CHAPTER 1

Understanding the U.S. Healthcare System

INTRODUCTION

The long-term success and prosperity of an organization is inextricably linked to the strategy it pursues over time. A firm understanding of the environment within which the organization exists is a critical ingredient in the strategy development process. This chapter identifies both the stakeholders in the healthcare system and the environmental forces that are at work and must be taken into account in the formulation of strategy.

The dramatic growth in the size and cost of the U.S. healthcare industry in the past few decades has refocused all stakeholders (providers, suppliers, payers, and consumers) on one message: the current trend is not sustainable. In response to this, stakeholders (perhaps excluding consumers) have pursued strategies that would enhance their individual positions in this sector of the economy. Fortunately, it would seem that most of these strategies have at their core a common concept: value (i.e., benefit versus cost) derived from health services provided, consumed, and reimbursed. Analyzing these forces with respect to the value proposition provides guidance to the organization's management with respect to setting of priorities, allocation of resources, and development of strategy.

In March 2010, in a rare and historic move, the U.S. Congress passed the Patient Protection and Affordable Care Act (PPACA), which was signed into law by President Obama and created significant changes that impact virtually every healthcare organization. Access and value (as defined by quality of care relative to the cost of care) are recurring themes in the legislation and will be discussed later

in this text as both are directly related to quality. The changes as a result of this legislation permeate the industry and will have a significant impact on payers and providers. Therefore, some of the more prominent components of these changes are discussed in this chapter.

GOALS AND OBJECTIVES

This chapter is designed to help the reader develop a firm grasp of the various components of the U.S. healthcare system and understand the major issues faced by the stakeholders within the system. Along with the next chapter, it serves as a foundation for the strategy development discussions presented later in this text.

After reading this chapter, the reader should be able to:

1. Categorize and describe the stakeholders in the U.S. healthcare system.
2. Discuss the performance of the U.S. healthcare system.
3. Discuss the differences in performance between the U.S. healthcare system and an average healthcare system in the industrialized world.
4. Discuss the major issues faced by the U.S. healthcare system.
5. Discuss the rising costs of care and its major components.
6. Discuss the problem of access and lack of universal healthcare coverage in the United States.
7. Discuss the highlights of the history of healthcare reform in the United States.
8. Discuss how reforms have addressed some of the performance challenges of the U.S. healthcare system.

THE U.S. HEALTHCARE SYSTEM STRUCTURE

The U.S. healthcare system is a product of decades of growth and maturation that too often have led to a variety of deficiencies and serious problems. The responses to these problems, whether they came from the private sector

or the government, have frequently been only short-term corrections. This shortsightedness in addressing the healthcare system's problems is a product of the preoccupation of most businesses with short-term financial performance at the expense of thoughtful and responsible course correction and the preoccupation of politicians with political gamesmanship and elections. As a result, the system is a complex of layered adjustments made up mostly of patchwork and temporary fixes to such an extent that any intelligent design is undetectable. This short-term thinking and the unintended consequences of legislated policies have created a complex healthcare system that is inefficient and difficult to understand.

At the core of any healthcare system, including the U.S. healthcare system, a product or service is offered to a consumer at a certain price. The rules that govern such transactions come from various entities, but all are expected to comply with the laws of their country—in this case, the United States. As such, one can categorize the major stakeholders as regulators and policy makers, payers, advocacy organizations, providers, suppliers, and consumers. These are broad categories that at times overlap, such that one entity may have more than one role; for example, a consumer may also be the payer. These will be discussed in more detail in the paragraphs that follow.

Regulators and Policy Makers in the U.S. Healthcare System

At the top of the pyramid, the federal government sets the tone for the entire system. Many other entities have been formed over the years in response to the need for control over various areas of the healthcare industry. Today, the most influential regulators include the U.S. Department of Health and Human Services (HHS), the Centers for Medicare & Medicaid Services (CMS), the Food and Drug Administration (FDA), and the Centers for Disease Control and Prevention (CDC). These entities have been charged to interpret, implement, and ensure compliance with the current laws of the United States that affect and govern the healthcare industry. The scope of regulatory influence of these entities is determined by the laws they enforce.

At the state level, state legislatures, state and local governments, health departments, state medical boards, and state insurance commissions also play significant roles while functioning within federal regulations. Nevertheless, state governments have been successful in introducing unprecedented moves that go beyond federal mandates for healthcare policy; for example, Massachusetts was able to mandate health insurance coverage for all its citizens in 2006.[1]

Payers in the U.S. Healthcare System

Financing in the U.S. healthcare system can be broken down into payments made by the public sector (the federal government, state and local governments), the private sector (private insurers and businesses), and the consumer (out-of-pocket expenses and self-pay). The share of each source in the total national healthcare expenditure in 2008 is shown in **Figure 1-1**.

As can be seen in the chart, 47% of the expenditure comes from public sources and 53% from private sources. Public funding of the U.S. healthcare system includes federal sources, such as Medicare and Medicaid programs, the Veterans Administration, and the U.S. Department of Defense, and state and local programs, such as Medicaid and state and local hospitals. Private funding includes out-of-pocket expenditure, private insurance, and philanthropy. As can be inferred from this list, many of these payers have other capacities and exert substantial influence in other areas of the U.S. healthcare system through policy making (e.g., CMS) or through advocacy groups and lobbying (e.g., private insurance companies).

Advocacy Organizations

This category encompasses organized efforts of smaller entities in the healthcare system around a common interest that is frequently self-serving. These organizations are numerous, and discussion of their role and influence in the U.S.

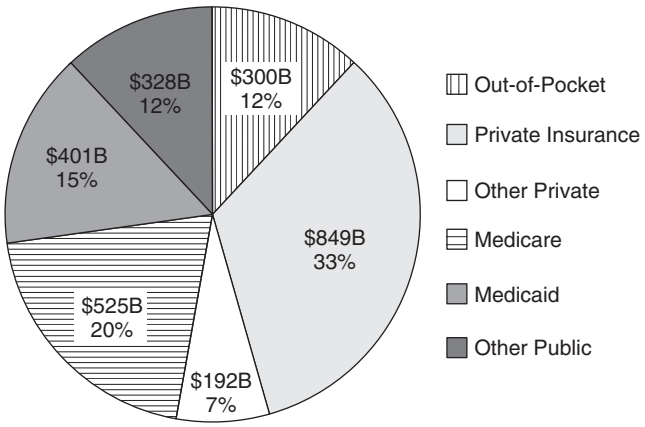


FIGURE 1-1. In 2010, the total national healthcare expenditure was $2,594 billion. The breakdown of where this money came from is presented in this chart. B, billion. Data from CMS.[2]

healthcare system is beyond the scope of this text. Examples of these groups include the American Medical Association (AMA), the American Society of Clinical Oncology (ASCO), the American Hospital Association (AHA), the American Nurses Association (ANA), America's Health Insurance Plans (AHIP), and the National Patient Advocate Foundation (NPAF).

Providers in the U.S. Healthcare System

This category includes all individuals and organizations that provide a healthcare service to the consumer. As such, it includes health practitioners, hospitals, nursing homes, and other similar entities. Although health professionals are central to the specific entity that actually provides care, hospitals, in particular, offer the environment in which care can be provided and are compensated by payers for the services provided. It is in the hospital setting that a substantial portion of healthcare resources are consumed.

