

MAJOR TRENDS IN HEALTH LEGISLATION IN THE
UNITED STATES OF AMERICA
2001-2005



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HEALTH LEGISLATION TRENDS IN THE UNITED STATES OF AMERICA 2001-2005

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I. INTRODUCTION

This legislation summary examines legislative trends in the United States with an emphasis on access to health care and the structure of the health care system. There is also a discussion of the structure and funding of the public health system. This analysis focuses primarily on legislation at the federal level and discusses state level legislation only tangentially. The discussion focuses on enacted legislation and mentions pending legislation only when particularly topical.

This summary particularly notes barriers to access, legal frameworks directed to the elimination of health inequities and through the Millennium Development Goals ("MDG"). The memorandum closes with needs for future reforms.

II. BACKGROUND

The United States operates on a federal system established by the U.S. Constitution. Under this system, the federal government has no direct grant of jurisdiction or authority over matters of health. Instead, matters of health are left to the states. The states may enact laws for the health and welfare under their police powers.¹ The federal government has no direct jurisdiction over health matters.

In the last century the federal government has exercised more legislative control over health under its other constitutional authority to regulate commerce and to spend funds. Through these constitutional powers, the federal government has exercised greater authority of health, especially in the latter half of the twentieth century.²

National Health Authority

The United States has no national health authority as understood in many other countries. Because of its federal system, national health programs are usually authorized under the government's spending power. In this arrangement, the government creates programs, e.g Medicare, and states implement the programs by

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¹ U.S. Const. amend. X.

² See the previous Trends in Health Legislation

receiving funding from the federal government. The government controls the programs through its power to control spending.

Access to Health Care

Access to health care in the United States is based on ability to pay as a first principle. Over the past sixty years, a growing number of government programs have been put into place to assist certain populations in accessing health care. Programs are in place to cover the cost of health care for the elderly, children, the disabled, and some low-income populations. Medicare provides health care to the elderly. Medicaid and the State Children's Health Insurance Program (SCHIP) provide health care to for the disabled, children, and some low-income populations. These programs are administered in varied forms but have recently been characterized by a reliance on market systems and ideologies to provide government entitlements to vulnerable populations. The current Administration has sought to intertwine private providers with government programs with ever increasing frequency.

Populations in the United States not covered by a federal or state program usually have access to health care through an employer-based health insurance program. These programs are typically based on a type of managed care organization ("MCO") that provides a set of comprehensive health care services for a monthly premium and a co-payment at the time services are provided. These MCO are private insurance companies. Employer-based plans may or may not include a prescription drug component. Individuals not covered by an employer-based plan or a state or federal program are *uninsured* and access health care on their ability to pay. Those uninsured, because of an inability to pay for service, often do not receive adequate health care and receive care only on an emergent basis at hospital emergency rooms.

Structure of the Health Care System

Health care is provided through a complex system of private and public hospitals, clinics and institutions. Some private systems are operated for-profit while others are operated as non-profit. The national health care system is decentralized with the majority of regulation and financing at the state level. The federal government funds many major programs that are administered at the state level.

The United States also has a relatively decentralized public health system and infrastructure. Public health is primarily the responsibility of the state governments. State health departments work in conjunction with the federal public health infrastructure that is spread across several federal agencies.

The United States government operates several research facilities, directs, and funds the majority of medical research in the United States through the National Institutes of Health.

Barriers to Access

The financing and structure of health care in the United States present significant barriers to access. There are often significant populations without insurance and access to care. When uninsured do access care, it is often through emergency rooms which usually entails higher costs and a greater risk of a negative health outcome than if they had had access to preventative clinical care. Low-income and uninsured populations may have access to health care through Medicaid and SCHIP³. However, in the recent Deficit Reduction Act of 2005, the federal government required that individuals present proof of U.S. citizenship to receive care under the program. There have been no new comprehensive efforts on part of the federal government to reduce barriers to access.

III. LEGISLATIVE TRENDS: 2001 – 2005

There are relatively few significant new trends in federal health legislation in the United States from 2001 – 2005. I have identified five legislative trends that were evident in the past five years. First, there were attempts to address the financing of health care with various federal programs. Second, the legislature made global HIV/AIDS a priority. Third, severe financial pressure has shaped legislation that has cut funding for a myriad of domestic health programs. Fourth, Congress has been preoccupied with terrorism and emergency preparedness. In light of the concerns, there have been extensive changes to the health infrastructure and an increase in funding for emergency health measures. Finally, the legislature has continued to respond to organized constituencies and has directed resources toward specific diseases and conditions.

