HEALTH SYSTEMS AND SERVICES PROFILE

UNITED STATES OF AMERICA

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ORGANIZATION AND MANAGEMENT OF HEALTH SYSTEMS AND SERVICES PROGRAM

DIVISION OF HEALTH SYSTEMS AND SERVICES

PAN AMERICAN HEALTH ORGANIZATION

EXECUTIVE SUMMARY

The United States is a federal republic with a population of 281,421,906 people. The government consists of a central governing authority and 50 individual states. The federal government contains three branches: executive, legislative, and judicial. Executive power is vested in the President, who conducts the nation's administrative business with the aid of a Cabinet consisting mainly of the Secretaries (heads) of the various federal departments. The United States Congress, the legislative branch, is bicameral, consisting of a Senate and a House of Representatives. The judicial branch consists of the federal courts, the highest of which is the nine-member United States Supreme Court. State governments have a structure similar to the federal system, with the executive of the state known as the governor and the legislative branch known as the legislature.

In the United States, whites comprise the largest racial/ethnic group (75.1%), followed by Hispanics of any race (12.5%), African Americans (12.3%), and Asians (3.6%). American Indians and Alaska Natives comprise approximately 0.9% of the population, and Native Hawaiians and other Pacific Islanders comprise approximately 0.1%. In 2000, it was estimated that 11.4% of the United States population was living below the national poverty level; minorities comprise a large percentage of this population. In 2000, the national unemployment rate was 4.0%. The United States ranks 3rd in terms of the Human Development Index, which measures life expectancy, educational attainment and adjusted real income. It ranks 3rd in the Gender-related development index of the United Nations Development Program (UNDP).

Health care services in the United States are divided between the public and private sectors. The country has no single, nation-wide system of health care. The largest provider of health services is a competitive private sector comprised of hospitals, physicians, dentists, nursing homes, home care agencies, insurance companies, medical supply companies and pharmaceutical manufacturers. Approximately 70% of the population is covered by private health insurance. Overall, total expenditures for health have hovered around 13.0% of the gross domestic product (GDP). Public expenditures accounted for approximately 45.3%, while private expenditures comprised approximately 54.7%. The national per capita health expenditure in 1999 was $4,358. In general, per capita expenditures over the past decades have increased sharply.

The Department of Health and Human Services (HHS) is the principal agency of the United States government for protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves. HHS is part of the executive branch, and the United States Congress determines its budget. In fiscal year 2001 its budget amounted to $429 billion.

The federal government is a direct provider of health services for military personnel (through the Department of Defense), veterans with service-connected disabilities (through the Veterans Administration), Native Americans (American Indians and Alaskan Natives through the Indian Health

Service) and inmates of federal prisons. Through a program known as Medicare, the federal government provides health insurance to all Americans over 65 years of age, those who have permanent kidney failure, and certain people with disabilities. The Centers for Medicare and Medicaid Services (CMS, formerly the Health Care Financing Administration, or HCFA), a division of HHS, administers Medicare. As the nation's largest health insurance program, it covers approximately 39 million Americans. The Federal Government, through CMS, also works with State governments to provide health insurance, known as Medicaid, to the nation's poor. Medicaid is a jointly funded, federal-state health insurance program that targets some segments of the low-income population. It covers approximately 36 million individuals including children, the aged, blind, disabled, and others who are eligible to receive income maintenance from the federal government. The federal government, through HHS, also sponsors medical research in a wide variety of areas.

The events of Sept. 11, 2001, brought many unprecedented challenges to the American people, calling on the reserve of public health officials, hospital workers, emergency personnel and the nation's citizens in response to terrorist attacks on the United States. The public health response was a defining moment, as HHS deployed health personnel from around the nation, activated the first use of the country's National Pharmaceutical Stockpile, provided special funding assistance, and convened a national summit on mental health. The Centers for Disease Control and Prevention (CDC) within HHS was also mobilized to investigate anonymous anthrax attacks surreptitiously delivered through the United States mail system. These events have forever changed the scope of the United States public health system.

The Secretary of Health and Human Services is responsible for steering the Department's broad response to terrorism and ensuring that critical health programs and initiatives are established and put into place, a need that is stronger today than ever. HHS has taken measures to protect America, hinging on a record budget request for fiscal year 2002 of $23 billion, a 13.5 percent increase over fiscal year 2001. HHS also plans to increase responsiveness, customer service and the flow of needed health information to beneficiaries of Medicare and Medicaid which are in the process of being reorganized. A multi-faceted Disease Prevention Initiative has also been designed to help all Americans achieve their full potential for health and wellness, focusing on critical health areas, such as obesity, diabetes and health disparities. Lastly, a new action plan has been formed to strengthen protections against BSE, or mad cow disease. The plan is a joint effort between three HHS agencies, the Food and Drug Administration (FDA), CDC and National Institutes of Health (NIH).

The United States as a whole has not undergone a comprehensive public health sector reform, but there have been many attempts at different levels to curb the main problems. There are some concerns that keep Americans constantly working towards improving their health care system. The two key issues are the large numbers of uninsured individuals and the rising cost of health care. Approximately 14% of the

population in 2000 was not covered by health insurance. In the 1990s, large-scale debates on health sector financing and delivery took place. One well-known attempt at reforming the health sector in the United States during this period was the Health Security Act (HSA). The underlying approach to the plan was a "make markets work" strategy. First introduced into Congress in 1994, this bill basically proposed to provide health insurance to all Americans, contain the rate of health spending increases, improve public health infrastructure, develop long-term care block grants for the states, and revise graduate medical education. Congress rejected the HSA, and much debate has ensued over why passage was unsuccessful.

In 1996, Congress passed the "Health Insurance Portability and Accountability Act" (HIPPA), otherwise known as the Kennedy-Kassenbaum Law, which set new rules for private health insurance and created standards for electronic health transactions. That same year, Congress also passed legislation on welfare reform known as the "Personal Responsibility and Work Opportunities Reconciliation Act" (PRWORA) which the United States Congress will reauthorize in 2002. This reform de-linked welfare (cash assistance) and Medicaid, created strict working requirements for welfare recipients and set a lifetime limit of 5 years for welfare enrollees. The welfare reforms being implemented throughout the United States in recent years seek to establish a stronger system of public assistance that enables all citizens to take advantage of economic opportunities.

The 1997 Balanced Budget Act (BBA) made the largest changes to Medicare and Medicaid since their enactment in 1965. The bill broadened Medicare's ability to contract with private health plans, and the option became known as Medicare+Choice, or Medicare Part C. The BBA also enacted the State Children's Health Insurance Program (SCHIP) to increase health insurance coverage of children. Most recently, the current Administration has declared its intention of having government take an active role in the reform of the United States health care system. The reform will be guided by three goals, namely to ensure a patient-centered health care system with affordable, high quality care; improve the health care system by creating an environment that encourages and rewards quality; and strengthen the health care safety net as well as increase biomedical research.

1. CONTEXT

1.1 Political Context: The United States is a federal republic in which power is divided between a central governing authority and 50 individual states. The principal framework of government is the Constitution of the United States, ratified in 1787. The federal government consists of three branches: executive, legislative, and judicial. Executive power is vested in the President, who conducts the nation's administrative business with the aid of a Cabinet consisting mainly of the Secretaries (heads) of the various federal departments. The United States Congress, the legislative branch, is bicameral, consisting of a Senate and a House of Representatives. Both the President and the members of Congress are independently elected. Laws must be approved by both houses of the Congress and signed by the President. Although the President can veto or reject legislation passed by the Congress, Congress can override the veto with a two-thirds majority of each house voting separately to approve the law. The judicial branch consists of the federal courts, the highest of which is the nine-member United States Supreme Court, which also functions as the court of last resort for the 50 state judiciary systems. State governments have a structure similar to the federal system, with the executive of the state being known as the governor and the legislative branch usually known as the legislature.

The country is comprised of 50 states, a federal district, and territories. The Constitution of the United States establishes the relationship between the state governments and Congress. It specifically grants certain powers to Congress.[1] However, the Constitution gives the states power over everything else. Health policy in the United States is addressed at both the federal and state level. Although the Constitution of the United States does not specifically refer to health services, it does grant the federal government the authority to raise taxes and provide for the general welfare of the population. Thus, by interpretation, the federal government has the power to allocate monies to the states to carry out activities for the public's general welfare and to set policies about how these monies may be used. The states are limited by their respective constitutions and by the federal government in areas where it has exclusive authority. Thus, states also have control over health policy. For example, licensure of hospitals, licensure of health professionals, and traditional public health activities (e.g., food quality and sanitation, vital statistics, etc.) are in the domain of the state government.

1.2 Economic Context: The 1990s was a period of significant economic growth for the United States. Unemployment dropped from 7.2% in 1985 to 5.6% in 1990 to 4.2% in 1999. The per capita gross domestic product (GDP) rose from $25,735 in 1993 to $33,885 by 1999. Total public spending remained relatively constant throughout the decade, hovering around 20% of GDP. The annual rate of inflation fluctuated throughout the 90s, and was approximately 2.2% during 1999. Total public expenditures in health increased significantly during the decade from $282.4 billion in 1990 to $548.5 billion in 1999.[2]

Selected Economic Indicators

INDICATOR	YEAR						
	1993	**1994**	**1995**	**1996**	**1997**	**1998**	**1999**
Per capita GDP in current US$ dollars	$25,735	$27,068	$28,131	$29,428	$30,968	$32,373	$33,885
Economically active population, in thousands	129,200	131,056	132,304	133,943	136,297	137,673	139,368
Total public spending as a percentage of GDP*	21.8	21.4	21.1	20.7	20.0	19.7	19.7**
Public spending on social programs as a percentage of GDP***	21.1	21.0	20.9	ND	ND	ND	ND
Annual rate of inflation	3.0	2.6	2.8	3.0	2.3	1.6	2.2

Source (s): Statistical Abstract of the United States in 2000 U.S. dollars, 2000 . * Federal spending only. ** Preliminary data.*** Social Welfare Expenditures Under Public Programs as % of GDP. ND means information is not available.

1.3 Demographic and Epidemiological Context: Life expectancy continues to rise in the United States, although disparities in life expectancy continue to exist across racial groups. The average life expectancy at birth in 1998 was 76.7 years.[3] The average annual rate of population growth in 1998 was 1.0%, which held steady from the previous year[4] and the average annual growth rate for the period 1990-98 was also 1.0%. Immigration continues to play a role in population growth in the United States. In 1998, net immigration to the United States was approximately 979,000, a slight decrease from the previous year.