Individual practitioners, practice groups, general hospitals, specialty hospitals, ambulatory facilities (surgery, imaging, etc.), and integrated healthcare systems are also examples of providers.

Suppliers

This category includes pharmaceutical companies and medical equipment companies. These entities have grown to be a significant part of the healthcare system and are in fact considered industries of their own. Although suppliers are integral to the healthcare system, the nature of their business is different. Like private insurance companies, most of these organizations are for-profit and publicly traded companies and exist in a different competitive environment. Unlike the payer category, the amount of not-for-profit activity in this category is small.

Consumers

People, whether sick or healthy, are consumers of care. In the industrialized world, one would be hard pressed to find anyone who has never received any care within a healthcare system. Consumers of healthcare services are somewhat different from consumers in other sectors of the economy. Two primary differences are (1) healthcare consumers often have to depend on the advice of a physician in making a health services "consumption" decision, and (2) in most instances, the consumer is unaware of the full costs of his or her choice because of the intermediary function of payers—even though there may be a significant out-of-pocket component of the full cost.

THE U.S. HEALTHCARE SYSTEM PERFORMANCE

From a global systems perspective, the performance of a healthcare system can be viewed in terms of the size and makeup of the population it serves, the healthcare outcomes it produces, and the amount of resources it consumes. Other factors, such as fairness issues that include equitable distribution of the healthcare services and financial burden and quality of care delivered within the system, should also be included in the mix.

The World Health Organization (WHO) proposed a framework for measurement of performance at the level of a healthcare system by first defining healthcare action as "any set of activities whose primary intent is to improve or maintain health."[3] This definition establishes boundaries within which the framework measures performance around three fundamental goals: improving health, enhancing responsiveness to the expectations of the population, and ensuring fairness of financial contribution.

Improvement of health involves both increase of average health status and decrease of health inequalities. Responsiveness involves respect for the individual (i.e., dignity, confidentiality, and autonomy) and client orientation (e.g., prompt attention and choice of provider). Fairness of financial contribution implies that the individual is protected from financial risks due to health care.

Based on this framework, performance relates attainment of the aforementioned goals to the resource allocation; furthermore, variations in performance are the results of four key functions: (1) stewardship (broader than regulation only), (2) financing, (3) service provision, and (4) resource generation. WHO suggests that by investigating these four functions, it is possible to understand the determinants of health system performance and identify major policy challenges.[3]

This framework was also adopted by the Organisation for Economic Co-operation and Development (OECD) with slight modification. In this modified framework, access to health care and outcomes are included among the goals (**Table 1-1**).

Table 1-1 Health System Goals in Relation to the Component for Assessment[4]

	Average Level	Distribution
Health Improvement/Outcomes (+)	✓	✓
Responsiveness and Access (+)	✓	✓
Financial Contribution/Health Expenditure (−)	✓	✓
	Efficiency	Equity

As seen in Table 1-1, this framework also links efficiency and equity to the performance measurement process. This framework sets three goals: higher levels of health improvement/outcomes, higher levels of responsiveness and access, and lower levels of financial contribution and health expenditures subject to the successful attainment of the first two goals.[4]

In the following sections, a current status of each of the three main goals in the U.S. healthcare system will be presented from a societal point of view.

Outcomes in the U.S. Healthcare System

Comparing the U.S. data with that of other countries could substantially contribute to one's understanding of what is right and what is not right in the U.S. healthcare system. To that end, a few key pieces of data are presented here.

As will be discussed later in this chapter, the United States is the only industrialized country in the world that does not offer universal healthcare coverage to its citizens. Infant mortality rate has steadily declined in industrialized countries over the past decades, but for the first time since records have been kept, the U.S. rate for infant mortality has climbed above that of the OECD median (**Figure 1-2**).[5]

Potential years of life lost due to diabetes per 100,000 population for the United States is 99, almost 3 times as high as the OECD median, and life expectancy at birth for the United States was 1.3 years lower than the OECD median in 2009 (in 1960 it was 1.7 years higher than the OECD median).[6,7] The United States has the second highest rate of hospital admission for asthma among the OECD countries (121 per 100,000, after the Slovak Republic

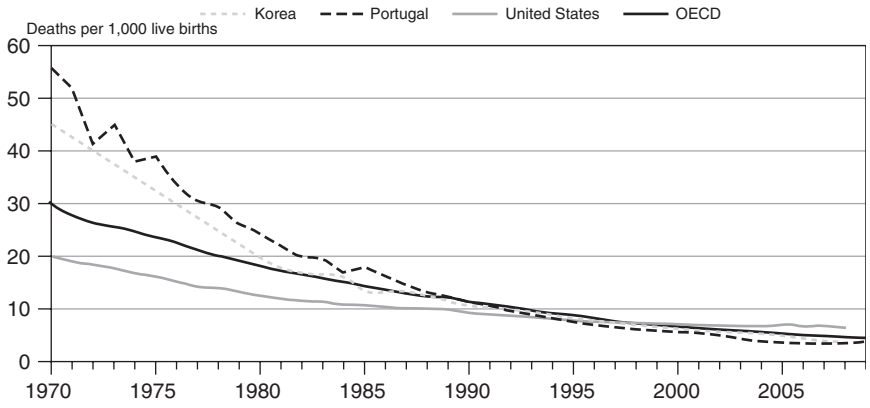


FIGURE 1-2. Data for 2009 from OECD.[5]

with 167 per 100,000), which is more than 2 times the OECD median of 52 per 100,000, whereas Canada and Mexico each have among the lowest rates, 16 and 19 per 100,000, respectively.[8]

The United States spends significantly more than other industrialized nations on health care, both as a percentage of gross domestic product (GDP)[9] and per capita[10] (**Figure 1-3** and **Figure 1-4**). Unfortunately, this spending does not translate into outcomes, for example, life expectancy at birth (**Figure 1-5**).

This suggests that there are significant inefficiencies in the U.S. healthcare system and that the *value** of the services in the U.S. healthcare system may be lower compared with that in other industrialized countries. Discussion of why this may be the case is beyond the scope of this text. However, addressing access to health care in the United States can significantly increase the magnitude of

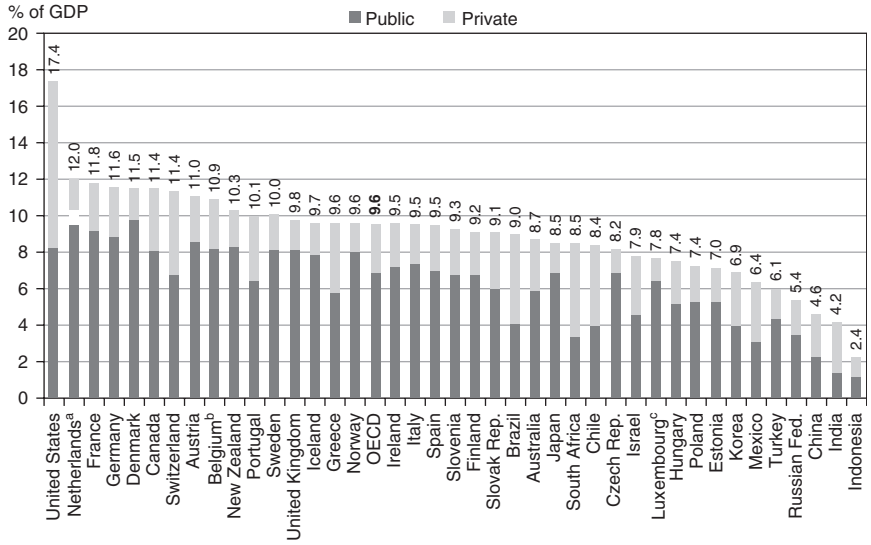


FIGURE 1-3. Total health expenditure as a share of GDP in 2009 (or nearest year). The United States spends more dollars as a percentage of GDP than any other country. [a]In the Netherlands, it is not possible to clearly distinguish the public and private share related to investments. [b]Total expenditure excluding investments. [c]Health expenditure is for the insured population rather than the resident population. From OECD.[9]

*Value is proportional to the ratio of quality or outcomes to costs, as discussed in the following chapters.