Restructuring Health Care Financing: Market Ideology

Health care in the United States is funded through a mix of private and public institutions. Public financing of health care on the federal level is only provided to

³ “Medicaid” is a program to provide medical services to certain low-income populations. SCHIP is the State Children’s Health Insurance Program. It provides health insurance to children that would not otherwise receive it.

certain populations through the Medicare and Medicaid programs. Most health care is provided through employer-based health insurance programs. The majority of these programs are managed care organizations (MCO) that grew in popularity in the latter decades of the 20th century as means to control ever-increasing health care costs. In the past five years, there has been a growing recognition that MCO's as cost containment systems are not able to hold costs down. As a result, there are growing trends to shift many of the burdens on the plan subscribers in the form of higher deductibles and co-payments. Some MCOs have also attempted to provide more prevention-oriented programs and to engage in close maintenance of high-cost patient groups.

As the twentieth century closed, it was apparent that managed care organizations were not able to contain growing health care costs as hoped and managed care organizations were losing money. There was a period of significant consolidation in the insurance sector, among hospitals, and among physicians. Organizations and institutions that provided health care responded to the financial constraints of the late 1990s early 2000s by merging and consolidating. For example the number of hospitals participating in any type of consolidated multi-hospital system increased from 30% in 1995 to 60% in 2001. Managed care organizations consolidated, and many states were dominated by a few remaining managed care organizations.

The decline of managed care organizations and the consolidation of health care institutions follows a wave of public hostility to managed care organizations. While the federal government did not act to regulate managed care organizations, state governments passed a myriad of "patients' rights" acts and other legislation that guaranteed minimum levels of care. These state acts helped to drive the wave of mergers and consolidation in the area. By 2005, the majority of states had patients' rights acts and other protections in place for populations receiving care through an MCO. These bills vary in their content but were generally written to address many of the more unpopular practices of MCO. These bills often required direct access to ob/gyn services for women, access to emergency rooms and physicians of choice. The bills also prohibited incentives to physicians to reduce care and set up independent review boards to evaluate treatment decisions. While these acts have become common, the managed care industry has also turned from many of these practices as it seeks to restore profitability.

As spending on services increased, health premiums became more expensive. Employers increased costs to their employees or dropped coverage altogether. From 2000 – 2005, the number of uninsured increased as employers dropped coverage and the economy entered a recession, Medicare and Medicaid costs increased, and the number of bankruptcies from medical debt rose.

There has been no national legislative activity to address the growing financing issues in health care over the past five years aside from the passage of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. Health care costs and quality of care are anticipated to be major political issues in the short term, and the continuing structural problems financing and providing health care will be long-term problems facing the United States. There is no coherent national strategy in this arena as the current administration and Congress prefer state-level solutions relying on markets.

While there has been no federal activity in this area, several states have acted to increase access to health insurance and to improve the quality of care received. Massachusetts has been particularly noted for the passage of a comprehensive health care reform act to provide universal and mandatory health insurance. Maine with its Dirigo plan and Hawaii with its requirements on employers are two other states that have moved in this area. The Massachusetts plan and Maine plan are the most comprehensive during the 2001 – 2005 period.

The Dirigo Health Reform Act became law in Maine in 2003. The Dirigo plan is a combination of programs to cut health care costs, to improve quality and to provide an affordable health insurance plan for eligible individuals called DirigoChoice. While Maine's plan took a step toward ensuring universal access, it does not *mandate* coverage per se.

The Massachusetts Plan ("Chapter 58") will provide universal health insurance and will *mandate* participation.⁴ Under Chapter 58, health insurance in Massachusetts will be significantly reorganized. Chapter 58 makes several key reforms. First, it creates the Commonwealth Health Insurance Connector ("The Connector"). The Connector is a unique approach to providing health insurance in the U.S. Under the Connector, different private plans will be provided and approved. Individuals can then select an offered plan through the Connector. If a person is employed, he can purchase a plan through the Connector and keep it if he transfers jobs. The plan would also be purchased using pre-tax income. Individuals who are unemployed can also purchase insurance through the Connector. Second, Chapter 58 creates the Commonwealth Care Health Insurance. This is an insurance plan for individuals that will be subsidized for individuals who don't qualify for MassHealth. This plan will be available through the Connector. Third, employers must offer health insurance to their employees. They may do so either by purchasing their own plan *or* by signing up with the Connector. If an employer uses the Connector, they make contributions, and the employee selects a plan

