Third Edition

Health Care Policy and Politics A to Z

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Preface

Insanity has been defined as doing the same thing over and over and expecting a different result. By that logic, everyone who has been working to overhaul the U.S. health care system during the past four decades is insane—including me. The publication of this third edition of *Health Care Policy and Politics A to Z* is timed to coincide with another predicted effort—the first since President Bill Clinton's failed attempt in the 1990s—to enact major changes in how health care is financed and delivered in the United States.

Whether or not that debate produces results—or even materializes—much has happened on the health policy front since the last edition to warrant an update of this volume. A new and controversial prescription drug benefit for Medicare was passed and implemented, Massachusetts mandated health insurance for all its citizens, and Tennessee eliminated coverage for hundreds of thousands of its residents. Many health issues remain stubbornly unresolved or have simply grown larger. As of this writing, forty-seven million Americans lacked health insurance, the nation's annual tab for health spending topped $2 trillion, and arguments over such sensitive social issues as abortion and euthanasia appeared no more amenable to compromise.

Yet I remain as fascinated as ever covering health policy, my professional focus since 1986. Health policy never gets boring, in part because while the big problems persist, many of the smaller issues keep changing. Who could have predicted in 1986 that little more than a decade later Congress would be debating such issues as a ban on the cloning of humans or discrimination based on genetic make-up? Or that fifteen years later national discussions would focus on the relative risks and benefits of the smallpox vaccine?

Unlike many of the issues that receive attention in Washington, D.C., health care affects all Americans, and it affects them in life-or-death ways. But health policy, like health care in general, is dauntingly complicated, rife with jargon and long-running conflicts that have continued for years or even decades. People who want to learn more about Medicare reform, to name just one example, are often put off by conversations that seem to take place in another language or by experts who presume that everyone knows as much as they do about the program's history and the controversies that have surrounded it. Meanwhile, politicians are frequently able to take advantage of the public's lack of knowledge about important programs such as Medicare to engage in unchecked demagoguery.

This volume provides background on many health issues on the national agenda. It presumes at least a high school civics class understanding of how the federal government works but no expertise in health care. Its intended audience is advanced high school and college students, professional government-watchers new to health policy, and people who want to be better able to follow the news.

Although many books and glossaries define health care terms, this one focuses comprehensively on health policy issues in all their dimensions, including their histories. This kind of information is more difficult to come by than definitions—and more valuable because it can enable more citizens to join the national conversation about the direction of health care policy.

This work is also "Congress-centric" because, for better or worse, the U.S. Congress is where much of the nation's health policy is made. While those who rail against "big government" campaign to prevent the federal

government from becoming more involved in the nation's health care system, the federal government continues to provide, by nearly any measure, the single largest share of funding for health care. In 2006 the federal government paid just under $450 billion of the nation's $2.1 trillion health care bill, a little less than a quarter of the total. Congress, as the holder of the federal purse strings, naturally wants to determine the policies that accompany those dollars.

Even though health care, according to pollsters, is usually among voters' top concerns, it has in the past commanded surprisingly little respect among policy makers, compared with such issues as taxes, trade, and national security. That is likely to change in the near future. The inexorable aging of the massive baby boom generation will bring health care issues front and center, because older people consume more health care resources than younger people. The financial future of Medicare is just one item on a long list of issues related to the aging "boomers" with which Congress will have to grapple. New technology is also driving current and future health policy. The ability to do new and marvelous things often prompts significant ethical questions—and creates the need to set new spending priorities. Finally, rapid changes in the private health care marketplace are not going unnoticed by lawmakers, if only because dislocations are prompting complaints from constituents and driving the number of uninsured Americans ever higher.

In the decade since the first edition of this book was published, scientists have isolated stem cells from human embryos and elsewhere and finished mapping the human genome, heralding the possibility of entirely new lines of treatment for dozens of ailments that have confounded medical professionals for generations. At the same time, fears about bioterrorism have led to new efforts to prepare for the possibility of outbreaks of ailments once thought conquered, such as smallpox. Further, the emergence of new diseases such as severe acute respiratory syndrome, or SARS, have served as a reminder that freedom from disease is an elusive goal.

Policy debates have also advanced. Lawmakers have tried to address what some have called an epidemic of medical mistakes; health care inflation has returned in force, leading to new efforts to control costs; and the number of Americans without any health insurance has remained stubbornly high. Efforts to remedy this short fall are hampered by the ideological divide between those who would have the government exercise most of the control in any program and those who favor a private sector solution.

Health policy is an ever-changing issue; as the content of health policy debate continues to evolve, so will this book. Any mistakes or omissions are mine alone, and suggestions for future editions will be gratefully accepted.

A Note on Sources

The majority of the information in this book comes directly from my own reporting: seven years covering health and welfare for the *Congressional Quarterly Weekly Report,* ten years for National Journal's *Congress-Daily,* and ten years for National Public Radio.

In compiling this volume I made liberal use of my own previously published material, particularly that from CQ *Weekly Reports* and *Almanacs.* Other information was drawn from reports prepared or funded by the Commonwealth Fund, the Henry J. Kaiser Family Foundation, the Robert Wood Johnson Foundation, the Employee Benefit Research Institute, the Alliance for Health Reform, and the Urban Institute.

I am also indebted to the public affairs staffs of several organizations, particularly the Department of Health and Human Services, the Centers for Medicare and Medicaid Services, the American Medical Association, and America's Health Insurance Plans, which provided more background papers and materials than I can enumerate here.

Acknowledgments

Learning an area as complex and diverse as health policy requires many teachers, and I am privileged to have been taught by some of the best. I especially want to thank the following people, many of them current or former Capitol Hill staff aides, for their patient explanations and unfailing availability on deadline, often provided at the expense of sleep following days or even weeks of around-the-clock drafting or negotiation sessions.

Medicare experts include the following former Hill staff: David Abernethy, Brian Biles, Mike Hash, Chip Kahn, Tricia Neuman, Karen Pollitz, Bill Vaughan, and Marina Weiss. Off the Hill, Diane Archer, Marty Corry, Geri Dallek, Karen Davis, Judy Feder, Ed Howard, Marilyn Moon, Ron Pollack, John Rother, Patricia Smith, and Gail Wilensky provided invaluable background.

I learned Medicaid at the knee of three of the most formidable experts in the field: Sara Rosenbaum, Diane Rowland, and Andy Schneider. Also adding to my understanding were Howard Cohen and Karen Nelson of the House Energy and Commerce Committee.

David Schulke and Chris Jennings, formerly of the Senate Aging Committee, taught me the intricacies of prescription drug prices and other issues concerning the Food and Drug Administration. Tobacco experts Matt Myers and Cliff Douglas were invaluable in helping me understand that complicated issue. Chai Feldblum and Pat Wright helped me through the debates over the Americans with Disabilities Act. Of the many people who guided me through the abortion debates on Capitol Hill, Rachel Gorlin, Jo Blum, Susan Cohen, and Douglas Johnson stand out as those I could not have done without.

Although I am grateful to all of my sources, two of them—Tim Westmoreland, formerly of the House Energy and Commerce Committee and now at Georgetown University Law Center, and David Nexon, formerly of the Senate Health, Education, Labor, and Pensions Committee—most influenced my thinking and understanding on a wide range of health issues, from Acquired Immune Deficiency Syndrome (AIDS) to insurance coverage to public health programs.

At CQ Press, I want to thank Dave Tarr for suggesting the idea for the book and for sponsoring the development of the first edition and, for this edition, Marc Segers, Andrew Boney, and Emily Bakely. Finally, I want to thank my editors at National Public Radio: Anne Gudenkauf and Joe Neel, who were so cooperative in putting up with me while I was working on this project in my "spare" time.

A

AARP

AARP, a nonprofit, nonpartisan association, concentrates its legislative efforts on health care and pension issues, particularly MEDICARE and Social Security. With more than thirty-eight million members, it is among the most influential special interest groups in the nation's capital. The group had formally changed its name in 1998 from the American Association of Retired Persons in recognition of the fact that half of its members are still working.

AARP has been highly successful in using its clout and knowledge to persuade members of Congress. Its leaders in Washington, D.C., experienced a stunning reversal in 1988–1989, however. They had helped develop and strongly backed the MEDICARE CATASTROPHIC COVERAGE ACT, which cleared Congress with bipartisan support. Before the measure could take effect, though, Congress repealed it in face of strong protests from local AARP chapters and others.

Despite the organization's avowed nonpartisan status, Republican senator Alan K. Simpson of Wyoming perceived it as having a Democratic tilt. After the Republicans assumed the majority in Congress following the 1994 elections, he launched a series of hearings looking into AARP's tax status. No legislation or evidence of wrongdoing emerged from those hearings, however. To the consternation of its Democratic allies in Congress, the group endorsed the mostly Republican-backed MEDICARE MODERNIZATION ACT, adding a prescription drug benefit to the Medicare program, which became law in 2003. In 2006, however, AARP staunchly supported legislation, criticized by Republicans, that would

Representatives of AARP and other consumer groups rallied on Capitol Hill on July 16, 2002, to urge Congress to add a drug benefit to Medicare.
Source: CQ Photo/Scott J. Ferrell

allow Americans to import prescription drugs from Canada and other industrialized countries. (See REIMPORTATION, PRESCRIPTION DRUG.)

Abortion

Abortion is perhaps the most polarizing social issue in American politics, not just in the arena of health policy making. After four decades of strife, the United States appears no closer to a compromise position than it was in the late 1960s, when the issue took center stage on the national agenda.

Politically, although support for abortion is generally associated with the Democratic Party and opposition with the Republican, abortion is not as strictly partisan an issue as many think. Although the Democratic Party platform since 1976 has supported leaving intact the U.S. Supreme Court landmark ruling in *ROE V. WADE,* as many as 20 percent of Democrats in Congress vote against abortion in many, if not most, circumstances. It was a prominent antiabortion Democrat, Pennsylvania governor Robert P. Casey, who signed into law the statute many thought the Court would use to overturn *Roe* in 1992. Similarly, although the GOP platform has embraced a "right to life for the unborn," also since 1976, a significant proportion of Republicans in the U.S. Congress (around 10 percent) support abortion rights some or most of the time. As Congress has become more polarized in recent years, however, the proportion of antiabortion Democrats and pro-choice Republicans has been dropping.

Making generalizations about abortion politics is difficult in part because lawmakers differ on various abortion-related issues. Many lawmakers who generally support a woman's right to choose abortion do not support the use of public funds to pay for it. Similarly, many legislators who oppose abortion in most instances support it in cases of rape or incest.

Although purists on both sides berate policy makers who waver on the issue, those very policy makers reflect the significant ambivalence most Americans have about abortion—an ambivalence that has persisted over the decades the abortion wars have been fought in the legislatures, the courts, and the streets in front of clinics. In general, Americans want abortion to be available but discouraged. They want it used only in rare or tragic cases (such as rape, incest, or severe birth defects), but they do not want to see abortion recriminalized. In a 2003 *Time*/CNN/Harris Interactive poll coinciding with the thirtieth anniversary of *Roe,* 46 percent of those surveyed said they thought abortion is an act of murder, but 66 percent said it should be legal during the first three months of pregnancy. At the same time, while only 25 percent of those responding to a Gallup/CNN/*USA Today* poll said they thought abortion should be permitted in the second three months of pregnancy, 53 percent said the Court's *Roe v. Wade* decision—which banned states from outlawing abortion during those second three months—was "a good thing for the country." Despite protests launched by abortion rights advocates over the appointment by President George W. Bush of two Supreme Court justices who changed the balance of the Court on the abortion issue (John G. Roberts Jr. and Samuel A. Alito Jr.) and a key abortion ruling in 2007 (*Gonzales v. Carhart*), polls showed the public's views on the issue had remained largely the same.

Although the public debate does not reflect it, those who think abortion should be legal all the time or illegal in every circumstance make up a small minority of the population. The only way to prevail in an abortion debate is to capture enough of the "muddled middle" to make a majority. That explains why Republicans in the early 1980s failed in their efforts to pass a constitutional amendment to ban abortion and why Democrats in the early 1990s could not muster the votes for their FREEDOM OF CHOICE ACT, which not only would have codified the tenets of *Roe* but also would have struck down many restrictions the post–*Roe* Court found acceptable.

Instead of seeking the middle ground, each side has concentrated on the issues on which it thinks it can muster a majority. For abortion rights forces, those include rape and incest, stem cell research using human embryos leftover from in vitro fertilization attempts, and early forms of abortion, such as the abortion pill RU486. For abortion opponents, the issues on which the public is most on their side include involving parents in the abortion decision of underage women and estab-

lishing guidelines for abortion procedures later in pregnancy. Pushing a ban on what they call PARTIAL-BIRTH ABORTION helped antiabortion forces in Congress persuade large majorities of legislators and the public to support an antiabortion position from 1995 on and, in 2003, to get the first-ever federal ban on a specific abortion procedure signed into law. The Supreme Court upheld the ban in 2007 in *Gonzales v. Carhart.*

Statistics

The term *abortion* applies to any premature expulsion of a fetus from a woman's womb. *Spontaneous abortion* is the medical term for a miscarriage, which occurs naturally for a variety of reasons related to the health of the woman or the fetus. The term *abortion* usually refers to what is medically known as *induced abortion,* sometimes called *elective abortion,* one brought about deliberately by a medical procedure.

The incidence of abortion has been declining. In 2005, according to the Alan Guttmacher Institute (AGI), which has been collecting abortion statistics since 1973, the abortion rate (number of abortions per one thousand women), the abortion ratio (percentage of pregnancies that end up in abortion), and the number of abortions performed were at their lowest since the mid-1970s.

An estimated 1.2 million abortions were performed in 2005, according to AGI. At the same time, the abortion rate dropped to 19.4 per one thousand women, the lowest since 1974. The ratio of pregnancies ending in abortion was 22.4 percent in 2005, down from 24.5 percent in 2000. Still, more than one in five of all pregnancies in the United States in 2005 ended in abortion.

Analysts say abortions are declining for several reasons. One is changing demographics. The huge baby boom generation is getting older, and older women generally have lower pregnancy rates. Also, teenage pregnancy rates are falling, partly because fewer teenagers are having intercourse than before and partly because of better use of contraception.

Another reason some say that the rate of abortions is going down is the decrease in providers. The 2005 AGI survey found a much smaller reduction in abortion providers than in earlier surveys, only 2 percent from five years earlier. According to the study, the decline was not larger in part because of the addition of providers offering medical, not surgical, abortions. RU486, for example, was approved by the FOOD AND DRUG ADMINISTRATION (FDA) in 2000, just as the previous survey was being done. Were it not for those providers of medical abortions, the number of providers overall would have declined by 8 percent, the study said.

Reported Abortions, Abortion Rate, and Abortion Ratio, United States, 1973–2005

Year	*Abortions (in thousands)*	*Abortion rate*	*Abortion ratio*
1973	744.6	16.3	19.3
1974	898.6	19.3	22.0
1975	1,034.2	21.7	24.9
1976	1,179.3	24.2	26.5
1977	1,316.7	26.4	28.6
1978	1,409.6	27.7	29.2
1979	1,497.7	28.8	29.6
1980	1,553.9	29.3	30.0
1981	1,577.3	29.3	30.1
1982	1,573.9	28.8	30.0
1983	(1,575.0)	(28.5)	(30.4)
1984	1,577.2	28.1	29.7
1985	1,588.6	28.0	29.7
1986	(1,574.0)	(27.4)	(29.4)
1987	1,559.1	26.9	28.8
1988	1,590.8	27.3	28.6
1989	(1566.9)	(26.8)	(27.5)
1990	(1,608.6)	(27.4)	(28.0)
1991	1,556.5	26.3	27.4
1992	1,528.9	25.7	27.5
1993	(1,495.0)	(25.0)	(27.4)
1994	(1,423.0)	(23.7)	(26.6)
1995	1,359.4	22.5	25.9
1996	1,360.2	22.4	25.9
1997	(1,335.0)	(21.9)	(25.5)
1998	(1,319.0)	(21.5)	(25.1)
1999	1,314.8	21.4	24.6
2000	1,313.0	21.3	24.5
2001	(1,291.0)	(20.9)	(24.4)
2002	(1,269.0)	(20.5)	(23.8)
2003	(1,250.0)	(20.2)	(23.3)
2004	1,222.1	19.7	22.8
2005	1,206.2	19.4	22.4

Source: Reproduced by permission from Rachel K. Jones, et al., "Abortion in the United States: Incidence and Access to Services, 2005," *Perspectives on Sexual and Reproductive Health* 40:1, Blackwell Publishing.

Note: The abortion rate is the number of abortions per one thousand women ages fifteen to forty-four; the abortion ratio is the number of abortions per one hundred pregnancies ending in abortions or live births. Figures in parentheses are estimates based on interpolations of abortion numbers.

Even with the wider availability of the abortion pill, however, access to abortion services remained spotty. In 2005 abortions were unavailable in 87 percent of all U.S. counties, home to 35 percent of women. And the broader use of medical abortion did not change that much. Its introduction tended to be in places where surgical abortion was also available, rather than in areas where no form of abortion was accessible, as many abortion rights advocates had hoped.

Another reason cited for the long decline in abortion is that states have imposed more restrictions on the procedure in the wake of Supreme Court decisions allowing them. A 2006 survey of state laws by NARAL PRO-CHOICE AMERICA found that women had less access to abortion that year than they had had in 1973, the year *Roe* was decided. Fifteen states still have on their books outright abortion bans or other laws that are unconstitutional or unenforceable under *Roe* and its successor cases. Altogether, states have passed hundreds of laws to restrict abortion access, including prohibitions of state funding for abortion as well as bans on abortion counseling and referrals. States have also imposed waiting periods, enacted PARENTAL NOTIFICATION or PARENTAL CONSENT laws for minors, mandated state-sponsored lectures urging against abortion, required "abstinence-only" education programs for teenagers, and passed laws to punish pregnant women who use alcohol or drugs.

Even with the decline, though, abortion remains the single most performed surgical procedure in the United States—and one of the safest. One death occurs for every 150,000 legal abortions, about one-tenth the risk of bearing a child. Early abortions are safer still, with one death reported for every 530,000 abortions at eight or fewer weeks of gestation. Abortions performed after twenty-one weeks are the most dangerous, with one death for every 6,000 performed. Serious complications, including hemorrhage, pelvic infection, or the need for major surgery, occur in less than 1 percent of abortions.

For all the attention focused on LATE-TERM ABORTION, the vast majority of abortions are performed early in pregnancy. In 2004, according to the CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC), 86.7 percent were performed in the first twelve weeks of pregnancy and 96.7 percent before twenty-one weeks' gestation. Only 1.3 percent took place after twenty-one weeks' gestation. (The remaining 1.9 percent of abortions occurred at an unknown time in pregnancy.)

A survey by AGI found that so-called partial-birth abortions, known medically as "intact dilation and extraction," or D&X, accounted for only about twenty-two hundred, or less than two-tenths of 1 percent, of the 1.31 million abortions in 2000. Although other estimates have put the number as high as several thousand, these procedures still represent a tiny fraction of abortions performed and less then 5 percent of abortions performed after the first thirteen weeks of pregnancy.

Most abortions are performed using a technique called *vacuum aspiration* or *suction curettage.* The procedure, performed on an outpatient basis with a local anesthetic, involves dilating a woman's cervix to about the width of a pencil, inserting a tube called a cannula, which is attached to a suction machine, then suctioning out the contents of the uterus. The person performing the abortion (usually a physician, but in some cases a physician assistant) then uses a spoon-shaped curette to scrape the uterine walls to ensure all the tissue has been removed. (See PHYSICIAN ASSISTANTS.) The entire procedure takes about ten minutes, and the woman can usually go home after resting for an hour or two and being checked for excessive bleeding. Some bleeding and cramping is normal with first-trimester abortions.

Abortions after thirteen weeks are usually performed using a technique called *dilation and evacuation* (D&E). A more advanced version of the vacuum aspiration method, D&E requires that the cervix be dilated to a much greater extent, a process that can take place over a few minutes, several hours, or overnight. The physician uses a suction machine, as well as forceps to dismember and remove fetal parts too large to pass through the machine's tube. That procedure is followed by curettage to ensure no portion of the fetus remains in the uterus. A D&E procedure takes from ten to thirty minutes to complete.

About 3 percent of abortions are performed by inducing labor. Labor can be induced using a saline solution, prostaglandin, or other substances. The injected substance causes contractions, and later the woman

Protesters gather in front of the Supreme Court on April 18, 2007, the day the court handed down its decision in Gonzales v. Carhart. *In its 5-4 ruling, the court upheld the federal ban on a practice commonly referred to as partial-birth abortion. Source: CQ Photo/Scott J. Ferrell*

vaginally delivers the fetus. Induction is considered one of the riskier forms of abortion.

A Brief History of the Abortion Debate

Until the mid-nineteenth century, abortion was both legal and common in the United States. Most early laws restricting abortion were instigated by the medical profession and had at least as much to do with establishing medicine as a profession (doctors did not want those who were not physicians performing abortions and urged the criminalization of abortion to get rid of economic competition) as with protecting women's health or the rights of unborn children. By 1900 abortion was illegal virtually across the country.

In the late 1960s, as the women's movement was gathering momentum, some states relaxed their abortion laws. A major turning point was the Supreme Court's 1965 decision *Griswold v. Connecticut,* which overturned a state law prohibiting the use of contraceptives by married couples. In 1972, in *Eisenstadt v. Baird,* the Court extended the right to contraception to unmarried individuals, citing a right to privacy, "to be free from unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child." The privacy rights expressed in *Griswold* and *Eisenstadt* would later be interpreted to encompass abortion.

Between 1967 and 1973, seventeen states rewrote their abortion laws; four—Alaska, Hawaii, New York, and Washington—repealed their bans entirely. In the two and a half years immediately preceding *Roe,* some 350,000 women traveled to New York from elsewhere in the country to obtain abortions.

6 Abortion

Most historians date the current abortion battles to January 22, 1973, the day the Court handed down *Roe v. Wade.* That 7-2 decision and its companion case, *Doe v. Bolton,* struck down state laws banning abortion in Texas (in *Roe*) and in Georgia (in *Doe*) and, by establishing precedents, similar laws across the country. *Roe* declared that the right of privacy expressed in *Griswold* and other cases "is broad enough to encompass a woman's decision whether or not to terminate her pregnancy." *Roe* divided a pregnancy into three trimesters and declared that during the first thirteen weeks of pregnancy, the decision on whether to have the procedure should be left up to "the attending physician, in consultation with his patient." During the second trimester, states may regulate abortion to protect the woman's health (by requiring, for example, that procedures be performed in hospitals or only by licensed physicians). Only after the fetus is *viable* (able to live outside the womb, with or without artificial life support) may the state "in promoting its interest in the potentiality of human life . . . regulate, and even proscribe abortion, except where it is necessary, in appropriate medical judgment, for the preservation of the life or health of the mother."

Roe not only legalized abortion nationwide, but it also had the paradoxical effect of energizing a nascent antiabortion movement. On the policy level, the remainder of the 1970s was largely devoted to deciding whether to use public funds to finance abortions for poor women through the state–federal MEDICAID program.

In 1976 the Supreme Court in *Planned Parenthood of Central Missouri v. Danforth* struck down requirements for parents and spouses to consent to abortions, on the grounds that the laws "delegated to third parties an absolute veto power which the state does not itself possess." The decision also struck down a ban on saline amniocentesis, then the most common second-trimester procedure, on the grounds that the choice of method must be left to the physician.

Meanwhile, Congress spent the next four years tussling over what would come to be called the HYDE AMENDMENT, in honor of its leading proponent (but not, ironically, its author), Rep. Henry J. Hyde, R-Ill. (The author of the language that eventually became law was Rep. Silvio O. Conte, R-Mass., longtime ranking Republican on the appropriations subcommittee that funded the then Department of Health, Education, and Welfare.) The Hyde amendment, in its various forms, restricted Medicaid funding of abortion to those procedures needed to protect the life of the pregnant woman and to those required in other special circumstances. This time the Court would go along with Congress. In 1977, in *Maher v. Roe,* the Court upheld a Connecticut law restricting Medicaid abortion funding to abortions that are "medically necessary." In 1980, in *Harris v. McRae,* the Court specifically upheld the Hyde amendment, noting that the government had no obligation to fund abortions for poor individuals.

With Ronald Reagan, who ran on a strong "right-to-life" platform, in the White House and Republicans in control of the Senate for the first time in a generation, the GOP in 1981 moved to keep its promise to overturn *Roe.* But, in 1982, legislation that would have banned abortion by statute fell victim to a Senate filibuster. Then, on June 28, 1983, the Senate rejected a proposed constitutional amendment that said merely that "a right to abortion is not secured by this Constitution." The 49-50 vote was seventeen short of the two-thirds needed to send the amendment to the states for ratification. Sen. Jesse Helms, R-N.C., voted "present" on the amendment because, he said, it did not go far enough to ban abortion.

Meanwhile, the Supreme Court continued to strike down proposed state restrictions on abortion. In *Akron v. Akron Center for Reproductive Health* the Court in 1983 invalidated a city ordinance requiring that all abortions after the first trimester be performed in a hospital; that parental consent be required for abortions on girls under age fifteen; that physicians deliver a state-mandated speech including details of fetal anatomy, a list of the risks and consequences of the procedure, and a statement that "the unborn child is a human life from the moment of conception"; that women wait at least twenty-four hours between providing INFORMED CONSENT for an abortion and having the procedure done; and that fetal remains be given some sort of "humane" disposal.

However, in a companion case decided the same day, *Planned Parenthood of Kansas City, Mo. v. Ashcroft,* the Court upheld certain requirements of a Missouri law, including those mandating that a pathology report be prepared for every abortion (deemed protective of the woman's health), that minors have parental consent or judicial permission for their abortions (because the law met the requirements set out in *Bellotti v. Baird* in 1979; see PARENTAL INVOLVEMENT LAWS), and that two doctors be present at abortions after fetal viability. The Court struck down other elements of Missouri's law, including a requirement that all second-trimester abortions be performed in hospitals.

However, in a third case decided that day, *Simopoulos v. Virginia,* the Court upheld a Virginia law requiring all post–first-trimester abortions to be performed in hospitals because the law provided for the designation of free-standing ambulatory surgical facilities as "hospitals."

In 1986, in *Thornburgh v. American College of Obstetricians and Gynecologists, Pennsylvania Section,* the Court struck down provisions of Pennsylvania's 1982 Abortion Control Act requiring a state-sponsored speech designed to deter women from having abortions, obligating physicians to use the abortion method most likely to result in fetal survival unless it would cause "significantly" greater risk to a woman's life or health, mandating detailed reporting to the state on each abortion, and requiring a second physician to be present at post-viability abortions. The Court said the speech requirement was unconstitutional because the state could not "intimidate women into continuing their pregnancies." The method requirement increased the risk to the woman, the Court held, and the two-physician requirement, unlike the one it upheld in *Planned Parenthood v. Ashcroft,* did not include an exception for emergencies.

Meanwhile, after defeat of their broader efforts to outlaw abortion, antiabortion lawmakers in Congress, with the aid of antiabortion presidents Reagan and George H. W. Bush, moved to an incremental strategy of rooting out federal support of the procedure wherever they could. By the end of the decade federal funding had been eliminated for all Medicaid abortions except those needed to save the woman's life; for abortions previously covered as a benefit under the FEDERAL EMPLOYEE HEALTH BENEFITS PLAN (FEHBP); for those performed in federal prisons; and for those performed in overseas military medical facilities on servicewomen or military dependents, even if the patient paid for the procedure herself. In addition, abortion funding by the District of Columbia, using city tax money, had been eliminated. Congress also ratified the Reagan administration's MEXICO CITY POLICY, barring funding for international family planning organizations throughout the world that used their own funds to "perform or actively promote abortion as a method of family planning," and cut off funding to the UNITED NATIONS POPULATION FUND (UNFPA), which was accused of underwriting coercive sterilization and abortion programs in China.

The next pivot point in the abortion debate came in 1989, when the Supreme Court, in *WEBSTER V. REPRODUCTIVE HEALTH SERVICES,* reversed course and upheld many of the restrictions it had previously struck down, including a ban on use of public employees or facilities for abortions and a restriction requiring physicians to perform tests to determine viability on fetuses of more than twenty weeks' gestation. In upholding the restrictions on a 5-4 vote, the Court signaled—but did not expressly say—that it no longer considered abortion a fundamental right. Thus, both sides agreed, it essentially invited states to pass their own laws limiting abortion.

But just as the abortion-supporting *Roe* decision had energized antiabortion forces in 1973, *Webster* mobilized abortion rights supporters who realized that the future of legalized abortion was in doubt. In the months immediately following the decision, both the House and Senate voted to roll back various restrictions imposed over the previous decade, including the ban on federal funding of abortion in cases of rape or incest and a restriction barring the District of Columbia from using its own tax dollars to pay for abortions. Four presidential vetoes, however, prevented any of the restrictions from being eliminated.

The Supreme Court again thwarted abortion rights supporters with its 1991 decision *Rust v. Sullivan,* upholding a Reagan administration regulation, known as

the GAG RULE, barring abortion counseling and referrals in federally funded family planning clinics. Congress voted repeatedly to overturn the regulations but never mustered the veto-proof supermajority needed to accomplish the goal. The same was true for efforts to overturn a 1988 ban on research using tissue from aborted fetuses. (See FETAL TISSUE RESEARCH.)

With abortion rights forces on the offensive, the Supreme Court threw them for another loop with its 1992 decision *PLANNED PARENTHOOD OF SOUTHEASTERN PENNSYLVANIA V. CASEY.* At issue in the case was a Pennsylvania law imposing a series of requirements—many of them struck down by the Court in earlier cases. But this time the Court decided that it was permissible to allow Pennsylvania to mandate a twenty-four-hour waiting period and to require women seeking an abortion to be given state-sponsored material about fetal development and abortion alternatives. That decision expressly overturned two earlier cases, *Thornburgh v. American College of Obstetricians and Gynecologists* (1986) and *Akron v. Akron Center for Reproductive Health* (1983).

But unlike the decision in *Webster,* in which the Court did not openly address the continuing viability of the framework established in *Roe,* the plurality opinion in *Casey* did address the fundamental question of a woman's right to abortion. And, much to the surprise of those on both sides, it affirmed it. But Justice Sandra Day O'Connor's opinion made it clear that the right she was embracing was not nearly as unlimited as the one for which *Roe* had become known. Instead, the decision lowered the threshold for state restrictions; only those that imposed "an undue burden" would be invalidated. Using that new standard, the justices overturned one of the Pennsylvania law's provisions that would have required a married woman to notify her husband before obtaining an abortion.

Although it significantly weakened *Roe,* the decision in *Casey* affirming even a somewhat more limited right to abortion impeded the progress of the abortion rights movement, and contributed to its failure to push through Congress the Freedom of Choice Act, which would have written the *Roe* protections into law and blocked many of the restrictions the Court had previously upheld.

What helped abortion rights advocates most was the election that November of Bill Clinton as president. On only his second full day in office, Clinton wiped out an entire series of restrictions imposed over the previous twelve years. With the stroke of a pen, Clinton struck from the books the gag rule barring abortion counseling and referrals at federally funded family planning clinics; canceled an "import alert" barring individuals from bringing into the country the French abortion pill RU486; lifted the moratorium on research using tissue from aborted fetuses; ended the ban on self-paid abortions in overseas military medical facilities; and canceled the Mexico City policy banning U.S. aid to international family planning programs that used their own funds to promote or perform abortions.

Congress would later that year undo several other restrictions. Various appropriations bills restored the ability of the District of Columbia to use locally raised funds to pay for abortions for poor women, permitted federal employee health plans to offer abortion as a covered benefit, and restored funding for the UNFPA. Moreover, a NATIONAL INSTITUTES OF HEALTH (NIH) reauthorization bill (PL 103–43) codified language allowing fetal tissue research.

Congress also restored Medicaid funding for abortions in cases of rape or incest, but that development was considered a loss for abortion rights groups. They had hoped to eliminate the Hyde amendment restrictions altogether but were outmaneuvered by abortion opponents—led by Rep. Hyde himself. At the same time, support for abortion rights in Congress turned out to be not as strong as some had thought. Similarly, Congress again failed to act on the Freedom of Choice Act, even though President Clinton had supported it on the campaign trail.

