs and biologicals. (The specific drugs currently covered in Parts A and B will remain covered there.) Part D coverage can consist of either standard coverage (defined later) or an alternative design that provides the same actuarial value. (However, the specific actuarial equivalence test leaves very little flexibility for plans to design alternative coverage.) For an additional premium, plans may also offer supplemental coverage exceeding the value of basic coverage.

To encourage employer and union plans to continue to offer prescription drug coverage to Medicare retirees, Part D also provides for certain subsidies to those plans that meet specific criteria.

It should be noted that some healthcare services are not covered by Medicare. Non-covered services include long-term nursing care, custodial care, and certain other healthcare needs, such as dentures and dental care, eyeglasses, and hearing aids. These services are not a part of the Medicare

program unless they are a part of a private health plan under the Medicare Advantage program.

Program Financing, Beneficiary Liabilities, and Provider Payments

All financial operations for Medicare are handled through two trust funds, one for HI (Part A) and one for SMI (Parts B and D). These trust funds, which are special accounts in the U.S. Treasury, are credited with all receipts and charged with all expenditures for benefits and administrative costs. The trust funds cannot be used for any other purpose. Assets not needed for the payment of costs are invested in special Treasury securities. The following sections describe Medicare's financing provisions, beneficiary cost-sharing requirements, and the basis for determining Medicare reimbursements to healthcare providers.

Program Financing

The HI trust fund is financed primarily through a mandatory payroll tax. Almost all employees and self-employed workers in the United States work in employment covered by Part A and pay taxes to support the cost of benefits for aged and disabled beneficiaries. The Part A tax rate is 1.45 percent of earnings, to be paid by each employee and a matching amount by the employer for each employee, and 2.90 percent for self-employed persons. Beginning in 1994, this tax is paid on all covered wages and self-employment income without limit. (Prior to 1994, the tax applied only up to a specified maximum amount of earnings.) The Part A tax rate is specified in the Social Security Act and cannot be changed without legislation.

Part A also receives income from the following sources: (1) a portion of the income taxes levied on Social Security benefits paid to high-income beneficiaries; (2) premiums from certain persons who are not otherwise eligible and choose to enroll voluntarily; (3) reimbursements from the general fund of the U.S. Treasury for the cost of providing Part A coverage to certain aged persons who retired when Part A began and thus were unable to earn sufficient quarters of coverage (and those Federal retirees similarly unable to earn sufficient quarters of Medicare-qualified Federal employment); (4) interest earnings on its invested assets; and (5) other small miscellaneous income sources. The taxes paid each year are used mainly to pay benefits for current beneficiaries.

The SMI trust fund differs fundamentally from the HI trust fund with regard to the nature of its financing. As previously noted, SMI is now composed of two parts, Part B and Part D, each with its own separate account within the SMI trust fund. The nature of the financing for both parts of SMI

is similar, in that both parts are primarily financed by beneficiary premiums and contributions from the general fund of the U.S. Treasury.

Part B is financed through premium payments ($78.20 per beneficiary per month in 2005) and contributions from the general fund of the U.S. Treasury. (Penalties for late enrollment may apply.) Beneficiary premiums are generally set at a level that covers 25 percent of the average expenditures for aged beneficiaries. Therefore, the contributions from the general fund of the U.S. Treasury are the largest source of Part B income.

Similarly, Part D, once under way in 2006, will be financed primarily through premium payments and contributions from the general fund of the U.S. Treasury, with general fund contributions accounting for the largest source of Part D income, since beneficiary premiums are to represent, on average, 25.5 percent of the cost of standard coverage (as described in the next section). The premiums and general fund contributions for Part D will be determined separately from those for Part B. (In 2004 and 2005, the general fund of the U.S. Treasury will finance the transitional assistance benefit for low-income beneficiaries by providing funds to a Transitional Assistance account within the SMI trust fund. The proceeds will be transferred to the Part D account at the conclusion of the temporary program.)

The SMI trust fund also receives income from interest earnings on its invested assets, as well as a small amount of miscellaneous income. For both Parts B and D separately, beneficiary premiums and general fund payments are redetermined annually, to match estimated program costs for the following year. (Beginning in 2007, the Part B premium will be increased for beneficiaries meeting certain income thresholds.)

Capitation payments to Medicare Advantage plans are financed from both the HI trust fund and the Part B account within the SMI trust fund in proportion to the relative weights of Part A and Part B benefits to the total benefits paid by the Medicare program.

Beneficiary Payment Liabilities

Fee-for-service beneficiaries are responsible for charges not covered by the Medicare program and for various cost-sharing aspects of both Part A and Part B. These liabilities may be paid (1) by the Medicare beneficiary; (2) by a third party, such as an employer-sponsored retiree health plan or private "Medigap" insurance; or (3) by Medicaid, if the person is eligible. The term "Medigap" is used to mean private health insurance that pays, within limits, most of the healthcare service charges not covered by Parts A or B of Medicare. These policies, which must meet federally imposed standards, are offered by Blue Cross and Blue Shield and various commercial health insurance companies.

For beneficiaries enrolled in Medicare Advantage plans, the beneficiary's payment share is based on the cost-sharing structure of the specific

plan selected by the beneficiary, since each plan has its own requirements. Most plans have lower deductibles and coinsurance than are required of fee-for-service beneficiaries. Such beneficiaries pay the monthly Part B premium and may, depending on the plan, pay an additional plan premium.

For hospital care covered under Part A, a fee-for-service beneficiary's payment share includes a one-time deductible amount at the beginning of each benefit period ($912 in 2005). This deductible covers the beneficiary's part of the first 60 days of each spell of inpatient hospital care. If continued inpatient care is needed beyond the 60 days, additional coinsurance payments ($228 per day in 2005) are required through the 90th day of a benefit period. Each Part A beneficiary also has a "lifetime reserve" of 60 additional hospital days that may be used when the covered days within a benefit period have been exhausted. Lifetime reserve days may be used only once, and coinsurance payments ($456 per day in 2005) are required.

For skilled nursing care covered under Part A, Medicare fully covers the first 20 days of SNF care in a benefit period. But for days 21–100, a copayment ($115 per day in 2005) is required from the beneficiary. After 100 days of SNF care per benefit period, Medicare pays nothing for SNF care. Home health care has no deductible or coinsurance payment by the beneficiary. In any Part A service, the beneficiary is responsible for fees to cover the first 3 pints or units of non-replaced blood per calendar year. The beneficiary has the option of paying the fee or of having the blood replaced.

There are no premiums for most people covered by Part A. Eligibility is generally earned through the work experience of the beneficiary or of his or her spouse. However, most aged people who are otherwise ineligible for premium-free Part A coverage can enroll voluntarily by paying a monthly premium, if they also enroll in Part B. For people with fewer than 30 quarters of coverage as defined by the Social Security Administration (SSA), the 2005 Part A monthly premium rate is $375; for those with 30 to 39 quarters of coverage, the rate is reduced to $206. Voluntary coverage upon payment of the Part A premium, with or without enrolling in Part B, is also available to disabled individuals for whom cash benefits have ceased due to earnings in excess of those allowed for receiving cash benefits. (Penalties for late enrollment may apply.)

For Part B, the beneficiary's payment share includes the following: one annual deductible ($110 in 2005); the monthly premiums; the coinsurance payments for Part B services (usually 20 percent of the medically allowed charges); a deductible for blood; certain charges above the Medicare-allowed charge (for claims not on assignment); and payment for any services that are not covered by Medicare. For outpatient mental health treatment services, the beneficiary is liable for 50 percent of the approved charges.

For Part D, standard coverage is defined for 2006 as having a $250 deductible with 25 percent coinsurance (or other actuarially equivalent amounts)

for drug costs above the deductible and below an initial coverage limit of $2,250. The beneficiary is then responsible for all costs until a $3,600 out-of-pocket limit is reached. For higher costs, there is catastrophic coverage that requires enrollees to pay the greater of 5 percent coinsurance or a small copay ($2 for generic or preferred brands and $5 for any other drug). After 2006, these benefit parameters are indexed to the growth in per capita spending in Part D. In determining out-of-pocket costs, only those amounts actually paid by the enrollee or another individual (and not reimbursed through insurance) are counted. The exception to this provision is cost-sharing assistance from Medicare's low-income subsidies and from State Pharmacy Assistance programs. The monthly premiums required for Part D coverage are described in the previous section.

Provider Payments

For Part A, before 1983, payments to providers were made on a reasonable cost basis. Medicare payments for most inpatient hospital services are now made under a reimbursement mechanism known as the prospective payment system (PPS). Under PPS, a specific predetermined amount is paid for each inpatient hospital stay, based on each stay's diagnosis-related group (DRG) classification. In some cases the payment the hospital receives is less than the hospital's actual cost for providing the Part A-covered inpatient hospital services for the stay; in other cases it is more. The hospital absorbs the loss or makes a profit. Certain payment adjustments exist for extraordinarily costly inpatient hospital stays. Payments for skilled nursing care, home health care, inpatient rehabilitation, and long-term hospital care are made under separate prospective payment systems. Payments for psychiatric hospital care are currently reimbursed on a reasonable cost basis, but a prospective payment system is expected to be implemented in the near future, as required by the BBA.

For Part B, before 1992, physicians were paid on the basis of reasonable charge. This amount was initially defined as the lowest of (1) the physician's actual charge; (2) the physician's customary charge; or (3) the prevailing charge for similar services in that locality. Beginning January 1992, allowed charges were defined as the lesser of (1) the submitted charges, or (2) the amount determined by a fee schedule based on a relative value scale (RVS). Payments for DME and clinical laboratory services are also based on a fee schedule. Most hospital outpatient services are reimbursed on a prospective payment system, and home health care is reimbursed under the same prospective payment system as Part A.

If a doctor or supplier agrees to accept the Medicare-approved rate as payment in full ("takes assignment"), then payments provided must be considered as payments in full for that service. The provider may not request any added payments (beyond the initial annual deductible and coinsurance) from the beneficiary or insurer. If the provider does not take assignment, the

beneficiary will be charged for the excess (which may be paid by Medigap insurance). Limits now exist on the excess that doctors or suppliers can charge. Physicians are "participating physicians" if they agree before the beginning of the year to accept assignment for all Medicare services they furnish during the year. Since Medicare beneficiaries may select their doctors, they have the option to choose those who participate.

Medicare payments to Medicare Advantage plans are based on a blend of local and national capitated rates, generally determined by the capitation payment methodology described in section 1853 of the Social Security Act. Actual payments to plans vary based on demographic characteristics of the enrolled population. New "risk adjusters" based on demographics and health status are currently being phased in to better match Medicare capitation payments to the expected costs of individual beneficiaries. As previously mentioned, the Medicare Advantage program will undergo changes beginning in 2006. Plan bids will be replacing the current payment structure for Medicare Advantage plans.

For Part D, in 2006 and later, PDPs (including the prescription drug portion of Medicare Advantage plans) will pay for most FDA-approved prescription drugs and biologicals under the benefit structure described in the previous section. Plans may set up formularies for their prescription drug coverage, subject to statutory standards.

Medicare Claims Processing

Medicare's Part A and Part B fee-for-service claims are processed by nongovernment organizations or agencies that contract to serve as the fiscal agent between providers and the Federal Government. These claims processors are known as intermediaries and carriers. They apply the Medicare coverage rules to determine the appropriateness of claims.

Medicare intermediaries process Part A claims for institutional services, including inpatient hospital claims, SNFs, HHAs, and hospice services. They also process outpatient hospital claims for Part B. Examples of intermediaries are Blue Cross and Blue Shield (which utilize their plans in various States) and other commercial insurance companies. Intermediaries' responsibilities include the following:

- Determining costs and reimbursement amounts.
- Maintaining records.
- Establishing controls.
- Safeguarding against fraud and abuse or excess use.
- Conducting reviews and audits.
- Making the payments to providers for services.
- Assisting both providers and beneficiaries as needed.

Medicare carriers handle Part B claims for services by physicians and medical suppliers. Examples of carriers are the Blue Shield plans in a State, and various commercial insurance companies. Carriers' responsibilities include the following:

- Determining charges allowed by Medicare.
- Maintaining quality-of-performance records.
- Assisting in fraud and abuse investigations.
- Assisting both suppliers and beneficiaries as needed.
- Making payments to physicians and suppliers for services that are covered under Part B.

Claims for services provided by Medicare Advantage plans (that is, claims under Part C) are processed by the plans themselves.

Once Part D begins in earnest in 2006, plans will be responsible for claims processing, as is the case under Part C. However, there are a number of complex Part D claims processing provisions, and the administration of some of these provisions is not yet fully resolved. Future versions of this article will address these issues as they unfold.

Quality improvement organizations (QIOs; formerly called peer review organizations, or PROs) are groups of practicing healthcare professionals who are paid by the Federal Government to generally oversee the care provided to Medicare beneficiaries in each State and to improve the quality of services. QIOs educate other healthcare professionals and assist in the effective, efficient, and economical delivery of healthcare services to the Medicare population. The ongoing effort to combat monetary fraud and abuse in the Medicare program was intensified after enactment of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191), which created the Medicare Integrity Program. Prior to this 1996 legislation, the Centers for Medicare & Medicaid Services (CMS) was limited by law to contracting with its current carriers and fiscal intermediaries to perform payment safeguard activities. The Medicare Integrity Program provided CMS with stable, increasing funding for payment safeguard activities, as well as new authorities to contract with entities to perform specific payment safeguard functions.

Administration

The Department of Health and Human Services (DHHS) has the overall responsibility for administration of the Medicare program. Within DHHS, responsibility for administering Medicare rests with CMS. SSA assists, however, by initially determining an individual's Medicare entitlement, by withholding Part B premiums (and, once applicable beginning in 2006, Part D

premiums) from the Social Security benefit checks of beneficiaries, and by maintaining Medicare data on the master beneficiary record, which is SSA's primary record of beneficiaries. The Internal Revenue Service in the Department of the Treasury collects the Part A payroll taxes from workers and their employers.

A Board of Trustees, composed of two appointed members of the public and four members who serve by virtue of their positions in the Federal Government, oversees the financial operations of the HI and SMI trust funds. The Secretary of the Treasury is the managing trustee. The Board of Trustees reports to Congress on the financial and actuarial status of the Medicare trust funds on or about the first day of April each year.

State agencies (usually State Health Departments under agreements with CMS) identify, survey, and inspect provider and supplier facilities and institutions wishing to participate in the Medicare program. In consultation with CMS, these agencies then certify the facilities that are qualified.

Data Summary

The Medicare program covers 95 percent of our nation's aged population, as well as many people who are on Social Security because of disability. In 2003, Part A covered about 41 million enrollees with benefit payments of $152.1 billion, and Part B covered about 38 million enrollees with benefit payments of $123.8 billion. Administrative costs for both Parts A and B were under 2 percent of disbursements in 2003. Total disbursements for Medicare in 2003 were $280.8 billion.

SOURCE: Reprinted from a summary of the Medicare program prepared by Earl Dirk Hoffman, Jr., Barbara S. Klees, and Catherine A. Curtis, Office of the Actuary, Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services. This version was prepared in November 2004. Periodic updates of the summary can be found on the CMS web site at www.cms.hhs.gov/publications/overview-medicare-medicaid/default.asp.