⁴ 2006 Mass. Acts Chp. 58.

through the Connector. Employers who do not provide insurance or contribute to it will be assessed a “Fair Share Contribution” which is estimated at approximately \$295 per employee per year. Finally, Chapter 58 requires that every citizen of Massachusetts be covered. Citizens will be required to prove coverage when filing their income taxes each year. Individuals without insurance will be penalized if they do not have a waiver demonstrating that there is *no affordable plan for their income level*. The requirement that everyone is insured is based on the assumption that the poor will be covered by MassHealth, those up to 300% of the federal poverty level will be subsidized through Commonwealth Care Health Insurance, others will obtain insurance on their own or with an employer through the Connector, and the remaining will be enrolled in plans provided by employers. The Massachusetts Plan is unique in the development of the Connector and in its requirement that everyone have health insurance.

In November 2005, Illinois enacted a program that will provide comprehensive health insurance coverage to all children in Illinois. The program, “All Kids,” will begin coverage in July 2006. The program provides insurance coverage for children with co-payments and premiums based on monthly income and family size.

Global HIV/AIDS Pandemic

In January 2003, President Bush announced his intention to create an emergency plan for AIDS relief. The President indicated that combating HIV/AIDS globally would be a key component of U.S. foreign policy. In the same year, Congress enacted legislation to authorize the President’s Emergency Plan for AIDS Relief (“PEPFAR”). The majority of funds in the plan would be directed toward the treatment of HIV/AIDS. About twenty percent of the funds were directed toward prevention. This plan has been generally positively received but has also raised some concerns in its implementation.

Fiscal Pressures: Cutting Domestic Health Spending

In the 2001 – 2005 period, the United States government has faced massive budget deficits. The wars in Iraq and Afghanistan; the rising costs associated with Medicare and Medicaid; the destruction of New Orleans and rebuilding after Hurricane Katrina; and large tax breaks for the wealthy have all contributed to significant financial pressure on the United States. The ongoing cost of the wars is particularly significant. Because of these pressures, recent federal budgets have drastically cut spending on domestic programs related to health and human services. As a result of this, there has been a drastic reduction in funding for health care in the United States. The most recent budget has even cut funding for Medicaid. The current Congress and Administration is ideologically disposed to reducing or terminating programs that are viewed as

“entitlements.” These programs typically are ones that provide health services to underserved populations or that are focused on public health services. The Healthy Communities Access Program created in 2002 once provided primary health care services to the poor and uninsured. In the most recent budget, the program was not funded and current programs will close once they have completed their funded activities this year.

Terrorism and Emergency Preparedness

After the events in September 2001, the federal government focused on issues of security and emergency preparedness. As part of this focus, the government began to pay greater attention to bioterrorism and the possible health consequences of chemical, nuclear and radiological terrorism. These perceived threats resulted in a significant restructuring of the public health system and a legislative emphasis on increasing capacity of the health system in emergencies and on stockpiling medications and equipment necessary in such events. The federal government also directed state and local governments to begin emergency planning.

The War in Afghanistan and the occupation of Iraq, coupled with the expense in rebuilding after Hurricane Katrina and associated failures of the previous emergency planning, have kept the legislature focused on the terrorism and emergency dimensions of the health care system. This focus on preparedness and terrorism comes with a diminished focus on traditional health care systems

Disease Specific Programs

Disease-specific programs remain a topic of health legislation. These programs are usually enacted after lobbying by a group affected by a particular disease. These types of enactments reflect the ad hoc and interest-based approach to health care on the federal level.

III. REDUCING HEALTH INEQUITIES: MILLENNIUM DEVELOPMENT GOALS

There is no comprehensive federal legislative plan to eliminate or reduce health disparities. The Department of Health and Human services has developed and released the Healthy People 2010 framework. Healthy People 2010 is a document that provides guides for health promotion and disease prevention through 2010. It also sets health goals for the population. One key goal of Healthy People 2010 is the elimination of

health disparities. Healthy People 2010 has been adopted by state and local governments. What legislative attempts there have been to reduce health disparities have taken place in state legislatures rather than in the Congress.