Studies of under-registration of mortality in the United States have not been conducted in the recent past. The percentage of death from ill-defined causes in 1998 was 1.1%.[5] Age-adjusted death rates for communicable diseases have declined over the past decade, ranging from 10.8 deaths per 100,000 in both sexes with 13+ years of education to 40.0 deaths per 100,000, for those with less than 12 years of education in 1998. Age-adjusted death rates for malignant neoplasms in all persons have also decreased over the past few decades, settling at around 124 deaths per 100,000 resident population in 1998, although they are the leading cause of death in individuals 45-64 years of age in the United States. The age-adjusted death rate for major cardiovascular diseases fell from 340.1 in 1970 to 161.2 in 1998. Nonetheless, cardiovascular diseases disproportionately affect certain population groups, such as black males.

Deaths from external causes have varied over the past two decades: The 1970 rates are: accidents, 53.7; homicides, 9.1; suicides, 11.8; while in 1990, the rates are: accidents, 32.5; homicides, 10.2; suicides, 11.5. The 1998 rates are as follows: accidents, 30.1; homicides, 7.3; suicides, 10.4.[6] Figures from 1998 indicate that the five leading causes of mortality in the United States in descending order are: Diseases of the heart, malignant neoplasms, cerebrovascular diseases, chronic obstructive pulmonary diseases, and unintentional injuries. Death rates for chronic communicable diseases as well as chronic non-communicable diseases have generally decreased over the past 5 years.

	YEAR						
	1993	**1994**	**1995**	**1996**	**1997**	**1998**	**1999**
Crude birth rate	15.5	15.2	14.8	14.7	14.5	14.6	14.5*
General fertility rate (Total number of live births per 1,000 women 15-44 yrs.)	67.6	66.7	65.6	65.3	65.0	65.6	65.8*
Crude death rate (1,000 pop)	8.8	8.75	8.8	8.72	8.65	8.65	ND
Maternal mortality rate (Health, US 2000; all ages, crude)	7.5	8.3	7.1	7.6	8.4	7.1	ND
Infant mortality rate	8.4	8.0	7.6	7.3	7.2	7.2	ND

Source: Health, United States, 2000; * Preliminary.

The five leading causes of infant mortality (children under 1 year) include: congenital anomalies, disorders related to short gestation and unspecified low birthweight, sudden infant death syndrome (SIDS), newborns affected by maternal complications of pregnancy, and respiratory distress syndrome (RDS).[7] The 1990 rates were: congenital, 198.1; short gestation, 96.5; SIDS, 130.3; maternal complications, 39.8; RDS, 68.5. In 1998, the rates for these leading causes were: congenital, 157.6; short gestation, 104.0; SIDS, 71.6; maternal complications, 34.1; RDS, 32.9. Acute diarrheal disease and acute respiratory infections comprise only a very small percentage of deaths of children under 5 years of age, accounting for 0.7% and 2.0% of registered deaths, respectively in 1998.

The emerging/re-emerging diseases that are of most importance in the United States are HIV/AIDS and Septicemia. The age-adjusted death rate for HIV/AIDS has fallen over the past decade from 9.8 in 1990 to 4.6 in 1998.[8] However, HIV/AIDS appears to disproportionately affect males: the age-adjusted death rate in 1998 was 7.2 for males and 2.2 for women. This gap between men and women has significantly decreased since 1990. Septicemia is slowly on the rise in the United States, with an age-adjusted death rate of 4.4 in 1998, up from 4.1 in 1990. In fact, septicemia was the 10th leading cause of death among women in 1998.

1.3 Social Context: U.S. Census data from 2000 place the population at 281,421,906, with approximately 77.2% living in urban settings.[9] The table below shows the population distribution among different racial/ethnic groups.

Less than 0.5% of Americans are illiterate.[10] In 1998, on average 82.8% of children completed high school.

Poverty levels appear to have declined slightly over the past 5 years. In 1998, it was estimated that 12.7% of people in the United States are living below the national poverty level.[11] Poverty is seen more frequently in ethnic minorities than in the white population. The ratio between the top 20%, or the richest

average income and bottom 20%, the poorest average income, is 8.9.[12] In 1990, the unemployment rate was 5.6% for the total population while in 2000, the rate was 4.0% for the total population.[13]

Population by Race and Hispanic/Latino Origin

Race and Hispanic Origin	Population as of April 2000	Percentage of Population
TOTAL POPULATION	281,421,906	100%
One race	274,595,678	97.6%
White	211,460,626	75.1%
Black or African American	34,658,190	12.3%
American Indian and Alaska Native	2,475,956	.09%
Asian	10,242,998	3.6%
Native Hawaiian & Other Pacific Islander	398,835	.1%
Some other race	15,359,073	5.5%
Two or more races	6,826,228	2.4%
Hispanic or Latino (of any race)	35,305,818	12.5%

Source(s): United States Census Bureau, 2000 Census

The United States ranks 3rd in terms of the Human Development Index, measuring life expectancy, educational attainment and adjusted real income and it ranks 3rd in the Gender-related development index of the UNDP Human Development Report.[14] Although the United States has the highest GDP per capita in the world, it lags behind Canada and Norway in some of the areas that the UNDP considers in its ranking, including life expectancy and education.

2. THE HEALTH SYSTEM

2.1 General Organization. Health services are largely delivered by the private sector and commercial insurers play a major role in the financing of health care. Most coverage for health services is obtained through a third-party payer, such as an employer or the government, which makes payments, directly or indirectly, to the service providers. This may include covering physician, hospital, laboratory, pharmaceutical costs, etc., depending on the type of insurance.

Public Institutions: The federal government is a direct provider of health services for military personnel, veterans with service-connected disabilities, Native Americans (American Indians and Alaskan Natives) and inmates of federal prisons. HHS is the United States government's principal agency for protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves. The Department has a budget, determined by the Congress, amounting to $429 billion for fiscal year 2001. Many HHS-funded services are provided at the local level by state, county or tribal agencies, or through private sector grantees. Eleven HHS operating divisions administer the

Department's programs. In addition to the services they deliver, the HHS programs provide for equitable treatment of beneficiaries nationwide, and they enable the collection of national health and other data.

HHS is not a direct provider of health services to the population of the United States, with one exception: The Indian Health Service (IHS). The IHS is the principal federal health care provider and health advocate for Indian people, and its goal is to assure that comprehensive, culturally acceptable, personal and public health services are available and accessible to American Indian and Alaska Native people.[15] The provision of health services to members of federally recognized tribes grew out of the special government-to-government relationship between the United States federal government and Indian tribes established in 1787. Outside HHS, the Department of Veterans Affairs (VA) and the Department of Defense (DOD) are the only federal government agencies that directly provide health services. The Department of Transportation (DOT) also provides direct health care services to Coast Guard enlisted officers and personnel. According to the Employee Benefit Research Institute, in 1999, 6.5 million Americans were enrolled in Tricare or Civilian Health and Medical Program for the Department of Veterans' Affairs (CHAMPVA).[16] With a budget of more than $20 billion, the Veterans Health Administration within the VA provides health care to veterans.[17] In addition to its medical care mission, the veterans health care system is the nation's largest provider of graduate medical education and one of the nation's largest medical research organizations. It also provides backup to the DOD and the National Disaster Medical System.

The federal government provides insurance to all Americans over 65 years of age, those who have permanent kidney failure and certain people with disabilities through a program known as Medicare. The Centers for Medicare and Medicaid Services (CMS), part of HHS, administers Medicare, the nation's largest health insurance program, which covers approximately 39 million Americans. Medicare is generally financed through a combination of payroll taxes, general revenues, and beneficiary premiums. Medicare has three Parts, Part A, which provides hospital insurance, Part B, which provides supplementary medical insurance, and Part C, which allows for Parts A and B to be delivered through private health plans[18]. The federal Government, through CMS, also works with state governments to provide health insurance to the nation's poor. Medicaid is a jointly funded, federal-state health insurance program for certain low-income and needy people. It covers approximately 36 million individuals including children, the aged, blind, and/or disabled, and people who are eligible to receive income maintenance payments from the federal government. Title XIX of the Social Security Act created Medicaid in 1965 as a cooperative venture between the federal and state governments to assist states in the provision of adequate medical care to eligible needy persons. Medicaid is the largest program providing medical and health-related services to America's poorest people.[19] The Medicaid program

varies considerably from state to state, as well as within each state over time, but the federal government requires certain basic services to all enrolled.

Modifications to Medicaid include expansions in the late 1980s to cover additional low-income women and children who are living slightly above the official federal poverty line. The Balanced Budget Act (BBA) of 1997 amended the Social Security Act to add a new title--Title XXI--State Children's Health Insurance Program. The purpose was to enable States to initiate and expand child health assistance to uninsured, low-income children. Assistance would come through expanding Medicaid or offering private insurance, or a combination of both.[20] The traditional public health functions of monitoring food and water quality, sanitation, vital statistics, licensure of hospitals and various health professionals (e.g., doctors, nurses, dentists), are also handled at the state and local levels.

Private Institutions: In the United States, health services are largely delivered by the private sector, and approximately 70% of the US population is covered by private health insurance.[21] The private sector is comprised of hospitals, physicians, dentists, nursing homes, home care agencies, insurance companies, medical supply companies, pharmaceutical manufacturers, etc. Most coverage for health services in the private sector is obtained through employment.

Obtaining health insurance through employment calls for the insured party to pay part of the insurance premium and for the employer to pay the remaining part. Insurance companies then make payment directly to the service providers, who are predominantly private physicians, hospitals, etc. Employer-provided health insurance is not required by law. It is instead encouraged by a tax policy that offers unlimited tax relief for the purchase of health insurance, as long as workers buy the plans their employers provide. In 1996, 75 percent of employees were offered insurance by their employer and about 80 percent took the plan.

The insurance plans offered by employers vary. Typically those who work for larger companies will receive better coverage than those who work for smaller businesses. In addition, some employers offer only one health insurance plan while others offer a choice of plans, for example a fee-for-service plan, a health maintenance organization (HMO), or a preferred provider organization (PPO). Remuneration on a fee-for-service basis used to be the norm in medical practice in the United States. However, with an increased concern about cost control a demand for quality care and greater flexibility in provider choice, health maintenance organizations (HMOs) and other forms of managed care, including PPOs, acquired a large portion of the health care market.

Managed care is generally defined as an organized effort that involves both insurers and providers of health care to use financial incentives and organizational arrangements to alter provider and patient behavior so that health care services are delivered and used in a more efficient and lower-cost manner.[22] The typical model of managed care is the HMO, but there are other variations of the model, including

PPOs. HMOs provide the entire range of health services for a group, including doctors' visits, hospital stays, emergency care, surgery, lab tests, x-rays, and therapy, in return for a lump-sum payment called capitation. The HMO arranges for care either directly in its own group practice or through doctors and other health care professionals under contract. Usually, choices of doctors and hospitals are limited to those that have agreements with the HMO to provide care and referrals are often required to see a specialist. Physicians and hospitals are, in many cases, paid on a per-capita basis instead of using the fee-for-service modality by managed care organizations. The idea behind this arrangement is to control spending and reduce unnecessary costly procedures.