The years 1993 and 1994 turned out to be the high-water marks for abortion rights supporters. In 1995 the new Republican majority in Congress moved quickly to reinstate the 1980s restrictions relaxed during Clinton's first two years in office. Despite President Clinton's vehement opposition, the bans on military abortions, D.C. abortions, prison abortions, and those performed as federal employee benefits were reinstated through various appropriations measures, and the UNFPA was

defunded. The Republican-led Congress also effectively blocked a requirement that doctors training to be obstetrician/gynecologists be taught to perform abortions unless they have a moral or religious objection (see ACCREDITATION COUNCIL ON GRADUATE MEDICAL EDUCATION [ACGME]) and imposed an explicit ban on research using human embryos (see EMBRYO RESEARCH).

Abortion opponents, however, were less successful than they had previously been at moving stand-alone abortion bills, including a ban on so-called partial-birth abortions and a measure to make it a crime to take a minor across state lines for an abortion in contravention of her home state's parental involvement law. (See CHILD CUSTODY PROTECTION ACT.) President Clinton also managed to fend off a reimposition of the Mexico City policy for international family planning groups, although only by allowing significant funding reductions to the international family planning aid program.

The 2000 victory of George W. Bush—who ran a more strongly antiabortion campaign than his father had in 1988—shifted the balance toward abortion opponents further still. Bush reimposed the Mexico City policy on his first weekday in office, which also was the *Roe v. Wade* anniversary. The administration supported several antiabortion bills passed by the GOP-controlled House of Representatives, and in one of the most watched policy decisions of his first year in office, the president decided to allow limited federal funding of research on STEM CELLS derived from destroyed human embryos. (See STEM CELL RESEARCH.)

The full Republican takeover of Congress in 2003 cheered abortion opponents—some of whose agenda had been delayed when Democrats took over the Senate in mid-2001—still further. Within weeks, the 108th Congress took up two priority bills for the antiabortion movement. The House on February 27, 2003, approved a bill to ban all forms of human cloning; and the Senate on March 13 approved a new version of the "partial-birth abortion" bill sponsors said would overcome the problems cited by the Supreme Court in 2000 when it struck down a substantially similar Nebraska law.

The cloning bill never found its way into law during that Congress, but on November 5, 2003, President Bush signed the Partial Birth Abortion Ban Act (PL 108–105). It became the first-ever federal ban on a specific abortion procedure. It was immediately challenged in court by abortion rights groups, based on the Supreme Court's invalidation of the nearly identical Nebraska law in 2000 (*Stenberg v. Carhart*). But on April 18, 2007, a Supreme Court newly reconfigured with two Bush appointees upheld the law on a 5-4 vote, essentially reversing in *Gonzales v. Carhart* the holding from seven years earlier in *Stenberg v. Carhart.*

The "partial-birth abortion" law was not the only legislative victory for abortion foes. A less-noticed bill, originally entitled the Unborn Victims of Violence Act, became law (PL 108–212) on April 1, 2004. The legislation's stated purpose made it a crime to injure or kill a fetus during the commission of a violent federal crime against a pregnant woman. But abortion rights supporters argued that the measure had a second purpose: to give legal status to a fetus for the first time under federal law, and thus lay the groundwork for an ultimate overturn of the federal right to an abortion. Sponsors of the measure, who renamed it Laci and Connor's Law, in honor of the pregnant California woman murdered shortly before she was due to give birth, denied any such ulterior motives. Laci Peterson's murder, however, was a state, not a federal, crime and would not have been eligible for prosecution under the law. Peterson's husband was subsequently convicted of double murder under an existing California law.

Abortion Non-Discrimination Act

See CONSCIENCE CLAUSE.

Abstinence education

An increasingly heated flashpoint in the abortion debate is what students are to be taught about sex in school. Starting in the late 1990s, and accelerating rapidly after President George W. Bush took office in 2001 and made the issue one of his top domestic priorities,

the federal government began dramatically increasing its investment in "abstinence-only" or "abstinence until marriage" education. These programs specifically prohibit teaching about contraception, stressing a complete lack of sexual activity as the only certain way to reduce the risk of pregnancy and sexually transmitted disease (STD). Teaching teens how to use contraception while urging them to refrain from becoming sexually active, say backers of abstinence-only programs, sends a mixed message that pre-marital sexual relations are acceptable. Opponents, however, say that expecting teens to remain abstinent is unrealistic and that failing to teach them how to use contraception will make them more likely to get pregnant or contract an STD and thus put their health and even their lives at risk.

The federal government funds abstinence-only education through three main programs. The oldest is the ADOLESCENT FAMILY LIFE (AFL) PROGRAM, created in 1981 as an alternative to the TITLE X FAMILY PLANNING PROGRAM, which provides a comprehensive array of contraceptive products as well as abortion referrals (although not abortions). In 1996, as part of that year's sweeping welfare reform law (PL 104–193), the federal government provided $50 million per year in matching funds for the states for "the exclusive purpose" of promoting abstinence. The largest program, added in 2001, is called the Special Programs of Regional and National Significance—Community-Based Abstinence Education. Together, in fiscal 2008 the programs received $189 million in funding, up from $76 million in fiscal 2001, the last year of the Clinton administration.

Even as federal funding rose, the two sides traded academic studies they insisted backed their argument that abstinence-only education either does or does not work. The problem was that all the studies came as teen pregnancy and abortion rates were dropping. Abstinence advocates insisted it was their message causing the reductions; opponents insisted it was better and more consistent use of contraception.

An April 2007 study from the nonpartisan group Mathematica Policy Research Inc. found both sides right—and wrong. After closely examining four federally funded abstinence education programs, it determined that the programs had no effect on the sexual abstinence of youth. But it also found that youth in these programs were no more likely to have unprotected sex, the main concern of abstinence-only opponents.

Meanwhile, others complained about what students in abstinence-only programs were being taught. A 2004 study by the Democratic staff of the House Government Reform Committee found over 80 percent of the curricula used by two-thirds of the grantees in the largest federal abstinence-only education program contained false, misleading, or distorted information about reproductive health. For example, the curricula contended incorrectly that HIV (human immunodeficiency virus, which causes ACQUIRED IMMUNE DEFICIENCY SYNDROME [AIDS]) could be spread by sweat or tears, presented as scientific fact the contention that life begins at conception, misrepresented the failure rates of condoms, and falsely implied that significant percentages of women who have abortions will become sterile as a result.

Academic health centers (AHCs)

The term describes entities consisting of a medical school and the hospitals with which it is affiliated. These roughly four hundred hospitals that are affiliated with one of the nation's 125 medical schools deliver some of the most advanced medical care in the nation. They include many familiar names in medicine—the Mayo Clinic, Johns Hopkins University Medical Center, and the Cleveland Clinic Foundation, to name a few. Sometimes referred to as academic medical centers, academic health centers (or AHCs) carry out a threefold role. Like other hospitals, they provide care, both to inpatients and outpatients, often serving as a major source of care for poor or uninsured individuals. They also teach the next generation of doctors, including those pursuing the most advanced and high-tech specialties. Finally, AHCs are the locus of significant biomedical research, both basic and applied.

Because of what they do, AHCs attract many sicker than average patients who are much more expensive than average to treat. (Virtually all teaching hospitals incur higher than average expenses per patient because

their teaching role by definition requires multiple doctors in various stages of their training to treat each sick person, and this style of treatment often results in more tests and other procedures as part of the training process.) In the 1990s, AHCs experienced significant financial stresses as MANAGED CARE became a predominant force in the nation's health care system. Before the rise of managed care, AHCs tended to finance their research and teaching operations in three major ways. The first way was through practice plans, in which members of the faculty charged premium rates, then returned a portion of their fees to the institution. AHCs also charged insurers higher hospitalization rates, using the excess to underwrite their noncare missions. Finally, the government, primarily through MEDICARE and MEDICAID, provided AHCs with extra payments in recognition of their multiple roles—spending approximately $7 billion annually.

But when managed care plans sought to lower costs, they tried to steer all but the sickest patients away from AHCs to less advanced—and less expensive—community hospitals, depriving AHCs of income from both the physician-faculty members and the hospital fees. At the same time, the federal government cut back on payments as part of its effort to rein in the cost of Medicare and Medicaid. The 1997 Balanced Budget Act was estimated to reduce payments to AHCs by 28 percent following a five-year phase-in. Congress subsequently increased payments to hospitals when the 1997 cuts went deeper than intended (see MEDICARE GIVEBACKS), and the decline of managed care enabled many AHCs to bargain for higher rates. But those who studied AHCs predicted that more hard times were in store. With health care costs again rising at double-digit rates in the early years of the twenty-first century, leading to another rise in the number of uninsured, and combined with an aging population likely to need more high-tech care, cost pressures were likely to once again take their toll on these highly expensive enterprises. At risk, noted a report on the future of AHCs issued in 2003 by the Commonwealth Fund, was the ability of AHCs to train doctors, conduct research, deliver such costly and specialized services as trauma and burn care, and serve their communities' uninsured. "To the extent that the American people value these missions, wish them to be pursued, and want AHC's to participate in them, society must find ways outside of normal market mechanisms to support that participation," the report said.

In addition to caring for patients, academic health centers like the Mayo Clinic in Rochester, Minnesota, conduct basic and applied research and instruct medical students in the most advanced health practices. *Source: Courtesy of the Mayo Clinic*

Accreditation Council on Graduate Medical Education (ACGME)

This body sets the standards for the nation's eighty-two hundred medical residency programs in more than one thousand institutions that train doctors to perform various specialties. The Accreditation Council on Graduate Medical Education (ACGME) sets guidelines for what residency programs should teach, then evaluates and accredits programs to ensure that no matter where doctors train, they complete that training with a consistent body of knowledge and experience. ACGME is composed of representatives of the American Board of Medical Specialties, American Hospital Association, AMERICAN MEDICAL ASSOCIATION (AMA), Association of

American Medical Colleges, and Council of Medical Specialty Societies. Standards are proposed by residency review committees (RRCs), composed of physician educators in each of the twenty-six recognized medical specialties. The RRCs, staffed by up to two hundred volunteers, evaluate each residency program on average every three and a half years and render decisions on accreditation. Standards for each specialty are updated approximately every five years to account for new discoveries, techniques, and changes in practice patterns.

In 1995 the ACGME came under fire in Congress for a change to the standards for training obstetrician/gynecologists that required residents without moral or religious objections to learn how to perform abortions. The chair of the ACGME testified before Congress that "it is the opinion of the obstetricians serving on the Residency Review Committee for Obstetricians and Gynecology and the medical organizations that reviewed and approved these standards that specific training is necessary in order to perform abortions safely and protect the public health." But abortion opponents argued that because ACGME accreditation is required for receipt of federal funds for a variety of activities, including MEDICARE reimbursement and medical student loans, the new requirement represented an unwarranted federal mandate for abortion training. "In effect, ACGME is drafting American obstetricians into a war on their unborn patients. It has no right to impose such a draft, with or without exemptions for 'conscientious objectors,' " said the antiabortion United States Catholic Conference in a statement. Congress ultimately overrode the ACGME ruling with a compromise crafted with the aid of the American College of Obstetricians and Gynecologists that permitted federal funding of an unaccredited obstetrician/gynecology residency program if the program's failure to provide abortion training was "a decisive factor in its lack of accreditation."

In 2003 the ACGME imposed work-hour restrictions for all residents. The new rules were a long-delayed reaction to the case of Libby Zion, the eighteen-year-old daughter of a prominent New York writer and attorney, who died in 1984 after being treated in a New York emergency room by sleep-deprived residents. The ACGME rules bar residents from working shifts longer than thirty hours straight and working more than eighty hours per week, averaged over a four-week period. Several studies showed, at least in the early years after implementation, that the rules were widely ignored. A 2006 study by Harvard University researchers published in the *Journal of the American Medical Association* found 84 percent of first-year residents nationwide were not compliant with the new rules. Even if the rules were followed, they likely are inadequate. Other studies found that residents who work long hours without sleep are more likely to make medical errors, to be in a car accident driving home, or to stab themselves with a needle or scalpel than those working shifts of twelve hours or less.

Acquired Immune Deficiency Syndrome (AIDS)

AIDS, or Acquired Immune Deficiency Syndrome, is not only a relatively new and frightening disease (it was first identified in 1981) but also one that has helped reshape the way the U.S. government addresses public health, research, and other medical and social issues. The AIDS epidemic in the United States and around the world has forced an examination of attitudes about sexual conduct (the first group affected in the United States was homosexual men), about the ability of the medical community to respond to previously unknown communicable diseases, and about the ability of well-organized lobbying groups to spur government action. AIDS activists' success in getting Congress to increase research funding helped inspire similar tactics by those pushing for more money for breast cancer, Parkinson's disease, and other, more common maladies. At the same time, AIDS activists pushed the FOOD AND DRUG ADMINISTRATION (FDA) for "fast-track" approval for drugs that could treat AIDS, even if they could not yet cure it. The fast-track procedures were later written into law for drugs for other life-threatening conditions as part of the 1997 FDA Modernization Act (PL 105–115).

Congress has addressed the AIDS epidemic in a variety of bills since it came to public awareness. Among these various legislative efforts were the following:

• As part of the fiscal year 1988 LABOR–HEALTH AND HUMAN SERVICES–EDUCATION APPROPRIATION (Labor-HHS), Congress adopted language, pushed by Sen. Jesse Helms, R-N.C., forbidding AIDS education funds from being used for activities that "promote or encourage, directly or indirectly, homosexual sexual activities." Helms's original amendment would have barred education efforts from "condoning" homosexual activity, but he was prevailed on to drop that language when health officials said it could cripple their efforts to stem the spread of the disease.

• In an omnibus health bill cleared in 1988 (PL 100–607) Congress authorized $270 million over three years for AIDS education efforts and a total of $400 million over two years for anonymous blood testing and counseling. The measure also authorized $2 million in operating costs for a new national AIDS commission. At Helms's insistence, however, sponsors of the bill dropped provisions guaranteeing confidentiality of AIDS test results. Helms and other conservative Republicans argued that AIDS should be treated like every other communicable disease, with mandatory testing and reporting of names to public health authorities. But health officials, including then SURGEON GENERAL OF THE UNITED STATES C. Everett Koop, argued that those at greatest risk for acquiring AIDS—homosexuals and intravenous drug users—would be driven underground by mandatory testing requirements, only spreading the epidemic further.

• The RYAN WHITE COMPREHENSIVE AIDS RESOURCES EMERGENCY (CARE) ACT was cleared by Congress in 1990 and signed reluctantly by President George H. W. Bush (PL 101–381). The Ryan White program rapidly became the major source of funding for treatment and detection of AIDS and HIV (human immunodeficiency virus), the AIDS virus. In fiscal year 2008 Congress appropriated $2.17 billion for the program, named for an Indiana teenager who contracted HIV from contaminated clotting factor he received for hemophilia and whose struggle attracted national attention early in the epidemic.

The act was reauthorized in 1996 and again in 2000 and 2006. The 1996 bill required mandatory testing of newborn babies for HIV if states did not successfully lower the "perinatal" (pregnant mother to newborn child) transmission of the virus. The 2000 bill authorized funding for newborn testing, as well as for state "partner notification" programs for those who tested positive for the virus. Both the 2000 and 2006 bills were delayed by fights among lawmakers from the large cities that traditionally had received the bulk of the funding under the measure and those from areas with fewer cases of AIDS and HIV but where caseloads were growing more quickly.

In 1988 the federal government mailed over 100 million copies of a brochure, Understanding AIDS, *to educate the public about HIV transmission and start a dialogue nation-wide about HIV/AIDS. This unprecedented campaign represented the first time that the federal government had attempted to directly contact by mail nearly every American concerning a public health issue. Source: Centers for Disease Control and Prevention*

• The 1990 AMERICANS WITH DISABILITIES ACT (ADA) (PL 101–336) banned discrimination against those with actual or perceived disabilities, including those with AIDS and HIV.

• Congress in 1993 enacted NATIONAL INSTITUTES OF HEALTH (NIH) reauthorization legislation (PL 103–43) that, in addition to creating in statute an office of AIDS research within the NIH to centralize research efforts, acknowledged in law that infection with HIV could be grounds for excluding immigrants and travelers from entering the United States. Congress had first imposed

limits on immigrants with HIV in 1987 and did so again in 1990, and Bill Clinton had vowed to change the policy on the campaign trail. But the Senate refused to go along with the president, and the final legislation continued to give the attorney general authority to grant waivers to those entering the country for medical treatment, tourism, or other short-term visits.

• Congress enacted the 1998 RICKY RAY HEMOPHILIA RELIEF FUND ACT, which authorized tax-free payments of up to $100,000 for hemophiliacs and their families who contracted HIV from contaminated clotting factor before blood tests for AIDS were in wide use. The measure (PL 105–369) was the culmination of years of lobbying by the hemophilia community, an estimated half of whose members became HIV-positive from using the contaminated clotting factor, which, unlike regular blood transfusions, was derived from thousands of donors, thus substantially increasing the risk of contracting the virus.

By the turn of the new millennium, attention in the United States turned to Africa, the Caribbean, and other places where the AIDS epidemic was threatening to decimate entire nations. In 2002 sub-Saharan Africa accounted for 11 percent of the world's population but represented 71 percent of the estimated forty-two million people living with AIDS/HIV. South Africa alone had five million people infected with the virus. By 2010 life expectancy in some of the hardest-hit nations was expected to drop to under thirty years.

In 2001, responding to a call from United Nations (UN) secretary-general Kofi Annan, the UN set up the Global Fund to Fight AIDS, Tuberculosis, and Malaria. The fund, backed by major industrialized countries known as the Group of 8 (G8), private foundations, and other donors, sought to raise $10 billion to combat the diseases not just in Africa but in developing nations as well. The fund, however, got off to a slower start than Annan had hoped. By May 2003 only $4.3 billion had been pledged to the fund through the year 2008, and only $866 million had been received, 80 percent from the G8 nations. By 2007, however, the fund had managed to award grants worth $7.6 billion to 136 countries; $3.7 billion of that had been distributed.

The United States formally agreed to participate in the fund as part of 2003 authorization legislation (PL 108–25) that pledged a total of $15 billion over five years.

Activities of daily living (ADLs)

Used to measure the degree of disability for those requiring long-term care or other services, activities of daily living (ADLs) include such necessities of life as bathing, getting in or out of a bed or chair, dressing, eating, and using the toilet. Individuals are generally considered severely disabled if they need assistance with three of five ADLs. Instrumental activities of daily living (IADLs) are those tasks persons must be able to perform to remain independent. They include things such as cooking, cleaning, shopping, using the phone, taking medication, and bill-paying. As the baby boom generation ages, the number of Americans who will require help with one or more ADLs or IADLs is expected to balloon. By the mid-2000s, an estimated one-quarter of the elderly population needed assistance with one or more ADLs or IADLs.

ADA

See AMERICANS WITH DISABILITIES ACT (ADA).

ADLs

See ACTIVITIES OF DAILY LIVING (ADLs).

Adolescent family life (AFL) program

Created by Title XX of the Public Health Service Act, the program was enacted in 1981 budget reconciliation legislation (PL 97–35) at the urging of antiabortion lawmakers to help fund programs that seek to convince teenagers to refrain from sexual activity instead of using contraception and to encourage young unmarried girls who do get pregnant to carry their babies to term. The

latter provision, along with another that encouraged religious organizations to apply for grants from the program, resulted in a lawsuit challenging the constitutionality of the entire program.

Like the much larger federal TITLE X FAMILY PLANNING PROGRAM, the adolescent family life (AFL) program has not been reauthorized by Congress since its last authority expired in 1985. Both programs have been caught up in continuing controversy over abortion-related questions. The AFL received a fiscal year 2008 appropriation of $29.8 million. The program authorizes grants to public and private nonprofit entities for programs that promote abstinence. Programs may provide family planning services but may not use funds for ABORTION (also banned under the Title X program) or for abortion counseling or referrals (both of which Title X requires).

Advance directives

These legal documents express an individual's health care desires in the event that that individual becomes incapacitated or is otherwise unable to communicate his or her wishes. The two basic types of advance directives are living wills and durable powers of attorney for health care (also known as medical powers of attorney). All fifty states recognize the legal power of advance directives for health care. Advance directives enable people to make their own medical decisions, even when they are incapacitated. The PATIENT SELF-DETERMINATION ACT OF 1990, part of that year's budget reconciliation bill (PL 101–508), required that all hospitals that participate in MEDICARE or MEDICAID advise all patients of their right to exercise advance directives, in an effort to encourage their use.

Advanced practice nurse

The term applies to a registered nurse (RN) who has undergone advanced training and clinical practice requirements beyond the two to four years required for an RN degree. Advanced practice nurses, who include nurse practitioners, certified nurse midwives, clinical

Advanced practice nurses, registered nurses who have undergone additional training, are caught in the crossfire between insurance companies, which benefit from the nurses' reasonable rates, and physicians, who argue that allowing nurses to practice without adequate supervision by doctors could endanger patients. Right, nurse practitioner Yvonne Barnes examines three-year-old Jaelyn Sanders. *Source: AP Images*

nurse specialists, and certified registered nurse anesthetists, provide many primary care and most specialized services with the supervision of a physician and, sometimes, without. (See NURSE PRACTITIONER [NP], CERTIFIED NURSE MIDWIFE, CLINICAL NURSE SPECIALIST [CNS], and CERTIFIED REGISTERED NURSE ANESTHETIST [CRNA].) Advanced practice nurses, along with PHYSICIAN ASSISTANTS and some therapists, are known collectively as mid-level practitioners. In many states turf battles have broken out between physicians and mid-level practitioners, with insurance companies arguing that the less-expensive practitioners can provide quality care at a lower cost, while physicians argue that they lack adequate skills to practice independently. However, a 1986 report by the Office of Technology Assessment found that advanced practice nurses "are more adept than physicians at providing services that depend on communication with patients and preventive actions."

Adverse selection

Adverse selection is said to occur when too many people who are likely to incur high medical costs join the same health plan. It often results from a health plan, policy, or network of specialists offering a particular benefit much more generously than its competition, thus attracting sicker than average people who need that benefit. Too much adverse selection can cause what insurers refer to as a "death spiral." As more sick people join, plans must raise premiums to cover their costs. As premiums rise, healthier people leave, joining other plans or becoming uninsured because they can no longer afford the coverage. The plan is eventually left with only sick people and ultimately fails because it can no longer spread risks between the sick and the healthy.

AFL

See ADOLESCENT FAMILY LIFE (AFL) PROGRAM.

Agency for Health Care Policy and Research (AHCPR)

Created in 1989, this federal agency examined the cost, quality, access to, and effectiveness of medical care in the United States. Its mission was to provide the government, health care professionals, and the public with information to help them obtain care that is both as appropriate and as effective as possible. In 1999 it was overhauled, given a new mission and a new name—the AGENCY FOR HEALTHCARE RESEARCH AND QUALITY (AHRQ).

Unlike other agencies such as the NATIONAL INSTITUTES OF HEALTH (NIH), whose biomedical research efforts help discover the causes of diseases and how to cure or prevent them, the Agency for Health Care Policy and Research (AHCPR) was the lead federal agency in what is known as HEALTH SERVICES RESEARCH, which examines the way the health system works and the intersection of care financing and delivery. Until 1996 AHCPR devised and issued its own clinical practice guidelines for patient care for a variety of conditions, from heart failure to children's ear infections to bedsores. Such guidelines are intended to lessen what other health services research has shown as tremendously wide variation in the treatment patients receive depending on where they live. (See SMALL MARKET VARIATION.) However, a 1994 guideline for acute low-back pain that found surgery to be relatively ineffective raised the ire of back surgeons, who set out to see the agency defunded. Although that effort failed, AHCPR in 1996 announced it was getting out of the business of developing guidelines per se. Other research had shown that doctors are most likely to follow guidelines they helped devise, making the guideline business more local and regional.

Agency for Healthcare Research and Quality (AHRQ)

Congress in 1999 reauthorized, refocused, and renamed the sometimes controversial AGENCY FOR HEALTH

CARE POLICY AND RESEARCH (AHCPR), which became the Agency for Healthcare Research and Quality (AHRQ). The law (PL 101–239) came a decade after Congress first created a federal agency to examine the financing and effectiveness of various health interventions. AHRQ (pronounced "arc") was given a new mission to go along with its new name—to help coordinate private sector efforts to measure and improve the quality of health care. In 2000 the agency was also designated to lead federal efforts to address MEDICAL ERRORS. In its original form, one of AHCPR's roles had been to develop "clinical practice guidelines" to help educate health care professionals about the best ways to treat common ailments. Some of the guidelines, however, ruffled feathers within the health care profession. In particular, AHCPR's guideline questioning the value of surgery to treat acute low-back pain prompted outrage from back surgeons, who set out—and nearly succeeded—to strip the agency of its funding in the mid-1990s. The agency subsequently had its budget cut roughly in half and soon got out of the business of publishing practice guidelines. The 1999 legislation eliminated that authority. Instead, the agency's new focus, as described in 2002, was to "support research designed to improve the outcomes and quality of health care, reduce its costs, address patient safety and medical errors, and broaden access to effective services."

In an effort to help practitioners sort through the impossibly large repository of studies, AHRQ created twelve "evidence-based practice centers" to try to determine which interventions are most effective. Other projects were aimed at "translating research into practice," or getting practitioners to use interventions already found to be effective, such as giving certain drugs to patients who have suffered a heart attack to prevent another. The agency's medical errors prevention portfolio included funding research aimed at better documenting errors, using computers and other technology to prevent errors, and assessing the impact of working conditions on errors.

In 2003, as part of the legislation that created a prescription drug benefit for MEDICARE, AHRQ was authorized to establish a program to compare the effectiveness of various drugs. It was a first, small step toward a federal program to study so-called comparative effectiveness, the first such effort since the Office of Technology Assessment was disbanded in 1995. AHRQ's fiscal 2008 budget was $335 million. (See COMPARATIVE CLINICAL EFFECTIVENESS RESEARCH.)

Agency for Toxic Substances and Disease Registry (ATSDR)

With a fiscal year 2008 budget of $74 million, the registry conducts public health assessments, health studies, surveillance activities, and health education training in communities around Superfund waste sites determined by the U.S. Environmental Protection Agency. The newest of the public health service agencies, the Agency for Toxic Substances and Disease Registry (ATSDR) was established in 1980 and is based in Atlanta, Georgia. It is an operating unit of the CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC).

AHCs

See ACADEMIC HEALTH CENTERS (AHCs).

AHPs

See ASSOCIATION HEALTH PLANS (AHPs).

AHRQ

See AGENCY FOR HEALTHCARE RESEARCH AND QUALITY (AHRQ).

AIDS

See ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS).

Alternative medicine

Also referred to as complementary medicine (particularly when used in conjunction with Western medical techniques), or "integrative" medicine, alternative medicine is, in essence, any healing practice or philosophy not widely taught in medical schools or widely available in hospitals. Many alternative medicine techniques, such as chiropractic, acupuncture, and biofeedback, are widely used and have some scientific evidence to back them up. Other treatments, such as aromatherapy and magnetic field therapy, are looked on more disdainfully by the mainstream medical community.

Regardless of how doctors look at alternative medicine, patients are embracing nontraditional medical methods as never before. According to a 2004 survey conducted by the federal government, 36 percent of adults used some form of alternative medicine, most often to treat back pain, colds, neck pain, joint pain or stiffness, anxiety, and depression. The survey found, however, that only about 12 percent of adults sought that alternative care from a licensed practitioner.

In recognition of the fact that more and more Americans are turning to nontraditional medical techniques, the U.S. scientific community is beginning to devote efforts to attempting to validate which methods work and which do not. In 1992 Congress established within the NATIONAL INSTITUTES OF HEALTH (NIH) the National Center for Complementary and Alternative Medicine (NCCAM). NCCAM's mission is "to facilitate the evaluation of alternative medical treatment modalities" to determine their effectiveness. In carrying out that mission, the center, with a budget of $121.6 million in fiscal year 2008, conducts and supports basic and applied research on alternative medicine topics and supplies information to the public. The center divides its studies into seven main fields: diet-nutrition-lifestyle changes, mind-body interventions, bioelectromagnetic applications, alternative systems of medical practice, manual healing, pharmacological and biological treatments, and herbal medicine.

Increasingly, people are seeking alternative forms of medicine such as acupuncture, herbal treatments, massage therapy, and hypnosis. In recent years, the medical establishment has begun to test the efficacy of such treatments in rigorous scientific studies. *Source: AP Images/Jim McKnight*

The medical community is also addressing alternative medicine in a concerted way. In 1998 the *Journal of the American Medical Association* devoted an entire issue to alternative medicine, publishing, among other things, a half-dozen rigorously scientific studies of various alternative medicine treatments. The studies' results were mixed. One found, for example, that chiropractic manipulation was relatively ineffective in treating tension headaches; another found that yoga techniques showed promise in treating carpal tunnel syndrome, a painful wrist condition; and still another demonstrated

that Chinese herbs may be effective in treating the symptoms of irritable bowel syndrome.

AMA

See AMERICAN MEDICAL ASSOCIATION (AMA).

American Association of Health Plans (AAHP)

The American Association of Health Plans (AAHP) was the leading organization representing the MANAGED CARE industry. The group's one thousand members included health maintenance organizations, preferred provider organizations, and other network-based plans. (See HEALTH MAINTENANCE ORGANIZATION [HMO] and PREFERRED PROVIDER ORGANIZATION [PPO].) The AAHP was officially formed in 1995 through the merger of the Group Health Association of America and the American Managed Care and Review Association. AAHP was most visible in the late 1990s in successfully fending off efforts to enact federal legislation establishing a managed care PATIENTS' BILL OF RIGHTS (PboR).

In 2003 the group merged with the HEALTH INSURANCE ASSOCIATION OF AMERICA to create AMERICA'S HEALTH INSURANCE PLANS (AHIP), a single trade group to represent both managed care and traditional health insurers.

American Association of Retired Persons (AARP)

See AARP.

American Medical Association (AMA)

Founded in 1847, the American Medical Association (AMA) calls itself the "voice of medicine" and lists as its core purpose "to promote the art and science of medicine and the betterment of public health." Although the organization, with its roughly 250,000 members, represents less than a third of the nation's medical doctors, it remains one of the most powerful lobbying organizations in Washington, D.C. A significant portion of the AMA's clout comes through its American Medical Political Action Committee, or AMPAC, which has traditionally been one of the largest contributors to political campaigns for the House and Senate. In the 2006 election cycle AMPAC contributed $2 million to federal candidates, about 70 percent to Republicans. That ranked the group eighteenth among all political action committees, according to the Center for Responsive Politics. The AMA is probably best known for its opposition to national health insurance in the 1950s, to the creation of MEDICARE in 1965, and to President Bill Clinton's health reform plan in 1993–1994. In 1995 and 1996 the AMA was one of the leading organizational backers of the Republican congressional leadership and one of the few health organizations to support GOP attempts to rein in spending on Medicare and MEDICAID. In 1998 the AMA broke with the GOP to support President Clinton's proposed PATIENTS' BILL OF RIGHTS (PboR), a measure to impose federal rules on managed care and other health insurance plans. But in 2003 the group tilted back toward Republicans, as President George W. Bush renewed efforts to cap damages in MEDICAL MALPRACTICE lawsuits, long a top AMA legislative priority.

Americans with Disabilities Act (ADA)

Signed by President George H. W. Bush on July 26, 1990, the Americans with Disabilities Act (ADA, PL 101–336) extended to people with disabilities protections from discrimination in employment and public accommodations similar to those afforded women and racial and ethnic minorities by the 1964 Civil Rights Act. The measure also required that public transportation systems, other public services, and telecommunications systems be accessible to the estimated forty-three million Americans with disabilities.

Discrimination against disabled individuals was already prohibited in federally funded activities by the 1973 Rehabilitation Act and in housing by the 1988 Fair Housing Act amendments. But the disabled were not among those protected under the 1964 Civil Rights Act, which barred discrimination in employment and public accommodations on the basis of race, sex, religion, or national origin.