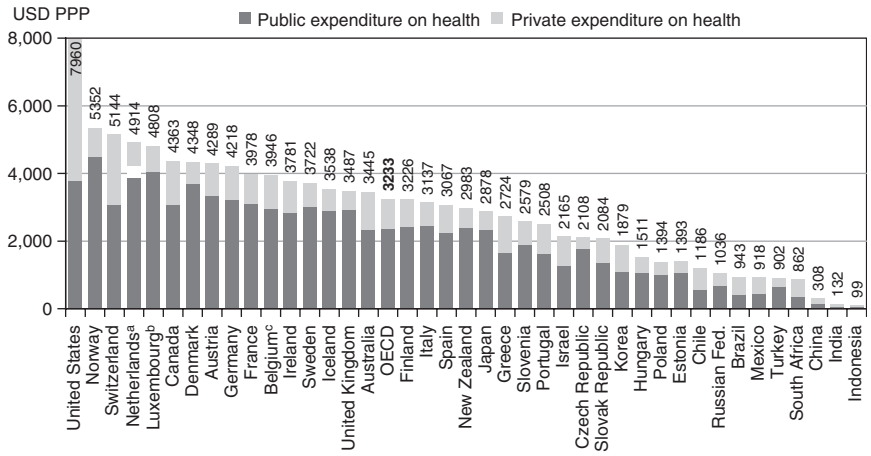


FIGURE 1-4. Total public and private health expenditure per capita in 2009 (or nearest year). The United States spends more dollars per capita than any other country. [a]In the Netherlands, it is not possible to clearly distinguish the public and private share related to investments. [b]Health expenditure is for the insured population rather than the resident population. [c]Total expenditure excluding investments. USD PPP, US$ purchasing power parity. From OECD.[10]

the beneficial effects of primary and preventive care by reducing the uninsured population. This could prevent the expensive complications of chronic conditions such as asthma, chronic obstructive pulmonary disease (COPD), diabetes, hypertension, and atherosclerosis, improving the outcomes for all. This improves quality and creates additional value by way of more equitable access and better outcomes.

Ironically, when compared with the countries that have public healthcare systems, the current healthcare system in the United States, which relies on the efficiency of markets and competition, has the highest administrative cost per capita ($486), twice as much as that for France, which occupies the second place at $243 among the OECD countries.[6]

Access in the U.S. Healthcare System

The U.S. government does not offer universal healthcare coverage to its citizens. As a result, a significant portion of the population does not have health insurance, and to access healthcare services within the system, individuals would have to pay out of pocket. This has been a primary reason for lack of access to health

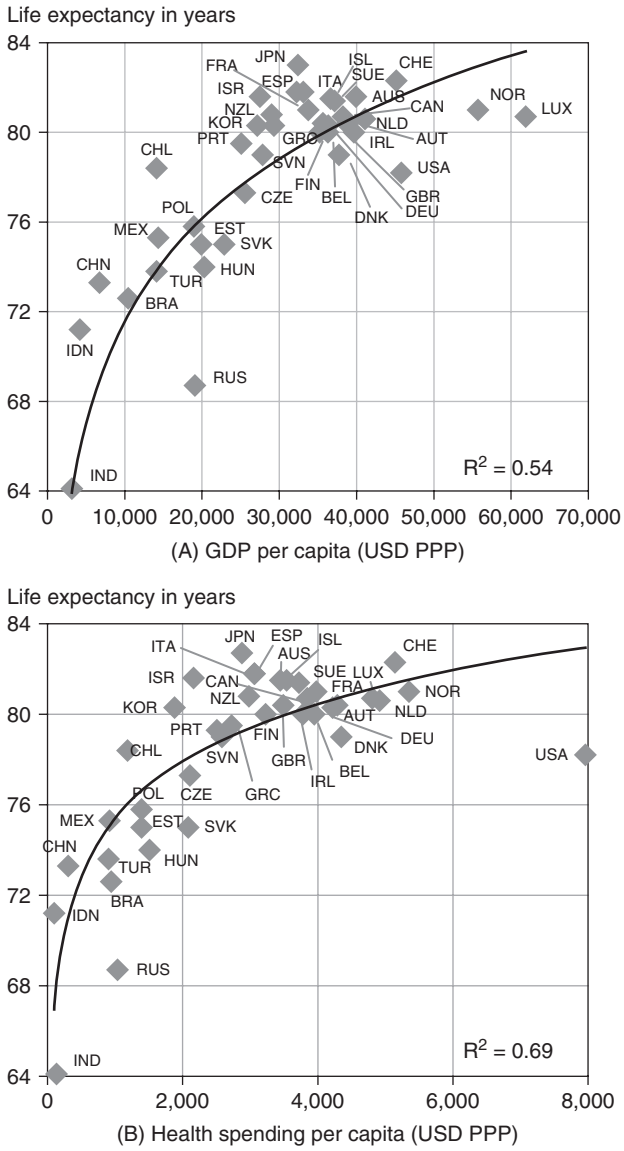
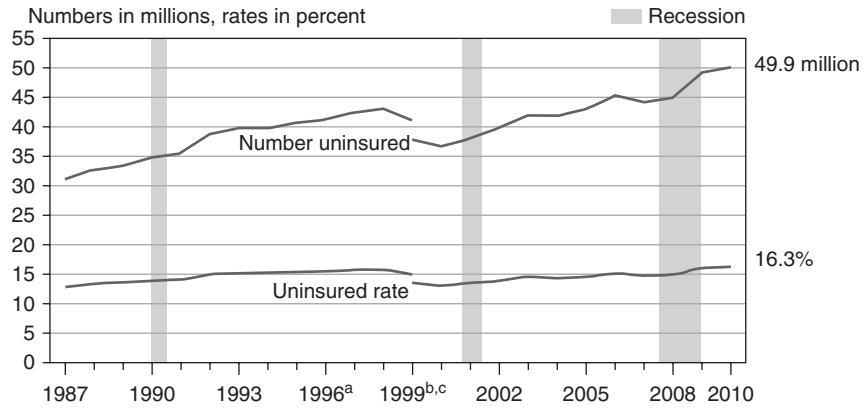


FIGURE 1-5. Correlation between GDP per capita (A), health spending per capita (B), and life expectancy at birth in OECD countries in 2007. The United States is one of the outliers in both curves.[7] USD PPP, US$ purchasing power parity.