Like the HMO, the PPO is another form of managed health care. The PPO is a combination of traditional fee-for-service insurance as well as some HMO qualities. Patients have a limited number of doctors and hospitals to choose from. When patients use the specified providers most of their medical bills are covered, but they may also choose doctors outside of the provided list and still receive some coverage. Americans who choose to independently purchase their insurance often pay high premiums, which are expected to climb an average of 13 percent during 2002. The high prices stem from some state laws that mandate these types of plans cover a vast array of treatments and procedures ranging from chiropractors, acupuncture and contraceptives to *in vitro* fertilization and therapy. Customers often do not use these types of procedures yet they pay a subsidy for the opportunity of these services as part of their coverage. These high prices often leave many unemployed Americans without health care insurance.

Besides the patient-insurer relationship in the private health care system, across the country there are many private, non-profit organizations that take pride in educating and fund-raising for health-related causes. For example, the Red Cross serves the American public by supporting the victims of conflict and disaster in the United States and around the world. It also provides a wide range of domestic services, including the coordination of biomedical blood and plasma donations and community programs for health awareness and volunteering. This non-profit organization is chartered by the United States government and occasionally receives some federal funding assistance for larger projects. The organization primarily functions on donations from the public [23]

Other health care organizations have formed with specific health care focuses. Organizations like the American Cancer Society, National Multiple Sclerosis Society, American Heart Association and others were created to raise awareness of specific ailments as well as raise funds for research and treatment of these diseases. Specifically, the American Cancer Society is a community-based, volunteer health organization dedicated to eliminating cancer and committed to prevention and research.[24] Similarly, the American Heart Association is a voluntary health agency with a mission to reduce stroke and cardiovascular diseases. This Association has also spent more than 1.7 billion dollars for research over the past 50 years.[25] In the health care field, there are also professional organizations like the American

Medical Association (AMA), American Hospital Association (AHA) American Nursing Association (ANA) and others, which align members of the health field. The associations are committed to ethical standards in the health care system, excellence in the field through education and advocacy on behalf of the medical profession and patients.[26] These associations provide the private sector with the capability to check their counterpart, the private sector insurance companies.

Private sector organizations, like those above, often provide financial support for research. Health research organizations, like the Henry J. Kaiser Family Foundation, also exist with the sole purpose of finding breakthroughs in the medical field. Often associated with academic institutions, research organizations study a variety of health-related subjects, providing information to the entire health care community. These organizations may also apply to receive some funding from the government, through the NIH, part of HHS.

The current Administration has established a Center for Faith-Based and Community Initiatives at HHS, allowing the private sector to participate with HHS and other governmental agencies in the assistance of the American public. Faith-based and community organizations have a long history of providing essential services to people in need in the United States, a tradition which originated this new initiative. The Administration has provided for increases in funding and removal of unnecessary barriers that may prevent these organizations from fully participating in their communities. Currently the HHS branch of the Faith-Based and Community Initiatives applies to several grant programs, including Temporary Assistance to Needy Families (TANF), Community Services Block Grant, Substance Abuse Prevention and Treatment Block Grant and Projects for Assistance in Transition from Homelessness (PATH). In these programs, HHS provides the funds to individual states and the states in turn award funds to a variety of community and faith-based groups. The funds are then to be used for non-sectarian help to communities.[27]

2.1 System Resources

Human Resources

According to the American Medical Association, 30% of male physicians and 46% of female physicians are general primary care physicians (i.e., family and general practice, internal medicine, obstetrics and gynecology, and pediatrics).[28] Six percent of male physicians and 7% of female physicians practice in primary care sub-specialties, while 64% of males and 47% of females practice some other specialty. The Bureau of Health Professions of the Health Resources and Services Administration (HRSA) of HHS reports the ratio of general practitioners (excluding general internal medicine and general pediatrics) to specialists has remained relatively consistent

over the past decade, slightly declining, however, in recent years: 1991, 0.137; 1995, 0.133, 1996, 0.135; 1997, 0.134, 1998, 0.133; and 1999, 0.12 (i.e., roughly 1 generalist to 8 specialists). There is no data available on the percentage of unemployment in the professional categories listed in the table below. The reason is that there is an assumption that unemployment among these professionals is close to zero; those who are not working are voluntarily choosing not to work.

HUMAN RESOURCES IN THE HEALTH SECTOR

TYPE OF RESOURCE	YEAR						
	1993	1994	1995	1996	1997	1998	1999
Ratio of physicians per 10,000 pop.	23.7	23.9	24.2	24.6	25.2	26	26.8
Ratio of registered* nurses per 10,000 pop.	75.9	77.8	79.8	81.5	82.3	82.8	84.4
Ratio of dentists per 10,000 pop.	6.1	6.2	6.2	6.2	6.2	6.2	6.2
Ratio of mid-level laboratory technicians per 10,000 pop.	12.1	12.2	12.3	12.4	12.5	12.6	12.7
Ratio of pharmacists per 10,000 pop.	6.8	6.8	6.9	6.9	7	7	7.1
Radiologic Service Workers per 10,000 pop.	7	7.2	7.4	7.6	7.8	8	8.2
No. of Public Health graduates	4175	4553	4,636	5,064	5,100	5,200	5,300

Source: HRSA, Bureau of Health Professions Estimates.

PHYSICIANS IN PUBLIC AND PRIVATE INSTITUTIONS, YEAR: 1998

Institution	Physicians
Non-Federal	648,009
Office-Based Care	468,788
Hospital-Based Practice	137,637
Other Professional Activity *	41,584
Federal	18,991
Total (prof. active)	**777,859**

Source(s): Health, United States 2000; * HRSA, 1996 national sample survey. *For physicians includes medical teaching, administration, research, and other.

In 1996, the average mean net income for all physicians was $199,000.[29] General practitioners in the past have earned on average $60,000 less than that figure, and specialists' incomes have varied widely, but have tended to be much higher. Salaries for physicians steadily increased through the 1980s, but have slightly decreased in recent years. The passage of the Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1985 that affected Part B Medicare payments and the growth of managed care are frequently cited as causing the slowed growth (and in some cases decline) in physician salaries.

Nonetheless, physicians in the United States are generally paid higher salaries than other professionals, such as engineers and teachers, who generally earn less than $100,000 annually. The American Medical Association provides information on mean hours in patient care provided by physicians per week.[30] In 1997, physicians in general provided 53.2 hours of care, which is fairly representative of the rest of the decade. Certain specialties such as surgery and obstetrics/gynecology logged more hours/week than the average (55.0 and 59.9 respectively).

In 2000, the HRSA Bureau of Health Professions conducted the National Sample Survey of Registered Nurses (RNs), which is the nation's most extensive and comprehensive source of statistics on all those with current licenses to practice in the United States, regardless of whether they are employed in nursing.[31] Preliminary findings from February 2001 report that the total estimated number of licensed registered nurses (RNs) was 2,696,540 as of March 2000. This was an increase of 137,666 over the 1996 figure (approximately 5.4%). Of the total licensed RN population, 58.5% reported working full-time, 23.2% reported working part-time, and 18.3% reported not being employed in nursing. Of the 2,201,813 RNs currently employed in nursing, 59.1% working in hospital settings, 6.9% worked in nursing homes or extended care facilities, 18.3% worked in public or community health settings (including occupational and school health settings), 9.5% worked in ambulatory care, and 3.6% worked in other settings.

Drugs and Other Health Products. The FDA is the agency within HHS that regulates food, drugs, and medical devices for all consumers in the United States. FDA's mission is to promote and protect the public health by helping safe and effective products reach the market in a timely way, and by monitoring products for continued safety after they are in use. Over the past decade, the total number of pharmaceuticals approved by the FDA has increased by over 3000, with generic drugs constituting a slight majority. Both total spending on drugs, as well as per capita spending, have increased significantly.

INDICATOR	1993	1994	1995	1996	1997	1998	1999
Total n° of FDA approved pharmaceutical products	7,071	7,380	7,817	8,411	9,039	9,575	10,002
Percentage of brand-name drugs	40.9	41.1	41.5	42	42.1	42.4	42.7
Percentage of generic drugs	59.1	58.9	58.5	58	57.9	57.6	57.3
Total spending on drugs & other medical non-durables (selling price to the public, in billions of dollars)*	76.2	81.5	88.6	98.0	108.6	121.9	NA
Per capita spending on drugs (sale price to the public)*	$284	$301	$325	$356	$390	$434	NA
Percentage of public spending on health allocated to drugs*	8.5%	8.6%	8.9%	9.4%	10.0%	10.6%	NA

Source (s): FDA publication: "Approved Drug Products with Therapeutic Equivalence Evaluations; * Statistical Abstract of the United States, 2000.

The federal government does not control or regulate drug prices in the United States. Rather, pharmaceutical companies freely set drug prices, which tend to follow market trends.[32] In 1999, the top

selling prescription products on the market based on the total number of prescriptions dispensed were: (1) hydrocodone with APAP, (2) atorvastatin, (3) conjugated estrogens, (4) levothyroxine, and (5) atenolol.[33]

The FDA keeps an ongoing list of approved drugs, which can be found in their publication known as "Approved Drug Products with Therapeutic Equivalence Evaluations." Otherwise known as the "Orange Book," it currently lists over 10,300 drugs approved on the basis of safety and effectiveness, not including drugs that are discontinued[34]. These evaluations have been prepared to serve as public information and advice to state health agencies, prescribers, and pharmacists to promote public education in the area of drug product selection and to foster containment of health care costs.

There are no specific distribution schemes to facilitate access to drugs by certain population groups. However, the FDA has two mechanisms to improve access to drugs: (1) fast-tracking of new drugs for target populations-terminal patients and (2) the Orphan Drug Act.[35] Accelerated development/review (Federal Register, April 15, 1992) is a highly specialized mechanism for speeding the development of drugs that promise significant benefit over existing therapy for serious or life-threatening illnesses for which no therapy exists. This process incorporates several novel elements aimed at making sure that rapid development and review is balanced by safeguards to protect both the patients and the integrity of the regulatory process.

The federal government does not develop standardized treatment protocols for pathologies. However, many health insurance plans may develop treatment protocols for physicians in their network to follow when treating common pathologies. In addition, medical associations may develop protocols that physicians voluntarily choose to follow.

A pharmacist is required to be present at private pharmacies and pharmacies found in hospitals. Only a pharmacist is allowed to dispense prescription medications in the United States.