But although the measure was approved overwhelmingly by Congress—the conference report was adopted in the House, 377-28, on July 12 and in the Senate, 91-6, a day later—it was not without controversy. Some business interests worried that the measure would expose them to unwarranted lawsuits and cost them thousands of dollars to comply with its requirements. Restaurateurs were worried that they would be required to permit workers with contagious diseases to remain in food-handling jobs. (Backers of the measure pointed out it already included an exemption from the antidiscrimination provisions for individuals "who posed a direct threat to the health or safety of others.") Hovering over the entire two-year debate about the measure was the specter of the ongoing and escalating ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS) epidemic, and some legislators attempted to exclude AIDS or HIV (human immunodeficiency virus), the AIDS virus, from the ADA's protections.

One major impetus for the measure was a group of members of Congress who themselves had overcome disabilities or who had a close family member with a disability. Among the lead sponsors were Sen. Tom Harkin, D-Iowa, whose brother was deaf; Sen. Lowell P. Weicker Jr., R-Conn. (sponsor of the original measure before his defeat in 1988), who had a child with a severe birth defect; Sen. Bob Dole, R-Kan., who had limited use of his right arm from an injury incurred during World War II; and House majority whip Tony Coelho, D-Calif., who had epilepsy. The measure was also strongly backed by President Bush, who spoke of it repeatedly during his 1988 campaign and who endorsed it again two days before his 1989 inauguration, calling it "simple fairness to provide the disabled with the same rights afforded other minorities."

The law defined an *individual with a disability* as a person with a physical or mental impairment "that substantially limited one or more major life activities, had a record of such an impairment, or was regarded as having such an impairment." The last part of the definition was to prevent discrimination against someone on the basis of a perceived disability, such as someone who had been disfigured by a birth mark or burn scars but who was not hindered from performing major life activities.

Among its key provisions was a ban on discrimination against "qualified individuals with a disability" by employers with more than fifteen workers. Employers were prohibited from discriminating in job application procedures; in hiring, advancing, training, compensating, and discharging employees; and in fulfilling other terms, conditions, and privileges of employment. Employers were required to make "reasonable accommodations" to workers with disabilities as long as doing so did not cause an "undue hardship," defined as an action requiring significant difficulty or expense. Reasonable accommodations could include job restructuring, providing qualified readers or interpreters, or acquiring or modifying equipment or devices.

Title II of the ADA prohibited public entities from discriminating against individuals with disabilities and stipulated that such individuals were not to be excluded from or denied the benefits of the "services, programs, or activities of a public entity." Public entities included not only state and local governments but also Amtrak and commuter rail authorities. Title II ensured accessibility to public transportation systems for those with disabilities, requiring "paratransit" systems for those unable to use fixed-route public transit.

Title III, the ADA's "public accommodation" section, applied to a much broader array of private entities than did the 1964 Civil Rights Act. It required access by those with disabilities to the restaurants, lodging, places of entertainment, and gasoline stations covered by the earlier law, and it also mandated their access to museums and sports stadiums, doctors' offices and hospitals, dry cleaners, pharmacies, grocery stores, and all other retail and service establishments. Owners of such pub-

lic accommodations were required to make new and renovated facilities accessible to disabled individuals and to make whatever "readily achievable" modifications in existing facilities were needed to accommodate disabled individuals. The law also required all newly purchased or leased buses and rail cars to be accessible by disabled individuals but did not mandate retrofitting of existing vehicles.

Finally, Title IV of the bill required that interstate and intrastate telecommunications relay services be available "to the extent possible and in the most efficient manner" to hearing- and speech-impaired individuals. Title IV also ordered that television public service announcements funded in whole or in part by the federal government be closed-captioned for the hearing impaired.

But for all its overwhelming support, the ADA had a tortuous trip to passage, taking more than two years and traveling through four separate House committees. Among the sticking points was the potential cost to business of complying with the measure's requirements and coverage of people with AIDS and HIV.

Supporters of the ADA assumed all along that it would cover both those with full-blown AIDS and those with earlier stages of HIV infection. They based those claims on a complicated framework of court decisions, legislative history, and administrative interpretation. The underpinning of the framework was a 1987 U.S. Supreme Court decision, *School Board of Nassau County, Fla., v. Arline,* which had held that a person with a contagious disease (in that case, tuberculosis) was handicapped as defined by amendments to the 1973 Rehabilitation Act. Although that definition almost certainly covered AIDS, it left open the question of whether asymptomatic HIV protection would also trigger the ADA's protections. The House in 1988 seemed to indicate that it would, when it specifically rejected, by 63-334, an amendment that would have sent a fair housing bill back to committee with instructions to eliminate protections for HIV. In October 1988 the Justice Department weighed in, agreeing that those with HIV as well as AIDS were covered under the Rehabilitation Act. "The SURGEON GENERAL [OF THE UNITED STATES] advises us that the impairment of HIV infection cannot be meaningfully separated from clinical AIDS, and that it is medically inappropriate to think of this disease as composed of discrete conditions," said a Justice Department official in announcing the change. "Because HIV infection may limit the likelihood of bearing a healthy child and may adversely affect intimate sexual relations, we believe that an individual proving these facts to a court could fairly be found to be an individual with handicaps for purposes of the [rehabilitation] act."

But it took a 1998 Supreme Court decision, *Bragdon v. Abbott,* to resolve the matter conclusively. On June 25, the Court, in a 5-4 decision, ruled that HIV infection alone, without symptoms, still entitled individuals to the ADA's protections. In this case, an HIV-positive Maine woman, Sidney Abbott, sued a dentist for refusing to provide her treatment. Abbott's attorneys argued that she had a disability in that her HIV status hindered her ability to have children, and the Court majority agreed. "Reproduction falls well within the phrase 'major life activity,' " wrote Justice Anthony M. Kennedy in the majority opinion. "Reproduction and the sexual dynamics surrounding it are central to the life process itself."

In 1999, however, the Supreme Court acted to limit the number of people who could qualify for the ADA's protections. In a 7-2 decision in separate cases handed down on June 22, the Court ruled that persons with disabilities that could be corrected (such as with medication or eyeglasses) were not entitled to sue for discrimination under the ADA. One of the cases, *Sutton v. United Airlines,* involved nearsighted identical twins who were rejected for pilot jobs with the airline because of their eyesight. The other, *Murphy v. United Parcel Service,* involved a mechanic fired by the United Parcel Service because of an inability to control his high blood pressure.

On the same day, the Court did hand one victory to advocates for disabled individuals. In a 6-3 ruling in *Olmstead v. L.C.,* the justices said that states must place disabled individuals in community-based settings, not institutions, if the individuals are capable of living outside institutions and desire such placement. That case

involved two mentally retarded women in Georgia who were kept institutionalized even after their doctors said such care was no longer needed.

In February 2001 the Court handed backers of the law another setback when it ruled in *University of Alabama v. Garrett* that the law did not allow disabled workers to sue state governments. In that case, nurse Patricia Garrett sued the university after she received a demotion on her return to work from breast cancer treatment. The case also incorporated a complaint by Milton Ash, an asthmatic corrections officer who sued Alabama's Department of Youth Services for failing to enforce its no-smoking rules. The Court ruled 5-4 that the ADA did not trump the U.S. Constitution's Eleventh Amendment, which barred most suits against states for money damages.

Later that year, however, in one of the highest profile ADA cases ever, the Court by a 7-2 majority ruled that the law required the PGA Tour to let golfer Casey Martin use a cart in its tournaments. The PGA had argued that letting Martin, who suffered from a rare circulatory disorder that made it impossible for him to meet the PGA tournament requirement that he walk all eighteen holes of a golf course, use a cart would "fundamentally alter the nature" of the game and give him an unfair advantage over other competitors. The Court disagreed. In the majority opinion, Justice John Paul Stevens wrote that in failing to take Martin's circumstances into account in deciding not to provide him an accommodation, the PGA's decision "runs counter to the clear language and purpose" of the ADA.

The Martin case, however, proved an aberration for the Court. In January 2002, in another 5-4 decision, the Court in *Toyota Motor Mfg. v. Williams* narrowed the definition of disability in ruling against a worker who suffered from carpal tunnel syndrome, a painful and often debilitating wrist condition. The Court ruled that Ella Williams's inability to perform many routine manual tasks "did not amount to such severe restrictions in the activities that are of central importance to most people's daily lives that they establish a manual-task disability as a matter of law."

America's Health Insurance Plans (AHIP)

This umbrella lobbying group representing the entire health insurance industry was created by the 2003 merger of the HEALTH INSURANCE ASSOCIATION OF AMERICA (HIAA) and the AMERICAN ASSOCIATION OF HEALTH PLANS (AAHP). In 2007 the group represented more than thirteen hundred companies that covered 200 million Americans with not just medical insurance, but also insurance for LONG-TERM CARE expenses, disability, dental care, and reinsurance for other insurance companies. Before the merger, the AAHP had represented the MANAGED CARE industry, and the HIAA represented mostly small and mid-size traditional health insurers. Both groups were best known for stopping major efforts to enact federal health legislation. HIAA in 1993 and 1994 was instrumental in helping defeat President Bill Clinton's health reform bill, and AAHP starting in the late 1990s led the successful opposition to creation of a managed care PATIENTS' BILL OF RIGHTS (PboR).

Asset test

Many federal programs aimed at those of modest means base eligibility on income as well as on assets. To be eligible for MEDICAID, SUPPLEMENTAL SECURITY INCOME (SSI), and the so-called MEDICARE savings programs (such as the QUALIFIED MEDICARE BENEFICIARY [QMB] program), among others, individuals must demonstrate not only that their income is low enough, but also that they own few assets (sometimes referred to as resources). For example, to qualify for SSI, an individual can have no more than $2,000 in assets; a couple, no more than $3,000. Excluded from that is the house the individual or couple lives in and the land on which the house sits, a life insurance policy worth less than $1,500, burial plots for members of the immediate family, and $1,500 in funeral expenses for the individual and spouse.

Asset tests vary by program and, in some cases, by state. The asset test for the Medicare prescription drug program, created in 2003, has been particularly contro-

versial. In 2007 individuals with incomes under $15,315 and couples with incomes under $20,535 were eligible for extra help from the federal government with their prescription drug expenses. But they also had to meet an asset test. They could have assets, defined as savings, stocks, bonds, and real estate, worth no more than $11,710 for individuals and $23,410 for couples. According to one study, nearly a fifth of those otherwise eligible for the additional help due to low income would be excluded as a result of the asset test. That led many consumer groups to call for the test's elimination, arguing that it unfairly penalized those seniors who had saved for their retirement.

Assignment (Medicare)

A physician who accepts "assignment" under MEDICARE agrees to take the program's predetermined fee as payment-in-full. That means that patients are responsible for their 20 percent copayment but no more. A physician who signs an annual agreement to accept assignment for all patients for all services is known as a PARTICIPATING PHYSICIAN and receives a 5 percent bonus from Medicare. Physicians may charge more than Medicare's approved rates, up to certain limits. (See BALANCE BILLING [MEDICARE].) In 2005, according to the CENTERS FOR MEDICARE AND MEDICAID SERVICES, 98.8 percent of Medicare claims were assigned.

Assisted suicide

See SUICIDE, ASSISTED.

Association Health Plans (AHPs)

AHPs, as Association Health Plans are informally known, are a pooling mechanism to help small businesses afford health insurance coverage for their workers. Efforts to allow creation of AHPs, which would be overseen by the federal Department of Labor, began in Congress in 1996, and enabling legislation passed the House several times. But the Senate never approved any of the bills as of the middle of 2008, despite a hard-fought lobbying campaign that included the strong backing of President George W. Bush.

Small businesses have traditionally been the least likely of any employers to offer workers health coverage. According to the Kaiser Family Foundation and Health Research and Educational Trust, 60 percent of small firms (those with 3–199 workers) offered health insurance to their employees in 2006, compared with 98 percent of firms with two hundred or more workers. The smallest firms are the least likely to offer coverage—only 48 percent of companies with fewer than ten workers offered insurance that year.

Smaller firms are less likely to offer coverage than larger ones for a number of reasons. Premiums tend to be higher for small groups because administrative costs must be spread over fewer participants; wages may be lower, so premiums become a larger part of total compensation; and, as economist Len Nichols told the Senate Small Business Committee in 2003, "employers offer health insurance if they think they need to in order to successfully compete for workers. If they do not offer health insurance, by and large it is because they can attract and retain the workers they need without offering it."

The idea behind AHPs is to let "bona fide" trade, industry, or professional associations create plans that would allow any small business to enroll. "By joining together, small employers will enjoy greater bargaining power, economies of scale, and administrative efficiencies," said a 2002 U.S. Department of Labor white paper urging creation of AHPs. "In this way, AHPs will level the playing field and give participating small employers the same advantage as larger employers and employers who provide benefits through TAFT-HARTLEY PLANS."

Backers noted that one of the chief price advantages for AHPs is that they would not be subject to state insurance regulations or benefit mandates, such as requirements for coverage of specific services.

But opponents of AHPs, including the health insurance industry, state officials, and consumer groups, insisted that the lack of state oversight makes the plans

ripe for fraud. "While we acknowledge State regulation does increase costs, it exists to protect consumers," Kansas insurance commissioner Sandy Praeger told the Senate Small Business Committee in 2003. "Insurance is a complicated business, involving billions of dollars, with ample opportunity for unscrupulous or financially unsophisticated entities to harm millions of consumers," she said.

The National Governors Association warned that AHPs seemed too much like Multiple Employer Welfare Arrangements, often fraudulent, lightly regulated pooling mechanisms "that have left over 100,000 consumers with unpaid claims."

ATSDR

See AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY (ATSDR).

B

Balance billing (Medicare)

Also known as "extra billing," balance billing refers to an amount a physician charges a MEDICARE patient over and above Medicare's approved fee. As part of the 1989 budget reconciliation bill that overhauled Medicare's physician payment system (PL 101–239), Congress limited physician charges to no more than 115 percent of the Medicare-approved amount. Thus, if Medicare allows $100 for a procedure, a physician may charge the Medicare patient no more than $115. The patient, however, would be responsible for paying $35: the $20 required COINSURANCE payment (because Medicare covers only 80 percent of allowed physician fees) plus the $15 balance billing. Four of the ten standardized private MEDIGAP INSURANCE policies cover some or all of a physician's balance bills.

Baseline

This term is used in federal budgeting to measure the effect of proposed changes in tax and spending law. The CONGRESSIONAL BUDGET OFFICE (CBO), the official arbiter of cost estimates for federal legislation, periodically estimates how much the federal government will spend on various programs over the ensuing five or ten years, assuming no legislative changes are made. This estimate is the official "baseline." The CBO then uses that baseline to estimate how much a proposed change would add to or subtract from that projection. Programs that would increase federal spending (such as new benefits covered under MEDICARE or a tax cut) are counted as "cost" provisions; those that would lessen spending (such as reductions in inflation updates for doctors or hospitals under Medicare or new fees or increased premiums to be paid by patients) are counted as "savings" provisions.

BCBSA

See BLUE CROSS/BLUE SHIELD ASSOCIATION (BCBSA).

Beneficiary

In health care parlance, a person entitled to benefits is known as a beneficiary. For example, those entitled to MEDICARE or MEDICAID are beneficiaries. Legally, beneficiaries are also those designated by wills or trusts.

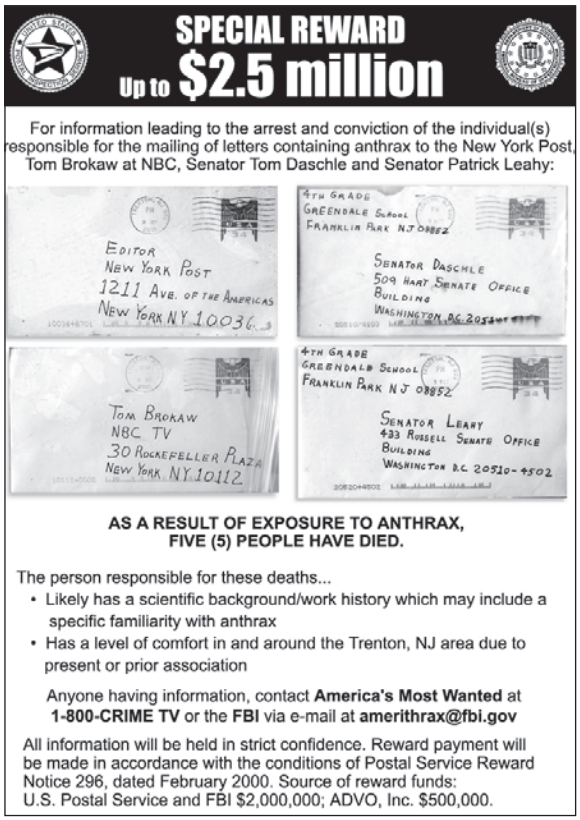
BioShield

See PROJECT BIOSHIELD.

Bioterrorism

Until October 2001, the idea that the United States would be attacked with a biological agent was largely theoretical. All that changed when someone began sending powdered anthrax bacteria through the mail. As of mid-2008 the identity of the person remained unknown, and whether the act was connected to the September 11, 2001, attacks on the World Trade Center and the Pentagon was still unclear.

Although the anthrax attacks took much of the country by surprise, the government had been preparing for



The FBI and U.S. Postal Service offered a $2.5 million reward for information about the person who sent anthrax-laced letters to two senators' offices and two media outlets in 2001.
Source: Federal Bureau of Investigation and U.S. Postal Service

such a possibility—as well as the possibility that someone would use diseases, including smallpox, tularemia, plague, and botulinim toxin, as weapons. Bioterrorism presented difficulties unlike other weapons of mass destruction, noted the Clinton administration in a May 2000 fact sheet: "Unlike explosions or chemical releases, a bioterrorist attack could be surreptitious and thus difficult and time-consuming to detect. Symptoms might not occur among victims for days or weeks, and those initially presenting themselves to physicians and clinics might be geographically dispersed. . . . Once detected, the situation could overwhelm traditional local health systems, faced not only with the tasks of caring for mass casualties but also with the demand of even larger numbers of people requiring preventive care."

That conclusion was based on an exercise called TOPOFF (short for "top officials"), a simulated release of the bacteria that causes plague, conducted in Denver, Colorado, in 2000, which spurred simulated riots by the fourth day. In a subsequent exercise, called Dark Winter, in which smallpox was the designated bioterror agent released in Oklahoma City, federal, state, and local officials found themselves unable to contain the resulting theoretical epidemic. By the sixth day, new smallpox cases were reported in fifteen states; by the twelfth day, the nation's entire supply of vaccine had been used up.

As early as May 1998, President Bill Clinton ordered federal agencies to take efforts to protect against and detect as soon as possible the use of unconventional weapons, particularly bioterrorism aimed at civilians. By fiscal 2000, the federal government was already spending $278 million on bioterrorism preparedness.

Congress's first effort aimed at directly addressing the possibility of a bioterrorist attack came with the passage in 2000 of the Public Health Threats and Emergencies Act (PL 106–505). The bill, part of a larger public health bill cleared just before the adjournment of the 106th Congress, authorized $540 million to help both local and federal agencies prepare to better detect and respond to disease outbreaks. The bill called for coordination of efforts with the HEALTH AND HUMAN SERVICES DEPARTMENT (HHS) and the Department of Defense to examine the nation's preparedness for a bioterrorist attack; required the HHS, the Federal Emergency Management Agency, and the U.S. attorney general to review the medical consequences of such an attack; and authorized health agencies to develop new vaccines for biological weapons. The measure also authorized $180 million for the CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC) to modernize its laboratories.

Following the anthrax attacks in 2001, Congress focused new attention on bioterrorism. "The anthrax outbreak is our fire bell in the night. We may not get another warning," said Rep. Jim C. Greenwood, R-Pa. But a series of hearings made clear the nation's local public health system was woefully underprepared. "Our traditional public health surveillance system—which in many parts of this country still relies on doctors mailing in postcards to their local public health departments—

is too limited with regard to what is reported, too slow to be effective, too late in the patient evaluation process, and too incomplete to meet our country's emerging needs in this area. It is the equivalent of relying on the pony express in the age of the world wide web," Greenwood said.

Numerous officials urged Congress to provide an infusion of funds to bolster frontline abilities to detect and respond to bioterrorism. Such spending, they noted, would be "dual-purpose," meaning that it would not only better prepare the nation to deal with a bioterrorist incident, but it would also improve the handling of naturally occurring infectious diseases.

Congress responded quickly. At the end of 2001, in an emergency spending bill, Congress appropriated $1.1 billion for state and local public health preparedness activities.

In May 2002 Congress followed up with a specific authorization for the money, with passage of the Public Health Security and Bioterrorism Preparedness and Response Act (PL 107–188). As signed into law by President George W. Bush on June 12, the bill authorized $1.5 billion to help state and local public health agencies improve communications and laboratory facilities and to train personnel to detect and respond to bioterrorist incidents. It called for $300 million for renovations at the CDC's main campus in Atlanta. Rep. Saxby Chambliss, R-Ga., had called the situation at the nation's preeminent public health agency "ridiculous," noting that many of the facilities dated back to the 1940s. "There are literally shower curtains hanging over million-dollar pieces of equipment to keep the rain from falling on them," he said. And the legislation authorized $1.5 billion for a national pharmaceutical stockpile with antibiotics and other medications in ready-to-deploy packs. The funds were also to be used to purchase enough smallpox vaccine for every American.

The bill incorporated another measure, originally passed unanimously by the House in October 2001, requiring laboratories and scientists who deal with any of thirty-six separate biological agents and toxins—including anthrax bacteria and the smallpox virus—to register with the Justice Department and meet strict security and safety requirements to be set by HHS. The transfer of such "biotoxins" had been regulated by the federal government, but no restrictions existed on who could possess them. "We have tighter control on the sale of guns than we do on the weapons of mass destruction," said HOUSE ENERGY AND COMMERCE COMMITTEE chair Billy Tauzin, R-La., during initial debate on the bill in October 2001. It prohibited certain classes of individuals—including convicted felons and foreign nationals who are not permanent residents—from possessing any of these substances. It also authorized the Department of Agriculture to develop similar regulatory schemes for agents that could severely injure crops or livestock.

The measure also addressed the potential for terrorism against the nation's food and water supply. It authorized $545 million for the FOOD AND DRUG ADMINISTRATION (FDA) and Agriculture Department to hire more inspectors to oversee imports of food and to devise new ways to protect domestic crops and livestock. It increased the FDA's authority to detain suspicious food and to gain access to records that would allow it to trace the origins of food-borne illnesses. The measure also authorized $100 million for the development of vulnerability analyses and emergency response plans for the nation's drinking water supply.

The following year, in 2003, Congress cleared legislation (PL 109–20) to compensate health and emergency workers injured or killed by side effects of the vaccine to protect against smallpox.

In December 2002 President Bush announced plans to vaccinate a half a million health care workers, firefighters, police, and other first responders against the disease considered among those most likely to be used in a bioterror attack: smallpox. But because the only available vaccine at the time used a live virus, it carried a significant risk of injury and a small risk of serious injury or death, especially in comparison with the mere theoretical risk of a smallpox attack. As a result, relatively few workers came forward to take the vaccine in the absence of available compensation. Congress and the Bush administration agreed that a compensation system needed to be set up to encourage better participation, but it took several months to reach a compromise on the levels. The final measure provided up to $50,000 per year in compensation for those permanently disabled by complications of

the vaccine, up to $262,000 in lost wages, with that same amount available to survivors of a worker who died from those complications.

In 2004 Congress created PROJECT BIOSHIELD (PL 108–276), an effort spurred by the Bush administration to create a government-guaranteed market for the development and ultimate purchase of countermeasures (vaccines, treatments, and means of detection) for potential bioterror agents such as anthrax, smallpox, and botulinim toxin. Because such products have little commercial value, companies have little financial incentive to pursue them. The law also allowed products not yet approved by the Food and Drug Administration to be used in cases of declared national emergency.

However, providing funding for the measure—$5.6 billion over ten years—proved easier than passing the authorizing legislation itself. Disputes arose over procurement rules, the lack of liability protection for firms making the countermeasures (which were likely to be tested almost exclusively in animals), and whether the incentives would prompt firms to develop needed products. The NATIONAL INSTITUTES OF HEALTH (NIH) provided funding for start-up research, and BioShield supplied funding for procurement, but particularly at issue was the gap between these caused by the absence of funding for clinical trials and other testing.

Project BioShield did turn out to be even more of a disappointment than lawmakers feared, which led to the next round of bioterrorism legislation passed by Congress late in 2006. That measure (PL 109–417) largely reauthorized the 2002 bioterror law, but it also made some key changes. The version signed by President Bush in December included language from a Senate-passed bill that sought to restore to the Department of Health and Human Services some public health authority that had been ceded to the Department of Homeland Security when that agency was created in November 2002. And it included language from a House-passed bill that basically took the idea of BioShield in-house, creating a new agency called the Biomedical Advanced Research and Development Authority, or BARDA. The new agency, charged with coordinating all federal efforts to research, develop, and produce bioterror countermeasures, would be modeled after DARPA, the Defense Department agency credited with helping spur the development of supercomputers and nanotechnology, among other things.

Blue Cross/Blue Shield Association (BCBSA)

Thirty-nine independent Blue Cross and Blue Shield member plans, which were originally (but are no longer exclusively) not-for-profit, comprise this trade association. The "Blues," as they are known, collectively covered 99 million people in all fifty states, the District of Columbia, and Puerto Rico in 2007—roughly one of every three Americans. The Blue Cross/Blue Shield plan covering 4.6 million federal workers and dependents is the largest privately underwritten health contract in the world. Although they have been traditionally associated with offering FEE-FOR-SERVICE care, Blue Cross/Blue Shield plans are also collectively the nation's largest provider of MANAGED CARE services, with 87 percent of subscribers belonging to a managed care network of some sort. (The Blues operate health maintenance organizations, preferred provider organizations, and point of service plans.) The Blues are also the largest processor of MEDICARE claims, a service provided under contract to the federal government. In fiscal 2005 Blues' plans processed an estimated 90 percent of hospital and other Medicare Part A claims and 72 percent of physician and other outpatient (Medicare Part B) claims. (See HEALTH MAINTENANCE ORGANIZATION [HMO], PREFERRED PROVIDER ORGANIZATION [PPO], and POINT OF SERVICE [POS] PLAN.)

The Blue Cross/Blue Shield Association (BCBSA) owns the names *Blue Cross* and *Blue Shield,* licenses their use to member plans, and enforces quality and financial standards, although each plan is independently owned and operated.

Among the nation's oldest health insurers, the Blues were founded in 1929, when Dallas's Baylor University devised the first Blue Cross plan to guarantee school teachers twenty-one days of hospital care for $6 per year. Blue Cross plans were largely begun by hospitals because the Great Depression of the 1930s had left hospital care out of financial reach of most Americans. Al-

though the early plans were offered by individual hospitals in competition with each other, ultimately the American Hospital Association stepped in to facilitate community-wide plans (it registered the Blue Cross trademark). Blue Shield plans, created to cover physician services, were begun in the Pacific Northwest, where employers, often in remote areas such as logging camps, contracted with groups of doctors to provide health services to their workers. As provider-sponsored plans, the Blues pioneered payments based on "usual and customary" charges, which Medicare would emulate on its creation.

In many but not all cases, Blue Cross and Blue Shield plans have merged to provide comprehensive health care coverage. The Blue Cross and Blue Shield associations merged in 1982, forming the current group. California is a notable exception, where Blue Cross of California and Blue Shield of California compete against each other, although both plans offer hospital and physician care.

Originally not-for-profit, the Blues benefited from special statutes passed by many states, which granted them preferential tax treatment in exchange for their agreeing to perform certain community service roles, such as insuring individuals or groups that commercial insurers would not cover and for their adopting COMMUNITY RATING policies, so that people would pay the same premium regardless of their health status. The federal government also made the Blues tax-exempt, although that exemption was ended with passage of the 1986 Tax Reform Act (PL 99–514), in recognition of the fact that many Blues plans were taking on characteristics of commercial insurers, including, in some cases, conversion from nonprofit status. (The largest conversion so far was that undertaken by Blue Cross of California, which became WellPoint Health Networks in 1996. A California law requiring built-up assets to be left in a nonprofit entity as part of the conversion process led to the creation of two foundations, to which Blue Cross left $3 billion. Overnight, the foundations became the nation's sixth-largest philanthropies, collectively. In 2004 WellPoint merged with Anthem, another for-profit conversion of Blues plans, to create the largest single insurer in the nation.)

Boren amendment

Originally passed in 1980 and named for its sponsor, Oklahoma Democratic senator David L. Boren, the Boren amendment sought to ensure that states provide adequate payments to nursing homes and other long-term care facilities, including intermediate care facilities for mentally retarded individuals. In 1981 budget reconciliation legislation (see BUDGET RECONCILIATION LEGISLATION AND HEALTH CARE), Congress extended the requirement to hospitals. It required not only that payment be "reasonable and adequate" to cover the costs of an "efficiently and economically operated facility," but also that the care provided meet applicable state and federal laws, regulations, and quality and safety standards. In 1990 the U.S. Supreme Court, in *Wilder v. Virginia Hospital Association,* upheld the right of health care providers to sue states under the Boren amendment for insufficient payment levels.

As part of the 1997 Balanced Budget Act (PL 105–33), Congress repealed the Boren amendment. In its place it required a public process under which proposed rates, methodologies underlying them, and reasons for them would be published and made available for public comment.

Budget reconciliation legislation and health care

Since 1980, budget reconciliation bills have been a principal way—if not the principal way—Congress has shaped health policy in general and made alterations to the MEDICARE and MEDICAID programs in particular. Technically, the purpose of the budget reconciliation bill is to reconcile the terms of the annual budget resolution with existing law for permanently authorized programs such as Medicare and Medicaid. In most cases, fulfilling that purpose means changing the terms of the programs to reduce their costs. But sometimes the budget resolution assumes additional spending, as in the case of expansions in Medicaid eligibility or new preventive benefits for Medicare.

Making policy using reconciliation is not ideal, according to lawmakers who have been involved in crafting the bills. They note that such policy changes are driven by the numbers—usually savings targets imposed by the budget resolution. More than once, say congressional aides, at the end of negotiations over a difficult reconciliation bill, staff would "run the numbers," see how far from their savings target they were, then back-fit a cut to meet the target, with more attention to the savings achieved than to the policy objective involved. Reconciliation is also "obsessed with the short-term," as one lawmaker put it, giving legislators little chance to think about big-picture health policy issues.

However, reconciliation has had some significant advantages. Aides note it has sometimes enabled legislators to make decisions that represented good policy but not-so-good politics, such as trimming reimbursements to health care providers that are also major contributors to legislators' campaign war chests. A reconciliation bill is also protected legislation, with amendments significantly limited in the House and both amendments and debate time limited in the Senate (it is one of the few bills that cannot be filibustered under Senate rules). Reconciliation is also a must-pass bill for Congress and usually a must-sign bill for the president. (President Bill Clinton proved the exception to that rule in his 1995 standoff with Congress over both the reconciliation and appropriations bills that year. Failure to sign the appropriations measures resulted in a temporary shutdown of the federal government. Clinton vetoed the reconciliation bill, largely because of changes Republicans wanted to make to Medicare and Medicaid. That measure eventually died, although pieces of it were included in the next reconciliation bill, the 1997 Balanced Budget Act.) Thus, getting a policy initiative into a reconciliation bill all but guarantees it will become law.

Reconciliation is all about meeting budget targets that add to or subtract from a budget BASELINE, or estimate of what a program will cost in the future, barring legislative changes. Legislators over the years have developed a series of budget tricks to meet reconciliation targets. (Budgeteers have closed some—though not all—of the loopholes allowing these practices. But the practices are listed below to illustrate why many of the reconciliation bills were shaped as they were.) On the savings side the techniques included:

• The *golden goose,* a provision that Congress extends only as long as required to achieve savings in a particular budget cycle, usually a single year. If such a cut were permanent, it would be factored into the baseline and could not be used to show savings in future years—thus the nickname, which comes from the provision's ability to lay annual "golden eggs" of savings. Probably the most often used golden egg was the continuing reimposition of the requirement that Medicare Part B premiums be set to cover 25 percent of the program's costs. During years of high health care inflation, the provision had the effect of boosting premiums for beneficiaries and thus saving federal dollars. (Without the provision the Part B premium would have reverted to a level dictated by underlying law, rising by either the amount needed to cover 50 percent of the program's cost or the percentage cost-of-living allowance [COLA] increase in social security benefits, whichever was lower.) Ironically, by the 1990s, when health inflation slowed, the 25 percent rule became a money loser, because the premium at 25 percent of program costs would have been lower than the premium as increased by the Social Security COLA. In 1997, in the Balanced Budget Act (PL 105–33), Congress made the 25 percent rule permanent.