APPENDIX

B

OVERVIEW OF MEDICAID

Title XIX of the Social Security Act is a Federal/State entitlement program that pays for medical assistance for certain individuals and families with low incomes and resources. This program, known as Medicaid, became law in 1965 as a cooperative venture jointly funded by the Federal and State governments (including the District of Columbia and the Territories) to assist States in furnishing medical assistance to eligible needy persons. Medicaid is the largest source of funding for medical and health-related services for America's poorest people.

Within broad national guidelines established by Federal statutes, regulations, and policies, each State (1) establishes its own eligibility standards; (2) determines the type, amount, duration, and scope of services; (3) sets the rate of payment for services; and (4) administers its own program. Medicaid policies for eligibility, services, and payment are complex and vary considerably, even among States of similar size or geographic proximity. Thus, a person who is eligible for Medicaid in one State may not be eligible in another State, and the services provided by one State may differ considerably in amount, duration, or scope from services provided in a similar or neighboring State. In addition, State legislatures may change Medicaid eligibility, services, and/or reimbursement during the year.

Basis of Eligibility and Maintenance Assistance Status

Medicaid does not provide medical assistance for all poor persons. Under the broadest provisions of the Federal statute, Medicaid does not provide healthcare services even for very poor persons unless they are in one of the groups designated below. Low income is only one test for Medicaid eligibility for those within these groups; their resources also are tested against threshold levels (as determined by each State within Federal guidelines).

States generally have broad discretion in determining which groups their Medicaid programs will cover and the financial criteria for Medicaid eligibility. To be eligible for Federal funds, however, States are required to provide Medicaid coverage for certain individuals who receive federally assisted income-maintenance payments, as well as for related groups not receiving cash payments. In addition to their Medicaid programs, most States have additional "State-only" programs to provide medical assistance for specified

poor persons who do not qualify for Medicaid. Federal funds are not provided for State-only programs. The following enumerates the mandatory Medicaid "categorically needy" eligibility groups for which Federal matching funds are provided:

- Individuals are generally eligible for Medicaid if they meet the requirements for the Aid to Families with Dependent Children (AFDC) program that were in effect in their State on July 16, 1996.
- Children under age 6 whose family income is at or below 133 percent of the Federal poverty level (FPL).
- Pregnant women whose family income is below 133 percent of the FPL (services to these women are limited to those related to pregnancy, complications of pregnancy, delivery, and postpartum care).
- Supplemental Security Income (SSI) recipients in most States (some States use more restrictive Medicaid eligibility requirements that pre-date SSI).
- Recipients of adoption or foster care assistance under Title IV of the Social Security Act.
- Special protected groups (typically individuals who lose their cash assistance due to earnings from work or from increased Social Security benefits, but who may keep Medicaid for a period of time).
- All children born after September 30, 1983 who are under age 19, in families with incomes at or below the FPL.
- Certain Medicare beneficiaries (described later).

States also have the option of providing Medicaid coverage for other "categorically related" groups. These optional groups share characteristics of the mandatory groups (that is, they fall within defined categories), but the eligibility criteria are somewhat more liberally defined. The broadest optional groups for which States will receive Federal matching funds for coverage under the Medicaid program include the following:

- Infants up to age 1 and pregnant women not covered under the mandatory rules whose family income is no more than 185 percent of the FPL (the percentage amount is set by each State).
- Children under age 21 who meet criteria more liberal than the AFDC income and resources requirements that were in effect in their State on July 16, 1996.
- Institutionalized individuals eligible under a "special income level" (the amount is set by each State—up to 300 percent of the SSI Federal benefit rate).
- Individuals who would be eligible if institutionalized, but who are receiving care under home and community-based services (HCBS) waivers.

- Certain aged, blind, or disabled adults who have incomes above those requiring mandatory coverage, but below the FPL.
- Recipients of State supplementary income payments.
- Certain working-and-disabled persons with family income less than 250 percent of the FPL who would qualify for SSI if they did not work.
- TB-infected persons who would be financially eligible for Medicaid at the SSI income level if they were within a Medicaid-covered category (however, coverage is limited to TB-related ambulatory services and TB drugs).
- Certain uninsured or low-income women who are screened for breast or cervical cancer through a program administered by the Centers for Disease Control. The Breast and Cervical Cancer Prevention and Treatment Act of 2000 (Public Law 106-354) provides these women with medical assistance and follow-up diagnostic services through Medicaid.
- "Optional targeted low-income children" included within the State Children's Health Insurance Program (SCHIP) established by the Balanced Budget Act (BBA) of 1997 (Public Law 105-33).
- "Medically needy" persons (described below).

The medically needy (MN) option allows States to extend Medicaid eligibility to additional persons. These persons would be eligible for Medicaid under one of the mandatory or optional groups, except that their income and/or resources are above the eligibility level set by their State. Persons may qualify immediately or may "spend down" by incurring medical expenses that reduce their income to or below their State's MN income level.

Medicaid eligibility and benefit provisions for the medically needy do not have to be as extensive as for the categorically needy, and may be quite restrictive. Federal matching funds are available for MN programs. However, if a State elects to have a MN program, there are Federal requirements that certain groups and certain services must be included; that is, children under age 19 and pregnant women who are medically needy must be covered, and prenatal and delivery care for pregnant women, as well as ambulatory care for children, must be provided. A State may elect to provide MN eligibility to certain additional groups and may elect to provide certain additional services within its MN program. As of August 2002, thirty-five States plus the District of Columbia have elected to have a MN program and are providing at least some MN services to at least some MN beneficiaries. All remaining States utilize the "special income level" option to extend Medicaid to the "near poor" in medical institutional settings.

The Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (Public Law 104-193)—known as the "welfare reform" bill—made restrictive changes regarding eligibility for SSI coverage that impacted the Medicaid program. For example, legal resident aliens and other qualified aliens

who entered the United States on or after August 22, 1996 are ineligible for Medicaid for 5 years. Medicaid coverage for most aliens entering before that date and coverage for those eligible after the 5-year ban are State options; emergency services, however, are mandatory for both of these alien coverage groups. For aliens who lose SSI benefits because of the new restrictions regarding SSI coverage, Medicaid can continue only if these persons can be covered for Medicaid under some other eligibility status (again with the exception of emergency services, which are mandatory). Public Law 104-193 also affected a number of disabled children, who lost SSI as a result of the restrictive changes; however, their eligibility for Medicaid was reinstituted by Public Law 105-33, the BBA.

In addition, welfare reform repealed the open-ended Federal entitlement program known as Aid to Families with Dependent Children (AFDC) and replaced it with Temporary Assistance for Needy Families (TANF), which provides States with grants to be spent on time-limited cash assistance. TANF generally limits a family's lifetime cash welfare benefits to a maximum of 5 years and permits States to impose a wide range of other requirements as well—in particular, those related to employment. However, the impact on Medicaid eligibility is not expected to be significant. Under welfare reform, persons who would have been eligible for AFDC under the AFDC requirements in effect on July 16, 1996 generally will still be eligible for Medicaid. Although most persons covered by TANF will receive Medicaid, it is not required by law.

Title XXI of the Social Security Act, known as the State Children's Health Insurance Program (SCHIP), is a new program initiated by the BBA. In addition to allowing States to craft or expand an existing State insurance program, SCHIP provides more Federal funds for States to expand Medicaid eligibility to include a greater number of children who are currently uninsured. With certain exceptions, these are low-income children who would not qualify for Medicaid based on the plan that was in effect on April 15, 1997. Funds from SCHIP also may be used to provide medical assistance to children during a presumptive eligibility period for Medicaid. This is one of several options from which States may select to provide healthcare coverage for more children, as prescribed within the BBA's Title XXI program.

Medicaid coverage may begin as early as the third month prior to application—if the person would have been eligible for Medicaid had he or she applied during that time. Medicaid coverage generally stops at the end of the month in which a person no longer meets the criteria of any Medicaid eligibility group. The BBA allows States to provide 12 months of continuous Medicaid coverage (without reevaluation) for eligible children under the age of 19.

The Ticket to Work and Work Incentives Improvement Act of 1999 (Public Law 106-170) provides or continues Medicaid coverage to certain disabled beneficiaries who work despite their disability. Those with higher incomes may pay a sliding scale premium based on income.

Scope of Medicaid Services

Title XIX of the Social Security Act allows considerable flexibility within the States' Medicaid plans. However, some Federal requirements are mandatory if Federal matching funds are to be received. A State's Medicaid program must offer medical assistance for certain basic services to most categorically needy populations. These services generally include the following:

- Inpatient hospital services.
- Outpatient hospital services.
- Prenatal care.
- Vaccines for children.
- Physician services.
- Nursing facility services for persons aged 21 or older.
- Family planning services and supplies.
- Rural health clinic services.
- Home health care for persons eligible for skilled-nursing services.
- Laboratory and x-ray services.
- Pediatric and family nurse practitioner services.
- Nurse-midwife services.
- Federally qualified health-center (FQHC) services, and ambulatory services of an FQHC that would be available in other settings.
- Early and periodic screening, diagnostic, and treatment (EPSDT) services for children under age 21.

States may also receive Federal matching funds to provide certain optional services. Following are the most common of the thirty-four currently approved optional Medicaid services:

- Diagnostic services.
- Clinic services.
- Intermediate care facilities for the mentally retarded (ICFs/MR).
- Prescribed drugs and prosthetic devices.
- Optometrist services and eyeglasses.
- Nursing facility services for children under age 21.
- Transportation services.
- Rehabilitation and physical therapy services.
- Home and community-based care to certain persons with chronic impairments.

The BBA included a State option known as Programs of All-inclusive Care for the Elderly (PACE). PACE provides an alternative to institutional care for persons aged 55 or older who require a nursing facility level of care. The PACE team offers and manages all health, medical, and social services and mobilizes other services as needed to provide preventative, rehabilitative,

curative, and supportive care. This care, provided in day health centers, homes, hospitals, and nursing homes, helps the person maintain independence, dignity, and quality of life. PACE functions within the Medicare program as well. Regardless of source of payment, PACE providers receive payment only through the PACE agreement and must make available all items and services covered under both Titles XVIII and XIX, without amount, duration, or scope limitations and without application of any deductibles, copayments, or other cost sharing. The individuals enrolled in PACE receive benefits solely through the PACE program.

Amount and Duration of Medicaid Services

Within broad Federal guidelines and certain limitations, States determine the amount and duration of services offered under their Medicaid programs. States may limit, for example, the number of days of hospital care or the number of physician visits covered. Two restrictions apply: (1) limits must result in a sufficient level of services to reasonably achieve the purpose of the benefits; and (2) limits on benefits may not discriminate among beneficiaries based on medical diagnosis or condition.

In general, States are required to provide comparable amounts, duration, and scope of services to all categorically needy and categorically related eligible persons. There are two important exceptions: (1) Medically necessary healthcare services that are identified under the EPSDT program for eligible children, and that are within the scope of mandatory or optional services under Federal law, must be covered even if those services are not included as part of the covered services in that State's Plan; and (2) States may request "waivers" to pay for otherwise uncovered home and community-based services (HCBS) for Medicaid-eligible persons who might otherwise be institutionalized. As long as the services are cost effective, States have few limitations on the services that may be covered under these waivers (except that, other than as a part of respite care, States may not provide room and board for the beneficiaries). With certain exceptions, a State's Medicaid program must allow beneficiaries to have some informed choices among participating providers of healthcare and to receive quality care that is appropriate and timely.

Payment for Medicaid Services

Medicaid operates as a vendor payment program. States may pay healthcare providers directly on a fee-for-service basis, or States may pay for Medicaid services through various prepayment arrangements, such as health maintenance organizations (HMOs). Within federally imposed upper limits and specific restrictions, each State for the most part has broad discretion in determining

the payment methodology and payment rate for services. Generally, payment rates must be sufficient to enlist enough providers so that covered services are available at least to the extent that comparable care and services are available to the general population within that geographic area. Providers participating in Medicaid must accept Medicaid payment rates as payment in full. States must make additional payments to qualified hospitals that provide inpatient services to a disproportionate number of Medicaid beneficiaries and/or to other low-income or uninsured persons under what is known as the "disproportionate share hospital" (DSH) adjustment. During 1988–1991, excessive and inappropriate use of the DSH adjustment resulted in rapidly increasing Federal expenditures for Medicaid. Under legislation passed in 1991, 1993, and again within the BBA of 1997, the Federal share of payments to DSH hospitals was somewhat limited. However, the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act (BIPA) of 2000 (Public Law 106-554) increased DSH allotments for 2001 and 2002 and made other changes to DSH provisions that resulted in increased costs to the Medicaid program.

States may impose nominal deductibles, coinsurance, or copayments on some Medicaid beneficiaries for certain services. The following Medicaid beneficiaries, however, must be excluded from cost sharing: pregnant women, children under age 18, and hospital or nursing home patients who are expected to contribute most of their income to institutional care. In addition, all Medicaid beneficiaries must be exempt from copayments for emergency services and family planning services.

The Federal Government pays a share of the medical assistance expenditures under each State's Medicaid program. That share, known as the Federal Medical Assistance Percentage (FMAP), is determined annually by a formula that compares the State's average per capita income level with the national income average. States with a higher per capita income level are reimbursed a smaller share of their costs. By law, the FMAP cannot be lower than 50 percent or higher than 83 percent. In fiscal year (FY) 2004, the FMAPs varied from 50 percent in twelve States to 77.08 percent in Mississippi, and averaged 60.2 percent overall. The BBA also permanently raised the FMAP for the District of Columbia from 50 percent to 70 percent and raised the FMAP for Alaska from 50 percent to 59.8 percent through 2000. The BIPA of 2000 further adjusted Alaska's FMAP to a higher level for FY 2001–2005. The Jobs and Growth Tax Relief Reconciliation Act of 2003 (Public Law 108-27), in order to bring about State fiscal relief in the current troubled economy, has made three temporary modifications to the States' FMAP calculation: (1) the FMAP for the last two quarters of 2003 will equal the greater of the current law FMAPs for 2002 or 2003; (2) the FMAP for the first three quarters of 2004 will equal the greater of the current law FMAPs for 2003 or 2004; and (3) for the last two quarters of 2003 and first three quarters of 2004, the newly calculated (under 1 and 2 above) FMAP will increase by 2.95 percentage points. The Federal Government pays States a higher share for children covered through

the SCHIP program. This "enhanced" FMAP averages about 70 percent for all States, compared to the general Medicaid average of 60.2 percent.

The Federal Government also reimburses States for 100 percent of the cost of services provided through facilities of the Indian Health Service, provides financial help to the twelve States that furnish the highest number of emergency services to undocumented aliens, and shares in each State's expenditures for the administration of the Medicaid program. Most administrative costs are matched at 50 percent, although higher percentages are paid for certain activities and functions, such as development of mechanized claims processing systems.