There has been no legislative attempt to meet or implement the Millennium Development Goals (MDG). While some programs, such as the President's Emergency Plan for Aids Relief, do involve some of the articulated MDG, there is no systematic effort to meet the goals. In December 2005, Senator Lugar introduced the International Cooperation to Meet the Millennium Development Goals Act of 2005.⁵ This legislation would express the sense of Congress that the United States should continue to pursue the MDG. It would also require the Secretary of State to report to Congress the U.S. government's efforts to achieve the MDG by 2015, an evaluation of U.S. efforts, and the likelihood of achieving the MDG. This legislation has been approved in the Senate but has not moved through the House and remains un-enacted. Given the current U.S. government hostility⁶ toward the Millennium Development Goals, it is unlikely that the act would move forward or that the U.S. government would address the MDG comprehensively.

IV. CHANGES FROM THE LAST HEALTH IN THE AMERICAS

There have been no significant changes in legislative trends since the last Health in Americans except the growing focus on emergency preparedness and security. The last report indicated that the legislature was concerned with slowing the growth of health expenditures and the cost of prescription drugs. The report also indicated that disease or constituency-focused legislation and on-going support of the National Institutes of Health remained priorities. In the five years covered by this memorandum, the government has sought to control costs through the MMA and the prescription drug benefit included in it. The Congress continues to pass legislation focused on particular diseases and populations. It also continues to fund the National Institutes of Health.

The attacks in 2001 in the United States directed significant federal attention on security and emergency preparedness. Unlike the previous report, spending and legislation in this area has become a major trend of health-related legislation. The period covered by this memorandum is also characterized by very limited budgets for health programs and health care systems. The ongoing wars in Afghanistan and Iraq, the recovery from Hurricane Katrina, ongoing reduction in government revenue

⁵ S. 1315, 109th Congr. §1 (2005).

⁶ Colum Lynch, *U.S. Wants Changes in U.N. Agreement*, WASHINGTON POST, August 25, 2005, at A1.

through tax cuts, and a slow economy through the period have induced significant cuts in domestic health care spending on the federal level.

V. NEEDS FOR FUTURE REFORMS – INTERNATIONAL HEALTH REGULATIONS AND FRAMEWORK ON TOBACCO CONTROL

Framework Convention on Tobacco Control

While the United States has signed the Framework Convention on Tobacco Control (“FCTC”), it has not ratified the treaty. While there have been repeated calls in the United States to do so, the Bush administration has not sent the FCTC to the Senate for approval. In the United States, the Senate must ratify treaties. To do so with the FCTC, the President must submit the FCTC to the Senate. To date, he has not done so.

International Health Regulations

The United States as a member state has supported the revision of the International Health Regulations. However, the United States expressed its reservation about its ability to fully implement the IHR given the federal structure of the United States. Implementation of the IHR would occur throughout the Executive agencies of the U.S. government. There has been no federal legislation that addresses the International Health Regulations and their implementation by the federal government.

V. CONCLUSION

There has been no significant change in legislative trends since the last report except for the new emphasis on security and emergency preparedness. The trends in place over the past ten years do indicate several areas that are likely to become pressing areas of future need and focus for legislative activity. First, the managed care organization model of health insurance looks unlikely to control growing health care costs either through employer-based plans or through government plans such as Medicare. The increasing costs and lack of systems to address them are poised to present a long-term problem to the U.S. health care system. This is an area that will most certainly require legislative attention. Second, the financial pressures from heavy spending on military ventures and foreign and domestic reconstruction efforts will place serious burdens on the financing of the U.S. health care system. This will also be an area of future legislative attention. Third, current legislative efforts directed toward emergency preparedness and public health systems have not shown themselves to be effective. While resources have been diverted to these areas, the traditional public health infrastructure has suffered. Fourth, environmental regulation and occupational

health have been virtually ignored over the past six years. The neglect of these areas will likely require significant legislative attention. Finally, the U.S. suffers chronic diseases and conditions associated with a high prevalence of overweight and obesity. This problem and its implications for health care in the United States will demand legislative and regulatory attention.