[a] The data for 1996 through 1999 were revised using an approximation method for consistency with the revision to the 2004 and 2005 estimates.
[b] Implementation of Census 2000–based population controls occurred for the 2000 Annual Social and Economic Supplement (ASEC), which collected data for 1999. These estimates also reflect the results of follow-up verification questions, which were asked of people who responded "no" to all questions about specific types of health insurance coverage in order to verify whether they were actually uninsured. This change increased the number and percentage of people covered by health insurance, bringing the Current Population Survey (CPS) more in line with estimates from other national surveys.
[c] The data for 1999 through 2009 were revised to reflect the results of enhancements to the editing process.
Note: Respondents were not asked detailed health insurance questions before the 1988 CPS.

FIGURE 1-6. Number of uninsured and the uninsured rate, 1987–2010. The rate of the uninsured has been growing over the years. From DeNavas-Walt et al.[11]

care. Uninsured individuals that are unable to pay often get the care they need through emergency departments when they are very sick, after the opportunity to avoid preventable conditions has long passed.

Unfortunately, the uninsured make up a significant and growing percentage of the U.S. population (**Figure 1-6**). The U.S. Census Bureau estimates the number of uninsured in 2010 at 49.9 million.[11]

As will be discussed later in this chapter, the PPACA, which was signed into law in March 2010, requires most U.S. citizens and legal residents to purchase qualifying health plans or pay a penalty.[12]

Expenditures in the U.S. Healthcare System

In 2010, national healthcare expenditure (NHE) amounted to $2.6 trillion, which is 17.9% of GDP in 2010.[13] For 2012 national healthcare expenditure is

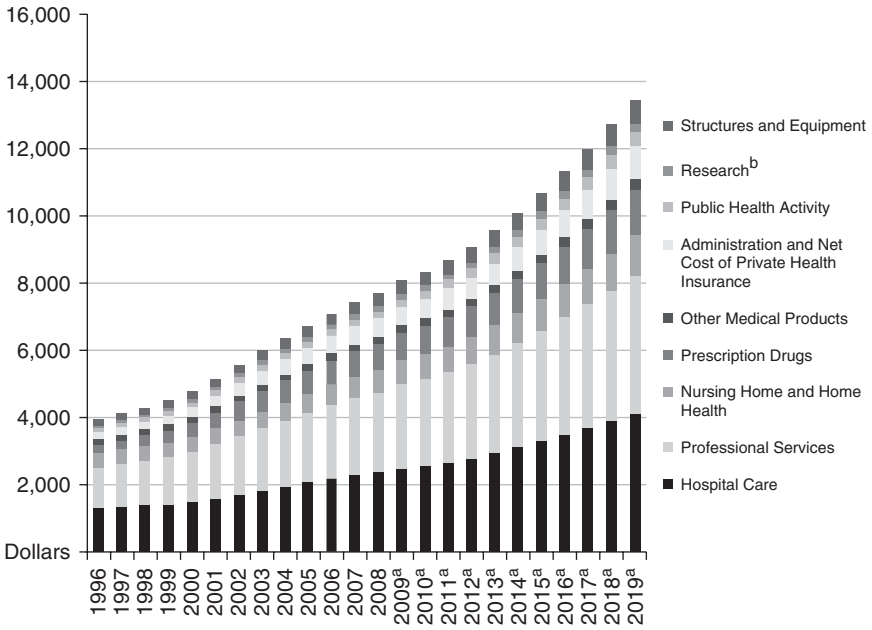


FIGURE 1-7. U.S. healthcare expenditure per capita. [a]Years 2009 through 2019 are based on projections. [b]Research and development expenditures of drug companies and other manufacturers and providers of medical equipment and supplies are excluded from research expenditures. These research expenditures are implicitly included in the expenditure class in which the product falls, in that they are covered by the payment received for that product. Data from U.S. Census Bureau.[14]

projected to go well over $2.8 trillion[15], which is 17.7% of the projected GDP for 2012.[16] **Figure 1-7** illustrates the per capita healthcare expenditures in the United States since 1996.

The national healthcare expenditure as a percentage of GDP has been increasing each year, as seen in **Figure 1-8**. This rate of growth is well above the inflation rate and has proved difficult to control.[2,17] Another concerning trend is that the national healthcare expenditure as a portion of GDP is also growing, essentially at the expense of lack of growth or shrinkage in other sectors (Figure 1-8).

Healthcare expenditures were thought to be immune from economic fluctuations, but the recent economic recession caused a decrease in expenditure growth rate to a historic low of 3.8% in 2009 and 3.9% in 2010, but projections for

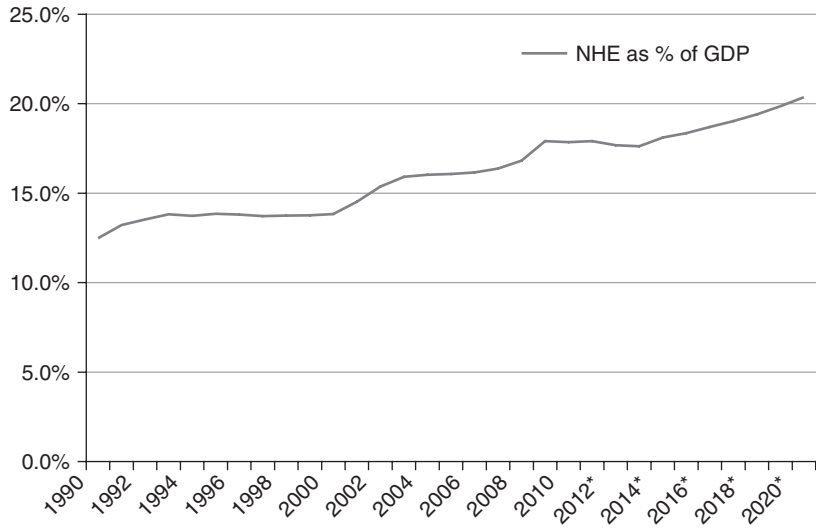


FIGURE 1-8. National healthcare expenditure (NHE) as a percentage of GDP. *Projection. Data from the Congressional Budget Office (CBO)[18] and CMS.[2]

2011 through 2014 show a continued increase in the healthcare expenditure growth rate.[14,16] (**Figure 1-9**).

The breakdown of where this money is spent is shown in **Figure 1-10**. Hospital care and professional services make up more than 60% of the expenditure, followed by prescription drugs.

PERFORMANCE CHALLENGES IN THE U.S. HEALTHCARE SYSTEM

For years, the challenges facing the U.S. healthcare system, including the rising costs and growing number of uninsured individuals, have been the topics of discussion in various business and policy circles. There has been no shortage of prescribed remedies for these challenges, which have ranged from leaving it to the markets, managed care, managed competition, evidence-based medicine, and single-payer universal coverage, none of which are mutually exclusive. To this, one must add growing concerns for the quality of care and increased awareness of poor outcomes within the system.