• The *noncut cut,* the practice of holding inflation increases for doctors, hospitals, and MANAGED CARE plans below the predicted inflation rate. For example, hospital payments are updated annually according to price increases in a typical market basket of goods and services hospitals purchase. In a reconciliation bill, Congress would typically provide an increase on the order of "market basket minus one percentage point," so if that year's market basket increase were scheduled to be 3.5 percent, hospitals would receive a 2.5 percent increase instead. Because they had reduced the baseline, these increases were scored as cuts, even though providers still received payment increases. It was just these sorts of cuts that led Republicans in 1995 to insist that they were not cutting Medicare by $270 billion at all, as Democrats had charged, but merely decreasing scheduled increases. Such noncut cuts sometimes gave rise to "re-

verse pork," in which an interest group sought to minimize its losses compared with those of other groups. Rural hospitals, for example, which are more financially dependent on Medicare than are other hospitals, frequently managed to obtain smaller decreases in their inflation increases.

• *Payment shifts,* a technique much favored in the early years of reconciliation (which were essentially blocked in the 1987 "fix" to the Gramm-Rudman-Hollings budget enforcement bill [PL 100–119]). This technique pushed payments due in one fiscal year to the next. In the 1982 Tax Equity and Fiscal Responsibility Act (TEFRA, PL 97–248), for instance, Congress suspended hospital payments for the last six weeks of fiscal years 1983 and 1984, pushing those outlays into the next year. Similarly, Congress on more than one occasion ordered the HEALTH CARE FINANCING ADMINISTRATION (HCFA), which oversaw Medicare and Medicaid, to slow claims payments, thus delaying some bills.

Just as lawmakers had techniques to make savings look larger, they also developed ways to make new spending look smaller. Those included:

• The *three-quarters rule,* designed to make outlays for new programs look as small as possible. Starting a new program one, two, or three quarters into a fiscal year minimizes outlays in that year and hence, for the purposes of that year's budget, scores lower. For example, the fiscal year 1988 bill, the Omnibus Budget Reconciliation Act of 1987 (OBRA '87, PL 100–203), authorized states to offer Medicaid coverage to pregnant women and young children with incomes of up to 185 percent of the poverty threshold, but not beginning until July 1, 1988, the first day of the last quarter of the fiscal year. That ensured that Medicaid's federal matching money would not begin to flow until the year's final quarter. In extreme cases lawmakers have resorted to the "September 30 option," in which a new program is begun on the final day of a fiscal year, thus raising the baseline by only one day's worth of spending.

• The *stretch-out,* or phasing in of a program, which can make it appear less costly. When Congress in the fiscal year 1988 law required states to increase payments to hospitals that serve a disproportionate share of Medicaid and low-income patients, for example, it required that the higher rates (with their higher federal match) be phased in over three years. (See DISPROPORTIONATE SHARE HOSPITAL [DSH] PAYMENTS [MEDICARE AND MEDICAID].)

• The *option-mandate,* a spending-reducing technique that transforms this year's voluntary program into next year's requirement. In Medicaid, for instance, allowing instead of requiring a state to extend coverage for a particular service or to a particular population is less expensive, because not all states will exercise the option. And if that option later becomes a mandate, it will still look less costly, because the cost for states that have already exercised it on their own will have already been factored into the baseline. The option-mandate technique was the key to Medicaid expansions for low-income pregnant women and children throughout the 1980s.

Here is a thumbnail history of major reconciliation bills, including their nicknames and some of the most important health policy changes in them.

• 1980. Unnamed, fiscal year 1981 (PL 96–499). Although less sweeping than reconciliation bills that would follow, this measure, among other things, authorized Medicare reimbursement for outpatient surgery and diagnostic tests performed subsequent to hospitalization. It also first used the payment-shifting technique of achieving budget savings by postponing Medicare payments to hospitals—in this case by six weeks.

• 1981. Unnamed, fiscal year 1982 (PL 97–35). In addition to making the largest Medicaid cut of the Reagan era ($2.9 billion over three years), this bill created the so-called Section 2176 waiver, which allowed states to obtain permission to use Medicaid to fund home- or community-based services for those who would otherwise require institutional care.

• 1982. Tax Equity and Fiscal Responsibility Act (TEFRA), fiscal year 1983 (PL 97–248). Although TEFRA, one of two budget reconciliation measures passed in 1982 (the other made spending reductions in agriculture, veterans', and other programs), produced the most dramatic Medicare savings of any reconciliation bill in the 1980s ($13.3 billion over three years), it also included the most

sweeping structural expansions. The bill first authorized contracts between Medicare and health maintenance organizations to enroll Medicare beneficiaries, allowed for the first time Medicare payment for HOSPICE services for terminally ill individuals, required federal employees to pay the Medicare payroll tax, and replaced the often-criticized Professional Standards Review Organization program with physician-run PEER REVIEW organizations. (See HEALTH MAINTENANCE ORGANIZATION [HMO].) The bill was also the first to require that the Medicare Part B premium be set to cover 25 percent of the program's costs, a provision that would be reenacted a half-dozen times before it was made permanent in 1997.

• 1984. Deficit Reduction Act (DEFRA), fiscal year 1984 (PL 98–369). Although DEFRA achieved fully a third of its $6.1 billion in Medicare savings by freezing physician fees, it created the PARTICIPATING PHYSICIAN (MEDICARE) program to encourage physicians to agree to accept Medicare's approved fee as payment-in-full for all Medicare patients' covered services. DEFRA was also the first of a series of reconciliation bills to expand eligibility for Medicaid, in this case by requiring states to extend pregnancy-related services to single, poor women pregnant with their first child (who were previously ineligible because they had no "dependent children") as well as to provide basic coverage to children up to age five in two-parent families with incomes at or below the state's welfare eligibility level.

• 1986. Consolidated Omnibus Budget Reconciliation Act of 1986 (COBRA), fiscal year 1986 (PL 99–272). COBRA, held up by non–health-related issues and thus not enacted until more than halfway through fiscal year 1986, broke ground on several fronts. It ordered creation of the PHYSICIAN PAYMENT REVIEW COMMISSION (PPRC, replaced in 1997 by the MEDICARE PAYMENT ADVISORY COMMISSION [MedPAC]), an independent board to make recommendations on Medicare physician payment issues. It also ordered all state and local employees hired after March 31, 1986, to pay the Medicare payroll tax. It barred PATIENT "DUMPING" by threatening hospitals with expulsion from Medicare if they failed to provide emergency department care to those without the ability to pay. And it took the first steps to address the problem of the uninsured by requiring employers to continue existing group health coverage for eighteen months for laid-off employees and to allow spouses and dependents who would otherwise lose coverage because of the death of or divorce from a worker to purchase coverage at the group rate through the employer. In Medicaid, COBRA required states to provide pregnancy-related services for women in two-parent families in which the principal wage earner was unemployed (such coverage had been optional).

• 1986. Omnibus Budget Reconciliation Act of 1986 (OBRA '86), fiscal year 1987 (PL 99–509). In the second of two reconciliation bills approved in 1986, Congress responded to a report from its organ-transplant task force by requiring hospitals, as a condition of participation in Medicare or Medicaid, to routinely make a request to the next of kin of a deceased patient for ORGAN DONATIONS AND TRANSPLANTS and authorized a year's worth of antirejection drugs for Medicare beneficiaries who have organ transplants. OBRA '86 also created "maximum allowable actual charge" limits (known as MAACs) for nonparticipating physicians in Medicare. The limits were aimed at preventing physicians from avoiding a Medicare fee freeze by passing fee increases along to patients, while at the same time allowing physicians who had been undercharging patients relative to their colleagues to begin to raise their fees. For Medicaid, it gave states the option of covering pregnancy-related services for pregnant women as well as programs for senior citizens and children up to age five (a year at a time) in families with incomes below poverty.

• 1987. Omnibus Budget Reconciliation Act of 1987 (OBRA '87), fiscal years 1988 and 1989 (PL 100–203). The use of reconciliation to advance non–budget-related proposals reached a pinnacle when congressional conferees appended to this measure a bill overhauling federal regulation of nursing homes that served Medicare and Medicaid patients. Also included in OBRA '87 were provisions to implement a 1986 law (PL 99–660) creating a no-fault compensation system for families of children with severe adverse reactions to vaccines to prevent childhood diseases. The bill allowed states to extend Medicaid coverage to pregnant women and infants in families with incomes of up to 185 percent of poverty.

• 1989. Omnibus Budget Reconciliation Act of 1989 (OBRA '89), fiscal year 1990 (PL 101–239). OBRA '89 outdid even OBRA '87 in its reach. It included a complete overhaul of Medicare's physician payment system, replacing a system based on doctors' historical charges with one based on the skill, time, and training needed to provide specific services, as well as volume controls to brake the then fastest growing portion of the program. The bill also imposed the first of two efforts to prevent physician self-referrals, the practice of doctors sending patients to laboratories or other facilities in which the doctor had an ownership interest (see SELF-REFERRAL CURBS). In addition, the measure created the federal AGENCY FOR HEALTH CARE POLICY AND RESEARCH (AHCPR) to research and promote quality and effectiveness in the health care system. In Medicaid, the bill required states to provide coverage to pregnant women (for pregnancy-related services) and to infants up to age one in families with incomes of up to 133 percent of the federal poverty line. That requirement represented an increase from that included in the 1988 MEDICARE CATASTROPHIC COVERAGE ACT (PL 100–360) for coverage of those populations in families with incomes at or below poverty. The measure also spelled out minimum requirements for coverage under the EARLY AND PERIODIC SCREENING, DIAGNOSTIC, AND TREATMENT (EPSDT; MEDICAID) program for children up to age twelve. The bill required that states cover treatment for conditions discovered through EPSDT, even if the state's Medicaid program did not otherwise cover such services. And the measure required state Medicaid programs to cover services provided by federally qualified health centers and to pay those centers 100 percent of their "reasonable costs."

• 1990. Omnibus Budget Reconciliation Act of 1990 (OBRA '90), fiscal year 1991 (PL 101–508). OBRA '90, the bill that emerged from the famous "budget summit" between Congress and the Bush administration after which President George H. W. Bush renounced his "no new taxes" pledge, included the largest yet Medicare reductions—an estimated $44.2 billion over five years. But that reduction was smaller than the amount originally negotiated by summiteers. The first effort was rejected in the House, and the measure was hastily rewritten. The bill also included a major benefit expansion for Medicare. For the first time, the program would cover a strictly preventive service—mammograms to detect breast cancer. The measure also required Medicare and Medicaid providers to inform patients about their rights under state law to execute LIVING WILLS or other ADVANCE DIRECTIVES about their care should they become unable to express their wishes. Also included in the measure was a major overhaul of federal regulation of MEDIGAP INSURANCE policies to supplement Medicare coverage. In Medicaid, the measure initiated a program requiring drug manufacturers to grant the same discounts to Medicaid as they provided for other bulk purchasers, such as managed care organizations and the Department of Veterans Affairs. And the bill capped off a half-dozen years of Medicaid coverage expansions by requiring states to cover, a year at a time, all children born after September 30, 1983, in families with incomes below the federal poverty line. The bill expanded mandatory Medicaid help with Medicare cost-sharing for more low-income elderly individuals, and it authorized two new, optional programs to help states pay for home- and community-based care for frail elderly people and for mentally disabled people and others with developmental disabilities.

• 1993. Omnibus Budget Reconciliation Act of 1993 (OBRA '93), fiscal year 1994 (PL 103–66). The pivotal bill that passed with only Democratic votes in the summer of the first year of Bill Clinton's presidency included the largest-to-date cuts in Medicare—$55.8 billion over five years. The measure contained the second round of prohibitions against physician self-referrals, as well as made it harder for individuals to divest themselves of their assets to qualify for Medicaid-covered nursing home care. It also created a new—and controversial—$1.8 billion child immunization program that effectively federalized the provision of vaccines for low-income and uninsured children.

• 1997. Balanced Budget Act of 1997, fiscal year 1998 (PL 105–33). The reconciliation bill to end all reconciliation bills—the first to anticipate a balanced federal budget—dramatically changed both Medicare and Medicaid. In addition to making cuts in Medicare nearly as large as all previous cuts combined—$115 billion over

five years—the measure ordered the Health Care Financing Administration to create updated payment systems for home health care, nursing home care, and hospital outpatient services. It created a new Medicare Part C, called MEDICARE+CHOICE, to encourage beneficiaries to join private managed care and other health plans. And it added a raft of new preventive benefits to Medicare in an effort to begin to update the program's meager benefit package. For Medicaid, the program continued a crackdown on what federal lawmakers said was state abuse of a program allowing special payments to hospitals that serve a disproportionate share of Medicaid and low-income patients. (See DISPROPORTIONATE SHARE HOSPITAL [DSH] PAYMENTS [MEDICARE AND MEDICAID].) The measure also made it easier for states to move Medicaid beneficiaries into managed care plans. And it created a $48 billion program to help cover up to half of the nation's estimated ten million uninsured children (see STATE CHILDREN'S HEALTH INSURANCE PROGRAM [SCHIP]).

• 2006. Deficit Reduction Act of 2005, fiscal year 2006 (PL 109–171). The first major reconciliation bill in nearly a decade passed in a flurry of partisan rancor, after Democrats who were unanimously opposed to the bill managed to delay its passage for some six weeks. The measure, signed by President George W. Bush on February 8, 2006, cut $6.4 billion from Medicare over five years and, in a major change from previous reconciliation bills, also cut Medicaid, by nearly $5 billion. The Medicaid provisions were particularly controversial and included changes to rules governing how seniors could dispose of assets and still qualify for Medicaid-paid nursing home care. The bill allowed states to increase cost-sharing for low-income Medicaid beneficiaries, and it required Medicaid applicants to prove their citizenship using original birth certificates or other documents.

C

Cafeteria benefits plans

Such plans, allowed by a 1978 law, permit employees to select from a "menu" of benefits provided by an employer and allow them to customize their compensation to their individual needs. For example, a worker with no dependents might not need life insurance but might prefer tuition aid or other educational assistance. Child or elder-care benefits are often offered under cafeteria plans, as well as health care coverage. Technically, cafeteria plans must allow workers to choose at least one taxable benefit, such as cash (including paid vacation leave), and one or more nontaxable benefits, such as life or health insurance.

California Public Employee Retirement System (CalPERS)

The California Public Employee Retirement System (CalPERS) provides pension and health coverage to more than 1.2 million state and local employees, retirees, and dependents, making it, after the FEDERAL EMPLOYEE HEALTH BENEFITS PLAN (FEHBP) and General Motors, the nation's third largest single purchaser of health care. CalPERS's health program, begun in 1962 to cover state workers and expanded in 1967 to cover local government employees as well, is considered a national model of group health negotiating and purchasing. It was one of the first large groups to adopt MANAGED COMPETITION, giving workers a broad choice of plans and negotiating with plans to increase quality and decrease premiums. With more than eleven hundred participating public employers and an estimated $5 billion in premiums paid in 2007, CalPERS has significant bargaining power over plans and has not been shy about using it. However, CalPERS was one of the earliest groups of plans to experience the resurgence of health inflation in the late 1990s.

CalPERS

See CALIFORNIA PUBLIC EMPLOYEE RETIREMENT SYSTEM (CalPERS).

Capitation

From the Latin for "head," capitation in health care refers to the practice of paying for medical care on a preset, per-head basis. Under capitation systems a physician or medical group generally receives a per-month payment intended to cover all of a patient's medical care for that period. If the patient needs more care, the capitated entity (the doctor or medical group) has to make up the difference itself; if the patient needs less or no care, the entity gets to keep the difference. *Partial capitation* is a payment mechanism in which the payer makes the medical providers responsible for only a subset of all medical care. A typical example is making a group of doctors financially at risk for all physician care but not for hospital or other care. *Global capitation* makes the capitated entity liable for all care. The theory behind capitation is that the payments for patients who need little care will offset the losses for those who need more than the capitated amount, while eliminating the incentive for practitioners to do more than may be necessary to increase their income. Critics of capitation

point out that although it eliminates the incentive to overserve, it simultaneously creates one to underserve because the capitated entity gets to keep money not spent on patient care.

Carrier (Medicare)

Carriers are private insurance companies that contract with MEDICARE to administer Medicare Part B services. Carriers make coverage and payment decisions under guidance from the CENTERS FOR MEDICARE AND MEDICAID SERVICES (formerly the HEALTH CARE FINANCING ADMINISTRATION [HCFA]), the agency of the federal HEALTH AND HUMAN SERVICES DEPARTMENT (HHS) that oversees Medicare. Carriers also act as beneficiaries' first contact with questions or complaints and help police the Part B program for fraud. Part A services are handled by an INTERMEDIARY (MEDICARE).

Carve-out organizations

These organizations contract with MANAGED CARE plans to provide a specialized set of services. *Carve-outs,* as they are called, may themselves be managed care entities or may provide services on a FEE-FOR-SERVICE basis. The term comes from the fact that the services are carved out of coverage by the patient's insurance plan, which delegates the care in question (for a fee, of course) to the carve-out organization. Carve-outs, which maintain their own networks and administrative operations, are most common in mental health and in pharmacy benefits.

Catastrophic illness

Definitions vary widely for what type of illness can be considered catastrophic, but policy analysts agree that it is the cost, not the nature of the malady, that makes a medical event catastrophic. One definition labels as catastrophic the average medical expenses incurred by the top 1 percent of the population. Others say it is any illness or condition that requires a family to spend more than 10 percent of its annual take-home income out-of-pocket for health care expenses, regardless of whether it has insurance or not. Families with insurance that could still leave them at risk for having to spend more than 10 percent of their income for a serious illness are considered UNDERINSURED. (See also MEDICARE CATASTROPHIC COVERAGE ACT.)

Categorical eligibility

This phrase, used in MEDICAID, describes people who are eligible for the program because they are members of a specific group or category, such as children, elderly individuals, or disabled individuals. It is because of Medicaid's categorical eligibility standards that the program only covers roughly half of all Americans who live in poverty. For example, a single, childless man who is not disabled cannot generally qualify for Medicaid no matter how poor, because he does not fit into any of the program's categories. A pregnant woman with income below 133 percent of poverty, meanwhile, is categorically eligible for Medicaid.

CBO

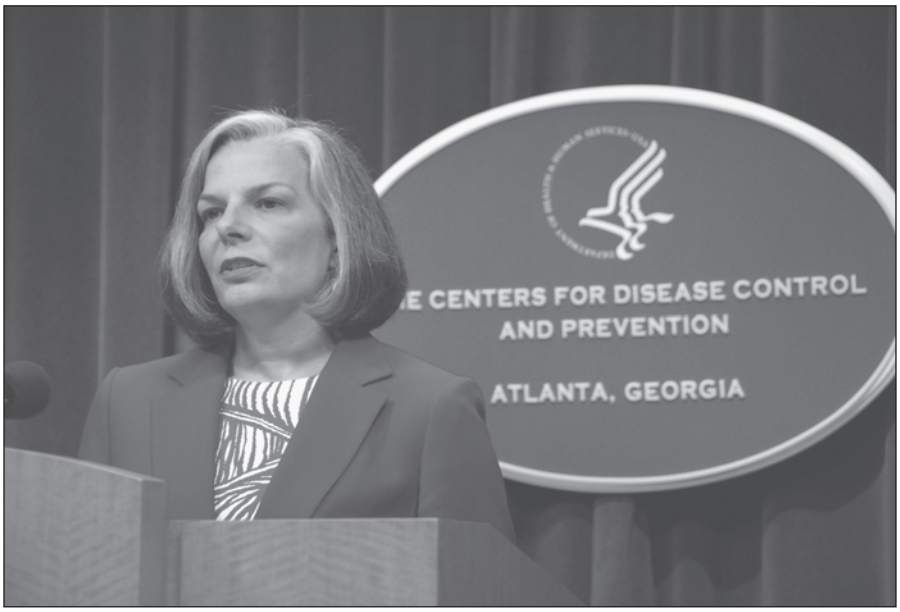
See CONGRESSIONAL BUDGET OFFICE (CBO).

CDC

See CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC).

Centers for Disease Control and Prevention (CDC)

The Atlanta, Georgia–based Centers for Disease Control and Prevention (CDC) is the agency of the U.S. PUBLIC HEALTH SERVICE responsible for promoting health and preventing disease, injury, and premature death. With a



CDC director Dr. Julie Gerberding addresses the press in 2007 on the CDC's response to a case of drug-resistant tuberculosis. The case received considerable attention due to the supposed "extensively drug-resistant" nature of the strain, the efforts to isolate the infected person, and the potential exposure of others due to the patient's international travel. *Source: Centers for Disease Control and Prevention/James Gathany*

workforce of eighty-nine hundred and a fiscal year 2008 budget of $6.48 billion, the CDC is the nation's preeminent public health agency. It was renamed in 1992 legislation, from the Centers for Disease Control.

The CDC dates back to 1946, with the establishment of the Communicable Disease Center in the Office of Malaria Control in War Areas in downtown Atlanta. CDC's original mission was to combat malaria (still common in the southern United States at that time), typhus, and other communicable diseases. A year later CDC officials provided disaster relief in the wake of chemical explosions in Texas that killed hundreds, after which the agency was designated as the Public Health Service agency to respond to disasters or epidemics. In 1951 the CDC established its most famous operating unit, the Epidemic Intelligence Service (EIS), which draws young physicians from around the nation and deploys them around the world to track down the source of communicable disease outbreaks.

In 2004 the CDC was reorganized in an effort to streamline what had been fifteen operating units performing research, education, and disease surveillance activities. The new structure created an Office of the Director, kept separate the National Institute for Occupational Safety and Health, and redistributed the remainder of CDC's activities into six other coordinating centers:

• The Coordinating Center for Environmental Health and Injury Prevention incorporates the National Center for Environmental Health, the AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY (ATSDR), and National Center for Injury Prevention and Control.

• The Coordinating Center for Health Information Services oversees the National Center for Health Marketing, which seeks to use marketing techniques to promote public health messages; the National Center for Health Statistics, and the National Center for Public Health Informatics. Health informatics involves the use of computer science and technology in health care.

• The Coordinating Center for Health Promotion includes the National Center for Birth Defects and Developmental Disabilities, the National Center for Chronic Disease Prevention and Health Promotion, and the Office of Genomics and Disease Prevention.

• The Coordinating Center for Infectious Disease brings together the National Center for HIV/AIDS, Viral Hepatitis, Sexually-Transmitted Disease, and TB Prevention; the National Center for Immunization and Respiratory Diseases; the National Center for Zoonotic,

Vector-Borne, and Enteric Diseases; and the National Center for Preparedness, Detections, and Control of Infectious Diseases.

• The Coordinating Office for Global Health provides health resources of the CDC internationally.

• The Coordinating Office for Terrorism Preparedness and Emergency Response oversees, among other things, the new responsibilities given to the agency in the wake of the September 11, 2001, attacks and the anthrax attacks that followed in October 2001.

Centers for Medicare and Medicaid Services

On July 1, 2001, the HEALTH CARE FINANCING ADMINISTRATION (HCFA)—the nemesis of countless health care providers and state and federal officials—got a new name, the Centers for Medicare and Medicaid Services (CMS). HEALTH AND HUMAN SERVICES DEPARTMENT (HHS) secretary Tommy G. Thompson said when the new agency was launched that it would strive to "encourage innovation, better educate consumers about their options, and be more responsive to the health care needs of Americans."

In 2007 the agency controlled three programs that together served more than 92 million Americans—MEDICARE, MEDICAID, and the STATE CHILDREN'S HEALTH INSURANCE PROGRAM (SCHIP). Together the programs accounted for more than $636 billion in health spending in 2007.

CMS is also responsible for overseeing the 1988 CLINICAL LABORATORY IMPROVEMENT ACT (CLIA) (PL 100–578), which called for federal regulation of some 175,000 nonresearch laboratories that perform testing on humans, as well as insurance regulation functions of the 1996 HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA) (PL 104–191).

Certified nurse midwife

An ADVANCED PRACTICE NURSE who provides routine gynecological and low-risk obstetrical care, including prenatal, labor-and-delivery, and postpartum care, a certified nurse midwife (CNM) may prescribe drugs in forty-eight states. An estimated six thousand CNMs are in practice in the United States, according to the American College of Nurse-Midwives. In 2004 they delivered nearly 308,000 babies, representing 11 percent of that year's vaginal births. CNMs study an average of 1.5 years beyond nursing school.

Certified registered nurse anesthetist (CRNA)

This type of ADVANCED PRACTICE NURSE specializes in anesthesia. Certified registered nurse anesthetists (CRNAs) practice the oldest of the advanced nursing specialties. An estimated thirty-six thousand CRNAs, who have completed two to three years of advanced training beyond the required four-year bachelor's degree, work in hospitals, dental offices, and outpatient surgery centers and administer anesthetics to an estimated twenty-seven million patients in the United States each year. They are the sole providers of anesthesia in 85 percent of rural hospitals. In most, though not all, cases, CRNAs work under the direct supervision of a physician–anesthesiologist. Whether CRNAs should be able to work independently has been a source of dissension in the medical community in recent years. Physicians say CRNAs are not well enough trained to deal with emergencies that occur with anesthetized patients; CRNAs respond that physicians' concerns are motivated by the potential loss of income.

Child Custody Protection Act

First introduced in Congress in 1998, the act (which failed to clear Congress that year) would have made it a crime for a person to accompany a minor across state lines for an ABORTION in contravention of the girl's home state PARENTAL INVOLVEMENT LAWS. Violators could have been subject to fines of up to $100,000 and a year in prison. Critics of the measure pointed out that it even made it illegal for a parent to accompany the girl if the

home state law required notification or consent of both parents (which several state laws did).

The measure was inspired by a case in Pennsylvania, where a woman named Rosa Hartford was convicted of violating that state's Interference with Custody of a Minor Act by taking her eighteen-year-old son's thirteen-year-old girlfriend across state lines to Binghamton, New York, for an abortion. Pennsylvania law required at least one parent's consent or a judge's permission for a minor to have an abortion; New York had no parental involvement law.

The measure was also intended to be abortion opponents' follow-up to the Partial Birth Abortion Ban Act, which had over the previous three years successfully shifted the focus of the abortion debate from issues on which the public largely supported abortion rights to those on which sympathies were against the procedure (see PARTIAL-BIRTH ABORTION). Parental involvement in a minor's abortion decision had long been an area of overwhelming public support.

Proponents of the measure insisted that regulating interstate activities was the federal government's natural role and pointed to Yellow Pages ads for clinics proclaiming "no parental consent required" in states without parental involvement laws. Opponents said that the act, however, would endanger, not protect, minors with unintended pregnancies. The bill, opponents complained, would force young women to travel alone to another state or go much farther away from home in their own state—causing unnecessary delays in obtaining the procedure that increased the risks to their health once the procedure was performed. Other opponents, including the Clinton administration, pointed out that the law made no exceptions for other adult family members to accompany a girl to have an out-of-state abortion. During debate on the measure in the House and Senate Judiciary Committees, amendments to allow other close relatives to be exempt from the ban were defeated.

In spite of strong opposition, however, the measure did enjoy significant support. President Bill Clinton said he would sign it if "it is carefully targeted at punishing nonrelatives who transport minors across state lines for the purpose of avoiding parental involvement requirements." It passed the House on July 15, 1998, by 276–150. But that vote was short of the two-thirds supermajority needed to override the veto promised by the president.

President Clinton, however, did not get a chance to veto the measure in 1998. The Senate took up the bill in September, but it got caught up in an unrelated fight over Senate Republicans' blocking from floor consideration legislation to regulate the practices of MANAGED CARE plans (see PATIENTS' BILL OF RIGHTS [PboR]). When Democrats tried to append their managed care measure to the abortion-travel bill, sponsors of the measure balked. On September 22, a vote to cut off debate on the abortion bill failed by 54-45, six short of the total needed for cloture. With the session approaching its conclusion and most of the appropriations bills still awaiting consideration, then Senate majority leader Trent Lott, R-Miss., pulled the bill, killing it for the rest of the year. Backers of the legislation came right back in 1999. The House on June 30 passed the Child Custody Protection Act by 270-159. The Senate, however, never considered the measure that year.

The House again passed the bill in 2002, on April 17, by 260-161. The Senate, however, by then under Democratic control, declined to bring the measure to the floor for a vote.

In the 109th Congress, it appeared that Congress could have passed the bill, and President George W. Bush was ready to sign it. But abortion opponents may have overreached. The House passed its version on April 27, 2005, by 270-157. The bill contained a new provision not included in previous versions. It would have imposed a twenty-four-hour waiting period for minors obtaining abortions in states other than their own. The waiting period was ostensibly for the physician to notify the minor's parents but would have applied even if a parent accompanied the minor and consented to the abortion in person.

The Senate passed its version of the bill on July 25, 2006, by 65-34. It was the first time the measure had been approved by that chamber. But it did not include the waiting period provision of the House bill, and Democrats were able to use procedural tactics to block a House-Senate conference. Instead of passing the Senate bill and sending the measure to President Bush for his

signature, the House opted to essentially re-pass the version it passed before. This time the vote, taken on September 26, 2006, was 264-153. With time running out before Congress was to adjourn for the mid-term elections, the Senate proved unable to muster the sixty votes needed to invoke cloture on the bill when it returned to that chamber. So, by 57-42 on September 29, the measure died.

Children's Health Insurance Program

See STATE CHILDREN'S HEALTH INSURANCE PROGRAM (SCHIP).

Civilian Health and Medical Program of the Uniformed Services (CHAMPUS)

The Civilian Health and Medical Program of the Uniformed Services (CHAMPUS) provided health coverage for military active-duty and retired personnel and their dependents. CHAMPUS has been replaced by a new, MANAGED CARE–based system called TRICARE.

Clinical Laboratory Improvement Act (CLIA)

Congress passed the Clinical Laboratory Improvement Act (CLIA, PL 100–578) in 1988, largely in response to news reports detailing how substandard laboratory practices had led to deaths and suffering, particularly for women whose Pap smears to detect cervical cancer were misread. A 1987 series in the *Wall Street Journal* documenting testing inaccuracies, lax regulations, and outright fraud won a Pulitzer prize and helped prompt legislative action. The far-reaching law, which took effect in 1992, put under federal purview nearly every clinical laboratory in the United States. (A previous federal law, also called CLIA, was passed in 1967, but it regulated only independent labs involved in interstate commerce.) In 2006 the CENTERS FOR MEDICARE AND MEDICAID SERVICES (replacing the HEALTH CARE FINANCING ADMINISTRATION [HCFA]), which ran the CLIA program, implemented quality assurance standards for approximately 195,000 laboratories, more than 106,000 of them located in physician offices.

CLIA requires federal registration of all laboratories, defined as "any facility which performs laboratory testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention, treatment of disease, or impairment of, or assessment of health." However, laboratories that perform only the most rudimentary tests are exempt from CLIA's inspection, proficiency testing, and training requirements. Such tests include nonautomated urine dipstick tests, tests to detect blood in the stool, urine pregnancy tests, and certain simple blood tests. Waived laboratories pay a fee of around $150.

Laboratories that perform tests of moderate or high complexity must meet a range of federal standards and undergo periodic inspections every two years, either by the Centers for Medicare and Medicaid Services or a private accrediting organization. CLIA is funded by user fees. Fees for laboratories that perform more advanced testing range from several hundred to several thousand dollars per year, depending on the volume of tests performed. Laboratories must meet quality-control and assurance standards and be subject to proficiency testing for every examination or procedure they are certified to perform. The law also sets separate standards for cytology testing (including the evaluation of Pap smears), such as a maximum number of slides an individual may examine in a twenty-four-hour period, a program of rescreening to ensure accuracy, and periodic retesting of personnel.