Except for the SCHIP program, the Qualifying Individuals (QI) program (described later), and DSH payments, Federal payments to States for medical assistance have no set limit (cap). Rather, the Federal Government matches (at FMAP rates) State expenditures for the mandatory services, as well as for the optional services that the individual State decides to cover for eligible beneficiaries, and matches (at the appropriate administrative rate) all necessary and proper administrative costs. The Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (as incorporated into Public Law 106-113, the appropriations bill for the District of Columbia for FY 2000) increased the amount that certain States and the territories can spend on DSH and SCHIP payments, respectively. The BIPA set upper payment limits for inpatient and outpatient services provided by certain types of facilities.

Medicaid Summary and Trends

Medicaid was initially formulated as a medical care extension of federally funded programs providing cash income assistance for the poor, with an emphasis on dependent children and their mothers, the disabled, and the elderly. Over the years, however, Medicaid eligibility has been incrementally expanded beyond its original ties with eligibility for cash programs. Legislation in the late 1980s assured Medicaid coverage to an expanded number of low-income pregnant women, poor children, and to some Medicare beneficiaries who are not eligible for any cash assistance program. Legislative changes also focused on increased access, better quality of care, specific benefits, enhanced outreach programs, and fewer limits on services.

In most years since its inception, Medicaid has had very rapid growth in expenditures. This rapid growth has been due primarily to the following factors:

- The increase in size of the Medicaid-covered populations as a result of Federal mandates, population growth, and economic recessions.
- The expanded coverage and utilization of services.

- The DSH payment program, coupled with its inappropriate use to increase Federal payments to States.
- The increase in the number of very old and disabled persons requiring extensive acute and/or long-term healthcare and various related services.
- The results of technological advances to keep a greater number of very low-birth-weight babies and other critically ill or severely injured persons alive and in need of continued extensive and very costly care.
- The increase in drug costs and the availability of new expensive drugs.
- The increase in payment rates to providers of healthcare services, when compared to general inflation.

As with all health insurance programs, most Medicaid beneficiaries incur relatively small average expenditures per person each year, and a relatively small proportion incurs very large costs. Moreover, the average cost varies substantially by type of beneficiary. National data for 2001, for example, indicate that Medicaid payments for services for 23.3 million children, who constitute 50 percent of all Medicaid beneficiaries, average about $1,305 per child (a relatively small average expenditure per person). Similarly, for 11.6 million adults, who comprise 25 percent of beneficiaries, payments average about $1,725 per person. However, certain other specific groups have much larger per-person expenditures. Medicaid payments for services for 4.4 million aged, constituting 9 percent of all Medicaid beneficiaries, average about $10,965 per person; for 7.7 million disabled, who comprise 16 percent of beneficiaries, payments average about $10,455 per person. When expenditures for these high- and lower-cost beneficiaries are combined, the 2001 payments to healthcare vendors for 47.0 million Medicaid beneficiaries average $3,965 per person.

Long-term care is an important provision of Medicaid that will be increasingly utilized as our nation's population ages. The Medicaid program paid for over 41 percent of the total cost of care for persons using nursing facility or home health services in 2001. National data for 2001 show that Medicaid payments for nursing facility services (excluding ICFs/MR) totaled $37.2 billion for more than 1.7 million beneficiaries of these services—an average expenditure of $21,890 per nursing home beneficiary. The national data also show that Medicaid payments for home health services totaled $3.5 billion for more than 1.0 million beneficiaries—an average expenditure of $3,475 per home healthcare beneficiary. With the percentage of our population who are elderly or disabled increasing faster than that of the younger groups, the need for long-term care is expected to increase.

Another significant development in Medicaid is the growth in managed care as an alternative service delivery concept different from the traditional fee-for-service system. Under managed care systems, HMOs, prepaid health plans (PHPs), or comparable entities agree to provide a specific set of services to Medicaid enrollees, usually in return for a predetermined periodic payment

per enrollee. Managed care programs seek to enhance access to quality care in a cost-effective manner. Waivers may provide the States with greater flexibility in the design and implementation of their Medicaid managed care programs. Waiver authority under sections 1915(b) and 1115 of the Social Security Act is an important part of the Medicaid program. Section 1915(b) waivers allow States to develop innovative healthcare delivery or reimbursement systems. Section 1115 waivers allow Statewide healthcare reform experimental demonstrations to cover uninsured populations and to test new delivery systems without increasing costs. Finally, the BBA provided States a new option to use managed care. The number of Medicaid beneficiaries enrolled in some form of managed care program is growing rapidly, from 14 percent of enrollees in 1993 to 59 percent in 2003.

More than 46.0 million persons received healthcare services through the Medicaid program in FY 2001 (the last year for which beneficiary data are available). In FY 2003, total outlays for the Medicaid program (Federal and State) were $278.3 billion, including direct payment to providers of $197.3 billion, payments for various premiums (for HMOs, Medicare, etc.) of $52.1 billion, payments to disproportionate share hospitals of $12.9 billion, and administrative costs of $16.0 billion. Outlays under the SCHIP program in FY 2003 were $6.1 billion. With no changes to either program, expenditures under Medicaid and SCHIP are projected to reach $445 billion and $7.5 billion, respectively, by FY 2009.

The Medicaid-Medicare Relationship

Medicare beneficiaries who have low incomes and limited resources may also receive help from the Medicaid program. For such persons who are eligible for full Medicaid coverage, the Medicare healthcare coverage is supplemented by services that are available under their State's Medicaid program, according to eligibility category. These additional services may include, for example, nursing facility care beyond the 100-day limit covered by Medicare, prescription drugs, eyeglasses, and hearing aids. For persons enrolled in both programs, any services that are covered by Medicare are paid for by the Medicare program before any payments are made by the Medicaid program, since Medicaid is always the "payer of last resort."

Certain other Medicare beneficiaries may receive help with Medicare premium and cost-sharing payments through their State Medicaid program. Qualified Medicare Beneficiaries (QMBs) and Specified Low-Income Medicare Beneficiaries (SLMBs) are the best-known categories and the largest in numbers. QMBs are those Medicare beneficiaries who have resources at or below twice the standard allowed under the SSI program, and incomes at or below 100 percent of the FPL. For QMBs, Medicaid pays the Hospital Insurance (HI, or Part A) and Supplementary Medical Insurance (SMI) Part B premiums and the Medicare coinsurance and deductibles, subject to limits

that States may impose on payment rates. SLMBs are Medicare beneficiaries with resources like the QMBs, but with incomes that are higher, though still less than 120 percent of the FPL. For SLMBs, the Medicaid program pays only the Part B premiums. A third category of Medicare beneficiaries who may receive help consists of disabled-and-working individuals. According to the Medicare law, disabled-and-working individuals who previously qualified for Medicare because of disability, but who lost entitlement because of their return to work (despite the disability), are allowed to purchase Medicare Part A and Part B coverage. If these persons have incomes below 200 percent of the FPL but do not meet any other Medicaid assistance category, they may qualify to have Medicaid pay their Part A premiums as Qualified Disabled and Working Individuals (QDWIs).

For Medicare beneficiaries with incomes that are above 120 percent and less than 175 percent of the FPL, the BBA establishes a capped allocation to States, for each of the 5 years beginning January 1998, for payment of all or some of the Medicare Part B premiums. These beneficiaries are known as Qualifying Individuals (QIs). Unlike QMBs and SLMBs, who may be eligible for other Medicaid benefits in addition to their QMB/SLMB benefits, the QIs cannot be otherwise eligible for medical assistance under a State plan. The payment of this QI benefit is 100 percent federally funded, up to the State's allocation.

The Centers for Medicare & Medicaid Services (CMS) estimates that Medicaid currently provides some level of supplemental health coverage for about 6.5 million Medicare beneficiaries. Starting January 2006, the new Medicare prescription drug benefit will provide drug coverage for Medicare beneficiaries, including those who also receive coverage from Medicaid. In addition, individuals eligible for both Medicare and Medicaid will also receive the low-income subsidy for both the Medicare drug plan premium and assistance with cost sharing for prescriptions. Medicaid will no longer provide drug benefits for Medicare beneficiaries.

Since the Medicare drug benefit and low-income subsidy will replace a portion of State Medicaid expenditures for drugs, States would see a reduction in Medicaid expenditures. To offset this reduction, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173) requires each State to make a monthly payment to Medicare representing a percentage of the projected reduction. For 2006 this payment is 90 percent of the projected 2006 reduction in State spending. After 2006 the percentage decreases by 1–2/3 percent per year to 75 percent for 2014 and later.

SOURCE: Reprinted from a summary of the Medicaid program prepared by Earl Dirk Hoffman, Jr., Barbara S. Klees, and Catherine A. Curtis, Office of the Actuary, Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services. This version was prepared in November 2004. Periodic updates of the summary can be found on the CMS website at www.cms.hhs.gov/publications/overview-medicare-medicaid/default.asp.

APPENDIX

C

BRIEFLY ANNOTATED CHRONOLOGICAL LIST OF SELECTED U.S. FEDERAL LAWS PERTAINING TO HEALTH[1]

1798

An act of July 16, 1798, passed by the Fifth Congress of the United States, taxed the employers of merchant seamen to fund arrangements for their healthcare through the Marine Hospital Service. In the language of the act, "the master or owner of every ship or vessel of the United States arriving from a foreign port into any port in the United States shall . . . render to the collector a true account of the number of seamen that shall have been employed on board such vessel . . . and shall pay to the said collector, at the rate of twenty cents per month, for every seaman so employed . . ." The act stipulated in Section 2 that "the President of the United States is hereby authorized, out of the same, to provide for the temporary relief and maintenance of sick or disabled seamen in the hospitals, or other proper institutions now established in the several ports. . . ."

1882

An act of August 3, 1882, was the nation's first general immigration law and included the first federal medical excludability provisions affecting those who wished to immigrate to the United States. The act authorized state officials to board arriving ships to examine the condition of passengers. In the language of the act, "if on such examination, there shall be found among such passengers any convict, lunatic, idiot, or any person unable to take care of himself or herself without becoming a public charge, . . . such persons shall not be permitted to land."

1891

An act of March 3, 1891, added the phrase, "persons suffering from a loathsome or a contagious disease" to the list of medical excludability criteria for people seeking to immigrate to the United States.

1902

P.L. 57-244[2] the *Biologics Control Act*, was the first federal law regulating the interstate and foreign sale of biologics (viruses, serums, toxins, and analogous products). The law established a national board and gave its members authority to establish regulations for licensing producers of biologics.

1906

P.L. 59-384, the *Pure Food and Drug Act* (also known as the Wiley Act), defined adulterated and mislabeled foods and drugs and prohibited their transport in interstate commerce. Passage of this legislation followed several years of intense campaigning by reformers and extensive newspaper coverage of examples of unwholesome and adulterated foods and of the widespread use of ineffective patent medicines.

1920

P.L. 66-141, the *Snyder Act*, was the first federal legislation pertaining to healthcare for Native Americans. Prior to the passage of this legislation, there were some health-related provisions in treaties between the government and the Native Americans, but this was the first formal legislation on the subject. The act provided for general assistance, directing "the Bureau of Indian Affairs, under the supervision of the Secretary of the Interior to direct, supervise, and expend such monies as Congress may from time to time appropriate, for the benefit, care, and assistance of the Indians throughout the United States. . . ."

1921

P.L. 67-97, the *Maternity and Infancy Act* (also known as the Sheppard-Towner Act), provided grants to states to help them develop health services for mothers and their children. The law was allowed to lapse in 1929, although it has served as a prototype for federal grants in aid to the states.

1935

P.L. 74-271, the *Social Security Act*, a landmark law developed and passed during the Great Depression, established the Social Security program of old-age benefits. The legislation also included provisions for other benefits such as federal financial assistance to the states for their public assistance programs

for the needy elderly, dependent children, and the blind. This legislation also provided incentives for the establishment of state unemployment funds and provided financial assistance for maternal and child health and child welfare services and significantly increased federal assistance for state and local public health programs.

1936

P.L. 74-846, the *Walsh-Healy Act*, authorized federal regulation of industrial safety in companies doing business with the U.S. government.

1937

P.L. 75-244, the *National Cancer Institute Act*, established the first categorical institute within the National Institute of Health (NIH), which had been created in 1930 to serve as the administrative home for the research conducted by the U.S. Public Health Service.

1938

P.L. 75-540, the *LaFollette-Bulwinkle Act*, provided grants in aid to the states to support their investigation and control of venereal disease.

P.L. 75-717, the *Food, Drug, and Cosmetic Act*, extended federal authority to ban new drugs from the market until they were approved by the Food and Drug Administration (FDA). This law also gave the federal government more extensive power in dealing with adulterated or mislabeled food, drugs, and cosmetic products.

1939

P.L. 76-19, the *Reorganization Act*, transferred the Public Health Service from the Treasury Department to the new Federal Security Agency (FSA). In 1953 the FSA was transformed into the U.S. Department of Health, Education, and Welfare (DHEW), which, with the subsequent establishment of a new cabinet level Department of Education in 1980, was itself transformed into the U.S. Department of Health and Human Services (DHHS).

1941

P.L. 77-146, the *Nurse Training Act*, provided schools of nursing with support to permit them to increase enrollments and improve their physical facilities.

1944

P.L. 78-410, the *Public Health Service Act*, revised and consolidated in one place all existing legislation pertaining to the U.S. Public Health Service. The legislation provided for the organization, staffing, and functions and activities of the Public Health Service. This law has subsequently been used as a vehicle, through amendments to the legislation, for a number of important federal grant-in-aid programs.

1945

P.L. 79-15, the *McCarran-Ferguson Act*, expressly exempted the "business of insurance" from federal antitrust legislation (the Sherman Antitrust Act of 1890, the Clayton Act of 1914, and the Federal Trade Commission Act of 1914) to the extent that insurance was regulated by state law and did not involve "acts of boycott, coercion, or intimidation." A significant part of the underlying reasoning Congress used in exempting insurance, including health insurance, was the view that the determination of underwriting risks would require the cooperation and sharing of information among competing insurance companies.

1946

P.L. 79-487, the *National Mental Health Act*, authorized extensive federal support for mental health research and treatment programs and established grants in aid to the states for their mental health activities. The legislation also transformed the Public Health Services' Division of Mental Health into the National Institute of Mental Health.

P.L. 79-725, the *Hospital Survey and Construction Act* (also known as the Hill-Burton Act), was "An Act to amend the Public Health Service Act (see the 1944 P.L. 78-410 above) to authorize grants to the States for surveying their hospital and public health centers and for planning construction of additional facilities, and to authorize grants to assist in such construction." The legislation was enacted because Congress recognized a widespread shortage of hospital facilities (few were built during the Great Depression and World War II). Under provisions of the act, the states were required to submit a state plan for the construction of hospital facilities based on a survey of need to receive federal funds, which could be dispersed for projects within states.

1948

P.L. 80-655, the *National Health Act*, pluralized NIH by establishing a second categorical institute, the National Heart Institute. Hereafter, NIH became the National Institutes of Health.

P.L. 80-845, the *Water Pollution Control Act*, was enacted in part "in consequence of the benefits to the public health and welfare by the abatement of stream pollution. . . ." The act left the primary responsibility for water pollution control with the states.