There is a constant need in the United States for blood donations. The Office of Blood Research and Review of the FDA reports that 12 million blood units per year are collected from 8 million donors at 3,200 registered facilities. For plasma for further manufacturing, 12 million units of Source Plasma are collected per year from 1 million donors at 450 licensed facilities. The American Red Cross reports that in 2000 it collected approximately 6.3 million units of blood from 4 million donors.[36] In addition to the Red Cross, there is also a network of non-profit, independent community blood centers that provides approximately 50% of the blood in the United States. 100% of the blood collected for transfusion is subject to the five layers of safety.[37]

Equipment and Technology

AVAILABILITY OF EQUIPMENT IN THE HEALTH SECTOR, YEAR: 1998

SUBSECTOR	TYPE OF RESOURCE	
	Countable Beds	**Blood banks per 100,000 pop.**
All Hospitals	1,012,582	ND
Federal	56,698	58*
Non-Federal[1]	955,884	ND
Community[2]	839,988	ND
Non-profit	587,658	ND
For Profit	112,975	ND
State-local government	139,355	117
TOTAL per 1000 population	**3.7**	**ND**

Source(s): Health, United States 2000. [1]The category of non-Federal hospitals is comprised of psychiatric, tuberculosis and other respiratory disease hospitals, and long-term and short-term hospitals; [2]Community hospitals are short-term hospitals excluding hospital units in institutions such as prison and college infirmaries, facilities for the mentally retarded, and alcoholism and chemical dependency hospitals. * Federal blood banks include 19 true "federal" blood banks and 39 military blood banks

Since 1980, the total number of hospital beds in the United States has declined by about 350,000. The number of beds available in federal hospitals has declined by roughly 60,000, while the number of non-federal beds has decreased by approximately 291,000. The decrease in beds has been largely attributed to an increase in outpatient procedures and shorter hospital stays, largely intended to decrease health expenditures.

High-tech medical equipment has become increasingly more prevalent in the United States. The number of Magnetic Resonance Imaging (MRI) units has increased from 1,040 in 1991 to 2,046 in 1997. There is no national data available regarding defective or out-of-order equipment. Individual hospitals, clinics, and other health centers determine their own budgets for purchase and maintenance of equipment.

2.3 Functions of the Health System

Steering Role: The management of the health sector is largely decentralized in the United States, involving many layers of government: federal, state, county, and city. The role of the federal government in health planning has traditionally been kept to a minimum. The Hospital Survey and Construction Act (otherwise known as the Hill-Burton Act) in 1946 entailed the first attempt to regionally plan for hospital construction.[38] In 1965, health planning advanced with the passage of legislation that created Medicaid and Medicare, which increased the visibility of health expenditures, and subsequently political interest. The National Health Planning Act of 1974 created a system of state and local health planning agencies, which were largely supported by federal funds. In general, health-planning actions have been relatively weak. The Health Planning Act was repealed during the 1980s. The federal

government's role has largely been in the realm of issuing guidelines, and not regulations. A recent example is "Healthy People 2010," which outlines a comprehensive nationwide health promotion and disease prevention agenda.[39]

General administration of the health system, like that of health planning, is characterized by decentralization. States are given control over the implementation of many of the health care programs [40] The delivery of health services by public and private providers is monitored in a variety of ways, again largely in a decentralized and voluntary fashion. State and local authorities, such as a county or state health departments, may monitor government hospitals and clinics. Private hospitals are typically self-governed, but undergo several forms of review. Medicare has rules governing quality that hospitals must follow in order to participate in the program. Other measures of quality control include accreditation by private organizations, such as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the National Committee for Quality Assurance (NCQA). Both government and private hospitals seek accreditation by JCAHO.[41]

Some inter-sectorial programs are promoted. For example, in 1987, in response to the growing impact of HIV infection, the CDC within HHS, began providing funds and technical assistance for state and large-city education agencies to help schools implement effective HIV-prevention education. In 1992, while continuing to provide funding to all states for HIV-prevention education, CDC started a new initiative to support coordinated school health programs that can reduce chronic disease risk factors: poor eating habits, physical inactivity, and tobacco use.[42]

The United States collects vast amounts of data on the health situation of the population, health financing, insurance and delivery of services. However, unlike countries that have a single financier, the United States has data that are divided among many insurers, which makes it extremely difficult to produce a complete profile or snapshot of health services. The Agency for Healthcare Research and Quality (AHRQ) part of HHS, collects a significant amount of data on medical expenditures through its National Medical Expenditure Survey (NMES). In addition, data are collected nationally by HHS through the National Center for Health Statistics of the CDC. The states contribute to this database by providing the data they collect on a regular basis. This information is used to help define the nation's health and health services problems. It was key in the development of Healthy People 2010 and other reports produced by HHS, which directly affect health policy decision-making. CMS maintains data on Medicare and Medicaid Programs.

The federal government also provides for medical research, in an attempt to uncover new knowledge and enable the medical field to grow and move forward. The NIH within HHS conducts research, supports non-governmental research and fosters communication within the medical field of information. The NIH's goal is to prevent, detect, diagnose and treat a wide range of diseases and disabilities and NIH

houses specific institutes and centers that specialize in different health care issues, including the National Cancer Institute, National Eye Institute, National Institute on Aging, National Institute of Child Health and Human Development along with over twenty others. NIH's budget request for fiscal year 2002 was $23 billion, to aid in necessary medical research, especially because of the increased threat of biological terrorism.[43]

The federal government does not directly control human resources in the health sector. In fact, the country has experienced shifts between health care professional shortages as well as surpluses. During a perceived physician shortage during the late 1940s, the federal and state governments tried to strengthen medical schools through grants. In contrast, worries of a physician surplus first surfaced in the mid 1970s and continued through the 1990s, which caused alarm among some who believed that excess physicians would create additional demand for health services and result in rising health care costs.[44] . Nonetheless, the United States continues to suffer from geographic maldistribution of physicians, leaving many parts of the country (particularly rural and inner-city areas) without a sufficient number of physicians to care for their populations. The government has tried to remedy this problem by creating incentives for recent medical graduates to work in these medically under-served communities, but the problem persists. Furthermore, the distribution of physicians by specialty has been of concern for a number of years. Approximately 33% of the nation's physicians practice primary care, and some fear this number will continue to fall. The quantity of other health professionals has also varied throughout the years. A recent report by the HRSA Bureau of Health Professionals, within HHS finds that there is a significant shortage of pharmacists in the United States, despite an increase in the supply over the past decade.[45]

Schools that train health professionals frequently undergo evaluations for accreditation by private organizations. Medical schools, nursing schools, dental schools, and schools of public health are all accredited by various organizations in an on-going effort to ensure the quality and content of the education being received by the students. In addition, each state sets its own licensure procedures for health professionals. In an effort to simplify procedures, the National Board of Medical Examiners created a nationally uniform examination for basic medical licensure for physicians. Regulation for certification in a medical specialization is under the jurisdiction of the non-governmental.[46] Once licensed, however, there is no real government regulation of specialized physicians.

New technologies are evaluated through multiple venues. Public agencies responsible for evaluating health technologies in the United States include the FDA, AHRQ and CMS within HHS, and the VA. In addition, state governments, universities, hospitals, medical specialty organizations, health plans and insurance companies and industry trade associations also participate in evaluation of new technologies. CMS and the VA evaluate health care technologies in support of coverage decisions. As part of the coverage decision process, CMS may request technology assessments from AHRQ. The Blue Cross-Blue

Shield Association (BCBSA) Technology Evaluation Center may provide technology assessments for its member plans. Other private health insurers have analogous technology assessment programs to support coverage decisions; an example is the Kaiser Permanente New Technology Committee. Private entities such as medical specialty societies also have programs to evaluate health technologies and produce voluntary guidelines for physicians. These entities can request technology assessments through AHRQ, which funds 12 Evidence-Based Practice Centers at universities and private organizations such as the BCBSA.

AHRQ promotes the development and use of evidence-based clinical practice guidelines in several ways. In 1997, AHRQ, then known as the Agency for Health Care Policy and Research, launched its initiative to promote evidence-based practice in everyday care through establishment of 12 Evidence-based Practice Centers (EPCs). The EPCs develop evidence reports and technology assessments on clinical topics that are common, expensive, and/or are significant for the Medicare and Medicaid populations. Evidence reports and technology assessments provide a foundation that public and private entities may use to develop and implement their own practice guidelines, performance measures, review criteria, and other clinical quality improvement tools.

In December 1998, AHRQ launched the National Guideline Clearinghouse(tm) (NGC) with AMA and the American Association for Health Plans (AAHP), an Internet-based database containing evidence-based guidelines located at <www.guideline.gov>. When NGC first became operational, it contained 200 evidence-based clinical practice guidelines submitted by over 50 health care organizations and other entities. Since then, the content on NGC has more than tripled to over 920 clinical practice guidelines submitted by over 150 health care organizations and other entities. All guidelines contained on NGC are abstracted into a standardized format that enables users to compare clinical practice guideline recommendations. New guidelines are being added to NGC weekly. Currently, weekly E-mail notifications are sent to over 4,200 users who want to know about updates to the site. Over the last two years, NGC has had over 2 million visitors, processed over 23 million requests, and received over 42 million hits. NGC now has over 28,000 visits a week from all over the world.

Financing and expenditure: Information on the financing of health costs is largely compiled by CMS within HHS from a variety of sources: Medicare data, Medicaid data, private insurers, the IHS, the DOD, and the VA. Expenditures for health care in the United States continued to rise during the 1990s, with public expenditures increasing more rapidly than private sector expenditures. Overall, total expenditures for health have hovered around 13.0% of the gross domestic product (GDP), totaling $1210.7 billion in 1999. Public expenditures accounted for approximately 45.3%, and private expenditure comprised approximately 54.7%.