CLIA has been controversial since its inception. The federal government extended its reach to all laboratories, regardless of whether they participated in federal health programs. Doctors have complained that the rules are so burdensome that many physicians have stopped doing many types of tests, thus inconveniencing patients. A 1995 study commissioned by a coalition of physician groups found that two-thirds of physician office laboratories had dropped some or all of their on-site testing between 1991 and 1995.

But federal officials maintain that the program has worked well, noting that the total number of deficien-

cies found by inspectors had dropped by some 40 percent between the first round of inspections and the second. Physician groups, though, still say evidence that CLIA has improved the quality and accuracy of tests is lacking and have urged Congress to repeal CLIA's oversight of in-office laboratories.

Clinical nurse specialist (CNS)

This type of ADVANCED PRACTICE NURSE specializes in a specific area of medicine (such as mental health, gerontology, or cancer care) or in research, education, or administration. The most numerous of advanced practice nurses (the National Association of Clinical Nurse Specialists estimated in 2007 that more than sixty-nine thousand nurses had both the necessary education and credentials), clinical nurse specialists have master's or doctoral degrees and provide primary care and psychotherapy. They also perform health assessments, make diagnoses and provide treatment, and develop quality control methods.

Clinical practice guidelines

According to the INSTITUTE OF MEDICINE of the National Academy of Sciences, clinical practice guidelines are "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances." Guidelines, which recommend specific therapies, often referred to as "algorithms," are intended to guide decision making on the treatment of medical conditions ranging from backaches to ear infections to congestive heart failure. They are a key element of EVIDENCE-BASED MEDICINE, the attempt to make medical care more of a science than an art by employing therapies and techniques scientifically shown to work best and most cost-effectively.

Guidelines are developed by a wide variety of entities, ranging from professional medical societies to public or private organizations, to government agencies, to health care organizations or plans. During its early years, development of clinical practice guidelines was a major part of the work of the AGENCY FOR HEALTH CARE POLICY AND RESEARCH (AHCPR) (renamed the AGENCY FOR HEALTHCARE RESEARCH AND QUALITY [AHRQ] in 1999). However, the agency's 1994 guideline on treatment of acute back pain, which suggested that surgery was not necessarily the most effective therapy, so outraged spine surgeons that they nearly succeeded in having the agency defunded. In 1996 the agency announced it would cease developing guidelines of its own. However, in 1998 it did launch a World Wide Web–based National Guideline Clearinghouse in conjunction with the AMERICAN ASSOCIATION OF HEALTH PLANS (AAHP) (now AMERICA'S HEALTH INSURANCE PLANS [AHIP]) and the AMERICAN MEDICAL ASSOCIATION (AMA).

Clinical trials

Research projects that test the safety and effectiveness of new drugs, treatments, or other therapies in humans are called clinical trials. Clinical trials can be sponsored by physicians, universities, voluntary health organizations, pharmaceutical companies, or others, and they can be funded privately or by such federal agencies as the NATIONAL INSTITUTES OF HEALTH (NIH), the Department of Defense, or the Department of Veterans Affairs.

Patients who participate in clinical trials can be referred by their physicians or recruited separately, but they must meet specific guidelines for participation. Some studies seek patients who are healthy; others are seeking patients with specific medical conditions. Patients may benefit individually from their participation in clinical trials, but they may also be part of a control group that does not receive the therapy being tested. Instead, members of the control group generally receive a placebo, an inert copy of the drug or treatment being tested. Patients who participate in clinical trials must provide INFORMED CONSENT for their participation, a process that ensures they understand the potential risks and benefits of the research.

Questions about insurance coverage have proved a barrier for some patients seeking to participate in clinical trials. Trials themselves normally pay for the

Lois Spiller (center) was the first study participant to receive a Jarvik 2000 left ventricular assist device as part of the Jarvik 2000 clinical trials. Spiller lived for seventy-nine days with the device while she waited for a donor heart, which she received on June 28, 2000. *Source: Texas Heart® Institute*

experimental treatment being tested, but patients—or their insurance companies—are expected to pay for routine medical costs associated with participation, such as hospital stays. In June 2000 President Bill Clinton issued an executive order providing MEDICARE coverage for routine costs associated with beneficiaries' participation in clinical trials as well as coverage of complications that might arise from experimental drugs or treatments. In making the announcement, which had been the subject of legislation for several years leading up to the change, the president noted that 63 percent of cancer patients were over age sixty-five, but they constituted only a third of patients enrolled in clinical trials. Requiring private insurance companies to cover costs associated with clinical trial participation was also a provision of several versions of a proposed PATIENTS' BILL OF RIGHTS (PboR) passed by the House and Senate but not yet law as of 2008.

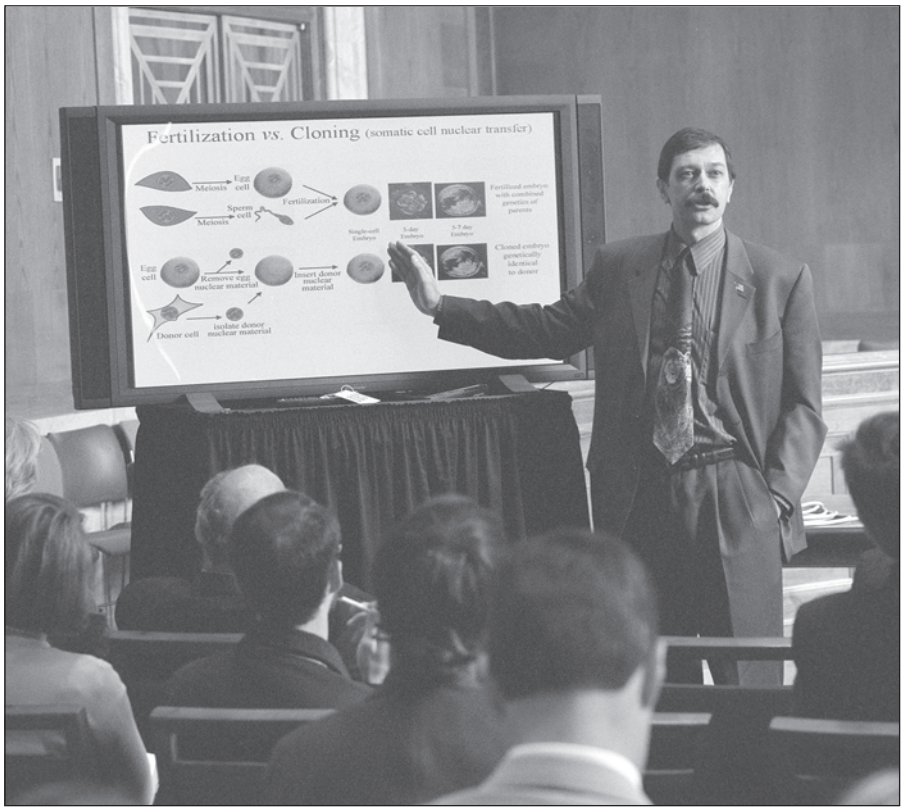
Clinton health care plan

See HEALTH SECURITY ACT.

Cloning, human

The 1997 announcement of the cloning of Dolly, a sheep, from another adult sheep's cells, raised for the first time the near-term possibility that a human could be created by a method other than by the union of a sperm cell from a man and an ovum from a woman. The mere possibility of human cloning touched off a heated debate in Congress about how such ethically far-reaching research should be regulated. Several bills were introduced in 1997 aimed at banning public, and in some cases even private, research on the cloning of humans, and President Bill Clinton on March 4 of that year issued a directive barring any federal agency from supporting, funding, or undertaking any research related to human cloning. The president also urged a private moratorium on such research, so "we can ensure that as we move forward on this issue, we weigh the concerns of faith and family and philosophy and values, not merely of science alone."

But the hand of President Clinton and Congress was forced by the announcement in January 1998 of a



Supporters of a ban on human cloning sponsored a Capitol Hill briefing June 7, 2002, with David Prentice, a life sciences professor at Indiana State University. Source: *CQ Photo/ Scott J. Ferrell*

Chicago scientist, Richard Seed, that he intended to raise private money to pursue the cloning of human beings. That announcement led Republicans to rush to the Senate floor with a hastily rewritten version of the 1997 bill introduced by Sen. Christopher S. Bond, R-Mo. That measure, rewritten with the input of Sen. Bill Frist, R-Tenn., the chamber's lone physician, would have banned the use of human SOMATIC CELL NUCLEAR TRANSFER technology. That was the same technology used to clone Dolly the sheep.

But some biotechnology organizations complained that the Republican bill would go further than intended, banning not only human cloning research but also other types of potentially breakthrough research into a wide array of diseases. Instead of supporting the bill, biotechnology groups rallied around a measure offered by Sens. Dianne Feinstein, D-Calif., and Edward M. Kennedy, D-Mass. That bill would have placed a ten-year moratorium on the implantation of human embryos created using the somatic cell nuclear transfer technique, whereby the nucleus of a female egg cell is removed and replaced with the nucleus of another cell from an adult male or female. The bill would have ordered the National Bioethics Advisory Board to report back to Congress and the president periodically about the scientific, ethical, and social issues surrounding human cloning and to recommend whether the ban should be continued. Antiabortion groups, however, opposed the Feinstein–Kennedy measure because, they said, it would encourage the creation, experimentation on, and killing of human embryos.

In the end, however, the politics of research trumped the politics of ABORTION. After several days of debate, the Senate on February 11 failed to break a filibuster on the GOP bill by 42-54, thus sending the measure back to committee. No further action was taken in the 105th Congress.

The issue returned to Congress in 2001, in the context of advances in STEM CELL RESEARCH. Many researchers said that cloning human embryos would be needed to realize the ultimate clinical use of stem cells, which involved growing replacement cells and tissues for diseased or damaged ones. Without the ability to clone a patient's own cells, scientists said, it would be difficult to create therapies that would not be rejected by patients' immune systems. Although just about every member of Congress expressed support for legislation to make cloning intended to produce a live birth a crime, the debate over whether to allow the cloning of embryos picked up right where it left off in 1998. Religious and antiabortion groups argued that creating embryos for the purpose of destroying them was inherently unethical. They also argued that legislation allowing embryo cloning for research would make it impossible to enforce a ban on "reproductive" cloning, because it would be too easy to implant a cloned embryo into a woman. Backers of what came to be called "therapeutic" or "research" cloning argued that banning the cloning of embryos would severely jeopardize some of the most promising medical research in generations.

As in 1998, the two sides fought to a draw in the 107th Congress. With the strong backing of President George W. Bush, the House on July 31, 2001, passed a bill that would have banned all forms of human cloning, as well as the importation of therapies developed using human cloning techniques, by 265-162. An amendment by James C. Greenwood, R-Pa., to ban reproductive cloning but continue to allow cloning of embryos for research was defeated by 249-178. The Senate, however, never took up the bill. In that chamber, backers of therapeutic cloning were more numerous, and at one point it appeared that there were more than sixty votes to expand federal funding for stem cell research beyond that allowed by President Bush in August 2001.

With Republicans having taken the Senate back as a result of the 2002 elections, the House made its cloning ban a top priority. It passed its total ban again on February 27, 2003, by 241-155. Greenwood again offered his amendment to allow reproductive cloning; it failed, 231-174.

COBRA

See CONSOLIDATED OMNIBUS BUDGET RECONCILIATION ACT OF 1985 (COBRA).

Coinsurance

A portion of a health care fee that must be paid by an insured patient is known as coinsurance. In Part B of MEDICARE, coinsurance is set at 20 percent. Thus, if a bill for a physician visit is $50, the patient would be responsible for $10 of that amount, with insurance paying the rest. In FEE-FOR-SERVICE plans and preferred provider organizations, coinsurance can vary from 10 percent to 40 or even 50 percent, with higher coinsurance for services such as mental health care or the most expensive brand-name drugs whose use plans wish to discourage. (See PREFERRED PROVIDER ORGANIZATION [PPO].) In the 1990s many MANAGED CARE plans replaced coinsurance with flat-fee copayments, charging $10 or $20 for a physician office visit, for example, and $10 or $15 for prescription drugs. That worked when plans had other ways to control use of service, such as by requiring a REFERRAL for specialty care. But when patients complained about overt use controls and plans relented, the copayments became a driver of ever-higher health spending. Suddenly, said Paul Ginsburg of the Center for Studying Health System Change, consumers were no longer aware of how much their medical care cost. "They think that an office visit, that's $10. And a prescription, that's $5. There's no way for consumers to find out, nor should they be interested in finding out [how much care actually costs], because it doesn't matter to them." As a result, many plans began replacing flat copayments with a return to coinsurance, to keep consumers aware, if nothing else, how fast costs for health care were rising.

Commissioned Corps of the U.S. Public Health Service

See PUBLIC HEALTH SERVICE, COMMISSIONED CORPS.

Common rule

The common rule was formally established in 1991 as the Federal Policy on Protection of Human Subjects. Seventeen separate federal departments and agencies in 2003 required entities that receive federal research funding to abide by this rule governing the use of human participants in research. The broadest authority is exercised by the NATIONAL INSTITUTES OF HEALTH (NIH), which monitors protection of human participants in federally funded biomedical and behavioral research, and by the FOOD AND DRUG ADMINISTRATION (FDA), which oversees private research on products it regulates.

The common rule requires entities receiving federal research funding or conducting research on drugs, medical devices, or other products regulated by the FDA to establish INSTITUTIONAL REVIEW BOARDS (IRBs) to ensure the ethical conduct of research using human participants. The rule requires research protocols to expose participants to the minimum risk possible to answer the scientific question posed and that research participants be fully briefed on the potential risks and benefits and the procedures to be followed in the research as part of the INFORMED CONSENT process.

Community health centers

The nation's more than one thousand community health centers (CHCs) are the cornerstone of the federal government's efforts to provide primary care services to the uninsured, those with low incomes, and others with difficulties obtaining health care, whether because of cultural or economic factors or geographic barriers.

Founded in the 1960s as part of the federal government's War on Poverty, CHCs and other clinics that are part of the federal government's Consolidated Health Centers Program (including migrant health centers, sites providing health care for homeless individuals, and those offering care to residents of public housing) in fiscal year 2007 provided services to an estimated sixteen million Americans at more than five thousand sites, roughly half urban and half rural. CHCs are by definition located in areas characterized by both a lack of health services and a large percentage of the population with low incomes. They also cater to those with nonfinancial barriers to care, providing transportation, translation, case management, and other services to those who may have the means to pay for care but nonetheless may lack access. Roughly 40 percent of health center patients have no health insurance.

CHCs provide all of the services offered by a typical private clinic—from preventive care to treatment of acute and chronic conditions to laboratory tests, imaging, and pharmacy services. But in recognition of their vulnerable patient base (virtually all patients have incomes under 200 percent of the poverty threshold), CHCs also provide a wide array of social services, including health education, nutrition guidance, and counseling.

CHCs receive about two-thirds of their funding from federal grants and MEDICAID payments. State, local, and private grants, private insurance, MEDICARE, and direct payments from patients provide the rest. In fiscal year 2008 Congress appropriated $2.1 billion for the health centers program. The program is one of the few domestic health programs that grew steadily during the George W. Bush administration, which made it a top priority.

Community rating

The insurance practice of charging the same rate to every member of a specified population (with allowances only for family size, benefits package, or geographic location), community rating tends to produce savings for those who consume more than average amounts of health care services and to cost healthier people more. Where it exists, community rating is often required by law, with proponents arguing that without it, sicker than average people would not be able to afford insurance. Opponents of community rating, however, say it boosts premiums for healthy people so high that they do not purchase coverage, leaving the entire insured pool sicker than it would have been and boosting costs for everyone left. This type of ADVERSE SELECTION

can result in what insurers refer to as the "death spiral," in which the more healthy people leave, the more rates climb because the insured pool is sicker, with the higher prices continuing to drive out all but the sickest. To avoid both extremes, some insurers and governments have adopted *modified community rating* schemes, in which rates can vary by factors such as age and gender, but only within certain limits.

Comparative clinical effectiveness research

A relatively new field of inquiry, comparative clinical effectiveness research considers the various ways medical conditions can be treated. Sometimes that means comparing different drugs or medical devices head to head; other times it can mean comparing drug therapy with surgery or some other medical intervention. Currently, in the United States, drugs are tested against placebos, not other drugs. As a result, it is not clear whether a new drug works better or not as well as other drugs that treat the same condition. Such information is important from a medical point of view and from a cost-effectiveness standpoint. If one intervention is both more effective and cheaper than another, it would be useful to know that.

England's National Health Service in 1999 set up a clinical effectiveness research agency called the National Institute for Clinical Effectiveness, known as NICE, which was renamed the National Institute for Health and Clinical Effectiveness in 2005. Bipartisan efforts have been made in Congress to establish a similar agency. The House in August 2007 included a provision to create such an agency in the STATE CHILDREN'S HEALTH INSURANCE PROGRAM (SCHIP) reauthorization legislation. However, some health care providers expressed concern that such research could lead to insurers refusing to pay for more expensive care that might be more appropriate for some patients.

Confidentiality of medical records

See MEDICAL RECORDS CONFIDENTIALITY.

Congressional Budget Office (CBO)

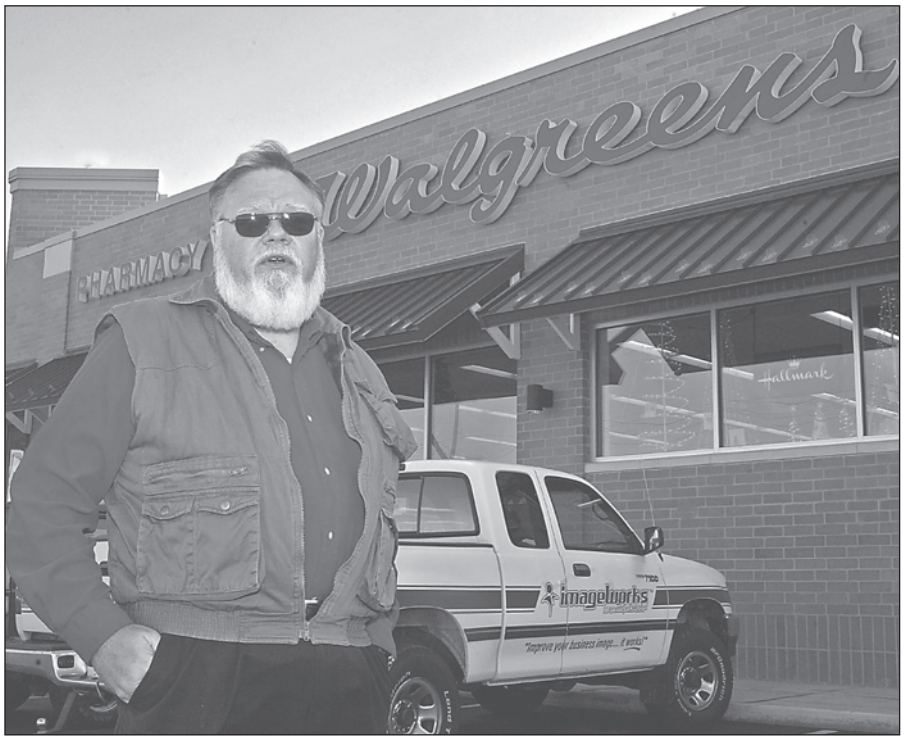
Created as part of the 1974 Congressional Budget and Impoundment Control Act, the Congressional Budget Office (CBO) is the official "scorekeeper" for federal legislation. CBO's mission is "to provide the Congress with objective, timely, nonpartisan analyses needed for economic and budget decisions and with the information and estimates required for the Congressional budget process." CBO is best known for "scoring" bills, or estimating if they would cost the federal government more money or reduce spending over the ensuing five or ten years. When CBO and the executive branch budget agency, the Office of Management and Budget, disagree (as they frequently do), the CBO's estimate prevails, under budget law. CBO measures its estimates of what a bill would cost against a BASELINE, its projection of federal spending absent legislative changes.

Although it is nonpartisan, CBO is far from nonpolitical. For example, in health policy, lawmakers have complained that CBO does not take into account savings from prevention strategies. Thus, most estimates of legislation to provide immunizations or other screening tests do not reflect enough in savings from preventing ailments or catching them before they become serious.

In 1994 CBO played a major role in the demise of President Bill Clinton's HEALTH SECURITY ACT. CBO, then under the directorship of a Democrat, Robert Reischauer, said that contrary to the administration's claims, the proposal would not save money but rather would add $74 billion to the federal deficit over the first six years of its existence. CBO analysts also said that the requirement in the bill that employers pay for health insurance for their workers should be treated as a tax for federal budget purposes.

Conscience clause

Generally applying to ABORTION, a conscience clause is any statutory language allowing an individual health care provider to refuse to perform a service he or she



Rich Quayle, a pharmacist from Illinois, was put on indefinite unpaid leave after he cited religious and ethical grounds for balking at the rule that he says wrongly forces him to dispense the morning-after pill. Source: *AP Images*

finds morally or religiously objectionable. Conscience clauses have also been used to exempt certain health care entities (such as Catholic hospitals) from providing services (such as distributing contraceptives for family planning) that violate their beliefs.

Congress passed its first conscience clause only weeks after the U.S. Supreme Court had legalized abortion nationwide with its 1973 *ROE V. WADE* decision. The so-called Church amendment, named for Sen. Frank Church, D-Idaho, gave individuals and medical facilities the right to decline to provide abortion or sterilization services. By the end of 1974, according to the Alan Guttmacher Institute, which studies reproductive health issues, nearly half the states had enacted similar laws, and by 1978 nearly all states had done so.

With the rise of MANAGED CARE and its blurred distinction between payers and providers, some states began taking another look at conscience clauses. In 1997 several states passed laws that in effect allowed entire health plans to opt out of providing certain services. In addition, services subject to conscience clauses were broadened from abortion and sterilization to family planning and other services.

In the 1997 Balanced Budget Act (PL 105–33), Congress included a conscience clause provision allowing MEDICARE and MEDICAID managed care plans to decline to provide any counseling or information on moral or religious grounds, including information about abortion, family planning, sterilization, and ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS) treatment.

Advocates of the language said it was needed to protect religion-based health plans, particularly those owned by the Catholic Church, from having to contract with health care providers that offer services the Church does not recognize as acceptable. Opponents of the language, however, argued that a health plan cannot have a "conscience" and that moral or religious objections should be exercised only by those who perform the services, not by those who pay for them.

Congress also added a conscience clause exception to a requirement imposed in 1999 that health plans serving federal employees cover all five of the reversible

contraceptive methods approved by the FOOD AND DRUG ADMINISTRATION (FDA). (See CONTRACEPTIVE COVERAGE.)

In 2002 the House tried to expand conscience clauses further still, passing the Abortion Non-Discrimination Act by 229-189 on September 25. Backers of the measure argued it was needed to override state laws requiring, for example, hospitals to provide abortion or contraceptive services, even when religious hospitals merge with other facilities. Opponents argued that the bill was so sweeping it would even have overridden state laws requiring that rape victims be referred for abortions if they request it.

As part of a 2004 omnibus spending bill (PL 108–447), the Republican Congress added language to the HEALTH AND HUMAN SERVICES DEPARTMENT (HHS) appropriation that expanded existing conscience clauses from individual to entire health care entities, and allowed them to decline to offer not just abortions, but also abortion referrals. Abortion opponents argued that the language protected religion-based hospitals and health plans. But family planning groups argued that the language violated long-standing rules for the federal TITLE X FAMILY PLANNING PROGRAM that required that women with unintended pregnancies be offered all options, including abortion referrals. A lawsuit challenging the language was unsuccessful, however.

By 2005 the conscience clause movement was spreading beyond abortion per se to birth control. More and more pharmacists started objecting to dispensing the "morning after" birth control pill and regular birth control pills containing progestin, on the grounds that both were thought to prevent a fertilized egg from implanting in a woman's uterus. Those pharmacists considered that blocking of implantation tantamount to an early abortion, although the mainstream medical community and the Food and Drug Administration (FDA) considered both to be contraception. States reacted in opposite ways. Some passed laws specifically allowing pharmacists to refuse to dispense medications; others passed laws requiring pharmacies to ensure that prescriptions be filled promptly and that, if a pharmacist objects, another willing pharmacist be readily available.

Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA)

The term for this massive bill now refers, in health policy parlance, to a single—and at the time considered minor—provision regarding health insurance continuation. Despite its name, the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA) did not become law until 1986 for reasons unrelated to its health provisions. The provision in question, formally known as "COBRA continuation," originally required employers with more than twenty employees to permit workers (and their spouses and dependents) who would otherwise lose coverage to continue under the employer's group health insurance plan for up to thirty-six months in certain situations if they pay for the coverage themselves. Events that qualify for COBRA continuation include voluntary resignations from a job, dismissal (except for cases of "gross misconduct"), or, in the cases of workers' families, the death of the worker or a divorce or legal separation from that worker. Also eligible for COBRA are spouses of workers who become eligible for MEDICARE and dependent children who "age out," or get too old to qualify under their parents' coverage or cease to be dependents. Congress has since enlarged and otherwise expanded COBRA provisions. In a 1989 budget reconciliation bill, Congress added eleven months to the eligibility period for workers who become disabled, to enable them to keep coverage until Medicare kicks in under SOCIAL SECURITY DISABILITY INSURANCE (SSDI) rules. In 1990 Congress allowed states to use their MEDICAID programs to pay COBRA continuation premiums. Congress also revised the penalty for employers who fail to comply. Originally those firms faced loss of deductibility of their health insurance costs. In 1988 Congress imposed an excise tax penalty instead.

Under COBRA rules the former workers and their families must pay the entire premium, including the portion, if any, formerly paid by the employer, plus an extra 2 percent to cover administrative costs. Even so, COBRA is often a good deal because group rates tend to be lower than those for individuals, and plans cannot

exclude or charge more for those with a PREEXISTING CONDITION. Some employers, however, particularly small employers, complain that COBRA participants are "self-selecting" to be sicker than average (because those most likely to need coverage are those who purchase it) and can end up raising premiums for an entire group.

Consumer-driven health plans

Also known as consumer-directed health plans, this is a catch-all term for a series of health insurance models that seek to control rising health spending for employers by increasing consumer choice. Consumer-driven plans can take any of a number of different shapes, but all are aimed at making consumers more aware of the cost of the health care they choose in the hope those consumers will make more cost-conscious choices. As one set of researchers put it, "[C]onsumer-driven health care is an effort to put patients in a position to say no to themselves."

In some types of consumer-driven plans, such as MEDICAL SAVINGS ACCOUNTS (MSAs), or "health reimbursement arrangements," first authorized by the Internal Revenue Service in 2002, consumers who are thrifty with the money they are provided (or who manage to stay healthy) can roll over those funds to the next year. Most consumer-driven plans combine a set amount of money provided by the employer with a very high deductible plan for CATASTROPHIC ILLNESS health care expenses. Generally, the employees are responsible for a gap between the initial deposit to the account and the amount before the catastrophic insurance begins paying—yet another incentive for consumers to watch what they spend on health care. Some consumer-driven plans allow workers to custom-design a network of health care professionals, with their premiums varying according to the panel of providers they choose.

Consumer-driven plans also may or may not be combined with a switch to a DEFINED CONTRIBUTION approach, in which the employer provides workers with a set amount of money for health care, instead of footing the ever-changing (usually rising) bill for a set amount of benefits.

Some critics worry about the move to consumer-driven health plans for a variety of reasons. First, they say people might be tempted to skimp on needed preventive care so that they can keep the money in their accounts. Second, patients with chronic ailments could be left paying large amounts out-of-pocket for care after the initial account has been exhausted and before the catastrophic coverage kicks in. For that reason, say critics, such plans might prove most attractive to those in good health, removing them from the broader risk pool. That would leave sicker people in more traditional plans, whose premiums would then rise because risk would be spread only across people with high health expenses. Finally, most of the plans are predicated on providing individuals with comprehensive, easy-to-understand information from which to make their health care choices—information that even by 2007, well after Congress expanded the availability of consumer-directed plans by creating HEALTH SAVINGS ACCOUNTS (HSAs), remained in short supply.

Contraceptive coverage

This major initiative for abortion rights forces beginning in the 105th Congress (1997–1999) had two objectives. First, it was meant to encourage contraception and prevent the need for ABORTION. Second, it was intended to change the subject, to steer the focus away from efforts to ban a specific abortion procedure in an attempt to win back some of the public support lost in the battle over the so-called PARTIAL-BIRTH ABORTION.

The centerpiece of the effort was the Equity in Prescription Insurance and Contraceptive Coverage (EPICC) Act, introduced in the House and Senate by two abortion rights Republicans, Sen. Olympia J. Snowe of Maine and Rep. James C. Greenwood of Pennsylvania. The measure would have required that health insurance plans offering prescription drug coverage also offer coverage of the five prescription methods of reversible contraception approved by the FOOD AND DRUG ADMINISTRATION

(FDA)—birth control pills, Norplant (a time-release device implanted under the skin of a woman's arm), Depo Provera (a long-acting, injectable medication), the diaphragm, and the intrauterine device (IUD).

Although most insurance plans covered prescription drugs in 1998, many did not cover prescription contraceptives or covered only some of them. One survey found that fewer than one in five FEE-FOR-SERVICE and PREFERRED PROVIDER ORGANIZATION (PPO) plans covered all five FDA-approved methods of contraception. For health maintenance organizations (HMOs) the coverage was only slightly better—about 40 percent. And many plans drew a distinction between contraceptives and other prescription drugs or devices. For example, although 97 percent of fee-for-service plans routinely covered prescription drugs, only 33 percent covered oral contraceptives. Similarly, whereas 83 percent of HMOs covered medical devices in general, only 44 percent covered Norplant. Yet a cost estimate commissioned by the Alan Guttmacher Institute found that requiring full contraceptive coverage would cost employers only an additional $17.12 per person annually and workers an additional $4.28 per year. (See HEALTH MAINTENANCE ORGANIZATION [HMO].)

In 1998 Maryland became the first state to require insurers to cover all five FDA-approved contraceptive measures, and it also required that women not have to pay higher cost-sharing fees for contraceptive drugs or devices than for other prescriptions. By 2007, twenty-five other states had passed contraceptive coverage requirements. Those laws, however, did not reach workers whose plans were self-insured and thus exempt from state benefit mandates. (See EMPLOYEE RETIREMENT INCOME SECURITY ACT [ERISA].)

Although the EPICC legislation was not considered by the House or Senate in the 105th Congress, Congress in 1998 did take a first step by requiring that plans serving federal workers provide contraceptive coverage. Among the plans serving more than nine million federal workers and dependents, coverage of contraception was even less generous than it was in the private sector. Only an estimated 19 percent of plans covered all five methods, and 10 percent provided no coverage whatsoever.

The requirement, however, almost did not happen. The House in July 1998 approved the mandate as part of the appropriations bill funding the U.S. Postal Service, the Treasury Department, and other federal agencies—after defeating an amendment by antiabortion lawmakers to exclude from the requirement any contraceptives that also act as "abortifacients" (drugs or devices that cause abortions; some abortion opponents consider any drug or device that prevents implantation of a fertilized egg into a woman's uterus an abortifacient), including the IUD and, in some cases, birth control pills. The Senate also approved the coverage in its version of the bill. But the requirement was dropped in conference when abortion foes complained. Backers of the original amendment blocked final approval of the Treasury-Postal appropriations bill in protest, and the measure had to be rolled into a huge year-end omnibus spending bill. At the insistence of the White House, the contraceptive coverage language was restored, along with a conscience clause permitting religion-based health plans, as well as individual practitioners with moral or religious objections to some or all of the methods, to opt out. President George W. Bush in his fiscal 2002 budget recommended that the requirement for coverage in federal insurance be dropped, but Congress refused to go along.

Meanwhile, although the legislation to require private plans to cover contraceptives continued to languish in Congress, other avenues proved more fruitful. In December 2000 the Equal Employment Opportunity Commission (EEOC) ruled that employers whose health plans failed to provide prescription contraceptives while covering other prescription drugs were in violation of sex discrimination prohibitions of Title VII of the 1964 Civil Rights Act and, specifically, the 1978 Pregnancy Discrimination Act that amended it. In the EEOC case, two unidentified nurses filed formal complaints against their employers. Although advocates of contraceptive coverage hailed the EEOC ruling, they also noted that it applied only to employers with more than fifteen workers.