The response to these challenges can be grouped into two major components: cost containment and improved access. Both of these components play roles in

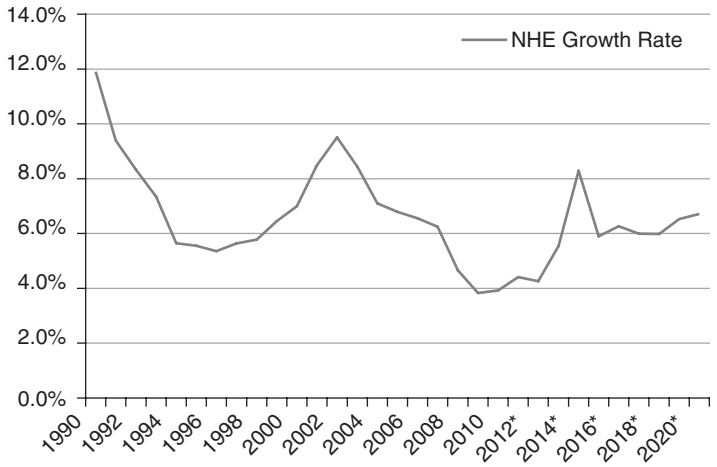


FIGURE 1-9. Growth rate for national healthcare expenditures. National healthcare expenditures have been growing at a rate of more than 5%, with the exception of a temporary dip in years 2008, 2009, and 2010 to 4.4%, 3.8%, and 3.9%, respectively. Mainly attributable to the slump in the U.S. economy.[19–23] *Projection. Data from CMS.[2]

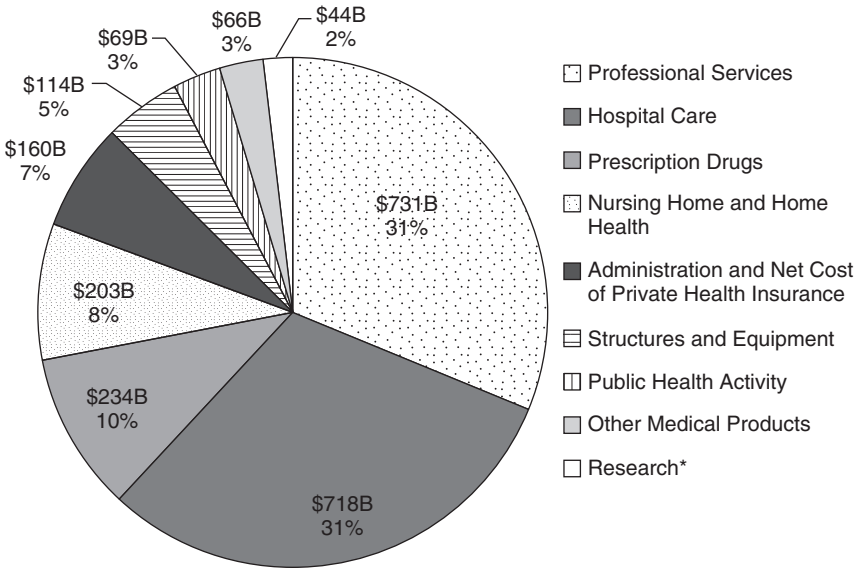


FIGURE 1-10. National healthcare expenditure in 2009: A breakdown of where the money is spent in the U.S. healthcare system. *Research and development expenditures of drug companies and other manufacturers and providers of medical equipment and supplies are excluded as they are implicitly included in the expenditure class in which the product falls. Data from CMS.[2]

the issues associated with healthcare quality measurement and improvement and will be separately discussed.

Healthcare Cost Containment

This has been a topic of great interest over the years, but as shown in the previous sections, healthcare costs continue to rise. To understand how these costs can be controlled, one must understand not only where the money comes from and where it goes, but more importantly what is driving these increases in costs. Typical cost-containment efforts would begin with identifying the major components and drivers of cost and examining opportunities for reductions in those components.

According to the CMS, changes in prices, specifically in medicine, as well as aging and an increase in population account for the majority of the growth of personal healthcare expenditures.[24] As shown in Figure 1-9, professional services, hospital care, and prescription drugs account for more than 70% of the national healthcare expenditure. This is followed by nursing home and administrative costs, which make up another 15% of the costs. This contributes to why chronic disease management, aging of the population, prescription drugs, and administrative costs are among the major factors considered in discussions of costs in health care.[25,26] Whereas one can address some of these drivers, clearly certain factors, such as an aging population, are not controllable.

In addition to age, other demographic factors should also be considered as explanatory but not necessarily controllable factors. Five percent of the U.S. population spends approximately 48% of all healthcare dollars, and 1% of the U.S. population spends more than 20% of the healthcare dollars[27] (**Figure 1-11**).

Geographic variations in healthcare expenditures are also noteworthy in the study of healthcare costs. These differences in costs have been the subject of studies and are not explained by differences in prices alone and may be attributable to utilization.[28,29] These geographical variations are important and controversial[29–32] and are not linked to improved quality[28,33,34] (**Figure 1-12** and **Figure 1-13**).

Another significant problem with healthcare expenditures is the waste in the system defined as "healthcare spending that can be eliminated without reducing the quality of care."[34] This has been a focus of discussion for some time but recently has come under closer scrutiny and is estimated to be upward of $700 billion annually. This is about 30% of the total expenditure and includes unnecessary care (40%), fraud (19%), administrative inefficiency (17%), healthcare provider errors (12%), preventable conditions (6%), and lack of care coordination (6%).[35,36]

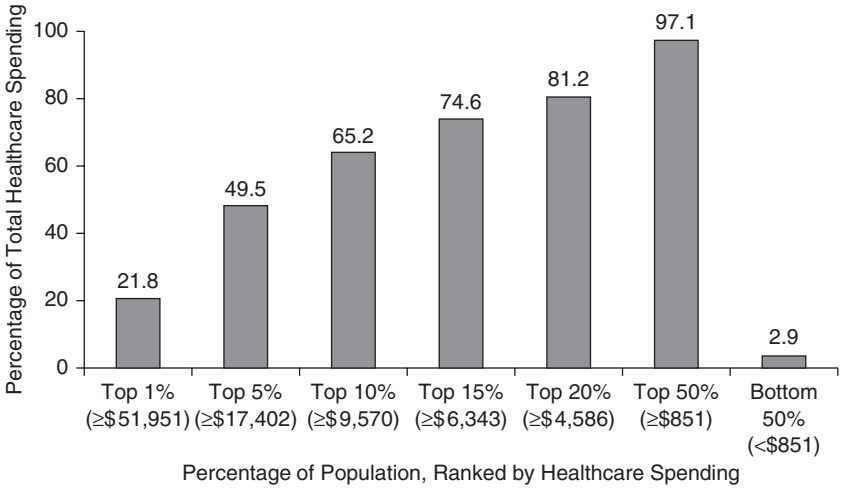


FIGURE 1-11. Concentration of healthcare spending in the U.S. population, 2009. Dollar amounts in parentheses are the annual expenses per person in each percentile. Population is the civilian noninstitutionalized population, including those without any healthcare spending. Healthcare spending is total payments from all sources (including direct payments from individuals, private insurance, Medicare, Medicaid, and miscellaneous other sources) to hospitals, physicians, other providers (including dental care), and pharmacies; health insurance premiums are not included. From Kaiser Family Foundation calculations[27] using data from the U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality, Medical Expenditure Panel Survey (MEPS), 2009.