107th Congress – 2001 – 2002

The Muscular Dystrophy Community Assistance, Research and Education Amendments of 2001⁷ directs the National Institutes of Health, the Centers for Disease Control and Prevention and other executive agencies to increase research and spending on the cure and treatment of muscular dystrophy and other associated conditions.

An Act to extend the authorization of the Drug-Free Communities Support Program for an additional 5 years, to authorize a National Community Antidrug Coalition Institute, and for other purposes⁸ continued funding for the Drug-Free Communities Support Program, a national program that seeks to reduce drug use among youth in the United States.

Following the destruction of the World Trade Center and the other events of September 2001, there was a clear shift in legislative focus to issues of terrorism, security, and emergency preparedness. Reacting to perceived threats, Congress passed the **Public Health Security and Bioterrorism Preparedness and Response Act** (“Bioterrorism Act”) in 2002.⁹ The Bioterrorism Act addressed the safety of the food and drug supply; the security of drinking water; and the control of dangerous biological agents in addition to its provisions addressing more traditional areas of health care. The act appropriate over \$4 billion for emergency preparedness. The Bioterrorism Act provided for the development and stockpile of vaccines and other drugs; for the improvement of hospitals and their capacities; and the improvement of state and local health departments.

While the Bioterrorism Act has improved the capacity and infrastructure of the health care delivery system, these improvements have been directed almost entirely toward public health emergencies, e.g. the stockpile of smallpox vaccine. The health and public health infrastructure has not been strengthened *generally* by the Bioterrorism Act. Exercises to test system responses, government reports, and private studies have suggested that the health system remains ill-prepared to respond to any public health threat that the Bioterrorism Act was designed to address.

⁷ Pub. L. No. 107-84, 115 Stat. 823.

⁸ Pub. L. No. 107-82, 115 Stat. 814.

⁹ Pub. L. No. 107-188, 116 Stat. 594 (codified in scattered sections of USC).

In addition to the legislation on the federal level, there has been legislative activity in this arena on the state level. Over forty states have passed some version of the Model State Emergency Health Powers Act (“MSEHPA”). MSEHPA is an attempt to create a uniform statutory framework for emergency public health powers. It significantly expands state power under public health emergencies granting expanded quarantine and surveillance abilities to the states.

The **Nurse Reinvestment Act**¹⁰ creates scholarships and other programs to increase the number of nurses trained and to improve the retention of nurses in areas experiencing nursing shortages. The act also provides loans and grants to increase the number of nursing faculty available to train new nurses.

The **Rare Diseases Act of 2002**¹¹ creates the Office of Rare Disease at the National Institutes of Health and appropriates funds for collaborative centers to study the treatment and cure of rare diseases.

The **Rare Diseases Orphan Product Development Act of 2002**¹² appropriates money to the Food and Drug Administration to increase funding for Orphan Products Research Grants to provide incentive to develop drugs that would not have wide commercial application because the number of potential users is so small.

The **Homeland Security Act of 2002**¹³ creates the Department of Homeland Security. This act transfers some functions of the public health service and other health and human service agencies to the Department of Homeland Security and lays out areas of coordination between government agencies in relation to health emergencies.

The **Hematological Cancer Research Investment and Education Act of 2002**¹⁴ directs the National Institute of Health to increase programs for research into blood cancers. The act also directs the Secretary of Health and Human Services to provide education and information to patients and the general public about the treatment of blood cancers.

The **Health Care Safety Net Amendments of 2002**¹⁵ creates the Healthy Communities Access Program to provide services for uninsured and underinsured. This program creates consortia of health care providers, community organizations and local

¹⁰ Pub. L. No. 107-205, 116 Stat. 811.

¹¹ Pub. L. No. 107-280, 116 Stat. 1988.

¹² Pub. L. No. 107-281, 116 Stat. 1992.

¹³ Pub. L. No. 107-296, 116 Stat. 2135.

¹⁴ Pub. L. No. 107-172, 116 Stat. 541.

¹⁵ Pub. L. No. 107-251, 116 Stat. 1621.

governments to create comprehensive systems to provide health care services to those without insurance and those with chronic conditions that are underinsured. Funding for this program was terminated in the current fiscal year, and existing programs will conclude their funded activities this year.