Backers of required coverage won another victory six months later when a federal district court in the Western District of Washington, in *Erickson v. Bartell Drug*

Co., found that the firm unfairly discriminated against Jennifer Erickson, a twenty-seven-year-old pharmacist at one of its stores, by failing to cover her prescription contraceptives. "Although the [firm's health plan] covers almost all drugs and devices used by men, the exclusion of prescription contraceptives creates a gaping hole in the coverage offered to female employees, leaving a fundamental and immediate health care need uncovered," wrote Judge Robert Lasnik.

Backers of coverage argued that the federal legislation was still needed, both to cover those women in employer plans not covered by Title VII (those with fewer than fifteen workers) as well as the millions of women with health insurance not provided by their employers. But opponents, including most members of the business community, argued that Congress should not establish a broad benefit mandate at a time when insurance costs were again rising rapidly. The legislation was not considered by the 106th or 107th Congress. In the 108th Congress, the Senate on March 11, 2003, defeated a multipart amendment that would have included the requirement during consideration of a bill to bar so-called partial-birth abortions.

Copayments

See COINSURANCE.

Cost shifting

This term refers to the overcharging by a health care entity of a patient or set of patients to make up for underpayments from other payers. For generations, hospitals underwrote care for the uninsured and indigent by padding the bills of those with insurance. Doctors and hospitals often also charged higher rates to private patients to offset relatively low reimbursements provided by government insurance plans. MANAGED CARE companies, however, have largely put an end to cost shifting by demanding lower prices. That, in turn, has threatened the ability of health care providers to care for those who cannot afford to pay.

CPT Codes

See CURRENT PROCEDURAL TERMINOLOGY (CPT) CODES.

CRNA

See CERTIFIED REGISTERED NURSE ANESTHETIST (CRNA).

Crowd out

Also known as "substitution," this term describes the replacement of private insurance with publicly funded health insurance. In designing the STATE CHILDREN'S HEALTH INSURANCE PROGRAM (SCHIP), which was part of the 1997 Balanced Budget Act (PL 105–33), for example, Congress was worried that if the federal government began paying for children's coverage, employers would stop offering it, thus transferring a cost previously borne by the private sector to taxpayers. In effect, lawmakers worried that public coverage would "crowd out" private insurance. In 2007 the Bush administration cited increased potential for crowd out as its justification for opposing congressional Democrats' efforts to expand SCHIP to cover children in families with higher incomes. Analysts had found that as income rose, the potential for crowd out was greater.

Current procedural terminology (CPT) codes

This system was devised by the AMERICAN MEDICAL ASSOCIATION (AMA) in 1966 to code procedures performed in hospitals and physicians' offices for reimbursement purposes and for research, allowing comparisons across various parts of the country. For example, a "brief" office visit would have one code, an "intermediate" visit another, and so forth. Current procedural terminology (CPT) codes have in many cases been augmented by ICD-9 CODES, which code actual diagnoses to facilitate research into appropriateness of care.

MEDICARE began requiring use of CPT codes in 1983; MEDICAID adopted the standard in 1986. Revisions to CPT are made by a panel of seventeen physicians: eleven nominated by the AMA and one each nominated by the BLUE CROSS/BLUE SHIELD ASSOCIATION (BCBSA), the CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS), AMERICA'S HEALTH INSURANCE PLANS (AHIP), and the American Hospital Association. The remaining two seats are filled by members of the CPT Health Care Professionals Advisory Committee.

D

Deductible

The amount a patient must pay, usually each calendar year, before insurance coverage begins is called the deductible. MEDICARE has two main deductibles. The Part B deductible was $135 in 2008, so the patient was required to pay the first $135 of covered costs incurred each year. Medicare's hospital deductible in 2008 was $1,024 per "benefit period," which begins when a patient enters a hospital and ends when the patient has not been in a hospital or skilled nursing facility for sixty days. Thus, if a patient leaves the hospital and needs to be readmitted within sixty days, no new deductible is required.

Defined benefit

The term refers to a benefits scheme (it can also apply to pensions) under which the employer or other grantor of benefits guarantees a certain level of benefits. MEDICARE is a defined benefit program in that the federal government guarantees patients a certain level of services (for instance, the first sixty days of hospital care) regardless of how much it costs. In a defined benefit scheme, the benefits payer is "at risk" for increases in the cost of the benefits.

Defined contribution

In contrast to a DEFINED BENEFIT plan, a defined contribution scheme assigns the risk of inflation to the recipient of the benefits in question. Under a defined contribution plan, the benefit grantor promises to pay only a set amount, or a percentage of an amount, toward a benefit. If inflation deflates the value of the benefit over time, the additional cost is shifted to the recipient. Many employers have moved from defined benefit to defined contribution schemes for pensions in an effort to hold down future costs. Health insurance may also be provided as a defined contribution to encourage workers to opt for less expensive policies. Employers are using defined contributions increasingly to pay for health benefits for retirees (see RETIREE HEALTH INSURANCE).

Diagnosis-related group (Medicare)

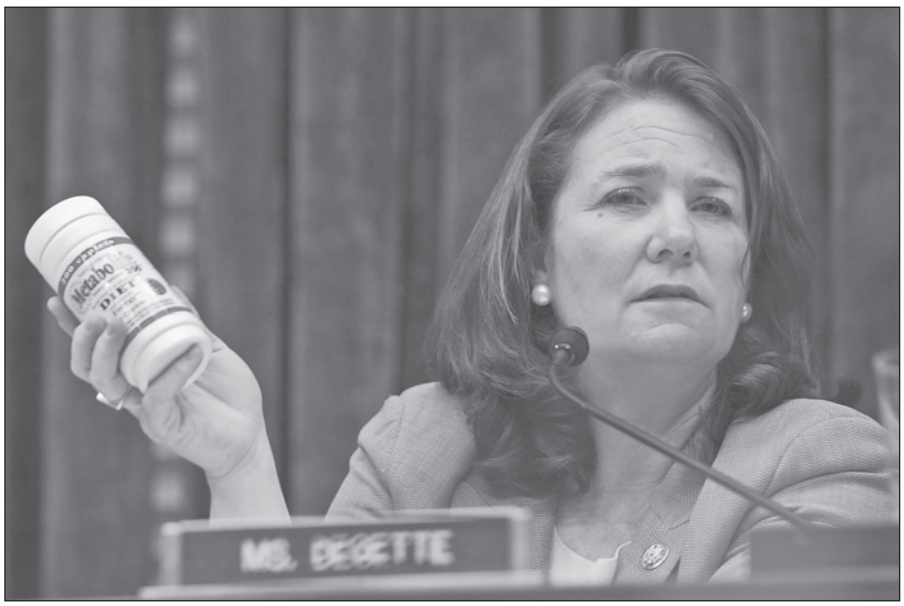
Under the MEDICARE prospective payment system, a diagnosis-related group (DRG) is any of more than five hundred different categories that help determine hospital payments. Payments are based on each patient's diagnosis and prescribed treatment (such as bypass surgery for coronary artery disease) and what it would cost to care for the average patient with that diagnosis. The idea is to reward efficiency—if the hospital can treat the patient for less than the average for that diagnosis, it can keep the difference. But if the patient costs more than the average, the hospital has to absorb the extra cost. (Actual payments are adjusted for a variety of factors, including labor costs, the type of hospital, and, in some cases, the severity of the patient's illness.) The DRG payment covers only the hospital's own costs; physician care is billed separately under Medicare Part B, according to its own fee schedule.

Dietary supplement rules

Congress in 1994 cleared legislation to limit the federal government's authority to regulate vitamins, minerals, and herbal remedies. The Dietary Supplement Health and Education Act (PL 103–417), signed by President Bill Clinton on October 25, was the culmination of more than two years of arguing back and forth between the FOOD AND DRUG ADMINISTRATION (FDA) and makers and users of dietary supplements, who deluged Congress with complaints about the FDA's alleged heavy-handed regulatory attacks on their products. Supplement manufacturers and advocates argued that the FDA was trying to cut off access to alternative medical treatments. Officials responded that they were merely trying to protect the public from potentially dangerous products that in some cases were being promoted as substitute drugs. Sales of dietary supplements grew throughout the 1990s, reaching nearly $21 billion in 2007.

As signed into law, the legislation allowed manufacturers leeway to explain a product's function on its label, with a disclaimer noting that the product did not promise to cure or treat disease. The bill did permit the FDA to halt sales of a supplement if it could be shown that a product caused "a significant or unreasonable risk." (In 1990 the agency ordered the supplement L-Tryptophan pulled from store shelves after contaminated pills caused a rare muscle disorder called Eosinophilia Myalgia Syndrome that sickened at least fifteen hundred people and killed thirty.)

The measure also permitted the FDA to enforce existing labeling regulations for four years, during which a seven-member, independent commission would decide what labeling regulations were needed. Manufacturers could sell new supplements without prior FDA approval, but they were required to submit evidence of a product's safety to the FDA seventy-five days before putting it on the market. If the FDA was not satisfied that the information was adequate to ensure that the new product was safe, it could block the marketing and sale. Finally, the measure established an Office of Dietary Supplements within the NATIONAL INSTITUTES OF HEALTH (NIH) to "promote scientific study of the benefits of dietary supplements in maintaining health and preventing chronic disease and other health-related conditions." In 1999 the Office of Dietary Supplements unveiled a new database to enable the public to locate "credible, scientific literature on dietary supplements."



Representative Diana DeGette (D-Colo) holds a bottle containing the diet supplement ephedra during a hearing investigating the safety of its use. The FDA later banned the sale of the popular supplement in 2004 due to concerns over its dangerous side effects. Source: *AP Images*

But passage of the 1994 bill hardly ended the struggle between the supplement industry and the FDA. In December 1998 the U.S. Supreme Court declined to take a case in which supplement makers argued that the FDA's approval requirement for product labels was an unconstitutional violation of their First Amendment rights to free speech. The Court left intact a lower court ruling that found the requirements reasonable to protect the public health.

Meanwhile, in response to the commission's recommendations delivered in 1997, the FDA in 1998 proposed rules for statements supplement makers could put on product labels. Under the rules, manufacturers were allowed to say that their products could affect the "structure or function" of the body without prior FDA review, but they could not claim that the products can prevent, treat, cure, mitigate, or diagnose any specific disease. Those rules were made final in January 2000.

Concern about supplements, particularly the stimulant ephedra, widely used to promote weight loss and to boost athletic performance, led to increased congressional and FDA scrutiny in 2002. In March 2003 a Florida medical examiner said that toxicology tests on Steve Bechler, a twenty-three-year-old pitcher for the Baltimore Orioles who collapsed from heatstroke during the team's spring training and later died, found "significant" levels of ephedra, which "played a significant role" in his death.

Also in March 2003 the FDA finally offered its long-anticipated regulations to ensure that supplements contained the ingredients claimed on their labels. The "good manufacturing practice" rules were intended to respond to studies that found some supplements contained far less of their active ingredients than they claimed and that some contained more than would be considered safe. In other cases, supplements were found to contain adulterants or other ingredients not listed on their labels. Under the proposed rules, manufacturers would be required to evaluate the identity, purity, quality, strength, and composition of their products. It took the FDA until June 2007 to make the rules final. Even then, they were to be phased in gradually. Large manufacturers would have to fully comply by August 2008; firms with fewer than two hundred workers would have until June of 2009; and the smallest companies, those with twenty or fewer workers, had until 2010.

Direct medical education payments

These payments are made by MEDICARE to teaching hospitals to reimburse them for the direct costs of caring for Medicare patients. Those costs include salaries of residents, teachers, nurses, and allied health professionals in training. Medicare made approximately $2.5 billion in direct medical education payments to teaching hospitals in fiscal year 2006. Medicare makes additional payments to teaching hospitals for the "indirect costs" of caring for beneficiaries. (See INDIRECT MEDICAL EDUCATION PAYMENTS.)

Disease management

Disease management is a catchphrase for a series of systems to help patients with chronic ailments—ranging from asthma to diabetes to congestive heart failure to end-stage kidney disease—take better care of themselves and hold down health care spending at the same time. Pioneered by MANAGED CARE plans and CARVE-OUT ORGANIZATIONS, disease management generally uses a team of health professionals, including doctors, nurses, pharmacists, therapists, and counselors, to provide intensive education to patients about how to best manage their disease and its treatments. Not only does disease management encourage more patient participation, but it also pulls together an often far-flung group of medical professionals providing an individual's care, and it seeks to make the best use of EVIDENCE-BASED MEDICINE, or treatments that have been scientifically demonstrated to work best. The goal of disease management is to keep the patient as healthy as possible, which cuts down on costs associated with hospital and emergency room care.

The use of disease management spread widely in the late 1990s, with insurance executives and researchers alike noting it represented a rare win-win situation in health care. "Financial results improve because patients become more engaged in managing their own health

care, take better care of themselves, get care that experts say they should be getting, avoid care that does them little good, improve their compliance with drug regimens, and generally experience improved health and functional status," Humana Inc.'s chief clinical strategy and innovation officer told the HOUSE WAYS AND MEANS COMMITTEE in 2002.

On paper the potential for savings is enormous. An estimated 130 million Americans—some 45 percent of the population—were living with at least one chronic condition in 2007, according to the Partnership to Fight Chronic Disease, a bipartisan coalition formed to raise the awareness of the issue as part of the 2008 presidential campaign. According to the CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC), chronic diseases were responsible for 70 percent of all deaths in the United States and 75 percent of the nation's health spending in 2006. Because the likelihood of having a chronic condition increases as people age, the numbers in MEDICARE are more dramatic still. In that program, the sickest 10 percent of patients accounted for more than two-thirds of the program's total spending in 2003. The sickest 6 percent alone accounted for 55 percent of spending. By contrast, the healthiest 52 percent of beneficiaries accounted for only 2 percent of Medicare spending. (See MEDICARE.)

Disproportionate share hospital (DSH) payments (Medicare and Medicaid)

Both MEDICARE and MEDICAID are required to make extra payments to hospitals that serve a disproportionate share of low-income or uninsured patients, although DSH (pronounced "dish") payments are best known for their role in running up Medicaid spending in the late 1980s and early 1990s.

Medicare's DSH program, begun in 1986, is by far the smaller of the two. It was formally established in 1986 budget reconciliation legislation (PL 99–272), with language requiring additional payments to hospitals that serve a disproportionate share of low-income patients. (See BUDGET RECONCILIATION LEGISLATION AND HEALTH CARE.) Payments are generally available to hospitals with more than 15 percent of beds occupied by low-income patients, calculated on the basis of the number of Medicare patients receiving federal SUPPLEMENTAL SECURITY INCOME (SSI) benefits and the number on Medicaid.

But the Medicaid DSH program has engendered the most attention—and the most controversy. The program dates back to adoption of the BOREN AMENDMENT in 1980 and 1981 budget reconciliation legislation, which required states to make "reasonable and adequate" payments to Medicaid providers. That legislation required that states "consider special payment needs for hospitals that serve a large portion of Medicaid and uninsured patients." The reasoning was that hospitals serving large numbers of Medicaid patients lost money because payments were often below costs and that those serving both Medicaid and uninsured patients had fewer privately insured patients from whom they could "cost shift." (See COST SHIFTING.)

The 1987 budget reconciliation legislation (PL 100–203) defined disproportionate share hospitals (those with Medicaid inpatient use rates one standard deviation above the mean for the state or those with low-income use rates of 25 percent) and required states to submit to the federal government their plans for making the additional payments. But what really set off the DSH explosion was a 1985 rule from the HEALTH CARE FINANCING ADMINISTRATION (HCFA) allowing states to receive "donations" from private health care providers. Using such programs, states could solicit payments from hospitals, collect federal Medicaid matching funds, and then return the hospital donation, plus a portion of the federal match, and retain the rest of the matching funds for whatever purpose the state wanted. Similarly, some states imposed "provider taxes" that essentially worked the same way, with the money from providers being returned with "free" federal money. States, in effect, did not have to put up any of their own funds.

In the early 1990s, with a recession going on, states strapped for cash, and Medicaid caseloads rising because of congressional mandates for increased eligibility, Medicaid DSH spending exploded, rising from $1.4

billion in 1990 to $17.5 billion in 1992—accounting in that year for 15 percent of total Medicaid spending. The number of states with provider tax or voluntary donation programs grew from six to thirty-nine during the same two years. Some states found the new funds irresistible—in Louisiana DSH spending accounted for 43 percent of its Medicaid program; in New Hampshire, 35 percent.

Congress responded with passage of the Medicaid Voluntary Contribution and Provider-Specific Tax Amendments of 1991. The measure (PL 101–234), negotiated among Congress, the Bush administration, and the National Governors Association, effectively banned provider donation schemes, required provider taxes to be "broad based" (to prevent a few providers from gaming the system), and capped DSH payments at roughly their 1992 levels.

Although the 1991 legislation did start DSH payments on a downward trend, policy makers were still worried that states were abusing the program by providing payments to hospitals that did not truly serve a disproportionate share of Medicaid and uninsured patients. As part of 1993 budget reconciliation legislation (PL 103–66), Congress cracked down again, this time limiting DSH payments to facilities that had 1 percent or more of their caseloads covered by Medicaid and limiting payments to no more than the amount of the shortfall the hospital incurred from serving Medicaid and uninsured patients.

Congress again addressed the DSH issue in the 1997 Balanced Budget Act (PL 105–33). Still worried that states were using DSH money inappropriately, lawmakers eliminated the formula adopted in the 1991 bill and put a firm cap of 12 percent on state DSH payments. It also limited, to one-third, the percentage of each state's DSH allotment that could go to long-term care facilities for mentally ill patients.

Researchers at the Urban Institute calculated that the 1997 changes would lower DSH spending by $5.8 billion between 1998 and 2002, an 11 percent decrease in spending. But by 1996 DSH spending had already dropped precipitously, falling by 19.6 percent from the year before. The reduction helped to keep that year's overall Medicaid spending increase to a historic low of 2.3 percent.

As part of the 2003 Medicare Modernization Act, Congress temporarily raised state DSH caps by 16 percent for fiscal 2004—much to the dismay of the Bush administration. States with low DSH spending (below 3 percent of their total Medicaid spending in fiscal 2000) would continue to see their DSH caps increased by 16 percent per year through fiscal 2008.

"Do-Not-Resuscitate" orders

Recognized in every state, "Do-Not-Resuscitate" (DNR) orders are legal directives for health care personnel not to perform cardiopulmonary resuscitation (CPR) on certain patients whose hearts stop. DNR orders are generally sought by patients with terminal illnesses for whom CPR is likely to be of limited use or who are in intractable pain. DNR requests can be written into LIVING WILLS or other forms of ADVANCE DIRECTIVES detailing a patient's health care desires if he or she becomes unable to communicate.

Drive-through deliveries

This term refers to the practice of sending new mothers and infants home from the hospital only twenty-four hours—and sometimes even sooner—after deliveries. Lawmakers who disapprove of the practice likened it to the "drive-through" service at a fast food restaurant. (Many lawmakers mistakenly referred to it as "drive-by" delivery, as in a random shooting.) Barring such practices was the first major legislative response to the growing backlash against MANAGED CARE. In fact, the trend toward shorter hospital stays for new mothers and newborns predated the rise of managed care. But the managed care industry, which made shortening hospital stays one of its preeminent cost-cutting practices, was seen as the primary force behind the trend.

The movement to restrict the practice began in 1994, when the media started carrying horror stories

about babies who died or were disabled by jaundice or other conditions that did not show up until more than twenty-four hours after delivery. Then, physician groups, led by the American Academy of Pediatrics and the American College of Obstetricians and Gynecologists, weighed in, calling on legislatures to guarantee minimum hospital stays. The legislatures responded. By the end of 1996, thirty states had maternity length-of-stay laws on the books, according to the Medical Group Management Association.

Congress joined the act, too. In 1996, as part of an unrelated spending bill for the Department of Housing and Urban Development and the Department of Veterans Affairs (PL 104–204), Congress required insurers to pay for stays of at least forty-eight hours after a vaginal birth and four days following a cesarean, unless the woman and her doctor agree to a shorter stay. The federal legislation was needed, its backers said, not only to protect citizens of states without their own maternity stay laws but also to reach the companies that self-insure by paying for health benefits on their own, instead of purchasing insurance coverage. An estimated 55 percent of workers belong to self-insured plans that are exempt from state insurance laws under the federal EMPLOYEE RETIREMENT INCOME SECURITY ACT (ERISA).

Drug Price Competition and Patent Term Restoration Act of 1984

See GENERIC DRUGS.

Dual eligibles

An estimated 7.5 million Americans were simultaneously enrolled in both MEDICARE and MEDICAID in 2007. These individuals are known as "dual eligibles." Medicaid coverage can be critical for dual eligibles, who are likely to be sicker and poorer than other Medicare beneficiaries. Medicaid provides not only Medicare's hefty cost-sharing requirements (PREMIUMS, deductibles, and copayments) but also services Medicare does not cover, most notably LONG-TERM CARE. Dual eligibles also consume substantially more health care services than typical beneficiaries of Medicare or Medicaid. In 2003 they constituted about 14 percent of Medicaid's caseload but consumed an estimated 40 percent of Medicaid spending. (See DEDUCTIBLE and BENEFICIARY.)

Some dual eligibles qualify for only limited aid from Medicaid, not full program benefits. Qualified Medicare Beneficiaries (QMBs, pronounced "quimbees") are those with incomes below the federal poverty line ($10,400 for an individual and $14,000 for a couple in 2008) and resources (savings and other assets) of less than $4,000 for an individual and $6,000 for a couple, but with still too much income and assets to qualify for full Medicaid benefits. QMBs are eligible to have Medicaid pay all their Medicare cost-sharing, including the Part B premium and all required deductibles and copayments (although states may pay providers at Medicaid, instead of the higher Medicare, rates). SPECIFIED LOW-INCOME MEDICARE BENEFICIARIES (SLMBs, pronounced "slimbees"), those with incomes between 100 and 120 percent of poverty, are eligible for Medicaid to pay their Part B premiums but must pay deductibles and other cost-sharing expenses themselves. (See QUALIFIED MEDICARE BENEFICIARY [QMB].)

The QMB program was created in the 1988 MEDICARE CATASTROPHIC COVERAGE ACT (PL 100–360) and subsequently left intact when the rest of that law was repealed in 1989. SLMBs were added under the 1990 Omnibus Budget Reconciliation Act (PL 101–508). As of 2006, according to a study by the National Academy of Social Insurance, about 430,000 individuals were enrolled in the QMB program, about a third of those potentially eligible. But the 370,000 individuals enrolled in the SLMB program represented only about 13 percent of those who could receive aid.

Although states and the federal government share the costs of the QMB and SLMB programs to the same extent they do in Medicaid in general, the 1997 Balanced Budget Act (PL 105–33) expanded coverage for low-income Medicare beneficiaries further still with a limited pool of fully federal funds. Those with incomes between 120 percent and 135 percent of the poverty line were

Medicaid Programs to Assist Low-Income Medicare Beneficiaries

Program	*Income limits (percent of federal poverty level)*	*Resource limits (individual/couple)*	*Funding*	*Benefits*
Full Medicaid	Varies by state; 74–100%[a]	$2,000/$3,000[a]	Medicaid funded entitlement	Full Medicaid benefits
QMB	Up to 100%	$4,000/$6,000	Medicaid funded entitlement	Medicare premiums, deductibles, and coinsurance[b]
SLMB	100–120%	$4,000/$6,000	Medicaid funded entitlement	Medicare Part B premiums
QI-1	120–135%	$4,000/$6,000	Federal block grant, first-come, first-served; funding has been periodically extended by Congress	Medicare Part B premiums

Source: Henry J. Kaiser Family Foundation, "Medicaid Programs to Assist Low-Income Medicare Beneficiaries: Medicare Savings Programs Case Study Findings," no. 4105, May 2003. Also available at www.kff.org/medicaid/4105-index.cfm, p. 14.

Notes: QMB is Qualifying Medicare Beneficiary; SLMB is Specified Low-Income Medicare Beneficiary; and QI-1 is Qualifying Individual-1.

a. Section 209(b) states may use more restrictive eligibility requirements for full Medicaid benefits, as long as they are no more restrictive than those in effect in the state's Medicaid plan as of January 1, 1972.

b. States are not required to pay for Medicare coinsurance if the Medicaid payment rates for a given service are sufficiently lower than the Medicare payment rates.

allowed to apply, on a first-come, first-served basis, to have Medicaid pay their Medicare Part B premium under a program known as Qualifying Individuals-1, or QI-1. Those with incomes between 136 percent and 175 percent of the poverty line were eligible, again on a limited basis, to have Medicaid pay a portion of their Medicare premiums as part of the Qualifying Individuals-2, or QI-2, program. The law made available $250 million for fiscal year 1999, $300 million for fiscal year 2000, $350 million for fiscal year 2001, and $400 million for fiscal year 2002, to be allocated to states based on the number of potentially eligible individuals. The QI-1 program has been renewed on a year-by-year basis through 2009; the QI-2 program was allowed to lapse. In 2006 an estimated 200,000 individual received benefits under the QI-1 program.

Durable power of attorney for health care

A legal document that invests the power in someone to make medical decisions on another person's behalf, a durable power of attorney is a form of advance directive for health care. Also known as a health care proxy, it can take effect whenever the person who has exercised it is incapacitated. It grants the agent the ability to make all medical decisions, including whether to undertake heroic measures to keep the individual alive. Agents named in durable powers of attorney for health care are generally family members or trusted friends, but they legally can be anyone except a health care professional who has a financial interest in providing health care services to the patient. (See ADVANCE DIRECTIVES and LIVING WILLS.)

E

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT; Medicaid)

States must offer this required benefit to all MEDICAID beneficiaries under age twenty-one. Under Early and Periodic Screening, Diagnostic, and Treatment (EPSDT), states must provide screening, vision, hearing, and dental services "at intervals which meet recognized standards of medical and dental practice." Screening services must include at least a comprehensive health and developmental history (including physical and mental conditions), a comprehensive physical exam, appropriate immunizations and laboratory tests, and health education. The most controversial aspect of the EPSDT program requires states to treat any conditions discovered through the required screening examinations, even if the treatment or condition is not otherwise a covered service under the state's Medicaid program.

Congress changed the rules regarding EPSDT as part of the Deficit Reduction Act of 2005 (PL 109–171). It gave states the option of providing a less comprehensive package of Medicaid benefits, then offering to provide any additional EPSDT services not covered (known as "wrap around coverage") to ensure that children under age nineteen are able to receive the required services. Child advocates, however, worried that, in practice, coordinating and obtaining services may prove difficult for low-income families.

Electronic medical records

Also known as an electronic health record, an electronic medical record, or EMR, is a computerized version of a patient's medical chart. Many health analysts think that digitizing the millions of paper records that now pack the file cabinets of doctors' offices and hospitals could be the key to both better health care and lower medical costs.

The goal of establishing electronic medical records is to build a national health information technology system that is "interoperable." In other words, information could be communicated instantaneously between doctors' offices, hospitals, pharmacies, laboratories, and other health care providers, while still protecting patient confidentiality.

The advantage for an individual patient would be to reduce the need to repeat tests or x-rays, to cut down on miscommunications between different medical professionals, and to expedite the process of obtaining prescription drugs. Information regarding drugs would be sent directly from physician to pharmacy, without the need for the patient to drop off a paper prescription.

For the health system as a whole, electronic medical records are considered a necessary prerequisite to gather the vast amounts of clinical information required to compare the effectiveness of various medical treatments and thus judge what works best. (See COMPARATIVE CLINICAL EFFECTIVENESS RESEARCH.) The efficiency aspect of electronic medical records that applies to individual patients in terms of reducing repeated tests or treatments can also multiply into vast savings for the system as a whole, some analysts say, although the CONGRESSIONAL BUDGET OFFICE (CBO) has said there is little evidence to show those savings would be as large as proponents claim.

But getting the operators of the fragmented U.S. health system to adopt information technology systems

that can communicate with each other has proved problematic, to say the least. In 2004 President George W. Bush appointed a national coordinator for health information technology, who moved to establish a National Health Information Network, which would set uniform standards for the adoption of health information technology systems. But progress toward a national system has been slow and painstaking, with considerable concern expressed by privacy advocates about the increased possibility for the release of sensitive information when it is in digital form. The 109th Congress worked on a bipartisan basis on legislation to encourage the establishment of electronic medical records, but it failed to pass.

Ironically, the one part of the U.S. health system hailed for having the most advanced electronic health recordkeeping system was among the most frequently maligned—the Department of Veterans Affairs (VA). The VA's Veterans Health Information Systems and Technology Architecture, known as VistA, has been in use since 1997. VistA allows clinicians in virtually any of the VA's hospitals, clinics, or nursing homes nationwide to instantly access all of any patient's medical information, including x-rays and other medical images.

Embryo research

This research has been explicitly banned by Congress since 1995, when antiabortion legislators appended to the LABOR–HEALTH AND HUMAN SERVICES–EDUCATION APPROPRIATION (Labor-HHS) bill language barring funding for "the creation of a human embryo or embryos for research purposes; or research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero." Before that, embryo research was largely banned by default, as part of a broader ban on research using human fetuses. (See FETAL TISSUE RESEARCH.) Regulations promulgated in 1975 theoretically allowed such research if approved by an ethics advisory board, but no board was ever able to convene, largely because of controversies related to ABORTION. (See also STEM CELL RESEARCH.)

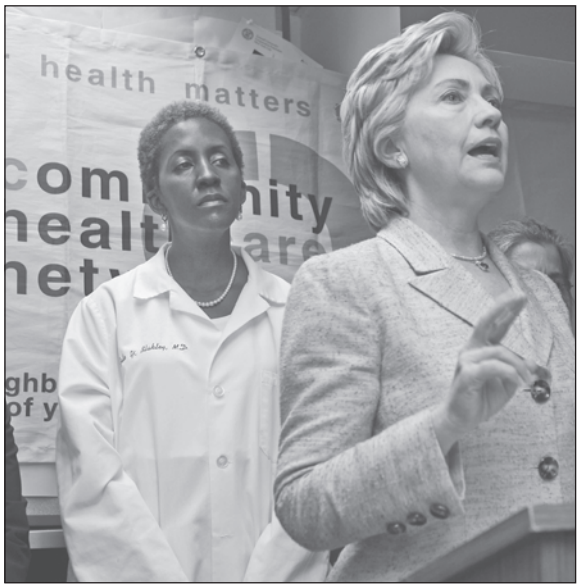
Emergency contraception

Also known as the "morning after" pill, emergency contraception is the use of high doses of standard birth control pills that can prevent pregnancy in most cases if taken within a specified time period after unprotected sex. Long used by rape crisis centers and university health services, many advocates called it "the best-kept secret in America." A 2004 survey by the Kaiser Family Foundation found that a third of women between ages eighteen and forty-four had never heard of the practice. As of 2003, only 6 percent of women say they have used the procedure, which involves taking one dose within seventy-two hours after unprotected sex and another dose twelve hours later. Yet emergency contraception using birth control pills can reduce the likelihood of pregnancy after unprotected sex by up to 90 percent. Insertion of a copper intrauterine device within five days after unprotected sex (a less-used form of emergency contraception) is 99 percent effective in preventing pregnancy.

As many as 1.7 million of the more than 3 million unintended pregnancies in the United States could be prevented by emergency contraception, experts estimate, including some 800,000 unintended pregnancies that currently result in ABORTION.

To encourage its use the FOOD AND DRUG ADMINISTRATION (FDA), in a relatively unprecedented move, in 1997 declared the use of birth control pills to prevent pregnancy after unprotected sex "safe and effective" and published guidelines for the use of ten separate brands of pills for emergency contraceptive purposes. The agency also invited manufacturers to package their products in a more user-friendly way. Until the approval of the first emergency contraceptive kit in September 1998, a physician had to prescribe a full month's supply of pills and explain to women which pills to take.

Antiabortion groups have been cautious about emergency contraception, which is different from RU486 or other drugs that cause abortions early in pregnancy.