As can be seen in the data presented thus far, healthcare costs have been rising regardless of the efforts made by the regulators and payers to contain them.[37] Perhaps the most well-known "failed" model has been that of the managed care organizations. Data suggest that managed care organizations were successful in containing costs in the early 1990s by controlling utilization, although this may have come at the expense of quality.[33,38] This practice quickly became equally unpopular among patients and physicians and led to the failure of the managed care model. However, there is empirical evidence that the use of gatekeepers in the managed care model still continues.[38]

A number of approaches have been proposed by experts to bring the costs under some control and include investment in information technology (IT), improvement of quality of care to increase efficiency, adjustment of provider compensation, additional government regulation, preventive medicine, increase in consumer

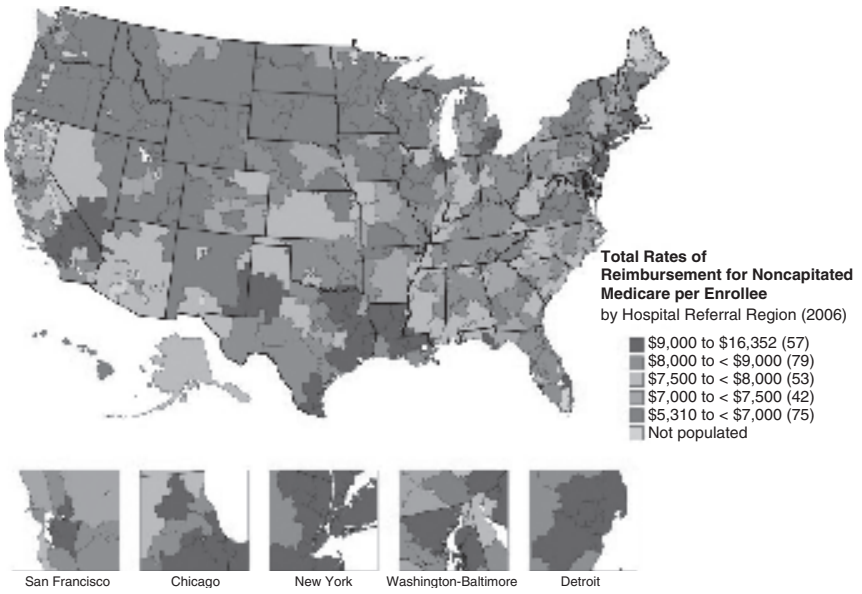


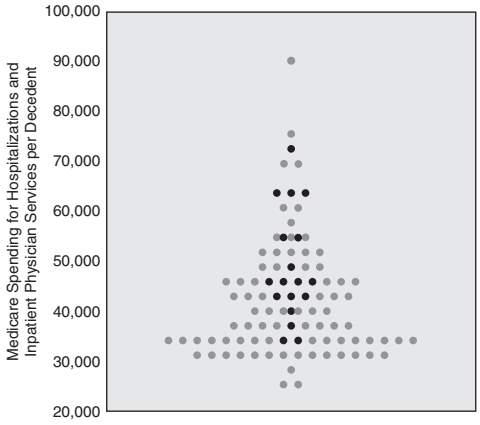
FIGURE 1-12. *Dartmouth Atlas* graphic demonstrating geographical variations in healthcare costs.[34]

involvement and price transparency, and finally tax incentives to expand insurance coverage.[26] To this list one must add reduction of waste in the system as it is a significant proportion of the overall expenditures and merits its own category.[36,39]

Healthcare Access

Decreased access and reduced utilization are sometimes by-products of cost pressures in the industry. Rising costs have resulted in a greater share of the costs being passed on to individuals and families in the form of increased premiums, higher deductibles, and other out-of-pocket expenses—the exclusion of preexisting conditions will also contribute to increased costs.

This problem of increasing costs is unlikely to be solved without the intervention of policy makers and has become a platform for calls for reform. If one day some form of basic healthcare coverage is offered to all of the U.S. population, then the United States will become the last Western country to offer universal coverage. It is important to recognize that the issue of access is not only a matter of fairness, equity, or even quality. Limited access only postpones the need to deal with a medical problem that inevitably comes back in the form of a complicated medical condition in need of urgent or emergent attention. The Emergency



Medicare Spending for Hospitalizations and Inpatient Physician Services per Decedent in the Last Two Years of Life Among Patients with At Least One of Nine Chronic Conditions Receiving Most of their Care from Selected COTH Integrated Academic Medical Centers (Deaths Occurring 2001–2005)

Among COTH integrated academic medical centers, per decedent Medicare reimbursements for inpatient care during the last two years of life varied by a factor of four, from about $24,000 to almost $92,000. Each point represents one of the 93 selected COTH academic medical centers. The 18 hospitals on USN&WR's Honor Roll for 2007 are highlighted in red.

Selected Academic Medical Center Data	
Cedars-Sinai Medical Center	$71,637
UCLA Medical Center	$63,900
Johns Hopkins Hospital	$63,079
New York-Presbyterian Hospital	$62,773
UCSF Medical Center	$54,669
Hospital of the University of Pennsylvania	$54,455
Brigham and Women's Hospital	$50,156
University of Washington Medical Center	$46,891
University of Michigan Hospitals	$46,397
University of Chicago Hospital	$45,718
Stanford Hospital and Clinics	$44,997
UPMC Presbyterian Shadyside	$43,504
Yale-New Haven Hospital	$43,325
Massachusetts General Hospital	$43,058
Barnes-Jewish Hospital	$40,681
Duke University Hospital	$37,751
Cleveland Clinic Foundation	$34,437
Mayo Clinic (St. Mary's Hospital)	$34,372

FIGURE 1-13. Geographical differences in spending illustrated across major medical centers of national and international reputation. Spending at Cedars-Sinai Medical Center is more than two times higher than that at the Mayo Clinic and the Cleveland Clinic.[32]

Medical Treatment and Active Labor Act (EMTALA), which passed as part of the Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1985, stipulates that emergency rooms can no longer refuse to treat these patients, which results in substantial uncompensated care, bad debt, and charity expenditures that are ultimately absorbed by the insured or the taxpayer.[40–42]

It has been suggested that a more efficient deployment of resources in our healthcare system would allow preventive care to be offered universally at no or minimal incremental costs over what is already spent.[43] Needless to say, this is controversial.

HEALTHCARE REFORM AND ITS HISTORY

Before discussing the recent healthcare reform bills signed into law by President Obama, a brief review of the highlights of healthcare reform history is helpful

as it puts the current state of affairs in a historical perspective. It also underlines the fact that reform is an ongoing process, and course corrections are inevitable.

In the United States, a strong dislike of "big government" prevented consideration of any significant healthcare reform until 1935.

The Social Security Act of 1935

The critical times after the Great Depression and lack of economic security required a response at the national level, which eventually came in the form of the Social Security Act, which was signed into law by President Franklin D. Roosevelt on August 14, 1935. The United States was the 35th nation to adopt such a measure to address economic security for its citizens.[44] Although the Social Security Act was not intended as a reform of the healthcare system, it did provide some assistance to the citizenry and to the states for purpose of medical care. Thirty years later, the Medicare bill was signed into law by President Lyndon Johnson on July 30, 1965, as an amendment to the Social Security Act providing health benefits to virtually all Americans above the age of 65 years. This was the first major reform of the healthcare system in the United States by way of regulatory changes. The CMS, a component of HHS, administers Medicare, Medicaid, and the State Children's Health Insurance Program (SCHIP). The Social Security Administration is responsible for determining Medicare eligibility and processing of premium payments for the Medicare program.