1952

P.L. 82-414, the *Immigration and Nationality Act* (also known as the McCarran-Walter Act), followed an extensive study by Congress of immigration policy and practice. Among the law's provisions were a number of modifications in the medical excludability scheme affecting people wishing to immigrate to the United States. The act contained extensive provisions for observation and examination of aliens for the purpose of determining if they should be excluded for any of a number of specified "diseases or mental or physical defects or disabilities."

1954

P.L. 83-482, the *Medical Facilities Survey and Construction Act*, amended the Hill-Burton Act (see the 1946 P.L. 79-725) to greatly expand the Hill-Burton program's scope. The legislation authorized grants for surveys and construction of diagnostic and treatment centers (including hospital outpatient departments), chronic disease hospitals, rehabilitation facilities, and nursing homes.

P.L. 83-703, the *Atomic Energy Act*, established the Atomic Energy Commission and authorized it to license the use of atomic material in medical care.

1955

P.L. 84-159, the *Air Pollution Control Act*, provided for a program of research and technical assistance related to air pollution control. The law was enacted in part "in recognition of the dangers to the public health and welfare . . . from air pollution. . . ."

P.L. 84-377, the *Polio Vaccination Assistance Act*, provided for federal assistance to states for the operation of their polio vaccination programs.

1956

P.L. 84-569, the *Dependents Medical Care Act*, established the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS) for the dependents of military personnel.

P.L. 84-652, the *National Health Survey Act*, provided for the first system of regularly collected health-related data by the Public Health Service. This continuing process is called the Health Interview Survey and provides a national U.S. household interview study of illness, disability, and health services utilization.

P.L. 84-660, the *Water Pollution Control Act Amendments of 1956*, amended the Water Pollution Control Act (see the 1948 P.L. 80-845) and provided for federal technical services and financial aid to the states and to municipalities in their efforts to prevent and control water pollution.

P.L. 84-911, the *Health Amendments Act*, amended the Public Health Service Act (see the 1944 P.L. 78-410) by initiating federal assistance for the education and training of health personnel. Specifically, the law authorized traineeships for public health personnel and for advanced training for nurses. This support has been gradually broadened and extended by subsequent legislation to many categories of health personnel.

1958

P.L. 85-544, *Grants-in-Aid to Schools of Public Health*, established a program of formula grants to the nation's schools of public health.

P.L. 85-929, the *Food Additive Amendment*, amended the Food, Drug, and Cosmetic Act (see the 1938 P.L. 75-717) to require premarketing clearance from FDA for new food additives. The so-called Delaney clause, after Representative James Delaney, who sponsored the provision, stated that "no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal. . . ."

1959

P.L. 86-121, the *Indian Sanitation Facilities Act*, provided for the surgeon general to "construct, improve, extend, or otherwise provide and maintain, by contract or otherwise, essential sanitation facilities for Indian homes, communities, and lands. . . ."

P.L. 86-352, the *Federal Employees Health Benefits Act*, permitted Blue Cross to negotiate a contract with the Civil Service Commission to provide health insurance coverage for federal employees. The contract served as a

prototype for Blue Cross's subsequent involvement in the Medicare and Medicaid programs as a fiscal intermediary.

1960

P.L. 86-778, *the Social Security Amendments* (also known as the Kerr-Mills Act), amended the Social Security Act (see the 1935 P.L. 74-271) to establish a new program of medical assistance for the aged. Through this program, the federal government provided aid to the states for payments for medical care for "medically indigent" persons who were 65 years of age or older. The Kerr-Mills program, as it was called, was the forerunner of the Medicaid program established in 1965 (see P.L. 89-97).

1962

P.L. 87-692, the *Health Services for Agricultural Migratory Workers Act*, authorized federal grants to clinics serving migrant farm workers and their families.

P.L. 87-781, the *Drug Amendments* (also known as the Kefauver-Harris amendments), amended the Food, Drug, and Cosmetic Act (see the 1938 P.L. 75-717) to significantly strengthen the provisions related to the regulation of therapeutic drugs. The changes required improved manufacturing practices and procedures and evidence that new drugs proposed for marketing be effective as well as safe. These amendments followed widespread adverse publicity about the serious negative side effects of the drug thalidomide.

1963

P.L. 88-129, the *Health Professions Educational Assistance Act*, inaugurated construction grants for teaching facilities that trained physicians, dentists, pharmacists, podiatrists, nurses, or professional public health personnel. The grants were made contingent on schools increasing their first-year enrollments. The legislation also provided for student loans and scholarships.

P.L. 88-156, the *Maternal and Child Health and Mental Retardation Planning Amendments*, amended the Social Security Act (see the 1935 P.L. 74-271). The changes were intended "to assist states and communities in preventing and combating mental retardation through expansion and improvement of the maternal and child health and crippled children's programs, through provision of prenatal, maternity, and infant care for individuals with conditions associated with childbearing that may lead to mental

retardation, and through planning for comprehensive action to combat mental retardation."

P.L. 88-164, the *Mental Retardation Facilities and Community Mental Health Centers Construction Act*, was intended "to provide assistance in combating mental retardation through grants for construction of research centers and grants for facilities for the mentally retarded and assistance in improving mental health through grants for construction of community mental health centers, and for other purposes."

P.L. 88-206, the *Clean Air Act*, authorized direct grants to states and local governments to assist in their air pollution control efforts. The law also established federal enforcement of interstate air pollution restrictions.

1964

P.L. 88-443, the *Hospital and Medical Facilities Amendments*, amended the Hill-Burton Act (see the 1946 P.L. 79-725) to specifically earmark grants for modernizing or replacing existing hospitals.

P.L. 88-452, the *Economic Opportunity Act*, sometimes referred to as the Antipoverty Program, was intended to "mobilize the human and financial resources of the nation to combat poverty in the United States." This broad legislation affected health in a number of ways as it sought to improve the economic and social conditions under which many people lived.

P.L. 88-581, the *Nurse Training Act*, added a new title, Title VIII, to the Public Health Service Act (see the 1944 P.L. 78-410). The legislation authorized separate funding for construction grants to schools of nursing, including associate degree and diploma schools. The law also provided for project grants whereby schools of nursing could strengthen their academic programs and provided for the establishment of student loan funds at these schools.

1965

P.L. 89-4, the *Appalachian Redevelopment Act*, sought to promote the economic, physical, and social development of the Appalachian region. Provisions in the law facilitated a number of steps to achieve this purpose, including the establishment of community health centers and training programs for health personnel.

P.L. 89-73, the *Older Americans Act*, established an Administration on Aging to administer programs for the elderly through state agencies on aging. The agenda for the joint efforts of the federal agency and the state agencies was detailed in ten specific objectives for the nation's older citizens, including several that were related to their health.

P.L. 89-92, the *Federal Cigarette Labeling and Advertising Act*, required that all cigarette packages sold in the United States bear the label, "Caution: Cigarette Smoking May Be Hazardous to Your Health."

P.L. 89-97, the *Social Security Amendments*, a landmark in the nation's health policy, established two new titles to the Social Security Act (see the 1935 P.L. 74-271): (1) Title XVIII, Health Insurance for the Aged, or Medicare, and (2) Title XIX, Grants to the States for Medical Assistance Programs, or Medicaid. Enactment of these amendments followed many years of often acrimonious congressional debate about government's role and responsibility regarding ensuring access to health services for the citizenry. This legislation was made possible by the landslide dimensions of Lyndon B. Johnson's 1964 election to the presidency and by the accompanying largest Democratic majority in Congress since 1934.

In addition to establishing Titles XVIII and XIX, the Social Security Act Amendments of 1965 also amended Title V to authorize grant funds for maternal and child health and crippled children's services. These amendments also authorized grants for training professional personnel for the care of crippled children.

P.L. 89-239, the *Heart Disease, Cancer and Stroke Amendments,* amended the Public Health Act (see the 1944 P.L. 78-410) to establish a nationwide network of Regional Medical Programs. This legislation was intended to "assist in combating heart disease, cancer, stroke, and related diseases." Through its provisions, regional cooperative programs were established among medical schools, hospitals, and research institutions to foster research, training, continuing education, and demonstrations of patient care practices related to heart disease, cancer, and stroke.

P.L. 89-272, the *Clean Air Act Amendments*, amended the original Clean Air Act (see the 1963 P.L. 88-206) to provide for federal regulation of motor vehicle exhaust and to establish a program of federal research support and grants in aid in the area of solid waste disposal.

P.L. 89-290, the *Health Professions Educational Assistance Amendments*, amended the original act (see the 1963 P.L. 88-129) to provide further support "to improve the quality of schools of medicine, dentistry, osteopathy, optometry, and podiatry." The law expanded the availability of student loans and introduced a provision whereby 50 percent of a professional's student loan could be forgiven in exchange for practice in a designated shortage area.

1966

P.L. 89-564, the *Highway Safety Act*, sought to improve the nation's system of highways to make them safer for users.

P.L. 89-642, the *Child Nutrition Act*, established a federal program of support, including research, for child nutrition. A key component of the legislation was its authorization of the school breakfast program.

P.L. 89-749, the *Comprehensive Health Planning Act* (also known as the Partnership for Health Act), which amended the Public Health Service Act (see the 1944 P.L. 78-410), was intended "to promote and assist in the extension and improvement of comprehensive health planning and public health services, [and] to provide for a more effective use of available Federal funds for such planning and services. . . ." This legislation sought to promote comprehensive planning for health facilities, services, and personnel within the framework of a federal/state/local partnership. It also gave states greater flexibility in the use of their grants in aid for public health services through block grants.

The law, in Section 314a, authorized grants to states for the development of comprehensive state health planning and, in Section 314b, authorized grants to public or not-for-profit organizations "for developing comprehensive regional, metropolitan area or other local area plans for coordination of existing and planned health services." State planning agencies created or designated under this legislation became known as "A" agencies or as "314a" agencies. Within states, the other planning agencies created or designated under this legislation became known as "B," "areawide," or "314b" agencies.

P.L. 89-751, the *Allied Health Professions Personnel Training Act*, provided grant support for the training of allied health professionals. The legislation was patterned after the 1963 Health Professions Education Assistance Act (see P.L. 88-129).

P.L. 89-794, the *Economic Opportunity Act Amendments*, amended the Economic Opportunity Act (see the 1964 P.L. 88-452) to establish Office of Economic Opportunity neighborhood health centers. Located especially in impoverished sections of cities and rural areas, these centers provided poor people a comprehensive range of ambulatory health services. By the early 1970s, approximately 100 centers were to have been established under this program.

1967

P.L. 90-31, the *Mental Health Amendments*, amended the Mental Retardation Facilities and Community Mental Health Centers Construction Act (see the 1963 P.L. 88-164) to extend the program of construction grants for community mental health centers. The legislation also amended the term "construction" so that it covered acquisition of existing buildings.

P.L. 90-148, the *Air Quality Act*, amended the Clean Air Act (see the 1963 P.L. 88-206) "to authorize planning grants to air pollution control agencies; expand research provisions relating to fuels and vehicles; provide for interstate air pollution control agencies or commissions; authorize the establishment of air quality standards; and for other purposes." The act provided

for each state to establish air quality standards depending on local conditions, but a minimum air quality was to be ensured through federal review of the states' standards.

P.L. 90-170, the *Mental Retardation Amendments*, amended the Mental Retardation Facilities and Community Mental Health Centers Construction Act (see the 1963 P.L. 88-164) to extend the program of construction grants for university-affiliated and community-based facilities for the mentally retarded. The legislation also authorized a new program of grants for the education of physical educators and recreation workers who work with mentally retarded and other handicapped children and for research in these areas.

P.L. 90-174, the *Clinical Laboratory Improvement Act*, amended the Public Health Service Act (see the 1944 P.L. 78-410) to provide for the regulation of laboratories in interstate commerce by the Centers for Disease Control through processes of licensure, standards setting, and proficiency testing.

P.L. 90-189, the *Flammable Fabrics Act*, was part of government's early efforts to rid the environment of hazards to human health. The legislation sought to regulate the manufacture and marketing of flammable fabrics.

P.L. 90-248, the *Social Security Amendments*, represented the first of many modifications to the Medicare and Medicaid programs, which were established by the Social Security Amendments of 1965 (see P.L. 89-97). Coming two years after their establishment, this legislation provided expanded coverage for such things as durable medical equipment for use in the home, podiatrist services for nonroutine foot care, outpatient physical therapy, and the addition of a lifetime reserve of 60 days of coverage for inpatient hospital care over and above the original coverage for up to 90 days during any spell of illness. In addition, certain payment rules were modified in favor of providers. For example, payment of full reasonable charges for radiologist and pathologist services provided to inpatients were authorized under one modification.

This law also sought to raise the quality of care provided in nursing homes by establishing a number of conditions that had to be met by nursing homes wanting to participate in the Medicare and Medicaid programs. There was also a provision for limiting the federal participation in medical assistance payments to families whose income did not exceed 133 percent of the income limit for Aid to Families with Dependent Children (AFDC) payments in any state.

1968

P.L. 90-490, the *Health Manpower Act*, extended previous programs of support for the training of health professionals (see the 1963 P.L. 88-129 and

the 1964 P.L. 88-581), in effect authorizing formula institutional grants for training all health professionals.

1969

P.L. 91-173, the *Federal Coal Mine Health and Safety Act*, was intended to help secure and improve the health and safety of coal miners.

P.L. 91-190, the *National Environmental Policy Act*, was enacted "To declare a national policy which will encourage productive and enjoyable harmony between man and his environment; to promote efforts which will prevent or eliminate damage to the environment and biosphere and stimulate the health and welfare of man. . . ." This law established the Council on Environmental Quality to advise the president on environmental matters. The legislation required that environmental impact statements be prepared prior to the initiation of major federal actions.

1970

P.L. 91-222, the *Public Health Cigarette Smoking Act*, banned cigarette advertising from radio and television.

P.L. 91-224, the *Water Quality Improvement Act*, a very comprehensive water pollution law, included among its numerous provisions those relating to oil pollution by vessels and on- and offshore oil wells, hazardous polluting substances other than oil, and pollution from sewage from vessels and provided for training people to work in the operation and maintenance of water treatment facilities. Perhaps its most important provisions pertain to the procedures whereby all federal agencies must deal with water pollution, including requirements for cooperation among the various agencies.

P.L. 91-296, the *Medical Facilities Construction and Modernization Amendments*, amended the Hill-Burton Act (see the 1946 P.L. 79-725) by extending the program and by initiating a new program of project grants for emergency rooms, communications networks, and medical transportation systems.

P.L. 91-464, the *Communicable Disease Control Amendments*, amended the Public Health Service Act (see the 1944 P.L. 78-410), which had established the Communicable Disease Center (CDC), by renaming the CDC the Centers for Disease Control. The legislation also broadened the functions of CDC beyond its traditional focus on communicable or infectious diseases (e.g., tuberculosis, venereal disease, rubella, measles, Rh disease, poliomyelitis, diphtheria, tetanus, whooping cough) to include other preventable conditions, including malnutrition.