National Health Expenditures by Type 1993-1999 (in billions of dollars)

TYPE OF EXPENDITURE	1993	1994	1995	1996	1997	1998	1999
Public expenditures	**390.3**	**427.3**	**458.2**	**484.4**	**505.8**	**522.9**	**548.5**
Percent federal of public	**70.3**	**69.9**	**70.7**	**71.5**	**71.5**	**70.6**	**70.1**
Health services and supplies	372.2	408.3	438.1	463.4	483.3	500.2	524.2
Medicare	148.3	166.2	184.8	200.3	211.2	211.4	213.6
Public assistance medical payments	126.6	139.2	149.5	157.6	164.9	176.9	193.4
Temporary disability insurance	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Workers' compensation (medical)	21.6	22.2	21.9	21.9	20.3	20.2	20.7
Defense Dept. hospital, medical	12.1	11.8	12.1	12.0	12.1	12.2	12.5
Maternal, child health programs	2.2	2.3	2.3	2.4	2.5	2.6	2.8
Public health activities	27.2	30.0	31.4	32.9	36.0	38.6	41.1
Veterans' hospital, medical care	14.1	15.1	15.4	16.3	16.3	16.9	17.6
Medical vocational rehabilitation	0.5	0.5	0.6	0.6	0.6	0.6	0.6
State and local hospitals	14.2	15.3	14.0	13.5	13.3	13.7	14.1
Other	5.3	5.6	6.0	5.9	6.1	7.0	7.8
Private expenditures	**497.3**	**509.4**	**528.8**	**553.6**	**588.0**	**623.2**	**662.1**
Health services and supplies	483.6	495.9	516.3	540.4	573.1	607.7	646.6
Out-of-pocket payments	148.9	146.2	149.2	155.0	165.5	176.1	186.5
Insurance premiums	295.7	308.9	322.3	337.4	355.6	376.8	401.2
Other	39.1	40.8	44.8	47.9	52.0	54.8	58.9
TOTAL	**887.6**	**936.7**	**987.0**	**1,038.0**	**1,093.9**	**1,146.1**	**1,210.7**
Percent of GDP	**13.4**	**13.3**	**13.3**	**13.3**	**13.2**	**13.0**	**13.0**

Source: Centers for Medicare & Medicaid Services (formerly U. S. Health Care Financing Administration)

The United States does not receive funds for the health sector from international cooperation agencies.

Health Expenditures 1993-1999

Expenditure	1993	1994	1995	1996	1997	1998	1999
Per capita public expenditure on health (in US$)	$1,486	$1,611	$1,711	$1,793	$1,855	$1,900	$1,975
Total per capita health expenditure (in US$)	$3,380	$3,532	$3,686	$3,842	$4,011	$4,164	$4,358
Total expenditure on health as a % of GDP	13.4	13.3	13.3	13.3	13.2	13.0	13.0
External health debt/Total external debt	0	0	0	0	0	0	0

Source: Centers for Medicare & Medicaid Services (formerly HCFA), Office of the Actuary: National Health Statistics Group.

The national per capita health expenditure in 1999 was $4,358. In general, per capita expenditures over the past decades have increased sharply. In 1980, the national per capita health expenditures were $1,067, and by 1990 they reached $2,737.[47]

Health Insurance: In the United States, health insurance is the most common method of paying for health care services. Without health insurance or the ability to pay with private funds, access to health services is limited or not available at all. There is no single, nation-wide system of health insurance, but the federal government sponsors Medicare and Medicaid as well as military plans. The majority of the population, however, is covered through private health insurance, largely obtained through employers.

National Health Expenditures by item, 1993-1999 (in billions of dollars)

OBJECT OF EXPENDITURE	1993	1994	1995	1996	1997	1998	1999
Spent by--							
Consumers	444.5	455.1	471.5	492.5	521.1	552.9	587.7
Out-of-pocket	148.9	146.2	149.2	155.0	165.5	176.1	186.5
Private insurance	295.7	308.9	322.3	337.4	355.6	376.8	401.2
Government	390.3	427.3	458.2	484.4	505.8	522.9	548.5
Other	52.7	54.3	57.3	61.1	66.9	70.3	74.4
Spent for--							
Health services and supplies	855.8	904.2	954.4	1,003.8	1,056.5	1,107.9	1,170.8
Personal health care expenses	775.8	816.5	865.7	911.9	958.8	1,002.3	1,057.7
Hospital care	320.0	332.4	343.6	355.9	367.7	377.1	390.9
Physician and clinical services	201.2	210.4	220.5	229.3	240.9	254.2	269.4
Dental services	38.9	41.4	44.5	46.8	50.2	53.1	56.0
Drugs/other medical nondurables	74.7	78.9	86.4	94.3	103.0	113.9	130.3
Vision products/other medical durables	12.8	13.3	14.2	15.3	16.2	16.3	16.9
TOTAL	**887.6**	**936.7**	**987.0**	**1,038.0**	**1,093.9**	**1,146.1**	**1,210.7**

Source: Centers for Medicare & Medicaid Services (formerly HCFA); Health Care Financing Review, spring 2001

However, as previously mentioned, employers are not required by law to provide insurance. Currently, there are around 3,000 health insurance companies in the United States.[48] The Health Insurance Association of America (HIAA) reports that nearly 152 million Americans are covered under employment-based health insurance plans. Some employers chose to purchase insurance from insurance companies, while others choose to "self-insure." Self-insurance allows employers an escape from state regulation of insurance because of the Employee Retirement Income and Security Act (ERISA to be discussed later in detail), and an estimated 40% of employees are covered by such plans. Currently the HIAA reports that there are over 1,000 employers (when aggregated across all states) that self-insure.[49]

Nonetheless, a significant number of Americans are without health insurance.[50] In the year 2000, 38.7 million people, or 14% of the population, were without health insurance, a decrease over 1998. This has been a significant concern over the past decade, and health care experts have been searching for reforms that could increase coverage. In general, racial minorities tend to comprise a greater portion of the uninsured, as well as the Medicaid population. Women are more likely to be enrolled in Medicaid than men (8.8% for men vs. 11.6% of women). Younger adults (age 18-34) are less frequently covered by insurance (either private or government) than children or older adults. Children remain under their parents' insurance policy typically until about age 18 or age 22, if the child is a full-time student.

In the United States, the Social Security Administration primarily provides pensions to retired and disabled citizens and does not provide health benefits. The two large public programs designed to finance health care, Medicare and Medicaid, were created by the Social Security Act and are managed at the federal level by CMS, within HHS. There is not a basic plan of health benefits to which all citizens are entitled.

Health Insurance Coverage by Selected Characteristics 1990-1998

Coverage	1990	1994**	1995**	1996**	1997**	1998**
Persons covered by private health insurance	182.1	184.3	185.9	187.4	188.5	190.0
Percent covered by private health insurance	73.2	70.3	70.3	70.2	70.1	70.2
Persons covered by government health insurance						
Medicare	32.3	33.9	34.7	35.2	35.6	35.9
Medicaid	24.3	31.6	31.9	31.5	29.0	27.9
Percent covered by Medicaid	9.7	12.1	12.1	11.8	10.8	10.3
Total persons covered by private or government health insurance*	**214.2**	**222.4**	**223.7**	**225.1**	**225.6**	**227.5**
Percent persons covered by private or government health insurance	86.1	84.8	84.6	84.4	83.9	83.7
Total persons not covered by health insurance	**34.7**	**39.7**	**40.6**	**41.7**	**43.4**	**44.3**
Percent not covered by health insurance	13.9	15.2	15.4	15.6	16.1	16.3
Total persons	248.9	262.1	264.3	266.8	269.1	271.7

Source: Statistical Abstract of the United States, 2000. *Includes other government insurance (military), not shown separately. Persons with coverage counted only once in total, even though they may have been covered by more than one type of policy. **Beginning in 1994, data based on 1990 census adjusted population control.

Population-based Health Services: Health promotion and disease prevention programs and activities are planned by the federal, state, and local levels. The National Center for Chronic Disease Prevention and Health Promotion within HHS has developed numerous programs to address issues including aging, arthritis, cancer (breast, cervical, colorectal, skin, and prostate), heart disease and stroke, diabetes, oral health, nutrition and obesity, reproductive health and tobacco. "Healthy People 2010," discussed previously, sets out 467 national objectives within 28 focus areas to improve health. In addition, "Healthy People 2010" lays out the 10 leading indicators that reflect the major public health concerns in the United States. They were chosen based on their ability to motivate action, the availability of data to measure their progress, and their relevance as broad public health issues[51]. The United States has been able to reduce the incidence of some types of cancer, cardiovascular disease, and infant mortality. Rates of asthma, diabetes, and obesity, unfortunately, continued to rise during the past decade.

Data are available for vaccinations of children aged 19-35 months of age in the United States. In 1998, approximately 79% of all children received the combined series vaccination (4 doses of diptheria-tetanus-pertussis (DTP) vaccine, 3 doses of polio vaccine, 1 dose of a measles-containing vaccine, and 3 doses of Haemophilus influenzae type b (Hib) vaccine).[52] This was an increase over previous years: 1994, 69%; 1995, 74%; 1996, 77%; and 1997, 76%. Vaccination rates have been lower among some ethnic minorities. Prenatal care has been increasing in the United States for the past decade. In 1998, 82.8% of all women began prenatal care during the first trimester of pregnancy.[53] Only 3.9% began during the third trimester or had no prenatal care. Prenatal care in the first trimester was most common among Whites and Asian/Pacific Islanders, with 84.8% and 83.1% respectively.

The events of Sept. 11, 2001, brought many unforeseen and unprecedented challenges to the American health care system calling on the reserve of public health officials, hospital workers, emergency personnel and the nation's citizens in response to terrorist attacks. The public health response set a precedent as the HHS Secretary deployed health personnel from around the nation, activated the first use of the country's National Pharmaceutical Stockpile, provided special funding assistance, and in the wake of attacks, convened a national summit on mental health. The CDC investigated anonymous anthrax attacks surreptitiously delivered through the United States mail system. These events have forever changed the scope of public health care.

HHS is taking vital steps to continue to protect the United States. HHS bioterrorism spending for 2002 will be 2.9 billion dollars, a tenfold increase from the previous year. This will help to prepare our nation's health care system and hospitals for future emergencies, build up emergency medical supply reserves and provide for the research of new treatments to cope with possible future incidents. State and local public health networks have also been fortified to facilitate a rapid response in the case of future bioterrorism attacks. There are also significant spending increases in many other areas of HHS, including the NIH, CDC, FDA and in the National Pharmaceutical Stockpile. HHS is also contributing to the September 11, 2001 recovery efforts.[54]

Shortly after September 11 2001, HHS created the Office of Public Health Preparedness, which will coordinate national response to public health emergencies.

Health Services to Individuals For Both Levels of Care: Health information systems have grown increasingly more common and complex in order to better track patients' care, to monitor utilization and costs, improve quality, etc. The widespread utilization of accreditation by JCAHO, and surveys such as HEDIS by NCQA contribute to improved information systems by requiring data from hospitals and managed care plans in a timely fashion.

PRODUCTION OF SERVICES. YEAR: 1998

	Number	Rate per 100 population
Ambulatory care visits to physician offices and hospital outpatient and emergency departments	1,005,101	378
Injury related visits to hospital emergency departments*	36,122	134

Source: Health, United States 2000. * 1997-1998 period.

On average, in 1998 19.7% of adults over the age of 18 visited an emergency department during the past year. 6.7% had two or more visits. Adults between the ages of 18 and 24 and those over the age of 75 were most likely to have more emergency visits.[55]

In 1998, roughly 66.2% of the United States population had a dental visit within the past year. Children between the ages of 2 and 17 were more likely to receive dental care within the past year compared to adults between the ages of 18 to 64 or adults over the age of 65.[56] An increasing portion of American

women has received a mammogram with in the past year. In 1991, only 54.6% of women age 40 and over had a mammogram within the past two years, compared to 66.9% of women in 1998.[57]

Hospital discharges have declined over the past decade from 113 in 1990 to 103 in 1998. Occupancy rates are slightly higher in federal hospitals, compared to non-federal hospitals. This may be attributed to an effort to reduce hospital length of stay and perform more procedures on an outpatient basis in order to reduce costs.