108th Congress – 2003 – 2004

The **Medicare Prescription Drug, Improvement, and Modernization Act of 2003** (“MMA”) is the most significant health-related legislative enactment in the 2001 – 2005 period.¹⁶ Aside from the sweeping changes in Medicare it imposed, the political activity leading up to the passage of the act was both significant and unusual. The proposed legislation was generally unpopular and was widely opposed. The MMA was enacted nonetheless by very narrow margins in the House of Representatives and the Senate. The passage of the MMA was surrounded by accusations of political maneuvering and of withholding of key information. Some legislators did not have access to the full text of this complex legislation less than thirty days before its passages. Additionally, claims that the Bush administration withheld actual estimates of the cost of the program from Congress before the vote were confirmed in an investigation in July 2004. The investigation found that the top administrator of Medicare threatened to terminate the program’s actuary if he revealed the true, and higher cost, of the drug benefit to Congress.

The MMA enacted a sweeping change to the long-standing and popular Medicare program which provides health insurance to the elderly. The program, before the MMA, had three parts: Part A, Part B, and Medicare+Choice. Part A is not voluntary and is funded through payroll taxes. Part A covers hospital and other institution costs. Part B is voluntary and is funded through a premium paid by the beneficiary. Part B covers doctor services, outpatient care, and other services not covered by Part A. Medicare+Choice was an early attempt to introduce private markets into Medicare. Medicare+Choice allowed Medicare participants to enroll in a managed care organization for the provision of their benefits.

The MMA created Medicare Part D (a prescription drug benefit), altered Medicare+Choice renaming it Medicare Advantage, and instituted numerous and significant changes to Medicare. The MMA injected private markets into Medicare significantly altering the program. These changes, in addition to the provision of prescription drugs, reflect a long ideologically driven goal to transform Medicare from a government benefit program to a program that supports private market financing of

¹⁶ Pub. L. No. 108-173, 117 Stat. 2066 (codified in sections of 42 USC).

health care. The MMA programs and changes shift more of the Medicare burden on to private plans and on to beneficiaries themselves. Additionally, the MMA has introduced market concepts into MMA that are poised to undermine its long-term financial stability and that provide opportunities for the eventual elimination of the program.

The prescription drug benefit (Part D) is available to anyone in Medicare Part A or Part B. The coverage is available if the beneficiary enrolls in a prescription drug plan (PDP). Beneficiaries will pay a penalty if they do not enroll in a PDP by May 2006. Once enrolled in a plan, the beneficiary cannot change plans except during a narrow period at the end of each calendar year. This penalty can be avoided if the eligible person has “creditable coverage” that they are already enrolled in. This coverage is coverage that is the “actuarial equivalent” to coverage that would be provided by a PDP. Eligible individuals can also join a Medicare Advantage plan that includes a drug benefit.

Participants will be required to pay a monthly premium of about \$37. In addition, they will be required to pay the first \$250 of their drug costs. Once the participant has paid the first \$250 of drug costs, Medicare will pay 75% and the participant 25% until costs reach the limit of \$2500. At that point, the participant is responsible for all costs. Once the participant reaches the “true-out-of-pocket” costs or “TROOP” of \$3600, Medicare will then step-in to cover almost all drug costs. This gap in Medicare coverage where the participant must pay directly for his/her prescriptions is known as the “doughnut hole”. This significant cost must be borne by the participant and cannot be covered by additional insurance. The MMA does provide for a low-income assistance to Medicare participants that meet certain income requirements.

Prescription drug plans (PDP) are provided by private insurance companies. To be eligible as PDP, the insurer must meet certain guidelines. These guidelines require that a certain number of pharmacies be available near the participants, that the insurer meet certain reporting requirements, and that the PDP formulary meet certain minimum guidelines, e.g. certain classes of drugs must be covered, there must be at least two drugs in each therapeutic class, etc. The rules around the PDP formularies have been particularly controversial. The MMA requires six classes of drugs that must be covered: anti-depressants, anti-psychotics, anticonvulsants, anti-cancer, immunosuppressant, and HIV/AIDS drugs. These classes represent costly and chronic conditions that can be expensive and the MMA did not want private insurers trying to offer plans only for the healthiest participants. For new users of any of these six classes of drugs, the PDP is free to impose utilization management, e.g. prior-approval, substitution, etc. The formulary is also controversial because it can be changed at any time during the year. The PDP must provide notice to the patient that the formulary is

changing and that the drug will no longer be covered. However, *participants cannot change plans because their drug is no longer covered. Participants are locked into a plan for a year.* If a drug becomes unavailable under the plan, the participant must switch drugs or petition for an exemption. The complexity of the system and the difficulty in understanding the PDPs has contributed to Part D's unpopularity and the political resistance to it.