The application to the FDA to allow over-the-counter sales of the emergency contraceptive Plan B became a lightning rod for accusations of political interference in the medical regulatory process. Here, in August, 2006, Sen. Hillary Clinton (D-NY), right, calls on acting FDA commissioner Andrew von Eschenbach to stop delaying a decision on the sale of Plan B without a prescription. Clinton had earlier vowed to place a hold on his nomination for FDA commissioner until a decision was made.
Source: AP Images/Kathy Willens

Emergency contraception does not work in women with already established pregnancies. The high-dose birth control pills can work either by preventing ovulation or by preventing implantation of an already fertilized egg. Because some consider the latter method tantamount to abortion, the NATIONAL RIGHT TO LIFE COMMITTEE (NRLC) "advises women faced with these situations to consult one or more physicians. If, in the best medical judgment of the physicians, the drug or drugs will cause an abortion, NRLC strongly opposes the taking of the drug. If the drug(s) will prevent fertilization, the National Right to Life Committee takes no position."

In 1998 South Dakota passed a law allowing pharmacists to opt out of dispensing medication if they have reason to believe it would be used to cause an abortion or "destroy an unborn child." The law was triggered by the case of a pharmacist who objected to dispensing birth control pills for emergency contraception.

In April 2003 Women's Capital Corp., the maker of the PLAN B emergency contraceptive kit, applied to the FDA for permission to sell the product without a prescription. The company, funded by foundations and other nonprofit organizations, submitted more than fifteen thousand pages of data from more than forty studies demonstrating that the drug met the FDA's requirement for nonprescription status—that it was safe, treated a condition patients can readily recognize themselves, and was simple enough to use without a physician's guidance. In October of that year, Barr Pharmaceuticals agreed to purchase Plan B from Women's Capital.

On December 16, 2003, two FDA advisory committees, meeting jointly, voted 23-4 that Plan B should be made available without prescription to women of all ages. The advisory panels also voted, 27-1, that the drug could be used safely by women of all ages. The FDA usually followed the recommendations of its advisory panels.

On May 6, 2004, however, after several delays and pressure from conservative groups and lawmakers to turn the application down, the FDA rejected Barr's application. In a letter to the company, it said the firm lacked enough data to show the drug could be used safely by girls under age sixteen without a doctor's supervision. FDA officials, however, in effect invited the company to re-apply to sell Plan B over-the-counter to women age sixteen and older, while keeping it prescription-only for younger teens. Backers of the drug immediately accused the FDA of having made the decision based on politics, not science, something both the FDA and Bush administration officials denied.

In July 2004 Barr submitted a revised application to the FDA, as suggested, seeking to allow Plan B to be sold without prescription to those age sixteen and older and still with a doctor's approval to those who are younger. The FDA, however, failed to meet its statutory deadline to decide on that application in early 2005.

The following February the Bush administration nominated Lester Crawford to succeed Mark McClellan

as FDA commissioner. In April Sens. Hillary Rodham Clinton, D-N.Y., and Patty Murray, D-Wash., announced they would block Crawford's confirmation until a decision was made on the Plan B application. The standoff continued until that July, when HEALTH AND HUMAN SERVICES DEPARTMENT (HHS) secretary Michael O. Leavitt wrote Clinton and Murray a letter promising an up-or-down decision on the application by September 1. With that promise in hand, Crawford was confirmed as FDA commissioner.

On August 26, 2005, however, instead of giving a yes or no answer on the Plan B application, Crawford announced he would instead solicit public comment through the formal federal rulemaking process, because the prospect of restricting sales of an over-the-counter medication based on age raised "novel questions" that might require new regulations. Backers of the application were outraged by the nondecision, and Susan Wood, director of the FDA's Office of Women's Health, resigned in protest five days later. Crawford himself would mysteriously resign only a few weeks after that. Later it would become public that his resignation had nothing to do with the firestorm over Plan B. He had failed to properly disclose substantial financial holdings in companies that were regulated by the FDA. He subsequently pleaded guilty to filing false financial reports and was sentenced to three years probation and a $90,000 fine.

Meanwhile, the nomination of Crawford's successor, former National Cancer Institute director Andrew von Eschenbach, was also held up by senators who wanted a guarantee of a decision on the Plan B application. The day before his confirmation hearing was scheduled, July 31, 2006, von Eschenbach sent Barr a letter telling the company that he did not think new regulations would be needed after all and that FDA had decided over-the-counter sales of Plan B should be restricted to those age eighteen and over, not age sixteen and over, as the company had requested.

Finally, on August 23, 2006, the FDA formally approved the sale of Plan B to women age eighteen and over without a prescription. Sales to younger women were to remain by prescription only. Within the first year, reported Barr, sales of the product were expected to double, to $80 million.

Emergency Medical Treatment and Active Labor Act (EMTALA)

See PATIENT "DUMPING."

Employee Retirement Income Security Act (ERISA)

This 1974 law (PL 93–406) is one of the most complicated statutes governing health policy—and one of the most pivotal. After some highly publicized failures of pension plans, the Employee Retirement Income Security Act (ERISA) was originally passed to protect the pensions of workers (by imposing financial and fiduciary standards) and to make it easier for employers with workers in multiple states to offer a single retirement plan without having to meet fifty different state standards. But late in the process (legend defines late as "in the middle of the last night of the conference on the measure," although that time frame is disputed by those who were in the room), health benefits were added to its purview. To this day, experts and courts still argue about the impact of ERISA on health insurance coverage, and its reach has blocked several states from imposing substantive health reforms for state residents. As of 2008 the U.S. Supreme Court had rendered nearly two dozen decisions on the relationship between ERISA and state laws regarding health benefits.

ERISA regulates different health plans in different ways. In 2006 the ERISA universe was composed of more than 132.8 million workers and their dependents, according to the Employee Benefit Research Institute. The only health plans not covered to some extent by ERISA are MEDICARE, MEDICAID, CIVILIAN HEALTH AND MEDICAL PROGRAM OF THE UNIFORMED SERVICES (CHAMPUS), plans covering state and local employees, those sponsored by churches or fraternal organizations, individually purchased plans, and those

purchased by groups outside of an employer-employee relationship.

ERISA prescribes a list of remedies for plans that fail to meet its requirements, and states are generally preempted from imposing laws regarding remedies (this is why ERISA blocks most people in employer-sponsored plans from suing for damages for benefit denials). Generally ERISA remedies for benefit denials consist of the cost of the denied benefit and, in some cases, attorney fees. Thus, if an ERISA plan denies a laboratory test, with the result that an undetected cancer becomes incurable, only the cost of the test can be recovered.

ERISA does not, however, block individuals in ERISA plans from filing medical malpractice suits or from collecting damages as a result of actions taken by health care professionals. Nevertheless, in most cases MANAGED CARE plans and utilization review firms have been able to avoid malpractice liability under ERISA. Legislative proposals, such as the PATIENTS' BILL OF RIGHTS (PboR) pushed by congressional Democrats in the 105th–107th Congresses, would permit lawsuits for damages arising from benefit denials and their consequences.

In what is known as ERISA's *savings clause,* the law permits states to regulate the "business of insurance," as ordered under the 1945 McCarran-Ferguson Act. But ERISA also includes what is commonly called the *deemer clause,* which prevents states from deeming employee welfare plans (plans that offer benefits other than pensions) to be in the business of insurance and therefore subject to state regulation. The deemer clause puts employer plans that are self-funded (meaning the company pays for the benefits, instead of taking out insurance) under the exclusive reach of ERISA and out of reach of state regulation. As a result, states cannot impose premium taxes or mandated benefits on self-insured plans. An estimated 55 percent of workers and dependents—some 73 million people—were in ERISA self-insured plans in 2006. Alternatively, if an ERISA plan buys an insurance product, putting the insurer at risk for the cost of the care, the state can regulate that insurance.

EMTALA (Emergency Medical Treatment and Active Labor Act)

See PATIENT "DUMPING."

End-stage renal disease (Medicare)

Some 418,000 Americans suffering from kidney failure were enrolled in MEDICARE in 2006, representing one of the program's fastest growing populations. Eligibility for those suffering from end-stage renal disease (also known as ESRD) was included in the 1972 Social Security amendments with little debate. It was added to the bill (which also made eligible for Medicare those who qualified for SOCIAL SECURITY DISABILITY INSURANCE [SSDI]) as a floor amendment in the Senate and included in the final bill with less than ten minutes' discussion. ESRD patients are eligible for Medicare if they meet the requirements for Social Security Old Age and Survivors Insurance Benefits (meaning they have worked forty quarters at a qualifying job), if they are entitled to monthly Social Security benefits, or if they are spouses or dependents of individuals who meet these requirements. The requirements make eligible more than 90 percent of the population suffering from kidney failure so severe as to require kidney dialysis or a kidney transplant. In 1994 only 7.7 percent of dialysis patients, and 9.3 percent of those requiring transplants, did not qualify.

Like Medicare in general, the ESRD program has been substantially more expensive than was projected when it was established. At the time it was estimated that by 1995 enrollment would level out at about ninety thousand individuals—a threshold passed in 1985. Between 1998 and 2003, enrollment in the program grew an average of 8.6 percent annually. In 2001, according to the GOVERNMENT ACCOUNTABILITY OFFICE, the cost per ESRD enrollee averaged $46,600, compared with $6,200 for the average Medicare beneficiary. The most significant trend in the program has been an increase in the number of older patients (the fastest growth has

been among people over age seventy-five, followed by those aged sixty-five to seventy-four) and in the number of patients whose kidney failure is the result of diabetes, which makes it more difficult to treat. Medicare's ESRD program pays both for dialysis (which remains the predominant treatment) and for kidney transplant surgery. In 2003 Medicare paid for 15,589 kidney transplants.

Entitlement

A benefit for which eligibility is automatic if a person meets specific requirements—and which the government has a legal obligation to provide—is called an entitlement. MEDICARE and MEDICAID are the major health care entitlement programs. Entitlements are also referred to as *mandatory spending programs* (as opposed to discretionary), in that Congress must provide funding for them, and their spending levels can be changed only by altering eligibility requirements or benefits.

EPSDT

See EARLY AND PERIODIC SCREENING, DIAGNOSTIC, AND TREATMENT (EPSDT; MEDICAID).

ERISA

See EMPLOYEE RETIREMENT INCOME SECURITY ACT (ERISA).

Evidence-based medicine

This term encompasses therapies or treatments whose effectiveness has been demonstrated scientifically. In highly respected double-blind studies, one group of patients, called the control group, is given a placebo, or inactive drug, or else treated with a known therapy, and the other group is provided the treatment being studied. Neither the patients nor the treating health professionals know which patients are in which groups—thus the term double-blind. Surprisingly, much of what is done in medicine is not evidence-based. It is simply passed down from doctor to doctor and believed to work, or believed to work better than another treatment, without any actual proof.

Experience rating

The insurance practice of setting premiums according to the health status of a group—that is, according to the insurer's "experience"—is called experience rating. Thus a group whose members have incurred significant medical bills in the past will pay more in the future.

External review

The process by which health care disputes are mediated by outside entities independent from the parties that disagree is known as external review. External review is used to resolve disagreements—often regarding payment or clinical issues—between patients and health care organizations.

MEDICARE has had an external review process since 1989, operated by the Center for Health Dispute Resolution (CHDR, pronounced "cheddar"). Medicare's program, which automatically forwards to CHDR cases denied by internal review mechanisms, is rarely used. For every one thousand Medicare beneficiaries in MANAGED CARE plans, about two cases go to Medicare's external review mechanism each year.

State laws mandating that managed care plans establish external review processes are also gaining in popularity. In 1998 eighteen states had such laws; five of them passed in the first six months of the year. The laws vary widely, however. Some simply specify the existence of an outside review entity, and others prescribe in more detail how that outside review should occur, how quickly, how much expertise outside reviewers should have, and who should pay the costs. By 2002 all but eight states had some sort of external appeal law or regulation.

A 1998 study by the Georgetown University Institute for Health Care Research and Policy found that external reviews uphold coverage or medical decisions made by health plans nearly as often as they overturn them, siding with the patient between 32 and 68 percent of the time. The study also found the state external review mechanisms were used even more rarely than Medicare's. Health plan officials say the low usage rate reflects the high quality of care provided and the efficiency of internal appeals mechanisms. But state regulators worried that many people denied care do not use external reviews because they do not know of their availability or because they are too sick or die before they can appeal.

The U.S. Supreme Court in June 2002 ruled that state external review laws did not violate the EMPLOYEE RETIREMENT INCOME SECURITY ACT (ERISA). In a 5-4 ruling in the case, *Rush Prudential HMO v. Moran,* the Court upheld an Illinois law that had permitted a speech therapist, Debra Moran, to get the second opinion on surgery to correct a nerve problem in her shoulder.

F

FACE

See FREEDOM OF ACCESS TO CLINIC ENTRANCES ACT (FACE).

False Claims Act

The False Claims Act is a Civil War–era statute (it was signed by President Abraham Lincoln in 1863) that has been used frequently since the 1980s in the effort to fight health care fraud. The original law was used to prosecute defense contractors who failed to supply the Union Army with promised goods or who delivered goods that were shoddy. A key element of the law was the ability of individual citizens to bring "whistleblower" lawsuits against those who had defrauded the government. These lawsuits are referred to as *qui tam* actions, Latin for "one who sues on behalf of the king as well as for himself." If successful, the whistleblowers could collect up to 50 percent of any recoveries. Congress updated the law in 1986, again in an effort to fight fraud by defense contractors. The new version (PL 99–562) increased penalties against those who defrauded the government, clarified the standards and procedures for bringing fraud suits, provided new incentives for private citizens to report suspected fraud, and protected whistleblowers who reported fraud cases. It also raised the percentage of recovery for individuals who brought *qui tam* suits against fraud perpetrators. In 1943 Congress had lowered the percentage to 10 percent; the 1986 law raised it to a potential 30 percent.

In the late 1990s, the federal government began using the False Claims Act to fight MEDICARE and other health care fraud. The much-publicized investigation against the giant hospital firm Columbia/HCA was initiated by a False Claims Act whistleblower suit filed by a hospital accountant from Montana. In fiscal 2005 alone, the government recovered $1.1 billion in health-related fraud settlements and judgments.

FDA

See FOOD AND DRUG ADMINISTRATION (FDA).

Federal Employee Health Benefits Plan (FEHBP)

The Federal Employee Health Benefits Plan (FEHBP) is the nation's largest employer-sponsored health benefits program, serving more than nine million federal workers, retirees, and dependents. Established by Congress in 1959, the FEHBP began covering enrollees in 1960. In 2007 federal workers could choose from some 350 different plans, including health maintenance organizations, preferred provider organizations, and consumer-driven options allowing workers to set up accounts from which to pay their routine health expenses. The federal government paid 72 percent of the weighted average cost of all plans in the program, up to a cap of 75 percent. The enrollee paid the remainder of the premium. Although the FEHBP has had its own problems with ADVERSE SELECTION (in the late 1980s one of its most popular plans dropped out after it got too many sick enrollees) and with premiums that have fluctuated, sometimes considerably, the program has worked well overall. Many see it as a model program

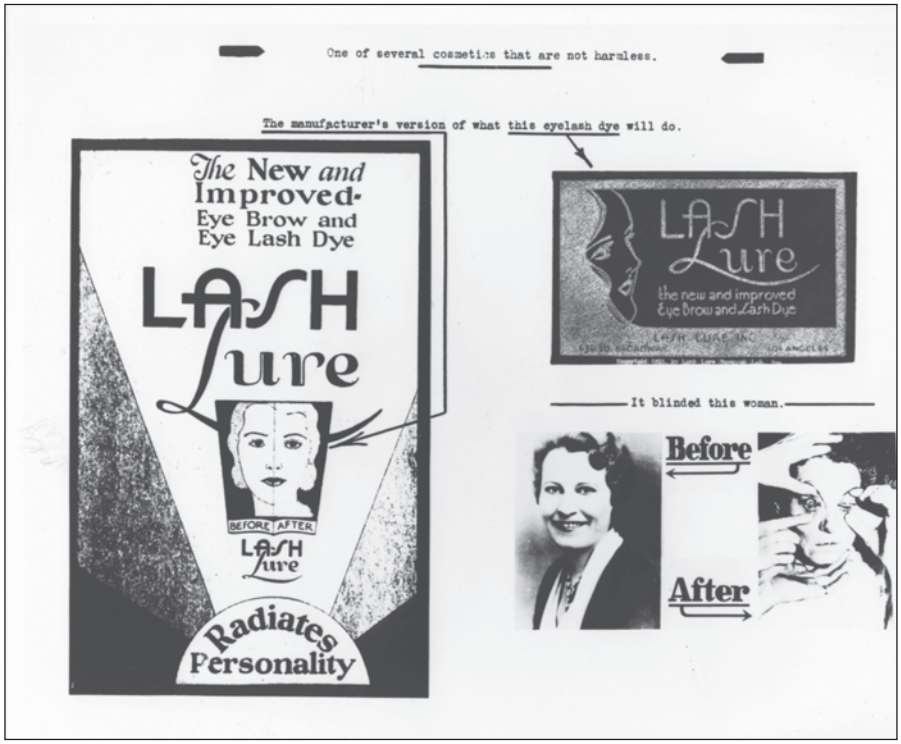
that provides a broad choice of plans at affordable premiums with excellent comparative information to help enrollees choose among the plans. Participants in FEHBP can change plans once a year during a month-long "open season." (See HEALTH MAINTENANCE ORGANIZATION [HMO], PREFERRED PROVIDER ORGANIZATION [PPO], and CONSUMER-DRIVEN HEALTH PLANS.)

Federal Food, Drug, and Cosmetic Act (FFDCA)

Originally passed in 1906 as the Pure Food and Drug Act, the 1938 Federal Food, Drug, and Cosmetic Act (FFDCA) is the governing statute of the FOOD AND DRUG ADMINISTRATION (FDA). It includes statutory language relating to human and animal drugs and biologic products, food, cosmetics, and medical devices. According to the HOUSE ENERGY AND COMMERCE COMMITTEE, which oversees the FFDCA, the act "is intended to assure the consumer that foods are pure and wholesome, safe to eat, and produced under sanitary conditions; that drugs and devices are safe and effective for their intended uses; that cosmetics are safe and made from appropriate ingredients; and that all labeling and packaging is truthful, informative, and not deceptive." The most recent overhaul of the statute was the 1997 FDA Modernization Act (PL 105–115). In 2007 Congress ordered the agency to improve its oversight of drugs after they reach the market as part of legislation to renew the agency's authority to levy user fees on drugmakers to help speed up the drug approval process. (See PRESCRIPTION DRUG USER FEE ACT [PDUFA].)

Federal medical assistance percentage (FMAP)

The federal medical assistance percentage, known as an FMAP, is the rate at which the federal government reimburses a state for spending on MEDICAID, the joint federal-state health program for the poor. FMAPs are



In an attempt to raise awareness of the dangers of certain consumer products the FDA created an exhibit dubbed the "American Chamber of Horrors" in the 1930s. Here, the benefits claimed by a cosmetic company's advertisements are graphically juxtaposed against the potential harm of the product. The 1938 Federal Food, Drug and Cosmetic Act strengthened government regulation of food, cosmetic, and other medical products.
Source: Food and Drug Administration History Office

determined annually using a formula that compares each state's per capita income with the United States as a whole. Wealthier states are matched at a rate of 50 percent, and states with lower per capita incomes get a larger share from the federal government, up to 76 percent. Overall, the federal government paid about 57 percent of Medicaid costs in 2006. In fiscal 2008, thirteen states (California, Colorado, Connecticut, Delaware, Illinois, Maryland, Massachusetts, Minnesota, New Hampshire, New Jersey, New York, Virginia, and Wyoming) had FMAPs of 50 percent. Mississippi had the highest FMAP at 76.29 percent, meaning that for every dollar the state spent on Medicaid, it contributed only twenty-three cents. Other states with FMAPs higher than 70 percent in fiscal 2008 were Arkansas (72.94), Louisiana (72.47,) New Mexico (71.04), Utah (71.63), and West Virginia (74.25). (For a complete list of fiscal 2009 FMAPs, see table on p. 132)

Federally qualified health centers (FQHCs)

Federally qualified health centers (FQHCs) include federally funded community health centers, migrant health centers, and health clinics run by Native American tribes, tribal organizations, and urban Native American organizations, as well as certain primary care clinics that meet the requirements for community health centers but do not receive federal funding. To meet those requirements such clinics must provide primary care services to people living in the clinic's service area, regardless of their insurance status or ability to pay, or be clinics recognized by the HEALTH RESOURCES AND SERVICES ADMINISTRATION (HRSA) as an FQHC as of January 1, 1990. Until passage of the 1997 Balanced Budget Act (PL 105–33), MEDICAID was required to reimburse FQHCs for care provided to Medicaid patients and to pay them 100 percent of the facility's reasonable costs for providing the services. Under the 1997 law, however, that was to be phased down, beginning in the year 2000, to a 95 percent reimbursement of the FQHC's costs, declining to 70 percent in 2003, and removing any minimum payment requirements after that. In 2000, however, as part of a MEDICARE and Medicaid "giveback" bill, Congress revoked those provisions and implemented a new PROSPECTIVE PAYMENT SYSTEM (PPS) for FQHCs instead that boosted payments.

Fee-for-service

Fee-for-service is a system under which physicians or other health care providers bill for each service individually as it is provided to a patient. Critics of fee-for-service systems note that they are inherently inflationary, giving providers an incentive to provide more services, because the more services given, the more money the provider can make. Insurance plans that cover fee-for-service care are known as *indemnity plans,* because the insurer "indemnifies" the patient from most of the cost of care. Generally, although not always, fee-for-service insurance plans permit patients to seek care from any licensed health care professional and cover a set portion of the costs after the patient has met an annual DEDUCTIBLE. Many patients, however, to the extent they can afford such plans, prefer fee-for-service because it gives them complete freedom to choose any health care provider, unlike MANAGED CARE, which employs limits on providers to a greater or lesser degree. The traditional MEDICARE program is one of the few remaining large-scale fee-for-service plans remaining in the United States. Most private insurers no longer offer unfettered fee-for-service because premiums would be too expensive for employers or individuals to afford.

FEHBP

See FEDERAL EMPLOYEE HEALTH BENEFITS PLAN (FEHBP).

Fetal tissue research

Fetal tissue research is an ABORTION-related science controversy that has continued for more than two decades. The first foray came in 1974, when, as part of a reauthorization of the NATIONAL INSTITUTES OF HEALTH (NIH) training programs (PL 93–348), Congress placed

a moratorium on federally funded research on "the living human fetus, before or after abortion," unless the purpose was to ensure the fetus's survival. The 1974 action came in response to horror stories about unregulated and ethically questionable research on fetuses dead and alive and on other living human research participants. The law also created a two-year National Commission on the Protection of Human Subjects of Biomedical and Behavioral Research, which was to recommend whether or how such research was to proceed.

That commission concluded that such research could be ethically acceptable if certain safeguards were imposed. According to 1995 regulations, research on live fetuses that would pose more than a "minimal risk" to the woman or fetus would be permissible only if performed to meet the health needs of that specific fetus or pregnant woman. Research on aborted fetuses was also acceptable, but only if it did not alter the timing or method of the planned abortion.

For much of the 1980s, however, virtually all fetal research was banned by default, because the Ethics Advisory Board, which was to consider and approve individual projects on in vitro research or research that would impose more than a minimal risk but not benefit the specific woman or fetus, was disbanded in 1980 (in favor of a separate President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research). The controversy continued throughout the 1980s, with various commissions unable to reach consensus, or even to establish themselves, because of continuing dissent over abortion-related issues. In 1985 and 1988 legislation, Congress blocked the agency's ability to waive the minimal risk standard for fetal research.

In 1988 a group of researchers applied to use federal funds to transplant fetal tissue in an attempt to treat Parkinson's disease. Fetal tissue, the scientists said, grows faster, is more adaptable, and is less likely to be rejected by a transplant recipient's immune system than other forms of tissue. Such use of fetal tissue, they argued, could help produce breakthrough treatments or even cures for such intractable ailments as Parkinson's disease, juvenile diabetes, epilepsy, and Alzheimer's disease. Abortion opponents, however, argued that such treatments, if proven successful, could encourage more abortions.

Instead of approving the project, Assistant Secretary for Health Robert Windom of the HEALTH AND HUMAN SERVICES DEPARTMENT (HHS) ordered a review of the ethical, legal, and scientific questions it posed. Two subsequent advisory panels found such research "acceptable public policy" as long as safeguards were adopted to protect against commercialization or inappropriate encouragement of women to have abortions to provide the tissue. But the George H. W. Bush administration decided to reject the recommendations of the commissions and to keep Windom's moratorium in place. Windom's successor, James O. Mason, told a House subcommittee that such research objectives "conflict with administration policy that seeks to ensure the protection of all human life." Even the NIH director, Bernadine Healy, who sat on both of the advisory panels that recommended letting the research go forward and who supported that view, agreed that the ban should remain when she assumed the NIH helm in 1991, presumably a condition for being given the job.

The moratorium was a narrow one—it affected only fetal tissue transplants and only tissue from "elective" abortions, not from ectopic pregnancies (in which the fetus grows outside the uterus, requiring termination to save the woman's life) or spontaneous abortions (miscarriages). But researchers insisted that the moratorium nevertheless blocked all their efforts, because tissue from miscarriages or other naturally occurring processes tended to be diseased or otherwise unusable, as well as being available only randomly. And although the moratorium did not block privately funded research, scientists argued that federal rules were needed to ensure that tissue was not inappropriately induced from women or bought and sold.

Congressional efforts to overturn the moratorium began in 1990, when the HOUSE ENERGY AND COMMERCE COMMITTEE approved a reauthorization bill for the NIH that included language eliminating the ban. But that measure never got to the House floor for a vote. In 1991 the House did pass an NIH bill overturning the ban—over a veto threat from President Bush. But the margin, although large (272-144), was nevertheless short of the

needed two-thirds to override the promised veto. The Senate did not act until 1992, but when it did, it acted more definitively, approving the measure by a veto-proof 85-12. Among the senators speaking in favor of lifting the fetal research ban were such antiabortion stalwarts as Strom Thurmond, R-S.C. (who spoke of the potential for the research to benefit his daughter, Julie, who had diabetes), and Mark Hatfield, R-Ore., a long-time backer of biomedical research efforts.

As promised, Bush vetoed the NIH bill in June 1992 over the fetal tissue issue as well as other matters. The bill, he said in his veto message, "is unacceptable to me on almost every ground; ethical, fiscal, administrative, philosophical and legal." On the matter of fetal research, Bush said, "I believe this moratorium is important in order to prevent taxpayer funds from being used for research that many Americans find morally repugnant, and because of its potential for promoting and legitimizing abortion." In an effort to head off a veto override, Bush ordered the establishment of a "tissue bank" to collect tissue from ectopic pregnancies and miscarriages. "This approach truly represents the pro-research and ethical alternatives that will allow this research to go forward without relying on a source of tissue that many find to be morally objectionable," the president said.

Many scientists insisted that the tissue bank was unworkable, but it apparently scored politically. Although the Senate voted to override by a vote of 73-26 on October 1, the House failed to override it by ten votes on October 2, by a margin of 266-148.

Just three months later, on January 22, 1993, President Bill Clinton abruptly ended the five-year saga. On his second full day in office, Clinton signed a series of executive orders repealing a number of abortion restrictions left over from the Reagan-Bush era, including the fetal tissue research moratorium.

Congress ratified Clinton's decision with passage in May of the often-delayed NIH reauthorization bill (PL 103–43). That legislation specifically authorized funding for "the transplantation of fetal tissue for therapeutic purposes" and instituted a series of safeguards. It required a woman providing tissue to sign a statement declaring that she was donating fetal tissue for research, that she understood she could not designate the recipient of the tissue, and that she was not aware of the recipient's identity. The physician performing the abortion was to certify that the woman gave her consent to have an abortion before she was asked about fetal tissue donation. The physician also had to disclose any financial or other interest in the subsequent research as well as any known medical risks. The measure barred the sale or purchase of human fetal tissue from induced abortions and any donation intended for a specific person, including a relative of the donor. This was meant to prohibit a woman from getting pregnant to have an abortion to donate the tissue to a family member. Violators could face up to ten years in prison.

Despite the antiabortion shift in Congress following the Republican takeover as a result of the 1994 elections, the fetal tissue controversy seemed settled by the late 1990s. In 1997, during Senate consideration of the fiscal 1998 LABOR–HEALTH AND HUMAN SERVICES–EDUCATION APPROPRIATION (Labor–HHS) bill, Sen. Daniel R. Coats, R-Ind., a leading antiabortion opponent, offered an amendment to reinstate the fetal tissue transplant research funding ban. Coats's amendment was defeated, 30–60. Instead, antiabortion forces turned most of their research efforts toward the human cloning and STEM CELL RESEARCH issues (see CLONING, HUMAN).

FFDCA

See FEDERAL FOOD, DRUG, AND COSMETIC ACT (FFDCA).

First-dollar coverage

Those with true "first-dollar coverage," the most generous form of health insurance, pay no deductibles or copayments for their health care. (See DEDUCTIBLE.) Economists argue that first-dollar coverage is inherently inflationary, because individuals, with none of their own money at risk, have no financial incentive to limit their consumption of health care services. If individuals pay all or a portion of the premiums, the coverage is more inflationary still, because they may feel they are wasting their money if they do not consume health care. First-dollar

coverage, however, is increasingly rare, as more and more employers have either moved workers to MANAGED CARE plans (which have other ways to limit spending) or else instituted higher cost-sharing for employees.

FMAP

See FEDERAL MEDICAL ASSISTANCE PERCENTAGE (FMAP).

FOCA

See FREEDOM OF CHOICE ACT.

Food and Drug Administration (FDA)

Born in the early 1900s at least partly in response to public outrage at the meat-packing methods detailed in muckraker Upton Sinclair's *The Jungle,* the Food and Drug Administration (FDA) in 2008 regulated products accounting for one of every four dollars spent in the United States. The FDA is charged with ensuring that the food Americans eat is prepared and packaged in a safe and sanitary manner; that packaged food displays truthful and informative labels; that prescription and over-the-counter drugs and medical devices are safe and effective for their intended uses; and that cosmetics are safe and unadulterated. In 2008 the FDA's ten thousand employees monitored the manufacture, import, transport, storage, and sale of $1 trillion worth of products.

The FDA is probably best known for its role in the drug approval process. The original 1906 Pure Food and Drug Act made it illegal to market misbranded or adulterated drugs, but it gave the federal government no authority to approve drugs before their introduction. Passage of the 1938 FEDERAL FOOD, DRUG, AND COSMETIC ACT (FFDCA) for the first time required that drugs be proven safe before they could be marketed. In 1962 the Kefauver-Harris amendments added the requirement that drugs be proven not only safe but also effective in meeting their intended purposes.

By the 1980s, though, manufacturers were turning out new drugs faster than the FDA could review them. In 1992, in response to complaints from drugmakers that the agency was taking too long to approve applications for new drugs, Congress passed the PRESCRIPTION DRUG USER FEE ACT (PDUFA), (pronounced "padoofa"; PL 102–571). The law, which required drug companies to pay extra to have the FDA review their drug applications (the FDA does not actually test drugs but only renders judgment on research conducted or commissioned by the companies themselves), cut drug approval times in half. In 1997 Congress renewed PDUFA as part of a broader FDA Modernization Act (PL 105–115). That measure codified many actions the agency had previously taken to speed drugs for life-threatening diseases to market and to make experimental drugs more available to patients with few or no other treatment options. In an effort to shorten the time frame for review of those applications, the measure expanded a program to test whether third parties could safely review applications for certain new medical devices. In 2002 Congress passed a separate bill (the Medical Device User Fee and Modernization Act) creating a user fee system for medical devices (PL 107–250). The law required fees ranging from a little more than $2,000 up to $154,000 for FDA to hire reviewers to speed up the approval process. The law also allowed outside reviewers to inspect device-manufacturing facilities. And it called for greater FDA oversight of "single-use" medical devices that were being reprocessed for additional purposes.