The most frequent reasons for hospitalization cited at discharge in 1997 for males and females under 15 years of age are bronchitis, pneumonia, asthma, injuries, and poisoning.[58] For men aged 15-44, reasons include: psychoses, diseases of the heart, invertebral disc disorders, injuries, and poisoning. For women, of the same age group, delivery, psychoses, diseases of the heart, invertebral disc disorders, and injuries and poisoning are the leading reasons. For both sexes ages 45-64, malignant neoplasms, diabetes, diseases of the heart, cerebrovascular diseases, pneumonia, injuries, and poisoning are the leading reasons. For older adults aged 65 and above, malignant neoplasms continue to top the list, followed by diabetes, diseases of the heart, cerebrovascular disease, and pneumonia.

SERVICE PRODUCTION, YEAR: 1998

INDICATOR	
Total no. of discharges per 1,000 (non-Federal short-stay hospitals)	103.0
Occupancy rate – All Hospitals (% of beds occupied)	65.4%
Federal Hospitals	78.9%
Non-Federal Hospitals	64.6%
Average days of stay per 1,000 population	4.9

Source: Health, United States 2000.

Quality: Quality of hospitals is generally measured by JCAHO through its audit and accreditation process. Public clinics also undergo audits by states, and private physicians are largely unmonitored. However, managed care programs monitor quality through their HEDIS performance measures as well as patient surveys. Many hospitals have ethics and oversight committees, but no data are available on the precise percentage.

In 1997, approximately 799,000 births, or 20.6% of all births, were performed by cesarean section. Of these cesarean deliveries, only 297,000 were repeat (*i.e.*, mother had previously delivery by cesarean). Vaginal delivery after previous cesarean delivery is encouraged, when a cesarean is not medically necessary, to reduce the number of cesareans being performed in the United States

There is increasing concern in the United States about the rate of infections contracted during hospital stays. In 1999, an Institute of Medicine (IOM) report said that medical mistakes kill up to 98,000 hospitalized Americans a year.[59] Mistakes included prescription errors, malfunctioning equipment, or physician error. A more recent study by Hayward *et.al.* estimates that between 5,000 and 15,000 deaths

annually are due to medical errors[19]. No national data are collected on how many patients are given a discharge report or care instructions at the time of discharge. Furthermore, it is unknown how many total infant or maternal deaths are investigated.

3. MONITORING AND EVALUATION OF HEALTH SECTOR REFORMS

3.1 Monitoring the Process. Monitoring the Dynamics

Unlike many countries in the region, the United States has not undergone comprehensive national health sector reform. There has been much debate regarding the need for reform, but there has been little consensus on which approach to take. Consequently, reform in the United States has been incremental and fragmented, despite the widespread belief that something needs to be done to improve the United States healthcare system. The two key issues are the large numbers of uninsured individuals and the rising cost of health care. From the 1950s through the 1970s, employer-based health plans and public plans provided health care to an increasing number of Americans. However, by the 1980s, growth in coverage slowed and the number of uninsured began to swell.[60] Today, roughly 39 million people in the United States do not have health insurance. Racial and ethnic minorities, as well as the economically disadvantaged, tend to comprise a greater portion of the uninsured in the United States. Lack of insurance reduces access to care and contributes to poor health outcomes. In addition, the continued growth of health care expenditures puts pressure on the federal and state governments, as well as on private businesses and individuals. There are numerous reasons for the upward spiral of health care costs, including increased utilization and provider pressure to increase payments.[61]

The roots of health sector reform in the United States reach as far back as the mid-1970's and 1980s. An important piece of legislation that has impacted health care is the ERISA, passed in 1974. Although the primary goal of the legislation was to regulate pension funds, it pre-empted state regulation of self-insuring employee benefit plans. In effect, ERISA provided incentives for employers to convert their employee health plans to self-insurance and thereby avoid paying costs for state-mandated benefits and be able to cut benefits.[62] In addition to ERISA, the other major development of the decade was the passage of the Health Maintenance Act of 1973, which set federal standards for HMOs, provided grants for HMOs, and required employers to offer federally qualified HMOs.

As costs continued to grow during the 1980s, the private sector was not alone in making attempts to control spending. The federal government made attempts to reduce costs in both Medicare and Medicaid. In 1983, in an attempt to regulate Medicare's hospital payment system (Part A), the government developed the "Prospective Payment System" (PPS). PPS, in effect changed hospital reimbursement from a cost-based, retrospective system to a prospective system in which hospitals receive a payment for each patient based upon diagnosis. Diagnosis was categorized as "diagnosis related groups," or DRGs,

intended to be clinically meaningful and statistically valid groupings of illness and injury cases. Initially, there were about 470 of these DRGs, which were homogeneous clinical groupings to which a price tag was attached.[63] While this move slowed the rate of increase in inpatient spending, total hospital spending continued to increase. Many speculated that the increase came from hospitals' attempts to compensate for the change by "upcoding" (using more expensive diagnosis) and increases in use of more technologically advanced procedures. In addition to PPS, the government approved a change in the manner of reimbursing physician spending known as Resource Based Relative Value Scale (RBRVS) in 1989, to be phased in by 1992. Like PPS, RBRVS set a price for input resources required to produce each service provided by a physician. However, there are mixed review over the success of RBRVS: while Medicare spending by physicians has slowed, some suggest that physicians have compensated for the loss of income by increasing volume.

Early in the 1980s the Congress enacted reductions to Medicaid eligibility and at the same time provided states with additional flexibility to set payment levels to providers. Consequently many states developed PPS to control costs. Unlike Medicare, Congress later expanded the number of people eligible for Medicaid during the late 1980s.

During the 1980s, many states also developed their own types of reform to the health care sector. They included a wide variety of plans, some of which have been successful in these limited areas.[64]

The states and federal government are not the only entities trying to reduce expenditures. Both employers and private insurers have implemented a number of strategies to control costs, including development of new hybrids of managed care, cost-sharing, drug controls, "carve-outs" (excluding certain services from a basic package), and utilization review. Utilization review encompasses a number of techniques intended to prevent unnecessary services and to control costs. Such measures include written justifications by physicians for the services that they order, filling out extra forms, reviews of appropriateness, and review of quality of care.

Health Sector Reform in the 1990s. By the 1990s, rising health care costs and rising numbers of the uninsured had caught the attention of the American public and large-scale debates on health sector financing and delivery were frequently heard. An economic recession from 1990 to 1991 also contributed to the sense of urgency developing around health care reform.[65]

Several health sector reform proposals have been debated over the last few decades. They include employer-mandated insurance, universal health insurance, involving government sponsorship, Medicaid expansion, Publicare or strengthening charity care, "Make Markets Work," modifying existing methods and National Health Service (making all systems public)[66]. Clearly, some of these options are not mutually exclusive. In fact, they speak to the breadth of possibilities for health sector reform in the United States.

In late 1991, health care reform burst onto the political scene in the United States, highlighted by the special election of a senator from Pennsylvania who campaigned largely on health insurance reforms.[67] The issue resonated so largely with the national public that many other politicians and congressmen soon picked up the issue. In the months after the November 1991 election, numerous bills on reforming the national system for financing health care were introduced in both the Senate and the House of Representatives. Proposals were even developed by business groups, unions, insurance companies and various health policy experts. Most of the plans that appeared at this time were variants of three basic approaches, namely market-oriented approaches ("make-markets work"), "single payer" taxed financed plans to cover all citizens (similar to universal health insurance), and "play or pay" (employer mandated financing).[68]

Perhaps the most well-known attempt at reforming the health sector in the United States during this period was the Health Security Act (HSA) of 1993. The underlying approach to the plan was a "make markets work" strategy. First introduced into Congress in 1994, this 1,432 page bill proposed to provide health insurance to all Americans, contain the rate of health spending increases, improve public health infrastructure, develop long-term care block grants for the states, and revise graduate medical education. The bill proposed universal health coverage through a combination of individual and employer contributions. Under the proposal, employers would have been responsible for 80% of a standard health plan premium for a broad, federally guaranteed minimum package of benefits. The remaining 20% would have been paid for by families/individuals. Those living below 150% of the poverty level would have received subsidies to pay this balance. The plans would have been known as Accountable Health Plans. Congress rejected the Health Security Act (HSA). Much debate has ensued over why passage was unsuccessful.[69]

Pressure continued to mount for incremental reform to the health sector, particularly in the area of "portability." Portability refers to the ability of a worker to retain health insurance when he/she changes jobs. In 1996, Congress passed the "Health Insurance Portability and Accountability Act" (HIPPA), otherwise known as the Kennedy-Kassenbaum Law. It contained four important provisions: (1) It gave the federal government a role in regulating private insurance for the first time by making rules that applied across large group, small group, and individual markets; (2) A person moving from one employer to another could continue insurance coverage; (3) Insurers were required to offer health insurance to small groups seeking coverage; and (4) the "Medical Savings Account" (MSA) demonstration program.[70] They are cash accounts that employees would be able to use to cover their health care expenses. This system was limited to self-employed persons and small businesses (<50 employees). The central idea is that the funds contributed to a MSA would be used to pay for "first dollar" coverage of health care. After the

substantial deductible is reached, health insurance would then cover the remaining costs. HIPPA also created national standards for electronic health transactions to protect the privacy of patients.

That same year (1996), Congress also passed legislation on welfare reform known as the "Personal Responsibility and Work Opportunities Reconciliation Act" (PRWORA). This reform basically de-linked welfare (cash assistance) and Medicaid. However, it also created strict working requirements, which, if unmet, could result in the termination of welfare benefits for recipients of welfare. Furthermore, it set a lifetime limit of 5 years for welfare enrollees and reduced eligibility for some groups of immigrants. Research is being conducted to determine the impact of the legislation, *vis á vis* a strong economy and other welfare strategies implemented by the states. The United States Congress will reauthorize PROWA in 2002.