P.L. 91-513, the *Comprehensive Drug Abuse Prevention and Control Act*, provided for special project grants for drug abuse and drug dependence treatment programs and grants for programs and activities related to drug education.

P.L. 91-572, the *Family Planning Services and Population Research Act*, established the Office of Population Affairs and added Title X, Population Research and Voluntary Family Planning Programs, to the Public Health Service Act (see the 1944 P.L. 78-410). The legislation authorized a range of projects, formulas, training, and research grants and contracts to support family planning programs and services, except for abortion.

P.L. 91-596, the *Occupational Safety and Health Act*, established an extensive federal program of standard-setting and enforcement activities that were intended to ensure healthful and safe workplaces.

P.L. 91-601, the *Poison Prevention Packaging Act*, required that most drugs be dispensed in containers designed to be difficult for children to open.

P.L. 91-604, the *Clean Air Amendments*, was enacted because Congress became dissatisfied with progress toward control and abatement of air pollution under the Air Quality Act of 1967 (see the 1967 P.L. 90-148). This law took away the power of the states to establish different air quality standards in different air quality control regions. Instead, this legislation required states to achieve national air quality standards within each of their regions.

P.L. 91-616, the *Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act*, established the National Institute of Alcohol Abuse and Alcoholism. The law provided a separate statutory base for programs and activities related to alcohol abuse and alcoholism. The legislation also provided a comprehensive program of aid to states and localities in their efforts addressed to combating alcohol abuse and alcoholism.

P.L. 91-623, the *Emergency Health Personnel Act*, amended the Public Health Service Act (see the 1944 P.L. 78-410) to permit the secretary of DHEW (now DHHS) to assign commissioned officers and other health personnel of the U.S. Public Health Service to areas of the country experiencing critical shortages of health personnel. This legislation also established the National Health Service Corps.

P.L. 91-695, the *Lead-Based Paint Poisoning Prevention Act*, represented a specific attempt to address the problem of lead-based paint poisoning through a program of grants to the states to aid them in their efforts to combat this problem.

1971

P.L. 92-157, the *Comprehensive Health Manpower Training Act*, was, at the time of its enactment, the most comprehensive health personnel legislation

yet enacted. The legislation replaced institutional formula grants with a new system of capitation grants through which health professions schools received fixed sums of money for each of their students (contingent on increasing first-year enrollments). Loan provisions were broadened so that health professionals who practiced in designated personnel shortage areas could cancel 85 percent of education loans. The legislation also established the National Health Manpower Clearinghouse, and the secretary of DHEW (now DHHS) was directed to make every effort to provide to counties without physicians at least one National Health Service Corps physician.

1972

P.L. 92-294, the *National Sickle Cell Anemia Control Act*, authorized grants and contracts to support screening, treatment, counseling, information and education programs, and research related to sickle-cell anemia.

P.L. 92-303, the *Federal Coal Mine Health and Safety Amendments*, amended the earlier Federal Coal Mine Health and Safety Act (see the 1969 P.L. 91-173) to provide financial benefits and other assistance to coal miners who were afflicted with black lung disease.

P.L. 92-426, the *Uniformed Services Health Professions Revitalization Act*, established the Uniformed Services University of the Health Sciences. The legislation provided for this educational institution to be operated under the auspices of the U.S. Department of Defense in Bethesda, Maryland. The legislation also created the Armed Forces Health Professions Scholarship Program.

P.L. 92-433, the *National School Lunch and Child Nutrition Amendments*, amended the Child Nutrition Act (see the 1966 P.L. 89-642) to add support for the provision of nutritious diets for pregnant and lactating women and for infants and children (the WIC program).

P.L. 92-573, the *Consumer Product Safety Act*, established the Consumer Product Safety Commission to develop safety standards and regulations for consumer products. Under provisions of the legislation, the administration of existing related legislation, including the Flammable Fabrics Act, the Hazardous Substances Act, and the Poison Prevention Packaging Act, was transferred to the commission.

P.L. 92-574, the *Noise Control Act*, much like the earlier Clean Air Act (see the 1963 P.L. 88-206) and the Flammable Fabrics Act (see the 1967 P.L. 90-189), continued government's efforts to rid the environment of harmful influences on human health.

P.L. 92-603, the *Social Security Amendments*, amended the Social Security Act (see the 1935 P.L. 74-271) to make several significant changes in the Medicare program. These amendments marked an important shift in the

operation of the Medicare program as efforts were undertaken to help control its growing costs. Over the bitter opposition of organized medicine, the legislation established professional standards review organizations (PSROs) that were to monitor both the quality of services provided to Medicare beneficiaries as well as the medical necessity for the services.

One provision limited payments for capital expenditures by hospitals that had been disapproved by state or local planning agencies. Another provision authorized a program of grants and contracts to conduct experiments and demonstrations related to achieving increased economy and efficiency in the provision of health services. Some of the specifically targeted areas of these studies were to be prospective reimbursement, the requirement that patients spend three days in the hospital prior to admission to a skilled nursing home, the potential benefits of ambulatory surgery centers, payment for the services of physician assistants and nurse practitioners, and the use of clinical psychologists.

Coincident with these and other cost-containment amendments, several cost-increasing changes were also made in the Medicare program by this legislation. Notably, persons who were eligible for cash benefits under the disability provisions of the Social Security Act for at least 24 months were made eligible for medical benefits under the program. In addition, persons who were insured under Social Security, as well as their dependents, who required hemodialysis or renal transplantation for chronic renal disease were defined as disabled for the purpose of having them covered under the Medicare program for the costs of treating their end-stage renal disease (ESRD). The inclusion of coverage for the disabled and ESRD patients in 1972 was an extraordinarily expensive change in the Medicare program. In addition, certain less costly but still expensive additional coverages were extended, including chiropractic services and speech pathology services.

P.L. 92-714, the *National Cooley's Anemia Control Act*, authorized grants and contracts to support screening, treatment, counseling, information and education programs, and research related to Cooley's Anemia.

1973

P.L. 93-29, the *Older Americans Act*, established the National Clearinghouse for Information on Aging and created the Federal Council on Aging. The legislation also authorized funds to establish gerontology centers and provided grants for training and research related to the field of aging.

P.L. 93-154, the *Emergency Medical Services Systems Act*, provided aid to states and localities to assist them in developing coordinated emergency medical service (EMS) systems.

P.L. 93-222, the *Health Maintenance Organization Act*, amended the Public Health Service Act (see the 1944 P.L. 78-410) to "provide assistance

and encouragement for the establishment and expansion of health maintenance organizations. . . ." The legislation, which added a new title, Title XIII, Health Maintenance Organizations (HMOs), to the Public Health Service Act, authorized a program of grants, loans, and loan guarantees to support the conduct of feasibility and development studies and initial operations for new HMOs.

1974

P.L. 93-247, the *Child Abuse Prevention and Treatment Act*, created the National Center on Child Abuse and Neglect. The legislation authorized grants for research and demonstrations related to child abuse and neglect.

P.L. 93-270, the *Sudden Infant Death Syndrome Act*, added Part C, Sudden Infant Death Syndrome, to Title XI of the Public Health Service Act (see the 1944 P.L. 78-410). The legislation provided for the development of informational programs related to this syndrome for both public and professional audiences.

P.L. 93-296, the *Research in Aging Act*, established the National Institute on Aging within the National Institutes of Health.

P.L. 93-344, the *Congressional Budget and Impoundment Control Act*, and its subsequent amendments, provided Congress with the procedures through which it establishes target levels for revenues, expenditures, and the overall deficit for the coming fiscal year (FY). The Congressional budget procedures are designed to coordinate decisions on sources and levels of federal revenues and on the objectives and levels of federal expenditures. These decisions have substantial impact on health policy. The procedures formally begin each year with the initial decision as to the overall size of the budget pie for a given year, as well as the sizes of its various pieces. To accomplish this, each year Congress adopts a concurrent resolution that imposes overall constraints on spending, based in part on the size of the anticipated revenue budget for the year, and distributes the overall constraint on spending among groups of programs and activities. These constraints are implemented through the reconciliation process. The result of this process is the annual omnibus reconciliation bill, which is, in effect, a packaging together of all legislative changes made in the various standing committees necessitated by reconciling existing law with the budgetary targets established earlier in the concurrent resolution on the budget.

This act also established the U.S. Congressional Budget Office (CBO). The nonpartisan CBO conducts studies and analyses of the fiscal and budget implications of various decisions facing Congress, including those related to health.

P.L. 93-360, the *Nonprofit Hospital Amendments*, amended the 1947 Labor-Management Relations Act (or the Taft-Hartley Act) to end the exclusion of nongovernmental, nonprofit hospitals from the provisions of this act as well as from the earlier National Labor Relations Act of 1935 (or the Wagner Act). Both of these acts pertain to fair labor practices and collective bargaining.

P.L. 93-406, the *Employee Retirement Income Security Act* (also known as ERISA), provided for the regulation of almost all pension and benefit plans for employees, including pensions, medical or hospital benefits, disability, and death benefits. The legislation provides for the regulation of many features of these benefit plans.

P.L. 93-523, the *Safe Drinking Water Act*, required the Environmental Protection Agency (EPA) to establish national drinking water standards and to aid states and localities in the enforcement of these standards.

P.L. 93-641, the *National Health Planning and Resources Development Act*, amended the Public Health Service Act (see the 1944 P.L. 78-410) in an attempt "to assure the development of a national health policy and of effective state and area health planning and resource development programs, and for other purposes." The legislation added two new titles, XV and XVI, to the Public Health Service Act. These titles superseded and significantly modified the programs established under Sections 314a and 314b of Title III of the 1966 P.L. 89-749, the Comprehensive Health Planning Act (or the Partnership for Health Act) as well as the programs established under the Hill-Burton Act (see the 1946 P.L. 79-725).

The legislation essentially folded existing health planning activities into a new framework created by the legislation. The secretary of DHEW (now DHHS) was to enter into an agreement with each state's governor for the designation of a state health planning and development agency (SHPDA). The states were to also establish state health coordinating councils (SHCCs) to serve as advisors in setting overall state policy.

A network of local health systems agencies (HSAs) covering the entire nation was established by the legislation. The HSAs were to (1) improve the health of area residents; (2) increase the accessibility, acceptability, continuity, and quality of health services; and (3) restrain healthcare cost increases and prevent duplication of healthcare services and facilities. An important feature of the planning framework created by P.L. 93-641 was a provision that permitted the HSAs in states that had established certificate-of-need (CON) programs to conduct CON reviews and to make recommendations developed at the local level to the SHPDA.

Congress repealed this law in 1986 (effective January 1, 1987), leaving responsibility for the CON programs entirely in the hands of the states.

P.L. 93-647, the *Social Security Amendments* (also known as the Social Services Amendments), amended the Social Security Act (see the 1935 P.L.

74-271) to consolidate existing federal-state social service programs into a block grant program that would permit a ceiling on federal matching funds while providing more flexibility to the states in providing certain social services. The legislation added a new title, Title XX, Grants to the States for Services, to the Social Security Act.

The goals of the legislation pertained to the prevention and remedy of neglect, abuse, or exploitation of children or adults, the preservation of families, and the avoidance of inappropriate institutional care by substituting community-based programs and services. Social services covered under this law included child-care service; protective, foster, and day-care services for children and adults; counseling; family planning services; homemaker services; and home-delivered meals.

1976

P.L. 94-295, the *Medical Devices Amendments*, amended the Food, Drug and Cosmetic Act (see the 1938 P.L. 75-717) to strengthen the regulation of medical devices. This legislation was passed, after previous attempts had failed, amid growing public concern with the adverse effects of such medical devices as the Dalcon Shield intrauterine device.

P.L. 94-317, the *National Consumer Health Information and Health Promotion Act*, amended the Public Health Service Act (see the 1944 P.L. 78-410) to add Title XVII, Health Information and Promotion. The legislation authorized grants and contracts for research and community programs related to health information, health promotion, preventive health services, and education of the public in the appropriate use of healthcare services.

P.L. 94-437, the *Indian Health Care Improvement Act*, an extensive piece of legislation, was intended to fill existing gaps in the delivery of healthcare services to Native Americans.

P.L. 94-460, the *Health Maintenance Organization Amendments*, amended the Health Maintenance Organization Act (see the 1973 P.L. 93-222) to ease somewhat the requirements that had to be met for an HMO to become federally qualified. One provision, however, required that HMOs must be federally qualified if they were to receive reimbursement from the Medicare or Medicaid programs.

P.L. 94-469, the *Toxic Substances Control Act* (TSCA), sought to regulate chemical substances used in various production processes. The legislation defined chemical substances very broadly. The purpose of TSCA was to identify potentially harmful chemical substances before they were produced and entered the marketplace and, subsequently, the environment.

P.L. 94-484, the *Health Professions Educational Assistance Act*, extended the program of capitation grants to professional schools that had been

established under the Comprehensive Health Manpower Training Act (see the 1971 P.L. 92-157). However, this legislation dropped the requirement that schools increase their first-year enrollments as a condition for receiving grants. Under this legislation, medical schools were required to have 50 percent of their graduates enter residency programs in primary care by 1980. They were also required to reserve positions in their third-year classes for U.S. citizens who were studying medicine in foreign medical schools. However, under intense protest from medical schools, this earlier provision was repealed in 1975.

1977

P.L. 95-142, the *Medicare-Medicaid Antifraud and Abuse Amendments*, amended the legislation governing the Medicare and Medicaid programs (see the 1965 P.L. 89-97) in an attempt to reduce fraud and abuse in the programs as a means to help contain their costs. Specific changes included strengthening criminal and civil penalties for fraud and abuse affecting the programs, modifying the operations of the PSROs, and promulgating uniform reporting systems and formats for hospitals and certain other healthcare organizations participating in the Medicare and Medicaid programs.

P.L. 95-210, the *Rural Health Clinic Services Amendments*, amended the legislation governing the Medicare and Medicaid programs (see the 1965 P.L. 89-97) to modify the categories of practitioners who could provide reimbursable services to Medicare and Medicaid beneficiaries, at least in rural settings. Under the provisions of this act, rural health clinics that did not routinely have physicians available on site could, if they met certain requirements regarding physician supervision of the clinic and review of services, be reimbursed for services provided by nurse practitioners and physician assistants through the Medicare and Medicaid programs. This act also authorized certain demonstration projects in underserved urban areas for reimbursement of these nonphysician practitioners.

1978

P.L. 95-292, the *Medicare End-Stage Renal Disease Amendments*, further amended the legislation governing the Medicare program (see the 1965 P.L. 89-97) in an attempt to help control the program's costs. Since the addition of coverage for ESRD under the Social Security Amendments of 1972 (P.L. 92-603), the costs to the Medicare program had risen steadily and quickly. This legislation added incentives to encourage the use of home dialysis and renal transplantation in ESRD.

The legislation also permitted the use of a variety of reimbursement methods for renal dialysis facilities, and it authorized funding for the conduct

of studies of ESRD itself, especially studies incorporating possible cost reductions in treatment for this disease. It also directed the secretary of DHEW (now DHHS) to establish areawide network coordinating councils to help plan for and review ESRD programs.