For years, concerns over many of the issues that were discussed in the previous sections continued to build up, and debate over the need for healthcare reform continued. In 1992 and 1993, the healthcare debate became front and center in American politics, and issues such as rising costs, access, and quality of health care were highlighted.[45–51] This culminated in an unsuccessful attempt by the Clinton administration to pass the Health Security Act of 1994. In August 1994, then Democratic Senate Majority Leader George J. Mitchell attempted to introduce an employer-friendly compromise to the earlier iterations of the bill (H.R. 3600). However, the bill failed to gain sufficient congressional support.[52]

The Clinton Reform and the Health Security Act of 1994

President Clinton envisioned a healthcare system where Americans would have choice and affordable relationships with healthcare providers. The administration recognized diminishing healthcare choices as a result of a new healthcare model

known as health maintenance organizations (HMOs).[53] The goal of the legislation as defined by its proponents was "to provide for health care for every American and to control the cost of the health care system."[54] Although the Health Security Act (HSA) of 1994 focused on expansive coverage, patient choice, and retention of healthcare providers, many provisions within the act also addressed quality of care. Despite the fact that this legislation was never enacted, the ideas in the bill are still relevant today and merit some discussion.

Proposed Reform in Access to the Healthcare System

Perhaps the most significant reform that was part of HSA was expansive access to health care. HSA envisioned provisions for universal healthcare coverage to ensure that all eligible individuals had access to a health plan that delivered a comprehensive benefit package. Eligible individuals were defined as citizens, nationals, permanent residents, and long-term nonimmigrants.[55] As part of the debate over HSA, the issue of whether individuals have a right to health care was revisited at the national level.[56–61]

Proposed Reform in the Structures of the Healthcare System

The 1993 and 1994 attempts at healthcare reform contained several structural suggestions to improve healthcare quality. Legislators proposed that the National Quality Management Council develop a set of national measures of quality performance. These measures would be used to assess the provision of healthcare services and patient access. Legislators envisioned that the council would ascertain the appropriateness of healthcare services provided to consumers and measure the outcomes of these services and procedures. The council would also be responsible for gathering customer satisfaction data and examining disease prevention and health promotion. Council members would conduct periodic surveys of healthcare consumers to gather information concerning access to care and the impact of the HSA on the general population of the United States, with some emphasis placed on vulnerable populations.[54]

Such national quality measures would be thoroughly applied in order to be meaningful to agencies and legislators. Once the appropriate quality measures were identified and the information on their status within the healthcare system was acquired, the HSA policy makers envisioned that the information would be stored in computerized data banks. These data banks would provide opportunities for transparent sharing of both quality outcomes and best practices. To ensure judicious measurement and adequate implementation of other HSA provisions, policy makers recommended the establishment of the National Institute for Health Care Workforce Development. Legislators tasked the institute

with development and implementation of high-performance and high-quality healthcare delivery systems.[54]

Proposed Reform in the Processes of the Healthcare System

The HSA contained many provisions geared toward measurement of quality outcomes and patient satisfaction. One such measurement process required the implementation of a national health information system. Policy makers sought to use this national health information system to gather national health information and establish quality standards. The findings would then be reported in quality report cards. The *Annual Quality Report* would contain national measures of quality for healthcare systems (hospitals, agencies, insurance providers) and would be delivered to the president and Congress annually. The Exclusion of Poor Quality Physicians Provision of the HSA allowed insurance carriers to bar poorly performing physicians from receiving reimbursement.[54]

The HSA allocated $400 million per annum to fund projects to train additional primary care physicians and physician assistants. Policy makers sought to enhance community-based generalist training for medical students, residents, and practicing physicians. Additionally, $200 million per annum would be provided for much needed training and education in managed care processes, cost-effective practice management, and continuous quality improvement.[54]

Proposed Reform in the Outcomes Measurement of the Healthcare System

Although the 1994 HSA ultimately did not pass through the 103rd Congress, there is evidence that some of the proposed quality structures and processes became reality via alternative pathways. The Agency for Healthcare Policy and Research founded by Congress in 1989 was renamed the Agency for Healthcare Research and Quality (AHRQ) in 1999. The focus and goals of AHRQ are similar to the goals of the 1994 HSA's proposed National Quality Management Council.[62] As will be discussed later in this text, many organizations today actively collect and process information on various outcomes within the U.S. healthcare system.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003

In 2003, President George W. Bush signed into law the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. This was the largest single expansion of the Medicare program since its creation.[63]

The Healthcare Reform of 2010

In March 2010, President Obama signed into law the PPACA (H.R. 3590, signed on March 23, 2010). The Health Care and Education Reconciliation Act of 2010 (HCERA; H.R. 4872, signed on March 30, 2010) reconciles PPACA with the Affordable Health Care for America Act (AHCAA; H.R. 3962). This complexity was due to the U.S. Senate passing the PPACA, which was somewhat different from the AHCAA passed by the U.S. House of Representatives. To resolve the differences, the House of Representatives passed PPACA and a "fixer" bill, the HCERA, which was later passed by the Senate, in a process referred to as *reconciliation*.

The PPACA and the fixes of the HCERA, collectively referred to as the Affordable Care Act, or ACA, aim to provide affordable health care to all Americans, reduce costs, improve healthcare quality, enhance disease prevention, and strengthen the healthcare workforce.[12,64] Both acts make significant changes that directly impact the U.S. healthcare system and the quality of care provided within it.

Reform in Access to the Healthcare System

Section 1001 of the PPACA provides an amendment to the Public Health Service Act of 1944[65] and aims to improve healthcare coverage for all Americans. This amendment provides coverage for preventive health services and extends dependent coverage. It also addresses quality and cost-of-care issues within the scope of the Public Health Service Act.[12]

Section 1101 of the PPACA immediately provides access to insurance for the uninsured with preexisting conditions.[12,66] This has been a challenging aspect of healthcare coverage in the United States. Under PPACA Title II, public programs are also reformed to provide expanded coverage. A contentious part of the PPACA makes it mandatory for individuals to maintain minimum health insurance coverage. Under section 1501, it is stated that this requirement would achieve near-universal coverage. It is important, however, to emphasize that even without the individual mandate, PPACA provides expanded coverage for as many as 23 million individuals.[67]

Reform in the Structures of the Healthcare System

The PPACA and HCERA contain a multitude of structural elements to foster and encourage superior healthcare quality outcomes and mandate the creation of the Patient Centered Outcomes Research Institute. This not-for-profit institute will support comparative effectiveness research (CER), previously under

the auspices of the Federal Coordinating Council for Comparative Effectiveness Research, and identify research priorities. The secretary of HHS will appoint a multistakeholder board of governors to manage the institute. The institute will use comparative healthcare economic analyses to compare and contrast the clinical effectiveness of medical interventions. However, the recommendations of the institute cannot be used to determine payment or coverage or treatment. Upon enactment, section 6302 of the PPACA will terminate the Federal Coordinating Council for Comparative Effectiveness Research, which was funded under the American Recovery Reinvestment Act of 2009.[12]