Following on the heels of welfare reform came the 1997 Balanced Budget Act (BBA). This bill focused largely on Medicare and Medicaid and expanding coverage to children through SCHIP. The BBA provided changes that slowed Medicare's spending increases. The BBA tightened hospital payment, then mandated prospective payment systems for outpatient hospital care, nursing home care, home health. The centerpiece of the health components to the bill is the development of Medicare+Choice, otherwise known as Medicare Part C. This new plan provides the beneficiary with a broader range of plans (managed care, private fee-for-service insurance, extension of MSAs, as well as "traditional" Medicare). BBA also requires internal and external quality review for plans and a feedback mechanism to provide consumers with data on plan performance. Reviews for Medicare Part C have been rather mixed, with recent evidence that the number of health plans participating has dropped in each of the last three years, with many elderly switching back to traditional Medicare. Also, the BBA enacted the State Children's Health Insurance Program (SCHIP). The federal government is contributing approximately $24 billion dollars over a 5-year period to this program.[71] All 50 States, as well as the District of Columbia, have implemented SCHIP programs. The report points out that SCHIP was implemented at a time when uninsured rates were rising, especially among the lowest income children, many of whom were eligible for Medicaid but were not enrolled. It is still too early to determine if the trend in the number of uninsured children has decreased because of the SCHIP program.

Throughout the 1990s, HHS has significantly increased investments in priority areas for children, such as immunizations, childcare, and health care, including biomedical and behavioral research. Funding for childhood immunization has more than doubled during the 1990s. The fiscal year 2002 budget for the National Immunization Program proposes $796 million for vaccine purchase through the Vaccines for Children Program and $575 million for immunization program activities. A record number of 2-year-olds are now fully vaccinated, while the incidence of most vaccine-preventable diseases is at record lows.

Under the current Administration, HHS is also creating new public and private partnerships to promote children's well-being. The President's fiscal year 2002 budget proposes a series of new investments and initiatives designed to strengthen families and reach at-risk children, especially those left behind by existing programs. These include efforts to provide after-school childcare services, promote safe and stable families, help children of prisoners maintain their family ties, and provide supervised group homes for young mothers and pregnant women.

Health Sector Reform in the New Millennium. Most recently, the current Administration has declared its intention of having government take an active role in the reform of the United States health care system.[72] The role of Government will not be to centralize or to control health care delivery. The reform will be guided by three goals with the intention of fixing the system where it is failing and preserving a private, patient-centered medical system. In order to address the needs of those who have inadequate or no health care coverage, initiatives such as Health Accounts[73], Association Health Plans[74], Health Credits[75], Innovative Options for those enrolled in Medicaid and S-Chips, Stronger Medicare Benefits, and Modern Long-Term Care, have been proposed. The second goal is improving the health care system by creating an environment that encourages and rewards quality through effective patient protections, better information for patients and support for efforts by health care professionals to improve quality. The third goal consists of providing effective support to strengthen the health care safety net and increasing biomedical research. The objective of strengthening the health care safety net is to improve access to preventive and primary health care. The major initiatives are to expand community health centers, improve service to the underserved through the National Health Service Corps, double the budget of the heightened vigilance for public health threats, and public health education. The proposed funding for attainment of these goals is 300 billion USD.[76]

The United States Congress is currently in the midst of working on a Patients' Bill of Rights, a bill meant to give explicit rights to patients especially when dealing with health care insurance. With HMO's dominating the health care scene, lawmakers have been prompted to give patients a stronger voice in decisions about which medical procedures will be covered by insurance. Both the Senate and House passed different forms of this bill. They both require health plans to provide many of the same services, but they differ in the power given to the patients to enforce those rights. If a compromise is found between the bills, patients would be allowed to have more information about their coverage, the ability to seek emergency attention as they see fit, the continuation of ongoing treatments if a person leaves the network and the establishment of a review process for claim denials.[77]

* The profile was prepared by a group of 15 professionals and national policy decision makers from the Department of Health and Human Services (HHS) of the United States of America, from 6 different Agencies and multiple Offices/Centers within those Agencies. Technical coordination of the national group was the responsibility of the Office of Global Health Affairs, HHS. An external review of a preliminary draft was completed by Leon Wyszewianski, Ph.D., of the University of Michigan School of Public Health and Stephen Mick, Ph.D., of the Department of Health Administration of Virginia Commonwealth University. Final review, edition, and translation are the responsibility of the Program on Organization and Management of Health Systems and Services of the Division of Health Systems and Services Development of PAHO/WHO.

BIBLIOGRAPHY AND NOTES

[1] Congressional powers include declaring war and raising armies, and the constitution prohibits the states from activities that could undermine the national government, such as making treaties, coining money, imposing tariffs, or making war.

[2] National Centers for Health Statistics. Health, United States, 2001 With Urban and Rural Health Chartbook. Hyatsville, Maryland, 2001.

[3] National Centers for Health Statistics. Health, United States, 2000 With Adolescent Health Chartbook. Hyatsville, Maryland, 2000. Women outlive men by almost seven years (women: 79.5 yrs; men: 73.8 yrs.). The gap is slowly closing as men's life expectancy improves.

[4] U.S. Census Bureau. Statistical Abstract of the United States: 2000. (120th Edition). Washington, DC, 2000.

[5] National Centers for Health Statistics. Health, United States, 2000 With Adolescent Health Chartbook. Hyatsville, Maryland, 2000.

[6] In 1998, the accident death rate was slightly higher for Blacks than Whites, the suicide rate for Whites was double the Black rate, and the homicide rate for Blacks was six times the White rate.

[7] Ibid.

[8] Ibid.

[9] U.S. Census Bureau: www.census.gov/prod/www/abs/decenial.html Whites comprise the largest racial/ethnic group within the United States (75.1%), followed by Hispanics of any race (12.5%), African Americans (12.3%), and Asians (3.6%). American Indians and Alaska Natives comprise approximately 0.9% of the population, and Native Hawaiians and other Pacific Islanders comprise approximately 0.1%.

[10] PAHO/WHO. "Basic Indicators, 2000." Program on Health Situation Analysis, Division of Health and Human Development, Washington, DC, 2000. Graduation rates in 1998 varied greatly by race/ethnicity: for whites, 83.7%; for blacks 76.0%; and for Hispanics, 55.5%. In 1990, the percentage of the population completing high school was 77.6%, with 79.1% for whites, 66.2% for blacks, and 50.8% for Hispanics.

[11] Ibid. In 1998, 26.1% of Blacks, 12.5% of Asian/Pacific Islanders, and 25.6% of Hispanics lived below the poverty level in 1998. The percentage of people living in poverty, by sex, is as follows: males 1990, 11.7; 1998, 11.1; 1999, 10.3. females: 1990, 15.2; 1998 14.3; 1999, 13.2.

[12] PAHO/WHO. "Basic Indicators, 2000." Program on Health Situation Analysis, Division of Health and Human Development, Washington, DC, 2000.

[13] U.S. Department of Labor. Bureau of Labor Statistics Data. http://www.dol.gov . In 1990, the unemployment rate was 4.8% for whites, 11.4% for blacks, and 8.2% for Hispanics. In 2000, the figures were 3.5% for whites, 7.6% for blacks, and 5.7% for Hispanics..

[14] The United Nations Development Programme. "Human Development Report 2000." New York, NY, 2000.

[15] It currently provides health services to approximately 1.5 million American Indians and Alaska Natives who belong to more than 550 federally recognized tribes in 35 states.

[16] Fronstin, Paul. "Sources of Health Insurance and Characteristics of the Uninsured: Analysis of the March 2000 Current Population Survey." Employee Benefit Research Institute Issue Brief. December 2000.

[17] This includes 173 medical centers, over 771 ambulatory care and community based clinics, 134 nursing homes, 42 domiciliaries, 206 readjustment counseling centers and various other facilities.

[18] Part A (largely paid for through payroll taxes) helps pay for inpatient care in hospitals, critical access hospitals (small facilities that give limited outpatient and inpatient services to people in rural areas), skilled nursing facilities, hospice care, and some home health care. Part B, which currently entails a premium of about $50/month (adjusted yearly), helps pay for doctors, services, outpatient hospital care, and some other medical services that Part A does not cover, such as the services of physical and occupational therapists, and some home health care. Part B helps pay for these covered services and supplies when they are medically necessary. Part C, otherwise known as

Medicare+Choice gives beneficiaries the opportunity to enroll in private health plans. Managed care plans may also charge beneficiaries a premium as well. The idea behind this was to offer an additional choice to seniors as well as promote competition among health plans to reduce costs for this population group. Medicare makes a monthly payment to the health plans, and the beneficiary continues to pay the $50/month as required under Part B.

[19]Within broad national guidelines that the federal government provides, each of the states: (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. However, since expansions in 1986 and 1990, children and pregnant women are allowed to qualify for Medicaid based on federal standards.

[20] To be eligible for funds, States must submit to, and obtain approval from, the Secretary of HHS for a State Child Health Plan. This program is a capped entitlement for States.

[21] U.S. Census Bureau. Statistical Abstract of the United States: 2000. (120th Edition). Washington, DC, 2000.

[22] Torrens, Paul R. and Stephen J. Williams. "Managed Care: Restructuring the System" in Stephen J. Williams and Paul R. Torrens (Eds.), Introduction to Health Services, 6th Edition, Albany, NY: Delmar Publishers Inc. 1999.

[23] http://www.redcross.org/index/html

[24] American Cancer Society web page, http://www.cancer.org

[25] American Heart Association web page, http://americanheart.org

[26] American Medical Association web, http://www.ama-assn.org.

[27] Faith based initiative web page, http://www.hhs.gov/faith

[28] American Medical Association. Physician Statistics Now: Graph. http://www.americanmedicalassociation.org

[29] U.S. Census Bureau. Statistical Abstract of the United States: 2000. (120th Edition). Washington, DC, 2000.

[30] American Medical Association. Physician Statistics Now: Graph. http://www.americanmedicalassociation.org

[31] U.S. Department of Health and Human Services, Health Resources and Services Administration, Bureau of Health Professions, Division of Nursing. The Registered Nurse Population: National Sample Survey of Registered Nurses – March 2000; Preliminary Findings February 2001. Washington, DC.

[32] To contain drug costs, most states have adopted laws and/or regulations that encourage the substitution of drug products. These state laws generally require either that substitution be limited to drugs on a specific list (the positive formulary approach) or that it be permitted for all drugs except those prohibited by a particular list (the negative formulary approach)

[33]RxList. "The Top 200 Prescriptions for 2000 by Number of U.S. Prescriptions Dispensed. http://www.rxlist.com

[34] It identifies drug products approved on the basis of safety and effectiveness by the FDA under the Federal Food, Drug, and Cosmetic Act (the Act). Drugs on the market approved only on the basis of safety (covered by the ongoing Drug Efficacy Study Implementation [DESI] review [e.g., Donnatal7 Tablets and Librax7 Capsules] or pre-1938 drugs [e.g., Phenobarbital Tablets]) are not included in this publication. The main criterion for the inclusion of any product is that the product is the subject of an application with an effective approval that has not been withdrawn for safety or efficacy reasons. Inclusion of products on the list is independent of any current regulatory action through administrative or judicial means against a drug product. In addition, the list contains therapeutic equivalence evaluations for approved multisource prescription drug products. Therapeutic equivalence evaluations in this publication are not official FDA actions affecting the legal status of products under the Act.