P.L. 95-559, the *Health Maintenance Organization Amendments*, further amended the Health Maintenance Organization Act (see the 1973 P.L. 93-222) to add a new program of loans and loan guarantees to support the acquisition of ambulatory care facilities and related equipment. The legislation also provided for support for a program of training for HMO administrators and medical directors and for providing technical assistance to HMOs in their developmental efforts.

1979

P.L. 96-79, the *Health Planning and Resources Development Amendments*, amended the National Health Planning and Resources Development Act (see the 1974 P.L. 93-641) to add provisions intended to foster competition within the health sector, to address the need to integrate mental health and alcoholism and drug abuse resources into health system plans, and to make several revisions in the CON requirements.

1980

P.L. 96-398, the *Mental Health Systems Act*, extensively amended the Community Mental Health Centers program (see the 1970 P.L. 91-211) including provisions for the development and support of comprehensive state mental health systems. Subsequently, however, this legislation was almost completely superseded by the block grants to the states for mental health and alcohol and drug abuse that were provided under the Omnibus Budget Reconciliation Act of 1981 (see P.L. 97-35).

P.L. 96-499, the *Omnibus Budget Reconciliation Act* (OBRA '80), was contained in Title IX of the Medicare and Medicaid Amendments of 1980. These amendments made extensive modifications in the Medicare and Medicaid programs, with 57 separate sections pertaining to one or both of the programs. Many of the changes reflected continuing concern with the growing costs of the programs and were intended to help control these costs.

Examples of the changes that were specific to Medicare included removal of the 100 visits per year limitation on home health services and the requirement that patients pay a deductible for home care visits under Part B of the program. These changes were intended to encourage home care over more

expensive institutional care. Another provision permitted small rural hospitals to use their beds as "swing beds" (alternating their use as acute or long-term-care beds as needed) and authorized swing-bed demonstration projects for large and urban hospitals. An important change in the Medicaid program required the programs to pay for the services that the states had authorized nurse-midwives to perform.

P.L. 96-510, the *Comprehensive Environmental Response, Compensation and Liability Act* (CERCLA), established the Superfund program that intended to provide resources for the cleanup of inactive hazardous waste dumps. The legislation assigned retroactive liability for the costs of cleaning up the dumps to their owners and operators as well as to the waste generators and transporters who had used the dump sites.

1981

P.L. 97-35, the *Omnibus Budget Reconciliation Act* (OBRA '81), in its Title XXI, Subtitles A, B, and C, contained further amendments to the Medicare and Medicaid programs. Just as in 1980, this legislation included extensive changes in the programs, with 46 sections pertaining to them. Enacted in the context of extensive efforts to reduce the federal budget, many of the provisions hit Medicare and Medicaid especially hard. For example, one provision eliminated the coverage of alcohol detoxification facility services, another removed the use of occupational therapy as a basis for initial entitlement to home health service, and yet another increased the Part B deductible.

In other provisions, OBRA '81 combined 20 existing categorical public health programs into four block grants. The block grants were (1) Preventive Health and Health Services, which combined such previously categorical programs as rodent control, fluoridation, hypertension control, and rape crisis centers among others into one block grant to be distributed among the states by a formula based on population and other factors; (2) Alcohol Abuse, Drug Abuse, and Mental Health Block Grant, which combined existing programs created under the Community Mental Health Centers Act, the Mental Health Systems Act, the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act, and the Drug Abuse, Prevention, Treatment, and Rehabilitation Act; (3) Primary Care Block Grant, which consisted of the Community Health Centers; and (4) Maternal and Child Health Block Grant, which consolidated seven previously categorical grant programs from Title V of the Social Security Act and from the Public Health Services Act, including the maternal and child health and crippled children's programs, genetic disease service, adolescent pregnancy services, sudden infant death syndrome, hemophilia treatment, Supplemental Security Income (SSI) payments to disabled children, and lead-based poisoning prevention.

1982

P.L. 97-248, the *Tax Equity and Fiscal Responsibility Act* (TEFRA), made a number of important changes in the Medicare program. One provision added coverage for hospice services provided to Medicare beneficiaries. These benefits were extended later and are now an integral part of the Medicare program. However, the most important provisions, in terms of impact on the Medicare program, were those that sought to control the program's costs by setting limits on how much Medicare would reimburse hospitals on a per-case basis and by limiting the annual rate of increase for Medicare's reasonable costs per discharge. These changes in reimbursement methodology represented fundamental changes in the Medicare program and reflected a dramatic shift in the nation's Medicare policy.

Another provision of TEFRA replaced PSROs, which had been established by the Social Security Amendments of 1972 (see P.L. 92-603), with a new utilization and quality control program called peer review organizations (PROs). The TEFRA changes regarding the operation of the Medicare program were extensive, but they were only the harbinger of the most sweeping legislative changes in the history of the Medicare program the following year.

P.L. 97-414, the *Orphan Drug Act* (ODA), provided financial incentives for the development and marketing of orphan drugs, defined by the legislation to be drugs for the treatment of diseases or conditions affecting so few people that revenues from sales of the drugs would not cover their development costs.

1983

P.L. 98-21, the *Social Security Amendments*, another landmark in the evolution of the Medicare program, amended the legislation governing the program (see the 1965 P.L. 89-97) to initiate the Medicare prospective payment system (PPS). The legislation included provisions to base payment for hospital inpatient services on predetermined rates per discharge for diagnosis-related groups (DRGs). PPS was a major departure from the cost-based system of reimbursement that had been used in the Medicare program since its inception in 1965. The legislation also directed the administration to study physician payment reform options, a feature that was to later have significant impact (see the 1989 P.L. 10–239).

1984

P.L. 98-369, the *Deficit Reduction Act* (DEFRA), among many provisions, temporarily froze increases in physicians' fees paid under the Medicare program. Another provision in the legislation placed a specific limitation on the

rate of increase in the DRG payment rates that the secretary of DHHS could permit in the two subsequent years.

The legislation also established the Medicare Participating Physician and Supplier program and created two classes of physicians in regard to their relationships to the Medicare program and outlined different reimbursement approaches for them depending on whether they were classified as "participating" or "nonparticipating." As part of this legislation, Congress mandated that the Office of Technology Assessment study alternative methods of paying for physician services so that the information could guide the reform of the Medicare program.

P.L. 98-417, the *Drug Price Competition and Patent Term Restoration Act*, provided brand-name pharmaceutical manufacturers with patent term extensions. These extensions significantly increased manufacturers' opportunities for earning profits during the longer effective patent life (EPL) of their affected products.

P.L. 98-457, the *Child Abuse Amendments*, amended the Child Abuse Prevention and Treatment Act (see the 1974 P.L. 93-247) to involve Infant Care Review Committees in the medical decisions regarding the treatment of handicapped newborns, at least in hospitals with tertiary-level neonatal care units.

The legislation established treatment and reporting guidelines for severely disabled newborns, making it illegal to withhold "medically indicated treatment" from newborns except when "in the treating physician's reasonable medical judgment, i) the infant is chronically and irreversibly comatose; ii) the provision of such treatment would merely prolong dying, not be effective in ameliorating or correcting all of the infant's life-threatening conditions, or otherwise be futile in terms of survival of the infant; or iii) the provision of such treatment would be virtually futile in terms of the survival of the infant and the treatment itself under such circumstances would be inhumane."

P.L. 98-507, the *National Organ Transplant Act*, made it illegal "to knowingly acquire, receive or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce."

1985

P.L. 99-177, the *Emergency Deficit Reduction and Balanced Budget Act* (also known as the Gramm-Rudman-Hollins Act), established mandatory deficit reduction targets for the five subsequent fiscal years. Under provisions of the legislation, the required budget cuts would come equally from defense spending and from domestic programs that were not exempted. The Gramm-Rudman-Hollins Act had significant impact on the Medicare program throughout the last half of the 1980s, as well as on other health programs such as community

and migrant health centers, veteran and Native American health, health professions education, and the National Institutes of Health. Among other things, this legislation led to substantial cuts in Medicare payments to hospitals and physicians.

P.L. 99-272, the *Consolidated Omnibus Budget Reconciliation Act* (COBRA '85), contained a number of provisions that affected the Medicare program. Hospitals that served a disproportionate share of poor patients received an adjustment in their PPS payments; hospice care was made a permanent part of the Medicare program, and states were given the ability to provide hospice services under the Medicaid program; FY 1986 PPS payment rates were frozen at 1985 levels through May 1, 1986, and increased 0.5 percent for the remainder of the year; payment to hospitals for the indirect costs of medical education was modified; and a schedule to phase out payment of a return on equity to proprietary hospitals was established.

This legislation established the Physician Payment Review Commission (PPRC) to advise Congress on physician payment policies for the Medicare program. The legislation also required that PPRC advise Congress and the secretary of DHHS regarding the development of a resource-based relative value scale for physician services.

Under another of COBRA's important provisions, employers were required to continue health insurance for employees and their dependents who would otherwise lose their eligibility for the coverage due to reduced hours of work or termination of their employment.

1986

P.L. 99-509, the *Omnibus Budget Reconciliation Act* (OBRA '86), altered the PPS payment rate for hospitals once again and reduced payment amounts for capital-related costs by 3.5 percent for part of FY 1987, by 7 percent for FY 1988, and by 10 percent for FY 1989. In addition, certain adjustments were made in the manner in which "outlier" or atypical cases were reimbursed.

The legislation established further limits to balance billing by physicians providing services to Medicare clients by setting "maximum allowable actual charges" (MAACs) for physicians who did not participate in the PAR program (see the Deficit Reduction Act of 1984, P.L. 98-369). In another provision intended to realize savings for the Medicare program, OBRA '86 directed DHHS to use the concept of "inherent reasonableness" to reduce payments for cataract surgery as well as for anesthesia during the surgery.

P.L. 99-660, the *Omnibus Health Act*, contained provisions to significantly liberalize coverage under the Medicaid program. Using family income up to the federal poverty line as a criterion, this change permitted states to offer coverage to all pregnant women, infants up to one year of age, and, by using a phase-in schedule, children up to five years of age.

One part of this omnibus health legislation was the *National Childhood Vaccine Injury Act*. This law established a federal vaccine injury compensation system. Under provisions of the legislation, parties injured by vaccines would be limited to awards of income losses plus $250,000 for pain and suffering or death.

Another important part of the omnibus health legislation of 1986 was the *Health Care Quality Improvement Act*. This law provided immunity from private damage lawsuits under federal or state law for "any professional review action" so long as that action followed standards set out in the legislation. This afforded members of peer review committees protection from most damage suits filed by physicians whom they disciplined. The law also mandated creation of a national data bank through which information on physician licensure actions, sanctions by boards of medical examiners, malpractice claims paid, and professional review actions that adversely affect the clinical privileges of physicians could be provided to authorized persons and organizations.

1987

P.L. 100-177, the *National Health Service Corps Amendments*, reauthorized the National Health Service Corps (NHSC), which had been created under a provision of the Emergency Health Personnel Act of 1970 (see P.L. 91-623).

P.L. 100-203, the *Omnibus Budget Reconciliation Act* (OBRA '87), contained a number of provisions that directly affected on the Medicare program. It required the secretary of DHHS to update the wage index used in calculating hospital PPS payments by October 1, 1990, and to do so at least every three years thereafter. It also required the secretary to study and report to Congress on the criteria being used by the Medicare program to identify referral hospitals. Deepening the reductions established by OBRA '86, one provision of the act reduced payment amounts for capital-related costs by 12 percent for FY 1988 and by 15 percent for FY 1989.

Regarding payments to physicians for services provided to Medicare clients, the legislation reduced fees for 12 sets of "overvalued" procedures. It also allowed higher fee increases for primary care than for other physician services and increased the fee differential between participating and nonparticipating physicians (see the 1984 P.L. 98-369).

The legislation also contained a number of provisions that affected the Medicaid program. Key among these, the law provided additional options for children and pregnant women and required states to cover eligible children up to age six with an option for allowing coverage up to age eight. The distinction between skilled nursing facilities (SNFs) and intermediate care facilities (ICFs) was eliminated. The legislation contained a number of provisions intended to enhance the quality of services provided in nursing homes, including

requirements that nursing homes enhance the quality of life of each resident and operate quality assurance programs.

1988

P.L. 100-360, the *Medicare Catastrophic Coverage Act*, provided the largest expansion of the benefits covered under the Medicare program since its establishment in 1965 (see P.L. 89-97). Among other things, provisions of this legislation added coverage for outpatient prescription drugs and respite care and placed a cap on out-of-pocket spending by the elderly for copayment costs for covered services.

The legislation included provisions that would have the new benefits phased in over a four-year period and paid for by premiums charged to Medicare program enrollees. Thirty-seven percent of the costs were to be covered by a fixed monthly premium paid by all enrollees, and the remainder of the costs were to be covered by an income-related supplemental premium that was, in effect, an income surtax that would apply to fewer than half of the enrollees. Under intense pressure from many of their elderly constituents and their interest groups who objected to having to pay additional premiums or the income surtax, Congress repealed P.L. 100-360 in 1989 without implementing most of its provisions.

P.L. 100-578, the *Clinical Laboratory Improvement Amendments*, amended the Clinical Laboratory Improvement Act (see the 1967 P.L. 90-174) to extend and modify government's ability to regulate clinical laboratories.

P.L. 100-582, the *Medical Waste Tracking Act*, was enacted in response to the highly publicized incidents of used and discarded syringes and needles washing up on the shores of a number of states in the eastern United States in the summer of 1988. The legislation itself was rather limited in that it focused on the tracking of medical wastes from their origin to their disposal rather than broader regulation of transportation and disposal of these wastes.

P.L. 100-607, the *National Organ Transplant Amendments*, amended the National Organ Transplant Act (see the 1986 P.L. 98-507) to extend the prohibition against the sale of human organs to the organs and other body parts of human fetuses.

P.L. 100-647, the *Technical and Miscellaneous Revenue Act*, directed the PPRC (see the 1985 P.L. 99-272) to consider policies for moderating the rate of increase in expenditures for physician services in the Medicare program and for reducing the utilization of these services.

1989

P.L. 101-239, the *Omnibus Budget Reconciliation Act* (OBRA '89), included provisions for minor, primarily technical, changes in PPS and a provision to

extend coverage for mental health benefits and add coverage for Pap smears. Small adjustments were made in the disproportionate share regulations, and the 15 percent capital-related payment reduction established in OBRA '87 was continued in OBRA '89. Another provision required the secretary of DHHS to update the wage index annually in a budget-neutral manner beginning in FY 1993.

As part of the OBRA '89 legislation, the Health Care Financing Administration (HCFA) was directed to begin implementing a resource-based relative value scale (RBRVS) for reimbursing physicians under the Medicare program on January 1, 1992. The new system was to be phased in over a four-year period beginning in 1992.

Another important provision in this legislation initiated the establishment of the Agency for Health Care Policy and Research (AHCPR; now the Agency for Healthcare Research and Quality, or AHRQ). This agency succeeded the National Center for Health Services Research and Technology Assessment (NCHSR). The new agency was created to conduct or foster the conduct of studies of healthcare quality, effectiveness, and efficiency. In particular, the agency was to conduct or foster the conduct of studies on the outcomes of medical treatments and provide technical assistance to groups seeking to develop practice guidelines.