Section 10333 of the PPACA provides grants to Collaborative Care Network Programs to facilitate coordination and integration of healthcare services for low-income uninsured and underinsured populations.[12] Section 2602 of the PPACA establishes the Federal Coordinated Healthcare Office under the CMS administrator for dual eligible beneficiaries to coordinate federal and state government entities to improve quality of care and access to services for those patients who are eligible for both Medicaid and Medicare benefits.[12]

Section 3012 of the PPACA establishes the Interagency Working Group on Health Care Quality with the goal of collaboration, cooperation, and consultation between federal departments and agencies with respect to developing and disseminating strategies, goals, models, and timetables that are consistent with the national priorities. Additional responsibilities of the working group include assessing the alignment of quality efforts in the public sector with private-sector initiatives and avoiding the inefficient duplication of quality improvement efforts and resources. Many federal agencies have a seat at this table.[12]

Section 3509 of the PPACA pays special attention to women's health and establishes special offices within HHS and the CDC. The objective is to coordinate with other offices and agencies to facilitate disease prevention, health promotion, and service delivery. Similarly, section 10334 of the PPACA mandates the transfer of the Office of Minority Health to be similarly situated within the Office of the Secretary of HHS. This office will award grants and contracts to public entities to evaluate community outreach activities, language services, and workforce cultural competence in the hopes of improving healthcare outcomes in minority populations.[12]

Reform in the Processes of the Healthcare System

The PPACA calls on the secretary of HHS to create a National Strategy for Quality Improvement in Health Care. This strategy should identify national priorities

and develop a strategic plan to achieve them. This national strategy and the corresponding plan is subject to periodic update.[12]

Section 3014 of the PPACA focuses on quality measurement. Under this section, the secretary of HHS may award grants and contracts to entities to support new or improve existing efforts to collect and aggregate quality and resource use measures.[12]

Section 3001 of the PPACA requires Medicare to implement value-based purchasing programs for skilled nursing facilities, home health agencies, and ambulatory surgical centers. Similarly, Medicare Advantage Plans with superior patient outcomes will also be rewarded with monetary bonuses.[12]

Section 3504 of the PPACA makes grants available for the design and implementation of Regionalized Systems for Emergency Preparedness and Response. These competitive grants are awarded by the secretary of HHS to entities to evaluate innovative models of regionalized, comprehensive, and accountable emergency trauma systems.[12]

Sections 3502 of the PPACA provide other grants including grants to establish Community Health Teams to support a Medical Home Model, awarded by the secretary of HHS, as well as grants to implement Medication Management in Treatment of Chronic Disease, awarded through the Patient Safety Research Center.[12]

Whereas some provisions seek to incentivize positive healthcare outcomes by providing rewards, there are other mandates that discourage poor-quality outcomes and wasteful practices by imposing penalties on the healthcare providers. For example, section 3025 of PPACA mandates a payment reduction for preventable readmissions and prohibits federal payments to states for Medicaid services related to conditions such as hospital-acquired infections and severe pressure ulcers resulting from poor skin care.[12]

Other mandates present within the PPACA discourage a disruption in the continuum of care, thus increasing quality patient outcomes. For example, section 1201 of the PPACA adds the Prohibition of Preexisting Conditions Exclusion by Insurance Providers section to the Public Health Services Act disallowing insurance companies to deny health insurance coverage for preexisting conditions or otherwise discriminate based on health status.[12]

These and additional elements of reform that are part of the PPACA are compared with the changes proposed in the HSA of 1994 in **Table 1-2**.

Table 1-2 Comparison of the HSA of 1994 and the PPACA with Respect to Reform in Structures and Processes[54,66]

Comparison Item	Health Security Act of 1994	Patient Protection and Affordable Care Act (PPACA)
Purpose	"..to provide health care for every American and to control the cost of the health care system."	"To make quality, affordable health care available to all Americans, reduce costs, improve health care quality, enhance disease prevention, and strengthen the health care workforce."
Proposed Reform in Structures		
Cost Effectiveness Centers		Patient Centered Outcomes Research Institute, Patient Safety Research Center
Patient Safety		Patient Safety Research Center
Collaborative Structures		Interagency Working Group on Health Care Quality, Collaborative Care Network Program
		Federal Coordinated Healthcare Office for Dual Eligibles, Medicaid Medical Home Option
Emergency/Trauma Care Programs and Centers		Trauma/Emergency Center Care and Efficiency Research Programs
Quality Improvement and Measurement Structures	National Quality Management Council	Quality Improvement Network Research Program, Value Based Purchasing Program
Women's Health Structures		Office of Women's Health
Minority Health Structures		Office of Minority Health
Payment Centers		The Center for Medicare and Medicaid Innovation—Payment Structure Evaluation
Miscellaneous Programs		Independence at Home Program
Proposed Reform in Processes		
Quality Measurement	Annual Quality Report	Gap Analysis, Grants for Developing Quality Measures, National Priorities for Quality Improvement
Reporting Quality Measures	Quality Report Card, Annual Quality Report	Quality Measure Endorsement, Public Reporting, Data Collection, Mandatory Reporting on Health Disparities
Efficiency and Delivery Incentives		Grants for Healthcare Delivery System Research, Grants for Studying Emergency Care Delivery
Preventitive Incentives		Coverage of Proven Preventative Services
Medical Home Incentives		Grants to Establish Community Health Teams—Medical Home Model
Medication Management Incentives		Grants for the Study of Medication Management

(continues)

Table 1-2 (continued)

Comparison Item	Health Security Act of 1994	Patient Protection and Affordable Care Act (PPACA)
High-Quality Rewards		Bonuses for Quality Improvement to Medicare Advantage Plans, Payment for Disease Stabilization at Mental Health Facilities
Poor-Quality Penalties	Exclusion of Poor Quality Physicians Provision	Prohibition on Exclusion for Preexisting Conditions, Nonpayment for Preventable Hospital Readmissions, Nonpayment for Hospital-Acquired Conditions (Medicaid)
Clinical Training Incentives	Primary Care and Physician Assistant Training (generalist training), National Institute for Health Care Workforce Development	Healthcare Delivery Training, Grants for Quality Improvement and Patient Safety Training
Health Disparities Processes		Exploration of Health Disparities, Mandatory Reporting on Health Disparities
Collaborative Initiatives		Bundled Payment System for Medicaid and Medicare
Legal Transparency	National Practitioner Data Bank (includes malpractice data)	Provider Screening for Fraud and Abuse, Demonstration Grants for Tort Reform, Database for False Claims, Medicare and Medicaid Compliance Programs, Demonstration Grants for Developing Alternative Medical Malpractice Processes, No Antitrust Exemption

The Supreme Court's Decision on the Affordable Care Act (ACA)

Twenty-six states challenged the constitutionality of the Affordable Care Act, and specifically the individual mandate, in the Supreme Court. On June 28, 2012, the Supreme Court largely let the ACA stand, but it did restrict the expansion of Medicaid by protecting nonparticipating states from being penalized by the Federal Government.[68]

While the decision fundamentally upholds the ACA, had it gone any other way it would not have diminished the need for a better definition of healthcare quality, better quality measurement, treating quality as an integral part of healthcare provider performance, and linking quality to cost and provider strategy. Certainly there are elements of the ACA that bring greater attention to and potential payment for quality and outcomes of care. Having those elements in place reinforces the importance of bringing greater clarity and discipline to considerations of quality in health care.

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