[35] The term "orphan drug" refers to a product that treats a rare disease affecting fewer than 200,000 Americans. The Orphan Drug Act was signed into law on January 4, 1983. Since the Act passed, over 100 orphan drugs and biological products have been brought to market. The intent of the Act was to stimulate the research, development, and approval of products that treat rare diseases.

[36] American Red Cross. 2000 Corporate Annual Report. http://www.redcross.org/pubs/car00/pgs17-27.pdf. While the Red Cross does not pay individuals for their blood donations, two facilities nationwide pay for donations of platelets (2/3200 total blood processing facilities or .0006% of facilities).

[37] All organizations that collect blood in the United States must follow a standardized protocol, designed and enforced by the FDA's Office of Blood Research and Review, referred to as the "five layers of safety." These layers include: (1) selection of suitable donors, (2) use of deferral registries to identify unsuitable donations, (3) infectious disease testing (HIV, HCV, HBV, HTLVI, HTLVII, STS, CMV), (4) Quarantining blood while verifying suitability and doing tests, and (5) monitoring, investigating, and taking corrective actions to address errors, accidents, and adverse reactions.

[38] The last Hill-Burton loan was made in the mid-1970s.

[39]Launched in 2000, it is designed to serve as a roadmap for improving the health of all people in the United States during the first decade of the 21st century and builds on initiatives pursued over the past two decades Developed under the auspices of HHS, "Healthy People" is designed to achieve two over-arching goals: (1) increase quality and

years of healthy life and (2) eliminate health disparities. A Healthy People Consortium, comprised of 350 national organizations, 250 state public health, mental health, substance abuse, and mental health agencies, contributed to the development of the initiative. Nonetheless, the states are not required by the federal government to fulfill the objectives laid forth in "Health People". Many states, however, have developed their own state "Healthy People" programs that are tailored to their specific health needs, based on the national objectives.

[40]Medicare, although a federally funded program, contracts with private insurance companies to make payments to health care providers, instead of issuing payments via local offices of the federal government. Medicaid (funded jointly by federal and state governments) is administered by the states under very broad federal guidelines, which results in considerable diversity among the state Medicaid programs. Private health insurance companies are regulated by state insurance commissioners, and are not generally regulated by the federal government. It is important to note, however, that the passage of ERISA by the United States Congress pre-empted state regulation of self-insured employee benefit plans, thereby "protecting" them from any state-level reform. For example, the states can specify that certain benefits be covered by all insurance policies within that state. These mandates do not apply to ERISA plans because the federal government regulates them. Also states may regulate increases in insurance premiums. In addition, the licensing of health facilities (hospitals and nursing homes) is handled by the states.

[41] The Commission, a not-for-profit organization, currently evaluates and accredits nearly 19,000 health care organizations and programs in the United States. JCAHO evaluates and provides accreditation for hospitals, healthcare networks, home care, long-term care, assisted living, behavioral healthcare, ambulatory care, and clinical laboratories. The NCQA is an independent, not-for-profit organization whose mission is to evaluate and report on the quality of the nation's managed care organizations. NCQA supports, sponsors, and maintains the Health Plan Employer Data and Information Set (HEDIS), which is a set of standardized performance measures designed to ensure that purchasers and consumers have the information they need to compare the performance of managed health care plans. The HEDIS performance measures are linked to public health issues and include a consumer-opinion survey focused on customer service, access to care, and claims processing. The Joint Commission on Accreditation of Healthcare Organizations. http://www.jcaho.org

The National Commission for Quality Assurance. http://www.ncqa.org/

[42] CDC currently supports 20 states for coordinated school health programs. CDC has established a national framework to support coordinated school health programs. More than 40 national nongovernmental education and health organizations work with CDC to develop model policies, guidelines, and training to assist states in implementing high-quality school health programs.

[43] NIH web page, www.nih.gov/about/NIHoverview.html

[44]There are various explanations for the increase in physician supply, including federal support for training during the 1960s and 70s (which was reduced by 1980) and a significant influx of foreign-trained physicians known as International Medical Graduates

[45] Health Resources and Services Administration, Bureau of Health Professions. The Pharmacist Workforce: A Study of the Supply and Demand for Pharmacists. Washington, DC.

[46] Roemer, Milton I. National Health Systems of the World. Vol. 1, Chapter 5. New York, New York: Oxford University Press. 1991.

[47] National Centers for Health Statistics. Health, United States, 2001 With Urban and Rural Health Chartbook. Hyatsville, Maryland, 2001.

[48] Health Insurance Association of America. Source Book of Health Insurance Data. Washington, DC, 1998.

[49] Health Insurance Association of America. Source Book of Health Insurance Data. Washington, DC, 1999.

[50] U.S. Census Bureau. Statistical Abstract of the United States: 2000. (120th Edition). Washington, DC, 2000. Approximately 44.3 million people or 16.3% of the population in 1998 were not covered by health insurance

[51]The indicators include: physical activity, overweight and obesity, tobacco use, substance abuse, responsible sexual behavior, mental health, injury and violence, environmental quality, immunization, and access to health care.

[52] National Centers for Health Statistics. Health, United States, 2000 With Adolescent Health Chartbook. Hyatsville, Maryland, 2000. Vaccine rates among minorities were: Blacks (73%) and Hispanics (75%), as well as for those living below the poverty level (74%).

[53] Ibid.

[54] HHS web page, http://www.hhs.gov/news/press/2002pres/20020125.html

[55] Ibid.

[56] Ibid.

[57] Ibid.

[58] Ibid.

[59] Kohn LT, Corrigan JM, Donaldson MS, eds. "To Err is Human: Building a Safer Health System." Washington, DC: National Academy Press; 1999.
[60] Skocpol, Theda. Boomerang: Health Care Reform and the Turn Against the Government. New York, New York: W.W. Norton Company Inc. 1997.
[61] DeLewN. Greenberg, G. "A Layman's Guide to the United States Health Care System in the Year 2000." UNPUBLISHED.
[62] DeLew N, Greenberg G, Kinchen K. "A Layman's Guide to the U.S. HealthCare System." Health Care Financing Review. Fall 1992, vol. 14, no. 1. pp.151-169
[63] The DRGs were homogeneous enough so that a price tag could be attached to each one, a reimbursement rate that the federal government calculated to be what it would really cost the hospital to deliver that DRG's worth of care. If the case became complicated, it would lead to a longer length of stay, and if it went beyond a certain length, it became an "outlier," and was reimbursed more generously. Reimbursement was subject to geographical area and relative costs in that area (nurses salaries, etc.), as well as if the facility was a teaching hospital.
[64] One common model was the "all-payer rate-setting system," which budgeted payments to hospitals by establishing payment rates for treatment regardless of who pays. Four states tried this approach, but only Maryland continues using it. This system relies heavily upon agreement among insurers, employers, hospitals and state government, and therefore was discontinued in many states, despite its success.
Hawaii is the only state of the Union that is not affected by ERISA, because of legislation that it passed before ERISA was enacted. It adopted a mandate that requires all employers to provide health insurance, which has resulted in nearly 100% coverage of the population. Hawaii's geographic isolation as well as a history of employers' providing health benefits has kept this legislation from causing significant problems. Massachusetts proposed a similar approach with a mandate known as "pay or play." This legislation basically stated that an employer must provide health insurance to employees or pay into a fund that would be used to provide public insurance for that company's employees. Nonetheless, this approach was never implemented, so it is unknown as to whether it would have been successful or not. Perhaps the most interesting attempt among the states to implement reform to the health sector was made by Oregon. The reform, frequently described as "rationing," involves the expansion of Medicaid to all persons below the poverty line, development of a list of health services (ranked from most-effective to least-effective outcomes), and annual determination of how far "down" the list services will be funded for any given year. Defenders say that this type of plan achieves greater equity by giving a larger percentage of the poor a higher-quality benefit package.
[65] Proposed a nationalized health care system for the United States included programs like that of Canada. Others argued the private insurance system was the right path, as competition fostered the growth of high-quality and high-tech medical care. In the 1990's, the industry, itself, reacted in a number of ways, as employers dropped coverage altogether, employers excluded employees with certain medical conditions, and insurers used "re-insurance" (a way to permit insurers to spread the burden and losses of high-risk enrollees).
[66] Employer-mandated insurance would basically imply a repeal of ERISA and a requirement by the federal government to employers to either offer health insurance to their employees or pay a tax. Universal health insurance would involve a government-sponsored (state or federal) health insurance program. Under this scenario, a payer (either the government or a regulated insurance industry) would be powerful enough to push costs down. Medicaid expansion would involve adjusting eligibility requirements to include those low-income segments of the population that are currently not receiving care. Publicare is built on the premise that financing reform is not feasible, and therefore the public hospitals, community health centers, public health departments, and other voluntary institutions involved in providing charity care should be strengthened. A "Make Markets Work" approach basically implies modifying existing mechanisms and markets to reform the system, as opposed to creating something entirely new. It could depend on a series of tax incentives and de-regulation, based on the fundamental concept of minimal government intrusion and maximum consumer education. Lastly, some proposed a National Health Service, similar to that of the United Kingdom, where the entire delivery and financing systems become public. The Canadian system was also considered a model during the 1990s.
[67] Skocpol, Theda. Boomerang: Health Care Reform and the Turn Against the Government. New York, New York: W.W. Norton Company Inc. 1997.
[68] Ibid.
[69] Ibid. Theories have included fear of a government take-over, secrecy over the development of the plan and lack of public input, belief that there was no solid evidence that it would indeed save money, skepticism about managed care models in general, belief that the plan was too long and complex, political reasons, etc.
[70] MSAs were originally a Republican alternative to the Clinton Administration HAS.

[71]. Mathematica Policy Research Inc. "Implementation of the State Children's Health Insurance Program: Momentum is Increasing After a Modest Start." January 2001.
[72] See, http://www.whitehouse.gov/infocus/medicare/health-care
[73] "Health Accounts" are a tax-favored initiative that would allow individuals to build up an account to cover high medical costs when needed and would allow them to pay out-of-pocket costs more easily. These proposals address an imbalance in current tax rules, which favor medical spending controlled by health plans over medical spending controlled by patients.
[74] "Association Health Plans" would enable small employers to provide better and more affordable health care coverage options for their employees. Like many large employers offer.
[75] "Health Credits" target the 40 million uninsured Americans (14% of the total population). It consists of government financial support for the purchase of individual and family health insurance plans through health credits for low and middle income workers who do not have good employer-based coverage options. The credits would make it possible for them to get affordable coverage that meets their needs.
[76] See, http://www.whitehouse.gov/infocus/medicare/health-care
[77] Washington Post Web page www.washingtonpost.com