1990

P.L. 101-336, the *Americans with Disabilities Act* (ADA), provided a broad range of protections for the disabled, in effect combining protections contained in the Civil Rights Act of 1964, the Rehabilitation Act of 1973, and the Civil Rights Restoration Act of 1988. The central goal of the legislation was independence for the disabled, in effect to assist them in being self-supporting and able to lead independent lives.

P.L. 101-381, the *Ryan White Comprehensive AIDS Resources Emergency Act* (CARE), provided resources to 16 epicenters, including San Francisco and New York City, and to states hardest hit by AIDS to assist them in coping with the skyrocketing cost of care and treatment.

P.L. 101-508, the *Omnibus Budget Reconciliation Act* (OBRA '90), contained the Patient Self-Determination Act, which required healthcare institutions participating in the Medicare and Medicaid programs to provide all of their patients with written information on policies regarding self-determination and living wills. The institutions were also required under this legislation to inquire whether patients had advance medical directives and to document the replies in the patients' medical records.

The legislation made additional minor changes in PPS, including further adjustments in the wage index calculation and in the disproportionate share regulations. Regarding the wage index, one provision required the

Prospective Payment Assessment Commission (ProPAC), which was established by the 1983 Social Security Amendments (see P.L. 98-21) to help guide Congress and the secretary of DHHS on implementing PPS to further study the available data on wages by occupational category and to develop recommendations on modifying the wage index to account for occupational mix.

The legislation also included a provision that continued the 15 percent capital-related payment reduction that was established in OBRA '87 and continued in OBRA '89 and another provision that made the reduced teaching adjustment payment established in OBRA '87 permanent. One of its more important provisions provided a five-year deficit reduction plan that was to reduce total Medicare outlays by more than $43 billion between FYs 1991 and 1995.

P.L. 101-629, the *Safe Medical Devices Act*, further amended the Federal Food, Drug and Cosmetic Act (see the 1938 P.L. 75-717) and the subsequent Medical Devices Amendments of 1976 (see P.L. 94-295) to require institutions that use medical devices to report device-related problems to the manufacturers and/or to FDA. Reportable problems include any incident in which any medical device may have caused or contributed to any person's death, serious illness, or serious injury.

P.L. 101-649, the *Immigration and Nationality Act of 1990*, restructured with minor modifications the medical exclusion scheme for screening people who desired to immigrate to the United States that had been in use since the enactment of the Immigration and Nationality Act of 1952 (see P.L. 82-414).

1992

P.L. 102-585, the *Veterans Health Care Act*, required the Department of Veterans Affairs to establish in each of its hospitals suitable indoor and outdoor smoking areas. This law ran counter to the department's 1991 internal policy of running its hospitals on a smoke-free basis and was out of step with the private-sector movement to establishing smoke-free hospitals.

1993

P.L. 103-43, the *National Institutes of Health Revitalization Act*, contained provisions for a number of structural and budgetary changes in the operation of NIH. It also set forth guidelines for the conduct of research on transplantation of human fetal tissue and added HIV infection to the list of excludable conditions covered by the Immigration and Nationality Act (see the 1990 P.L. 101-649).

P.L. 103-66, the *Omnibus Budget Reconciliation Act* (OBRA '93), established an all-time-record five-year cut in Medicare funding and included a number of other changes affecting the Medicare program. For example, the legislation included provisions to end return on equity (ROE) payments for capital to proprietary SNFs and reduced the previously established rate of increase in payment rates for care provided in hospices. In addition, the legislation cut laboratory fees drastically by changing the reimbursement formula and froze payments for durable medical equipment, parenteral and enteral services, and orthotics and prosthetics in FYs 1994 and 1995.

OBRA '93 contained the *Comprehensive Childhood Immunization Act*, which provided $585 million to support the provision of vaccines for children eligible for Medicaid, children who do not have health insurance, and Native American children.

Note on 1994 and 1995

Chronologies of American health policy will always show these years as a period in which health policymaking appeared dormant because almost no important new federal laws pertaining to health, nor amendments to existing laws, were enacted. This apparent dearth of health policy, however, is misleading. This was a period of extraordinary consideration of health legislation, although very little was enacted. President Clinton attempted a fundamental reform of the American healthcare system through introducing his Health Security proposal in late 1993. The proposed legislation died with the 1994 Congress. The debate consumed almost all of the health-related legislation development energy expended during 1994. Then, following this bill's demise, the 1995 attempt to enact unprecedented cutbacks in the Medicare and Medicaid programs as part of a far-reaching budget reconciliation bill that sought a balanced federal budget ended in veto by President Clinton. The political wrangling over the budget grew even worse in 1996. Proposed changes in the Medicare and Medicaid programs, changes that were linked to the development of a plan to balance the federal budget over a seven-year span, would have meant massive cuts in these programs. The differences over these plans between the Republican-controlled Congress and President Clinton, a Democrat, were so fundamental that they led to a complete impasse in the budget negotiations in 1996, including a brief shutdown of the federal government in the absence of budget authority to operate.

1995

P.L. 104-65, the *Lobbying Disclosure Act*, contained provisions requiring registration with the Secretary of the Senate and the Clerk of the House of

Representatives by any individual lobbyist (or the individual's employer if it employs one or more lobbyists) within 45 days after the individual first makes, or is employed or retained to make, a lobbying contact with either the president, the vice president, a member of Congress, or any of a number of specified federal officers. This law defines a lobbyist as any individual employed or retained by a client for financial or other compensation for services that include more than one lobbying contact, unless the individual's lobbying activities constitute less than 20 percent of the time engaged in the services provided to that client over a six-month period.

1996

P.L. 104-134, the *Departments of Veterans Affairs, Housing and Urban Development, and Independent Agencies Appropriations Act*, contained several provisions that offered certain protections for enrollees in managed care plans. One provision prohibited plans from restricting hospital stays for mothers and newborns to less than 48 hours for vaginal deliveries and 96 hours following a cesarean section. Another provision required that group health plans that offer both medical and surgical benefits and mental health benefits not impose a more restrictive lifetime or annual limit on mental health benefits than is imposed on medical or surgical benefits.

P.L. 104-191, the *Health Insurance Portability and Accountability Act* (HIPAA) (also known as the Kassebaum-Kennedy Act), provided employees who work for companies that offer health insurance to their employees with guaranteed access to health insurance in the event that they change jobs or become unemployed. In addition, the legislation guaranteed renewability of health insurance coverage so long as premiums are paid. It also provided for increased tax deductions for the self-employed who purchase health insurance and allowed tax deductions for medical expenses related to long-term-care insurance coverage. The legislation also established a limited "medical savings accounts" demonstration project.

P.L. 104-193, the *Personal Responsibility and Work Opportunity Reconciliation Act* (also known as the Welfare Reform Act), made significant changes in the nation's welfare policy with implications for such health determinants as the social and economic environments faced by affected people and affected eligibility for the Medicaid program in a fundamental way. Since the establishment of the Medicaid program in 1965 (see P.L. 89-97), eligibility for a key welfare benefit, Aid to Families with Dependent Children (AFDC), and eligibility for Medicaid benefits have been linked. Families receiving AFDC have been automatically eligible for Medicaid and enrolled in the Medicaid program. The Personal Responsibility and Work Opportunity Reconciliation Act, however, replaced AFDC with the Temporary Assistance to Needy Families (TANF) block grant. Under the provisions of the TANF

block grant, states are given broad flexibility to design income support and work programs for low-income families with children and are required to impose federally mandated restrictions, such as time limits, on federally funded assistance. The welfare reform law does provide that children and parents who would have qualified for Medicaid based on their eligibility for AFDC continue to be eligible for Medicaid, but, in the absence of AFDC, states must utilize different mechanisms to identify and enroll former AFDC recipients in their Medicaid programs.

1997

P.L. 105-33, the *Balanced Budget Act of 1997* (BBA), contained the most significant changes in the Medicare program since the program's inception in 1965. Overall, this legislation required a five-year reduction of $115 billion in the Medicare program's expenditure growth and a $13 billion reduction in growth of the Medicaid program. A new "Medicare+Choice" program was created, which gives Medicare beneficiaries the opportunity to choose from a variety of health plan options the plan that best suits their needs and preferences. Significant changes were also made in the traditional Medicare program. Among them, hospital annual inflation updates were reduced, as were hospital payments for inpatient capital expenses and for bad debts. Other provisions established a cap on the number of medical residents supported by Medicare graduate medical education payments and provided incentives for reductions in the number of residents.

An important provision of this act established the State Children's Health Insurance Program (SCHIP) and provided states with $24 billion in federal funds for 1998 until 2002 to increase health insurance for children.

Other provisions established two new commissions. One of these, the Medicare Payment Review Commission (MedPAC), replaced the Physician Payment Review Commission and the Prospective Payment Review Commission. MedPAC was required to submit an annual report to Congress on the status of Medicare reforms and to make recommendations on Medicare payment issues. The second new commission, the National Bipartisan Commission on the Future of Medicare, established by this legislation was charged to develop recommendations for Congress on actions necessary to ensure the long-term fiscal health of the Medicare program. This commission was to consider several specific issues that were debated in the development of the BBA of 1997, but rejected. These issues included raising the eligibility age for Medicare, increasing the Part B premiums, and developing alternative approaches to financing graduate medical education.

P.L. 105-115, the *Food and Drug Administration Modernization and Accountability Act*, directs the secretary of DHHS, at the request of a new drug's sponsor, to identify the drug as a "fast track product" and to facilitate

development and expedite review if the new drug is intended for serious conditions and demonstrates the potential to address unmet medical needs for those conditions. The law also mandates development, prioritization, publication, and annual updating of a list of approved drugs for which additional pediatric information may produce health benefits in the pediatric population. It also mandates development of guidance on the inclusion of women and minorities in clinical trials. Among numerous other provisions, the law also authorizes the secretary of DHHS to permit the shipment of investigational drugs or investigational devices for the diagnosis, monitoring, or treatment of a serious disease or condition in emergency situations. It permits any person through a licensed physician to request, and any manufacturer or distributor to provide to the physician, such a drug or device if specified requirements are met.

1998

P.L. 105-357, the *Controlled Substances Trafficking Prohibition Act*, amends the Controlled Substances Import and Export Act to prohibit U.S. residents from importing into the United States a nonschedule I controlled substance exceeding 50 dosage units if they (1) enter the United States through an international land border and (2) do not possess a valid prescription or documentation verifying such a prescription. This law has a provision that declares that the federal requirements under the law not limit states from imposing additional requirements.

P.L. 105-369, the *Ricky Ray Hemophilia Relief Fund Act*, establishes in the U.S. Treasury the Ricky Ray Hemophilia Relief Fund. The law mandates a single payment of $100,000 from the fund to any individual infected with the human immunodeficiency virus (HIV) if the individual has any blood-clotting disorder and was treated with blood-clotting agents between July 1, 1982, and December 31, 1987; is the lawful current or former spouse of such an individual; or acquired the HIV infection from a parent who is such an individual. The law declares that it does not create or admit any claim of the individual against the United States or its agents regarding HIV and antihemophilic factor treatment and that acceptance of a payment under this act is in full satisfaction of all such claims of the individual.

1999

P.L. 106-113, the *Medicare, Medicaid and SCHIP Balanced Budget Refinement Act of 1999* (BBRA), changed the provisions in the Balanced Budget Act of 1997 in a number of ways. One change, for example, pertained to the

way that hospitals treating a disproportionate share (DSH) of low-income Medicare and Medicaid patients receive additional payments from Medicare. BBRA froze DSH adjustments at 3 percent (the FY 2000 level) through FY 2001 and reduced the formula to 4 percent from the BBA-established 5 percent in FY 2002 and then to 0 percent for subsequent years. The law increased hospice payment by 0.5 percent for FY 2001 and by 0.75 percent for FY 2002. Medicare reimburses teaching hospitals for their role in providing graduate medical education (GME). Prior to BBA, Medicare's indirect medical education adjustment (IME) payments increased 7.7 percent for each 10 percent increase in a hospital's ratio of interns and residents to beds. BBA decreased the adjustment to 6.5 percent in FY 1999, 6.0 percent in FY 2000, and 5.5 percent in FY 2001 and subsequent years. BBRA froze the IME adjustment at 6.5 percent through FY 2000, reduced it to 6.25 percent in FY 2001, and reduced it to 5.5 percent in FY 2002 and subsequent years.

P.L. 106-117, the *Veterans Millennium Health Care and Benefits Act*, directs the secretary of Veterans Affairs to provide nursing home care to any veteran in need of such care through December 31, 2003, (1) for a service-connected disability or (2) who has a service-connected disability rated at 70 percent or more. The law prohibits a veteran receiving such care from being transferred from the providing facility without the consent of the veteran or his or her representative. It also directs the secretary to operate and maintain a program to provide the following extended care services to eligible veterans: (1) geriatric evaluation; (2) nursing home care, either in facilities of the Department of Veterans Affairs or in community-based facilities; (3) domiciliary services; (4) adult day healthcare; (5) noninstitutional alternatives to nursing home care; and (6) respite care. The law has a provision that prohibits the secretary from furnishing such services for a nonservice-connected disability unless the veteran agrees to make a copayment for services of more than 21 days in a year and requires the secretary to establish a methodology for establishing the copayment amount.

2000

P.L. 106-354, the *Breast and Cervical Cancer Prevention and Treatment Act*, amends Title XIX (Medicaid) of the Social Security Act to give states the option of making medical assistance for breast and cervical cancer—related treatment services available during a presumptive eligibility period to certain low-income women who have already been screened for such cancers under the Centers for Disease Control and Prevention breast and cervical cancer early detection program. The law also provides for an enhanced match of federal funds to help states pay for these treatment services through their Medicaid programs.

P.L. 106-430, the *Needlestick Safety and Prevention Act*, revised the bloodborne pathogens standard in effect under the Occupational Safety and Health Act of 1970 to include safer medical devices, such as sharps with engineered sharps injury protections and needleless systems, as examples of engineering controls designed to eliminate or minimize occupational exposure to bloodborne pathogens through needlestick injuries. Other provisions require certain employers to (1) review and update exposure control plans to reflect changes in technology that eliminate or reduce such exposure and document their consideration and implementation of appropriate commercially available and effective safer medical devices for such purpose; (2) maintain a sharps injury log, noting the type and brand of device used, where the injury occurred, and an explanation of the incident (exempting employers who are not required to maintain specified OSHA logs); and (3) seek input on such engineering and work practice controls from the affected healthcare workers.

P.L. 106-525, the *Minority Health and Health Disparities Research and Education Act*, amends the Public Health Service Act to establish within the National Institutes of Health (NIH) the National Center on Minority and Health Disparities to conduct and support research, training, dissemination of information, and other programs with respect to minority health conditions and other populations with health disparities. This law requires the center director, in expending funds, to give priority to conducting and supporting minority health disparities research (research on minority health conditions, including research to prevent, diagnose, and treat such conditions). It also requires coordination of center research with other health disparities research conducted or supported by NIH and requires the center director, the NIH director, and the directors of all other agencies of NIH to, among other things, establish a comprehensive plan and budget for the conduct and support of all minority health and other health disparities research activities of the agencies of NIH. The law also has a provision requiring the directors to work together to carry out provisions of the act relating to participation by minority groups in clinical research.