Insurers that provided PDP must be meet certain requirements to participate. Insurers make bids to Medicare on PDPs that they will offer. Medicare then accepts these bids. The MMA *expressly forbids* the federal government from negotiating drug price reductions with pharmaceutical companies. Medicare has traditionally administered prices with providers in its other programs. The prohibition on negotiating drug discounts prohibits Medicare from leveraging its huge participant pool to keep costs down. This prohibition is viewed as ideologically driven as government negotiated drug discounts has been effectively employed by other countries and is effectively employed by the United States Veterans Administration in its plan.

A participant who does not enroll in a PDP may be covered by an employer-sponsored retiree prescription drug plan. If these plans are considered "creditable coverage" they participant will not be penalized if they ever move over to a private PDP. The MMA provided for a tax-free subsidy paid to employers with retiree prescription drug plans. This provision was included to ensure that employers would not drop existing plans upon passage of the MMA. While the subsidy will cover a percentage of costs up to a certain amount per enrollee. Eventually, if prescription drug costs continue to rise as expected, it is unlikely that employers will continue to offer these plans, and, if they do, increased costs will likely be passed to the enrollee in the form of higher co-payments or deductibles.

The MMA created Medicare Advantage to replace Medicare+Choice. Medicare Advantage was created to shore up declining participation in Medicare+Choice. Managed care organizations had been on the decline through the 1990s and their potential to cut costs was never truly realized as costs continued to rise. The managed care plans were and are also extremely unpopular. Medicare Advantage seeks to move more participants into these plans by making them more competitive. The MMA increases Medicare reimbursement rates for these plans and pays more for participants enrolled. The Medicare Advantage plan is viewed primarily as an ideologically driven attempt to shore up managed care organizations that were in decline as the twentieth century closed.

The MMA also imposed means-testing on Medicare Part B. Before the MMA, wealth was not used as a determinant of premium level. Each person paid the same premium amount. With the MMA, means-testing was introduced where wealthier participants will pay higher premiums. Means-testing can be implemented in mandatory programs with little effect. However, the implementation of means-testing on voluntary social insurance programs, like Medicare Part B, will prove disastrous for the long-term stability of the program. If premiums are high for wealthy participants, it may be in their best economic interest to opt-out of Plan B. If that happens, the diversified risk pool of Medicare will be disrupted. With wealthier participants opting out, it is poised to erode popular support for the Medicare program and drive costs higher for those remaining in Part B. The long-term implication will be continually increasing premiums and the erosion of the financial stability of the program.

The MMA also incorporated budget control provisions that set certain funding caps on the program as a percentage of general revenues. As such, these provisions have incorporated into the program the necessary means to effectively terminate or curtail the program in the future.

In 2003, the **United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act** (“Leadership Act”) was enacted.¹⁷ The Leadership Act authorized the President’s Emergency Plan for AIDS Relief (“PEPFAR”) and represents a significant increase in United States commitment to a global strategy for the prevention and treatment of HIV/AIDS and other infectious diseases. The Leadership Act also created the Office of the U.S. Global AIDS Coordinator (OGAC) at the U.S. State Department. The United States had been committed to provide \$5 billion dollars to bilateral HIV/AIDS initiatives. The Leadership Act has increased the U.S. commitment to global HIV/AIDS programs by 200%. PEPFAR is a five year initiative. Its primary goal in prevention is to avert seven million HIV infections by 2010. Twenty percent of the funds allocated in the program are tasked to prevention, and of those funds, at least 33% have been further restricted to “abstinence-until-marriage” programs. The majority of funds in the program are allocated for treatment.

The HIV/AIDS prevention programs focusing on sexual transmission of HIV employ the ABC model of prevention first used in Uganda. This model uses three prevention messages: Abstain, Be faithful, use Condoms. All three, used in conjunction as part of a comprehensive HIV prevention program, were credited with the significant reduction of HIV prevalence in Uganda. The key to the model was its flexibility and adaptability to multiple targets. Under the Leadership Act, 33% of the funding for

¹⁷ Pub. L. No. 108-25, 117 Stat. 711 (codified in scattered sections of 22 USC).

prevention *must* be allocated to “abstinence-until-marriage” programs. This requirement has caused difficulty in the targeted countries. Specifically, lack of clear guidance regarding the requirement and target country difficulty in meeting the requirements threatens to undermine key components of the PEPFAR prevention program undermining the integrative approach of the ABC model and the ability of local public health workers to address local social and cultural norms. PEPFAR also places additional restrictions on the availability of condoms. The “abstinence-until-marriage” requirements reflect US cultural sensibilities more than the local cultural sensibilities and requirements.