P.L. 106-554, the *Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA)*, changed numerous provisions previously enacted in BBA and BBRA. Among the important changes were the following:

- an increase of 3.4 percent for Medicare inpatient payments in FY 2001 and an estimated 3.5 percent in FY 2002;
- an increase of 4.4 percent in Medicare outpatient payments in 2001;
- indirect medical education (IME) payments at 6.5 percent in FY 2001 and FY 2002;
- elimination of the additional 1 percent cut in Medicare disproportionate share (DSH) hospital payments in FY 2001 and 2002;
- an increase from 55 to 70 percent in Medicare payments for bad debt;

- an increase for the direct graduate medical education (GME) payment floor to 85 percent of the national average;
- elimination of BBA's FY 2001 and 2002 Medicaid DSH cut;
- removal of the 2 percent payment reduction for rehabilitation hospitals in FY 2001;
- a 3.2 percent increase in skilled nursing service payments in FY 2001;
- a one-year delay of the 15 percent reduction for home health and the full market basket in FY 2001;
- an increase of 2 percent in incentive payments for psychiatric hospitals/units; and
- expansion of Medicare payment for telehealth services to rural areas.

P.L. 106-580, the *National Institute of Biomedical Imaging and Bioengineering Establishment Act*, amends the Public Health Service Act to provide for the establishment of the National Institute of Biomedical Imaging and Bioengineering. The law requires the director of the institute to establish a national biomedical imaging and bioengineering program, which includes research and related technology assessments and development in biomedical imaging and bioengineering. It also requires the director to prepare and transmit to the secretary of DHHS and the director of the National Institutes of Health (NIH) a plan to initiate, expand, intensify, and coordinate institute biomedical imaging and bioengineering activities. It requires (1) the consolidation and coordination of institute biomedical imaging and bioengineering research and related activities with those of NIH and other federal agencies and (2) the establishment of an institute advisory council.

2001

P.L. 107-9, the *Animal Disease Risk Assessment, Prevention, and Control Act*, directs the secretary of Agriculture to submit a preliminary report to specified congressional committees concerning (1) interagency measures to assess, prevent, and control the spread of foot and mouth disease and bovine spongiform encephalopathy ("mad cow disease") in the United States; (2) related federal information sources available to the public; and (3) the need for any additional legislative authority or product bans. The law directs the secretary, in consultation with governmental and private-sector parties, to submit a final report to such committees that discusses such diseases' economic impacts; public and animal health risks; and related legislative, federal agency, and product recommendations.

P.L. 107-38, the *Emergency Supplemental Appropriations Act for Recovery from and Response to Terrorist Attacks on the United States*, makes emergency supplemental appropriations for FY 2001 for emergency expenses to respond to the terrorist attacks on the United States on September 11, 2001, to provide assistance to the victims, and to deal with other consequences

of the attacks. The law makes $40 billion available to the Executive Office of the President and Funds Appropriated to the President for the Emergency Response Fund for such expenses as (1) providing federal, state, and local preparedness for mitigating and responding to the attacks; (2) providing support to counter, investigate, or prosecute domestic or international terrorism; (3) providing increased transportation security; (4) repairing damaged public facilities and transportation systems; and (5) supporting national security.

P.L. 107-109, *Best Pharmaceuticals for Children Act*, amends the Public Health Service Act to direct the secretary of DHHS, through the National Institutes of Health (NIH), to develop an annual list of approved drugs for which (1) there is a referral, an approved or pending new drug application, or no patent or market exclusivity protection and (2) additional pediatric safety and effectiveness studies are needed. The act also directs the Secretary to award contracts to entities with appropriate experience for pediatric clinical trials of such drugs; requires the results of such trials to be reported to the Commissioner of Food and Drugs who shall then determine and request any necessary labeling changes; authorizes the Commissioner to deem a drug misbranded if the holder of an approved application refuses to make the requested change; requires the Secretary to send a nonbinding letter of recommendation to an approved application holder if such studies indicate a reformulation is necessary; and sets forth reporting, label change, and dispute resolution requirements.

P.L. 107-121, the *Native American Breast and Cervical Cancer Treatment Technical Amendment Act of 2001*, amends Title XIX of the Social Security Act to clarify that Indian women with breast or cervical cancer who are eligible for health services provided under a medical care program of the Indian Health Service or of a tribal organization are included in the optional Medicaid eligibility category of breast or cervical cancer patients added by the Breast and Cervical Prevention and Treatment Act of 2000.

P.L. 107-205, *Nurse Reinvestment Act*, amends the Public Health Service Act to direct the secretary of DHHS to promote the nursing profession through public service announcements and to make grants to support state and local advertising campaigns, excluding particular employment opportunities. The legislation expands eligibility for the nursing loan repayment program to include service at any healthcare facility with a critical shortage of nurses. The legislation also authorizes the secretary to award grants or contracts to schools of nursing or healthcare facilities to expand nursing opportunities (1) in education, through increased enrollment in four-year degree programs, internship and residency programs, or new technologies such as distance learning and (2) in practice, through care to underserved populations, care in noninstitutional settings or organized healthcare systems, and through developing cultural competencies.

2002

P.L. 107-250, the *Medical Device User Fee and Modernization Act*, amends the Federal Food, Drug and Cosmetic Act to establish a new program that beginning on October 1, 2002, subjects each medical device manufacturer to a medical device fee for certain applications, reports, application supplements, and submissions sent to the FDA for evaluation. The legislation grants exceptions, including for humanitarian devices and certain devices sponsored by state governments or the federal government and directs the secretary of DHHS to waive one premarket application, or one premarket report where the applicant is a small business submitting its first premarket application or its first premarket report, respectively, for review.

P.L. 107-251, the *Health Care Safety Net Amendments of 2002*, amends the Public Health Service Act to reauthorize and strengthen the health centers program and the National Health Service Corps and to establish the Healthy Communities Access Program to help coordinate services for the uninsured and underinsured.

P.L. 107-280, the *Rare Diseases Act*, amends the Pubic Health Service Act to (1) establish the Office of Rare Diseases at the National Institutes of Health and (2) provide for rare disease regional centers of excellence. The legislation sets forth the duties of such an office and such regional centers, including research and educational duties. It also defines *rare disease* as any disease or condition affecting fewer than 200,000 persons in the United States.

P.L. 107-296, the *Homeland Security Act*, establishes the Department of Homeland Security (DHS) as an executive department of the United States, headed by the Secretary of Homeland Security (secretary) appointed by the president by and with the advice and consent of the Senate to (1) prevent terrorist attacks within the United States; (2) reduce the vulnerability of the United States to terrorism; (3) minimize the damage, and assist in the recovery, from terrorist attacks that occur within the United States; (4) carry out all functions of entities transferred to DHS; (5) ensure that the functions of the agencies and subdivisions within DHS that are not related directly to securing the homeland are not diminished or neglected except by a specific act of Congress; (6) ensure that the overall economic security of the United States is not diminished by efforts, activities, and programs aimed at securing the homeland; and (7) monitor connections between illegal drug trafficking and terrorism, coordinate efforts to sever such connections, and otherwise contribute to efforts to interdict illegal drug trafficking.

P.L. 107-313, the *Mental Health Parity Reauthorization Act*, amends the Employee Retirement Income Security Act of 1974 (ERISA) and the Public Health Service Act to extend the mental health benefits parity provisions through 2003.

2003

P.L. 108-74, the *State Children's Health Insurance Program Allotments Extension*, amends Title XXI (State Children's Health Insurance Program, or SCHIP) of the Social Security Act to revise the special rule for the redistribution and availability of unexpended FY 1998 and 1999 SCHIP allotments, including to (1) extend the availability of FY 1998 and 1999 reallocated funds through FY 2004 and (2) permit 50 percent of the total amount of unexpended FY 2000 and 2001 SCHIP allotments that remain available to a state through the end of FY 2002 and 2003 to remain available for expenditure by the state through the end of FY 2004 and 2005, respectively.

P.L. 108-155, the *Pediatric Research Equity Act*, amends the Federal Food, Drug and Cosmetic Act to authorize the Food and Drug Administration (FDA) to require license applications for new drugs and biological products to assess such drug's or product's safety and effectiveness for relevant pediatric subpopulations, including dosage. The legislation permits deferral of such assessments under specified circumstances, including if the secretary of DHHS finds that the drug or biological product is ready for approval for use in adults before pediatric studies are complete. It also permits full waiver of such assessments under certain conditions, including if (1) studies are highly impractical or impossible or (2) there is no meaningful therapeutic advantage or benefit in the pediatric population and the drug or biological product is not likely to be used in a substantial number of pediatric patients.

P.L. 108-170, the *Veterans Health Care, Capital Asset, and Business Improvement Act*, amends Title 38, United States Code, to improve and enhance provision of healthcare for veterans, to authorize major construction projects and other facilities matters for the Department of Veterans Affairs, to enhance and improve authorities relating to the administration of personnel of the Department of Veterans Affairs, and for other purposes.

P.L. 108-173, the *Medicare Prescription Drug, Improvement, and Modernization Act (MMA)*, created a new drug benefit as Part D of Medicare. The new benefit is to begin in 2006, with an interim Medicare-endorsed drug discount card available to beneficiaries. In addition, this law adds certain preventive benefits including an initial routine physical examination for new beneficiaries, as well as cardiovascular blood screening tests and diabetes screening and services. MMA also renamed Medicare+Choice to Medicare Advantage (MA) and changed some of the enrollment and disenrollment rules for beneficiaries

Another fundamental change in the Medicare program resulting from MMA is the Part B premium determination, which has been uniform for all beneficiaries since the program's inception. Beginning in 2007, this premium will be higher for those with incomes over $80,000 for a single beneficiary or $160,000 for a couple. In addition, the Part B deductible, set at $100

since 1991, is increased to $110 and thereafter will increase by the annual percentage increase in Part B expenditures.

2004

P.L. 108-216, the *Organ Donation and Recovery Improvement Act*, amends the Public Health Service Act to authorize the secretary of DHHS to award grants to states, transplant centers, qualified organ procurement organizations, or other public or private entities to reimburse travel, subsistence, and incidental nonmedical expenses incurred by individuals toward making living organ donations. The legislation also directs the secretary to establish a public education program to increase awareness about organ donation and the need to provide for an adequate rate of donations. It authorizes the secretary to (1) make peer-reviewed grants to or contracts with public and not-for-profit private entities for studies and demonstration projects to increase organ donation and recovery rates, including living donations; (2) make grants to states for organ donor awareness, public education, and outreach activities and programs designed to increase the number of organ donors within the state; and (3) support the development and dissemination of educational materials to inform healthcare professionals about organ, tissue, and eye donation issues.

P.L. 108-276, the *Project BioShield Act*, amends the Public Health Service Act to provide protections and countermeasures against chemical, radiological, or nuclear agents that may be used in a terrorist attack against the United States by giving the National Institutes of Health contracting flexibility to make infrastructure improvements and expedite the scientific peer review process and by streamlining the Food and Drug Administration approval process of countermeasures.

P.L. 108-355, the *Garrett Lee Smith Memorial Act*, amends the Public Health Service Act to support the planning, implementation, and evaluation of organized activities involving statewide youth suicide early intervention and prevention strategies and to authorize grants to institutions of higher education to reduce student mental and behavioral health problems.

P.L. 108-358, the *Anabolic Steroid Control Act*, amends the Controlled Substances Act to clarify the definition of anabolic steroids and to provide for research and education activities relating to steroids and steroid precursors. The legislation defines *anabolic steroid* as any drug or hormonal substance, chemically and pharmacologically related to testosterone (other than estrogens, progestins, corticosteroids, and dehydroepiandrosterone).

2005

P.L. 109-18, *Patient Navigator Outreach and Chronic Disease Prevention Act*, amends the Public Health Service Act to authorize a demonstration grant

program to provide patient navigator services to reduce barriers and improve healthcare outcomes. This act permits the secretary of DHHS, acting through the administrator of the Health Resources and Services Administration, to make grants to eligible entities for the development and operation of demonstration programs to provide patient navigator services to improve healthcare outcomes. The act requires the secretary to coordinate with and ensure the participation of the Indian Health Service, the National Cancer Institute, the Office of Rural Health Policy, and such other offices and agencies as deemed appropriate by the secretary regarding the design and evaluation of the demonstration programs.

P.L. 109-41, *Patient Safety and Quality Improvement Act*, amends the Public Health Service Act to designate patient safety data as privileged and confidential. The act defines a patient safety organization (PSO) as an organization certified by the secretary of DHHS that conducts efforts to improve patient safety and the quality of healthcare delivery through the collection and analysis of patient safety data. The act requires the secretary to (1) maintain a patient safety network of databases that has the capacity to accept, aggregate, and analyze non-identifiable patient safety data voluntarily reported and that provides an interactive resource for providers and PSOs; (2) develop or adopt voluntary national standards to promote the electronic exchange of healthcare information; and (3) contract with a research organization to study the impact of medical technologies and therapies on healthcare.

Notes

1. The Library of Congress maintains a web site (thomas.loc.gov), on which extensive information on federal legislation is provided. This is an excellent source of additional information on public laws that pertain to health. Information about public laws can also be accessed through www.firstgov.gov, the official United States government web site, or through www.access.gpo.gov, a site maintained by the Government Printing Office.
2. Reflecting the convention adopted by Congress, acts began to be referred to by their public law numbers. These numbers reflect both the number of the enacting Congress and the sequence in which the laws are enacted. For example, Public Law (P.L.) 57-244 means the 244th law passed by the 57th Congress. Hereafter, the public law numbers of health-related federal laws in this chronology are provided.

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ABOUT THE AUTHOR

Beaufort B. Longest, Jr., is the M. Allen Pond Professor of Health Policy and Management in the Department of Health Policy & Management of the Graduate School of Public Health at the University of Pittsburgh. He is also the founding director of Pitt's Health Policy Institute.

He received his undergraduate education at Davidson College and received his Master of Health Administration (MHA) and Ph.D. degrees from Georgia State University. He is a Fellow of the American College of Healthcare Executives and holds memberships in the Academy of Management, Academy for Health Services Research and Health Policy, American Public Health Association, and the Association for Public Policy Analysis and Management. He has the unusual distinction of having been elected to membership in the Beta Gamma Sigma Honor Society in Business as well as in the Delta Omega Honor Society in Public Health.

His research on issues of health policy and management has generated substantial grant support and has led to the publication of numerous peer-reviewed articles. His most recent articles focus on the role of healthcare organizations as corporate citizens. In addition, he has authored or coauthored 10 books and 28 chapters in other books. His most recent book is *Managing Health Programs and Projects.* He is coauthor of *Managing Health Services Organizations and Systems*, which is among the most widely used textbooks in graduate health management programs.

He consults with healthcare organizations and systems, universities, associations, and government agencies on health policy and management issues.