The majority of funds under the Leadership Act are allocated for the treatment of HIV/AIDS. These funds provide antiretroviral (ARV) treatment in the targeted countries. As of September 2005, the program has provided ARV therapy for over 400,000 individuals in targeted areas. While the program has provided ARV to populations with limited access previously, it is unclear how the program will unfold over the long-term and what the potential long-term implications of ARV therapy are in countries without infrastructure to sustain treatment. ARV therapy programs are of two types. One type seeks to increase enrollment in ARV therapy programs. Another type looks not only to enrollment but also to building systems to ensure that people adhere to the regimen. The sustainability of the project has been brought into question and there are public health concerns about the use of ARV therapy without a commitment to build an infrastructure to support adherence.

The **Partial-Birth Abortion Ban Act of 2003**¹⁸ made it a criminal offense for physician to perform a particular medical procedure in providing an abortion. The government has been enjoined from enforcing this act, and the act is under judicial review as being unconstitutional.

The **Project Bioshield Act of 2004**¹⁹ authorizes over \$5 billion dollars to purchase and to stockpile drugs and vaccines for anthrax, smallpox and other agents that might be used in bioterrorism. The act also increases the Strategic National Stockpile of vaccines and drugs for smallpox, chemical agents, and radiation exposure. The act also increases research into countermeasures and treatments in response to biological, radiological, and nuclear attacks. Finally, the act alters the procedures at the Food and Drug Administration to allow the rapid release and use of experimental and unapproved drugs during public health emergencies.

¹⁸ Pub. L. No. 108-105, 117 Stat. 1201.

¹⁹ Pub. L. No. 108-276, 118 Stat. 835.

The **Child Nutrition and WIC Reauthorization Act of 2004**²⁰ provided amendments to the National School Lunch Program (“NSLP”). The NSLP provides nutritional free or reduced-cost meals to students in public schools across the United States. The amendments include alterations to the nutritional requirements of the meals and the creation of “Wellness Policies.” These Wellness Policies must be in place at the beginning of the 2006 – 2007 school year and are to guide schools in improving the nutritional quality of foods offered on campus. This policy is a weak attempt by the federal government to begin to address the serious epidemic of obesity in the United States.

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The **Patient Navigator Outreach and Chronic Disease Prevention Act of 2005**²¹ creates a demonstration program to provide patient navigators to populations at risk for cancer and chronic disease. These programs will help navigate patients through potential barriers to care, alerting them to clinical trials, and assisting them in obtaining public or private health insurance. The navigators will also provide outreach to vulnerable populations to diminish health disparities.

The **Stem Cell Therapeutic and Research Act of 2005**²² expands the clinical use of stem cells derived from umbilical cord blood. The act also reauthorizes the National Bone Marrow Registry. The **Stem Cell Research Enhancement Act of 2005** is currently pending in the Senate and would authorize research on embryonic stem cells. While the federal government has not moved forward in this area, several states have passed legislation permitting stem cell research.

The **Department of Defense, Emergency Supplemental Appropriations to Address Hurricanes in the Gulf of Mexico, and Pandemic Influenza Act**²³ is a general appropriations act funding a variety of programs related to the military. The act also appropriates funds to the Secretary of Health and Human Services for planning and preparation for pandemic influenza.

²⁰ Pub. L. No. 108-265, 118 Stat. 729.

²¹ Pub. L. No. 109-18, 119 Stat. 340.

²² Pub. L. No. 109-129, 119 Stat. 2550.

²³ Pub. L. No. 109-148, 119 Stat. 2680.

The **Deficit Reduction Act of 2005**²⁴ made changes to the Medicare, Medicaid and SCHIP programs. Most noted, the legislation made proof of U.S. citizenship a requirement for access to Medicaid.

²⁴ Pub. L. No. 109-171, 120 Stat. 4.