In 1996 the FDA asserted authority to regulate a previously unregulated area of U.S. commerce—the sale of tobacco products. Regulations issued on August 28, intended to deter smoking by children and teenagers, claimed that the FDA had authority over cigarettes and smokeless tobacco because they fall under the Federal Food, Drug, and Cosmetic Act's definition of "drugs" and "devices." In 1998, however, a three-judge federal appeals court panel ruled that the agency had overstepped its authority. The U.S. Supreme Court in 1999 agreed to consider the case. On March 21, 2000, the Court in *Food and Drug Administration v. Brown & Williamson Tobacco Corp.* upheld the appeals court ruling that the FDA lacked congressional authority to regulate tobacco. Con-

Former FDA commissioners Donald Kennedy, left, David Kessler, third from left, Frank Young, far right, and then commissioner Andrew C. von Eschenbach, second from left, are sworn in during the House Oversight and Government Reform Committee hearing "Food and Drug Administration Critical Mission and Challenges for Future" in May 2007. The hearing was called to examine funding, scientific integrity, and enforcement of regulations by the agency.
Source: CQ Photo/Scott J. Ferrell

gress in 1998 had failed to pass legislation to implement the global tobacco settlement reached between tobacco companies and state attorneys general that would have given the FDA explicit authority to regulate tobacco products and, in 2000, declined to take up legislation to address the Supreme Court ruling.

In the early 2000s, concerns were raised that the FDA might be approving drugs too fast, with too little focus on safety. In 2004, after reports linking suicide with the use of popular antidepressant drugs by children and teenagers, the FDA ordered stronger warnings put on the drugs. Then, in September of that year, drugmaker Merck withdrew from the market the popular pain drug Vioxx, after reports linking its use to increased chances of heart attacks and strokes. That November, FDA whistleblower David Graham testified before a Senate committee that the agency was incapable of pulling dangerous drugs off the market, because safety reviewers had to report to officials who had approved the drugs in the first place and who did not want to admit that they might have erred in allowing dangerous products on the market.

After a two-year battle, Congress declined to create a separate office of drug safety within the FDA, as Graham and many lawmakers wanted. But as part of a larger bill passed in 2007 to reauthorize the FDA's drug review user fees, Congress did enact some sweeping changes to beef up the agency's authority to ensure the safety of medicines. The measure (PL 110–85) gave the agency authority to require drugmakers to change drug labels and to conduct follow-up studies on drugs after they are approved. It also allowed the agency for the first time to review "direct to consumer" advertising before it can be presented to the public. Print ads would have to include a toll-free phone number for consumers to report harmful side effects. The law also called for creation of a database with results of clinical trials of drugs that would be available to the public via the Internet.

Formulary

A formulary is a list of prescription drugs and their appropriate dosages covered by a particular insurance plan. Hospitals, government agencies (including the Department of Veterans Affairs), and individual insurers develop their own formularies, generally by appointing a group consisting of physicians and pharmacy experts.

Their task is to select the drugs considered to be most effective and cost-effective. According to the Academy of Managed Care Pharmacy, "a well-developed and managed formulary improves quality of care by assuring that only those drugs determined by clinical experts to be the most safe and effective for patients with certain medical conditions are dispensed on a regular basis." Some plans will not pay for drugs not on the formulary; others charge extra for nonformulary prescriptions. Consumer advocates and even some doctors have complained that some insurers limit their formularies to only the least expensive drugs or to one or two drugs to treat conditions for which patients' needs differ. Their arguments were buttressed by a controversial 1996 study by researchers from the University of Utah medical school who found that tightly controlled formularies raised overall medical costs, in some cases twice as high as plans without formularies. The researchers, whose study was published in the *American Journal of Managed Care,* theorized that by using the lowest cost drugs, patients got sicker, saw the doctor more, were hospitalized more often, and ended up using more medications to cure their ailments.

FQHCs

See FEDERALLY QUALIFIED HEALTH CENTERS (FQHCs).

Freedom of Access to Clinic Entrances Act (FACE)

The Freedom of Access to Clinic Entrances Act (PL 103–259) was the principal piece of abortion rights legislation enacted by the 103d Congress. It was prompted by a 1993 U.S. Supreme Court decision, *Bray v. Alexandria Women's Health Clinic,* which invalidated the use of a Reconstruction-era civil rights law to stop antiabortion protesters from harassing women seeking to enter ABORTION clinics. It also came in response to escalating violence among antiabortion extremists, including the shootings in 1993 of two physicians who performed the procedure. Supporters of the measure argued that local laws were inadequate to address the problem and successfully framed the issue as one of law enforcement instead of one of abortion. That helped win the support of even some strong abortion opponents, despite complaints from antiabortion groups that the law would impinge on the free speech rights of abortion foes.

The Supreme Court, however, in 1994 upheld the law, and the right in general of governments to restrict protesters to ensure access to abortion clinics, in *Madsen v. Women's Health Center, Inc.*

As cleared by Congress on May 12, 1994, the measure made it a federal crime to use force, or the threat of force, to intimidate abortion clinic workers or women seeking abortions. Violators faced criminal penalties of jail time and fines. The bill also allowed affected individuals to sue for compensatory damages or court injunctions to restrain blockaders.

Both the House and Senate originally passed the bills in 1993, but the Senate had made changes to its version during floor debate in November that prevented a final measure from clearing before the end of the year. One key amendment, offered by Sen. Orrin G. Hatch, R-Utah, extended the bill's reach to protect not just those seeking abortions but also "any person lawfully exercising or seeking to exercise the First Amendment right of religious freedom at a place of worship." During conference with the House, Hatch cited several instances in which churchgoers had been harassed by protesters for various causes. House conferees agreed to the provision after clarifying that it would not create a new legal recourse for those praying while simultaneously demonstrating outside an abortion clinic. House negotiators also accepted an amendment added to the Senate bill by Edward M. Kennedy, D-Mass., to impose lower maximum criminal penalties for nonviolent obstruction, such as lying down in front of a clinic door. Whereas those found guilty of violent offenses could be subject to fines of up to $100,000 and a year in prison for a first offense and up to $250,000 and three years in prison for a second offense, nonviolent offenders could be fined only up to $10,000 and imprisoned for six months for a first offense and up to eighteen months and up to $25,000 for a second offense.

Freedom of Choice Act

The Freedom of Choice Act, also known as FOCA, was drafted by ABORTION rights backers in 1989 who said they wanted to write into statute the protections for the procedure guaranteed by the U.S. Supreme Court in the 1973 case *ROE V. WADE*. But opponents insisted that the bill would go much further, invalidating even some restrictions the Court had deemed permissible under the *Roe* framework, such as state laws requiring PARENTAL NOTIFICATION or PARENTAL CONSENT for a minor's abortion or bans on using public funds for the procedure.

House and Senate Democratic leaders had vowed to bring the bill to the floor in 1992 just before the Republican National Convention, to highlight disagreement within the GOP over abortion rights. They also hoped that President George H. W. Bush's opposition to abortion rights would help Democratic candidates in the fall elections.

But disarray within Democratic ranks, combined with a lack of public outcry over the Supreme Court's decision upholding such provisions of a controversial Pennsylvania law as a twenty-four-hour waiting period and a requirement that women hear a state-sponsored lecture on abortion before having the procedure, ultimately derailed the effort. Democratic vote-counters in both houses said they could produce margins for passage but doubted they could fend off amendments adding restrictions such as those in the Pennsylvania law. Although the Democrats knew all along that they lacked the votes to override a promised veto from President Bush, they had hoped outrage over the Court's decision would propel the bill to passage. That outrage, however, never materialized, because the central holding in the case, *PLANNED PARENTHOOD OF SOUTHEASTERN PENNSYLVANIA V. CASEY,* upheld the central tenet of *Roe,* the right of a woman to have an abortion.

In 1993, with a president who had supported the bill while on the campaign trail, backers of the FOCA thought they would have smooth sailing. But they badly underestimated the depth of ambivalence on the abortion issue in both the House and Senate, as well as the public at large. And although both the House and Senate Judiciary Committees would ultimately approve the measure, it never reached the floor of either chamber for a vote.

Congress balked at a number of the bill's possible effects, such as prohibiting restrictions on third-trimester abortions, overturning several states' requirements that teenagers obtain the consent of one or both parents before having an abortion, and prohibiting requirements for a twenty-four-hour waiting period before a woman could obtain an abortion. And, with the budget, health care reform, and the North American Free Trade Agreement occupying much of his time, President Bill Clinton proved unwilling to spend political capital on the divisive abortion issue, leaving the bill to languish.

The Supreme Court's 2007 decision upholding the Partial Birth Abortion Ban Act, the first-ever federal ban on a specific abortion procedure, brought new calls for passage of a federal Freedom of Choice Act from Democrats who had recently taken control of both the House and Senate for the first time since 1995. But with an antiabortion president, George W. Bush, still in the White House and essentially antiabortion majorities still in power in both chambers, the calls were considered rhetorical at best. (See PARTIAL-BIRTH ABORTION.)

G

Gag clauses (in managed care)

Gag clauses are jargon for language in contracts between MANAGED CARE plans and physicians that limits what physicians may tell patients about their treatment options. Some of these gag clauses are explicit, such as prohibitions on telling patients about specialists or other providers not covered under the health plan or barring physicians from discussing procedures considered experimental or otherwise not covered. Others are less overt, such as language requiring doctors not to "disparage" the health plan or requiring physicians to consult the health plan before having certain discussions with patients.

A 1997 General Accounting Office report that examined 1,150 contracts used by 529 health maintenance organizations (HMOs) found no explicit gag clauses, buttressing the arguments of managed care advocates and legislators who opposed federal regulation of managed care practices. But the report did find that 60 percent of the contracts included language "that some physicians might interpret as limiting communication about all treatment options," such as forbidding physicians from denigrating the health plan or encouraging patients to choose another plan. The report also noted that, even without explicit contract language, the ability of managed care plans to terminate doctors and thereby deprive them of a significant portion of their patients "can bring significant pressure to bear on physicians to modify their practice patterns or discussions with patients." (See HEALTH MAINTENANCE ORGANIZATION [HMO].)

By June 1998, forty-five states (all except Alabama, Illinois, Mississippi, South Carolina, and South Dakota) had passed laws barring managed care plans from blocking physicians from discussing all potential treatment options with patients, whether covered by the plan or not. In the 1997 Balanced Budget Act (PL 105–33), Congress also by statute barred gag clauses in managed care contracts serving MEDICARE and MEDICAID beneficiaries. (President Bill Clinton had decreed such clauses impermissible in orders issued in December 1996 for Medicare and in March 1997 for Medicaid.) But that left unprotected not only those in states without laws but also the estimated forty-nine million workers with employer-provided coverage in self-insured health plans that under the federal EMPLOYEE RETIREMENT INCOME SECURITY ACT (ERISA) were exempt from state regulation. (See SELF-INSURANCE.)

Efforts to enact separate legislation to protect those left uncovered, although drawing strong bipartisan support since members began pushing them in 1996, remained unsuccessful as of 2008.

In July 1996 the House Commerce Committee approved the Patient Right to Know Act, sponsored by Rep. Greg Ganske, R-Iowa, a physician who would later become one of a handful from his party to endorse the Democrat-backed PATIENTS' BILL OF RIGHTS (PboR), and Edward J. Markey, D-Mass. Under the measure, doctors who provided complete information to their patients could not be removed from a health plan's list of authorized health care providers. The health plan also could not break the doctor's contract or refuse to pay the costs of treatment. The bill included civil penalties of up to $25,000 per offense for an entity that, through written or oral communications, attempted to restrict doctors from disclosing medical information to patients. The full House, however, never took up the bill.

The Senate also acted on the gag clause issue in 1996. During consideration of that year's Treasury–Postal

Service appropriation bill in September, fifty-one senators voted for an anti–gag clause amendment offered by Sen. Ron Wyden, D-Ore. But because the CONGRESSIONAL BUDGET OFFICE (CBO) had estimated that the proposal would increase health care costs for the federal government, sixty votes were needed to overcome a budget "point of order." Wyden quickly rewrote his amendment to render it revenue-neutral, but Senate GOP leaders managed to block it from reaching the floor for the remainder of the 104th Congress.

In 1997 the issue picked up still more support. The Ganske-Markey Patient Right to Know Act attracted 302 cosponsors, more than two-thirds of the House. And both Republicans and Democrats in 1998 included anti–gag clause language in broader bills to regulate the managed care industry. But none of those broader bills was ever enacted, as the type of managed care plans that required doctors to sign contracts that might include gag clauses fell increasingly out of favor among both doctors and patients in the early 2000s.

Gag rule (in abortion)

Gag rule is the name family planning advocates attached to regulations proposed during the Reagan administration to bar ABORTION counseling and referrals in federally funded family planning facilities. The battle raged almost nonstop from September 1987, when the rules were first proposed, until January 22, 1993, when, on his second full day in office, President Bill Clinton officially struck them from the books. In between were veto fights that held up massive LABOR–HEALTH AND HUMAN SERVICES–EDUCATION APPROPRIATION (Labor-HHS) legislation and a U.S. Supreme Court case, *Rust v. Sullivan,* in which the rules were upheld by a single vote.

From its inception in 1970 (three years before the Supreme Court legalized abortion nationwide in *ROE V. WADE*) the federal TITLE X FAMILY PLANNING PROGRAM, established in the Public Health Service Act, prohibited funding of programs "where abortion is used as a method of family planning." (Title X funds a broad array of family planning and other primary health care services.) Officials in the Department of Health, Education, and Welfare (later, the HEALTH AND HUMAN SERVICES DEPARTMENT [HHS]) first interpreted the law to permit abortion counseling and referrals. In 1981 the department required that women be given, on request, information on all options for an unplanned pregnancy, including abortion.

The gag rule was officially published in the *Federal Register* in September 1987 and made final in February 1988. It barred Title X recipients from performing abortion counseling or referrals; required that Title X clinics "physically separate Title X-funded activities from abortion-related activities"; and forbade recipients from using nonfederal funds for lobbying, distributing information, or in any way advocating or encouraging abortion.

While the rules were making their way through the federal courts (PLANNED PARENTHOOD FEDERATION OF AMERICA [PPFA], among others, had filed suit to block their implementation), Congress entered the fray. As part of the fiscal 1988 Labor-HHS appropriation bill, the Senate voted to block the rules. However, conferees dropped the language under a veto threat from President Ronald Reagan. In 1990 the Senate, acting on a Title X reauthorization bill, voted 62-36 for an amendment to codify the 1981 guidelines requiring that pregnant women be provided "non-directive counseling . . . and referral upon request" about alternatives including prenatal care and delivery, infant foster care or adoption, and pregnancy termination. But that bill was pulled after sponsors could not cut off debate (and after antiabortion forces prevailed on a vote to require PARENTAL NOTIFICATION before minors could receive an abortion at facilities that also received Title X funds).

On May 23, 1991, the Supreme Court threw the issue directly back to Congress. In a 5-4 ruling, the majority in *Rust v. Sullivan* said that the rules did not violate Title X recipients' free speech rights. Instead of trying again to reauthorize Title X, a move guaranteed to tangle the Senate in other abortion-related issues, opponents of the rule moved a freestanding measure to overturn it, which passed that chamber by a voice vote on July 17. The House of Representatives, however, appended its language blocking the rule to the fiscal 1992 Labor-HHS appropriation bill. President George H. W. Bush made

good on his promise to veto the measure, and the House failed to override by a dozen votes.

In March 1992 the Bush administration issued a directive on the implementation of the rules stipulating that "nothing in these regulations is to prevent a woman from receiving complete medical information about her condition from a physician." But opponents of the rules argued that the directive was effectively meaningless, because the vast majority of counseling in family planning clinics was delivered not by physicians but by nurses, nurse practitioners, PHYSICIAN ASSISTANTS, and social workers. (See NURSE PRACTITIONER [NP].) That directive touched off another legal battle. Title X recipients went back to court, arguing that allowing physicians to counsel about abortion after all amounted to an "arbitrary, capricious and irrational" action in violation of requirements for public notice and comment on federal rule changes. A federal district court judge agreed with the plaintiffs in May, again blocking enforcement of the rules. A federal appeals court judge disagreed and lifted the stay on July 30, clearing the way for implementation to begin October 1.

The five-year battle concluded with more of a whimper than a bang. On October 2, the House fell ten votes short of an override on the Senate-passed freestanding bill to block the counseling rules. But in the end it was the courts that put the rules on ice. A three-judge appeals court panel reversed the July appeals court ruling on November 3, blocking implementation that began only a month earlier. In January President Bill Clinton ended the saga, at least for the rest of the 1990s, by repealing the rules by executive order.

GAO

See GOVERNMENT ACCOUNTABILITY OFFICE.

Gatekeeper

Gatekeeper is a term used for a PRIMARY CARE PHYSICIAN (PCP) or other health care professional who controls the access of a patient in a HEALTH MAINTENANCE ORGANIZATION (HMO) to other forms of care. In a system using gatekeepers, that practitioner must provide a referral for the patient to see a specialist, obtain laboratory tests or other ancillary care, or enter the hospital. The idea behind a gatekeeper (MANAGED CARE plans rarely use the term, preferring *case manager, primary care physician,* or some other description) is that a single health practitioner can best coordinate care for an individual patient. A 1997 study by the Robert Wood Johnson Foundation's Center for Studying Health System Change found that, nationwide, 40 percent of Americans with health insurance were in some type of gatekeeper arrangement and more than 90 percent of primary care physicians surveyed said they acted as a gatekeeper for at least some of their patients. In practice, however, patients resented having to seek permission to see specialists with whom they already had preexisting relationships, and studies showed that busy primary care practitioners disliked the additional administrative burden. For those reasons and others, most managed care plans moved away from gatekeepers in the late 1990s and sought alternative ways to control use of health care services.

General Accounting Office

See GOVERNMENT ACCOUNTABILITY OFFICE.

Generic drugs

Generic drugs are copies of brand name medications determined by the FOOD AND DRUG ADMINISTRATION (FDA) to be safe and effective for their intended use. Generic copies of brand name drugs cannot be sold until after the expiration of the brand name product's patent. In 1984, with the price of prescription drugs spiraling, Congress sought to encourage competition in the drug industry with passage of the Drug Price Competition and Patent Term Restoration Act (PL 98–417). The FDA estimated that passage of the measure could save consumers $1 billion over the ensuing twelve years, because the generic copies sold for 50 to 80 percent less

than the "innovator" (brand name) drugs they replicated. At the same time, so as not to punish makers of brand name drugs, the bill extended by up to five years their patents, during which no generic copies could be marketed. Makers of brand name drugs had been complaining for years that the lengthy process for FDA approval robbed drugs of most of their seventeen years of patent life before they even made it to market.

The measure ordered the FDA to use an abbreviated approval system for generic copies of brand name drugs already on the market. Instead of having to demonstrate safety and efficacy, the standard for a new drug, the generics only had to prove they are "bioequivalent" to the product of which they are a copy.

In the 1984 act, however, Congress failed to anticipate the tremendous financial advantage for the first generic copy to make it to market after the expiration of the brand name drug's patent. Because that first copy often ended up with as much as half the generic market, some manufacturers took illegal means to ensure that their drug was the first approved under the abbreviated process. In 1992, in response to a series of scandals involving the bribing of FDA officials and even the substitution of samples of actual brand name drugs for generic copies to ensure passage of the bioequivalence tests, Congress passed the Generic Drug Enforcement Act (PL 102–282).

The bill required the secretary of the HEALTH AND HUMAN SERVICES DEPARTMENT (HHS) to bar applications for generic drugs from corporations convicted of a felony in connection with the generic drug approval process for at least one year and up to ten years. Any subsequent violation of the process would result in mandatory permanent debarment. Also subject to permanent exclusion from applying for generic drug approvals were individuals convicted of any felony related to the development or approval of any prescription drugs, brand name or generic. The HHS secretary was given permissive authority to exclude both companies and individuals in certain cases, such as those convicted of misdemeanors related to the drug approval process. The law provided for civil penalties of up to $250,000 for individuals and up to $1 million for companies guilty of abusing the approval process and required the revocation of approval for drugs whose approval was "obtained, expedited or otherwise facilitated" through illegal means.

The issue returned in the year 2001, when generic firms convinced some members of Congress that brand name companies were gaming the system to keep their products from entering the market well after the brand name drug's patents should have expired. Brand name firms in some cases filed late patents, just before the main patent on a drug was set to expire. In other cases, brand name firms were blocking generic copies through the use of automatic thirty-month stays that were allowed under the original 1984 law. Some brand name drugmakers were able to file several consecutive stays, thus delaying market entry for years at a time. Finally, in some highly publicized cases, a brand name firm would pay a generic firm to keep its copy off the market, thus blocking all other generics until the first copy's exclusivity expired.

In 2002 the Senate passed the Greater Access to Affordable Pharmaceuticals Act, which would have addressed what its sponsors, Charles E. Schumer, D-N.Y., and John McCain, R-Ariz., said were the most egregious ways generics were being blocked. As approved by the Senate July 31 by 78-21, the bill would have limited brand name companies to a single thirty-month stay of a generic firm's challenge to a patent. It also would have made it easier for generic firms to challenge allegedly frivolous patents intended to block generic entry, and it would have made it more difficult for brand name firms to stop generic entry by paying the first generic approved to keep its product off the market. The CONGRESSIONAL BUDGET OFFICE (CBO) estimated the bill could have saved consumers $60 billion over ten years by making generics available more quickly.

The House failed to consider the measure, which was vehemently opposed by the brand name drug industry. Brand name drugmakers said the measure unfairly infringed on their patent rights and could have threatened their ability to underwrite the development of new drugs.

In October 2002, however, with the drug price issue gaining concern among voters, President George W. Bush proposed regulations to make some—although not all—of the changes included in the Senate-passed

bill. The proposed rules, like the Senate bill, would generally have limited brand name drugmakers to a single thirty-month stay, but it did not include provisions allowing generic firms to seek to strike allegedly frivolous patents.

The rules, which the Bush administration estimated would save an estimated $35 billion over ten years, became final in June. That was just days before a compromise was reached between administration officials and sponsors of the 2002 Senate legislation. The compromise, which went further than the administration's proposal but less far than the 2002 proposal, was included in the Senate version of a Medicare prescription drug bill that passed that chamber June 26, 2003. A slightly different version was included in the House Medicare bill, passed the same day. The final Medicare bill (PL 103-173) included the Senate language.

Genetic discrimination

One of the many areas in which scientific advances have outstripped public policy is the ability to identify the genetic basis of certain diseases and potentially determine if a person will develop a particular ailment, perhaps years before the ailment manifests itself clinically. Much of this new knowledge is itself the product of government effort, or at least government funding, through the National Human Genome Project, which in 2003 completed the process of identifying the exact locations of the estimated twenty-five thousand to thirty thousand genes that compose each human's genetic makeup.

Research on the genetic basis of disease has produced tests that can identify a person's predisposition for diseases, from certain types of breast cancer and colon cancer to some forms of glaucoma and kidney cancer. But although knowing in advance the likelihood of developing a disease can be of significant benefit—closer screening can identify ailments at earlier stages when they are most treatable—many people have avoided getting tested for fear that a positive result could be used against them by a prospective employer or insurer. In testifying before the Senate Labor and Human Resources Committee in 1998, Dr. Francis Collins, director of the National Human Genome Research Institute, stated, "Discrimination in health insurance, and the fear of potential discrimination, threaten both society's ability to use new genetic technologies and improve human health and the ability to conduct the very research we need to understand, treat, and prevent genetic disease."

By 1998 more than half of the states had enacted legislation to bar insurers from using genetic information to discriminate in providing coverage or setting rates. But those states could not reach the estimated fifty-five million Americans with SELF-INSURANCE—plans that, under the federal EMPLOYEE RETIREMENT INCOME SECURITY ACT (ERISA), were exempt from state regulation.

Congress, in the 1996 HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA) (PL 104–191), did bar insurers from discriminating on the basis of genetic information for those enrolled in group health plans. Under that law, insurers cannot use genetic information to deny coverage to a member of a group plan or to charge higher premiums, and it explicitly prohibits insurers from using genetic information as a preexisting condition unless the condition has been diagnosed.

But HIPAA left significant gaps, many complained. It covered only members of groups, leaving unprotected those who purchase their own coverage. And although it prohibited an insurer from charging one member of a group higher premiums because of a genetic predisposition, it left open the possibility that the insurer could raise rates for the entire group based on a single group member's genetic information. Finally, the law did not limit insurers from requiring individuals to undergo genetic testing to obtain coverage, and it did not protect what insurers did with that information.

Another full decade passed before the Genetic Information Nondiscrimination Act, known as GINA, became law. President George W. Bush signed the measure May 21, 2008. The legislation, first introduced in the 105th Congress by Rep. Louise M. Slaughter, D-N.Y., and Sen. Olympia J. Snowe, R-Maine, closed most of those loopholes. Beginning eighteen months following enactment, it prohibited insurers from denying or canceling health insurance coverage or from raising premi-

ums on the basis of genetic information, prohibited insurers from requiring individuals to disclose genetic information, and barred the disclosure of that information without prior written consent. The measure also prohibited employers, in most cases, from requiring or using genetic information to make hiring or promotion decisions.

Although the measure took more than twelve years to become law, it enjoyed wide bipartisan support. President Bill Clinton called on Congress to pass it in 1997. "It's wrong when someone avoids taking a test that could save a life just because they're so afraid that the genetic information will be used against them," the president said. And Senate Republicans included provisions of the measure in their MANAGED CARE regulation bill, which also did not pass.

But insurance companies argued that the legislation was unnecessary and could result in higher rates, particularly in the price-sensitive individual insurance market. Insurers also argued that little solid evidence existed that insurers were discriminating on the basis of genetic information. After the Senate rejected a Democratic-backed genetic discrimination bill in late 1999, President Clinton in February 2000 acted on his own to ban genetic discrimination against federal workers. "We must not allow advances in genetics to become the basis for discrimination against any individual or group," he said in issuing the executive order. President George W. Bush in 2001 also called for Congress to pass less sweeping genetic discrimination legislation. (He signed a similar bill as governor of Texas.)

Following that call, the Senate passed genetic nondiscrimination bills twice, by 95-0 in October 2003 and by 98-0 in February 2005. But the House failed to follow suit.

The House passed such a bill for the first time 420-3 on April 25, 2007. The House bill was then blocked in the Senate by a handful of objecting members. A compromise was finally worked out in early 2008. The Senate passed a slightly amended version by 95-0 on April 24. The House cleared the final version May 1, by 414-1. Ron Paul, R-Texas, was the only member of either chamber to vote against the measure. A former Libertarian, he usually voted against measures increasing federal regulation.

Global gag rule

See MEXICO CITY POLICY.

Global tobacco settlement

Global tobacco settlement is the term for an agreement reached in June 1997 between attorneys general for forty states and the five major tobacco companies. The settlement called for the companies to pay a total of $368.5 billion over twenty-five years and accept new government regulation of tobacco products in exchange for immunity from future lawsuits. The settlement never took effect, because Congress failed to pass needed legislation to implement its provisions. However, forty-six states reached a more limited settlement with the tobacco companies in November 1998.

The original settlement arose from a series of lawsuits charging that tobacco products, by causing disability and disease, cost state governments billions of dollars in expenses through MEDICAID and other PUBLIC HEALTH programs. The tobacco companies, which had previously prevailed in virtually every other lawsuit filed against them, were moved to settle when documents that were highly damaging to the industry were disclosed in some of the trials. These documents included strategy memos on how the companies sought to attract underage smokers.

Under the settlement, $60 billion of the fees paid by the companies would have been "dedicated as punishment for past industry wrongdoing." Half of that amount would have been used for health care for uninsured children. (Congress would later boost cigarette taxes by fifteen cents per pack to pay for a separate STATE CHILDREN'S HEALTH INSURANCE PROGRAM [SCHIP].) The remainder of the company payments would have been parceled out by a presidential commission to reimburse states, provide free smoking-cessation programs, fund antismoking education efforts, and enforce the settlement.

The provisions of the settlement also permitted the FOOD AND DRUG ADMINISTRATION (FDA) to regulate

State attorneys general announce the $206 billion settlement of states' lawsuits against tobacco firms in November 1998. In accepting the deal, the firms promised to curb advertising and undertake measures to discourage teen smoking. Source: Mark Wilson, Reuters

nicotine as a drug but not ban it until 2009, and then only if the FDA could show that a ban would not produce a black market in tobacco products. On the advertising front, the settlement would have banned all outdoor advertising of cigarette products, eliminated human images from advertising, ended vending machine sales, banned brand name sponsorship of sporting events, and restricted ads in magazines with "significant youth readership" to text. The industry also would have placed new and larger warnings on their products, including such bluntly worded messages as "cigarettes are addictive" and "smoking can kill you."

The settlement would have ended both the lawsuits filed by states to reimburse them for smoking-related health costs as well as twenty-three pending class action suits in seventeen states filed by groups of smokers. Under the plan, individuals could still have sued the industry, but only those who became ill after the accord took effect would have been able to collect punitive damages.

Many aspects of the settlement, however, particularly the provisions related to the FDA, needed to be approved by Congress. But pressed by public health advocates who thought the settlement let the companies off too lightly and limited the FDA too much, anti-tobacco senators built the proposal into a $516 billion behemoth that would have raised cigarette prices by at least $1.10 per pack, granted the FDA authority to regulate nicotine as a drug, and imposed severe financial penalties on tobacco companies if the rate of underage tobacco consumption did not fall by 60 percent over ten years. As approved 19-1 by the Senate Commerce Committee on April 1, 1998, the Senate bill did not grant actual immunity to tobacco companies for lawsuits but did cap at $6.5 billion the amount companies would have to pay out in court judgments. In exchange, companies would voluntarily limit advertising and marketing to young people. The latter was a key point, because there was significant question whether Congress could limit advertising activities without violating the Constitution's guarantee of free speech.

The tobacco companies balked at the Senate's alterations, however, and launched an aggressive effort to kill the bill. In the end, though, the measure simply proved so immense that it basically fell of its own weight. After four weeks of debate on the Senate floor and numerous amendments on unrelated matters, such as child care

and eliminating the so-called marriage tax, leaders finally pulled the measure in June after the Senate failed to grant a waiver of a "budget point of order."

Instead, in November 1998 forty-six states agreed to settle pending suits against the tobacco companies for a payment of $206 billion over twenty-five years. The four states that did not participate in the settlement—Florida, Minnesota, Mississippi, and Texas—had previously settled their tobacco suits for a total of $40 billion. The much less sweeping agreement (with no congressional legislation needed to implement it) would require the four companies involved to end the use of billboards in advertising, to stop using cartoon characters that could appeal to children (such as Joe Camel), to limit sponsorship of sporting events to one per year, and to fund a $1.5 billion campaign to deter youth smoking. Although the settlement did not grant the FDA new authority to regulate nicotine or require increases in the prices of tobacco products, it also did not grant the companies immunity from future lawsuits but merely settled those already filed.

GME

See GRADUATE MEDICAL EDUCATION (GME).

Government Accountability Office

The Government Accountability Office, better known as the GAO, began life in 1921 as Congress's official accountants and auditors. Until 2004, the agency was officially known as the General Accounting Office. Today the GAO is an independent, nonpartisan agency that performs audits and other tasks at the request of members of Congress. Its more than three thousand employees also investigate virtually every aspect of how the federal government does its work. The GAO is headed by the comptroller general of the United States, who is appointed to a fifteen-year term by the president from a slate of candidates proposed by Congress.

GAO's reports and recommendations are taken seriously by both members of Congress and presidential administrations. At the end of fiscal 2007, 82 percent of the recommendations GAO had made in the previous five years had been implemented, the agency reported.

Graduate medical education (GME)

Unlike most other professions, medicine requires that doctors undergo significant periods of training after they graduate from school. Doctors-in-training spend from three years (for most PRIMARY CARE roles) to seven or eight years (for specialized surgery slots) in residency programs, where they practice under the supervision of more experienced physicians. In 2006, according to the AMERICAN MEDICAL ASSOCIATION (AMA), 104,879 residents were in accredited specialty programs.

Graduate medical education (GME) is financed from a variety of sources, including the federal government, state and local governments, and revenues from hospital patient care. The federal government, through MEDICARE and MEDICAID, is by far the largest source of funding for graduate medical education. In 2006 Medicare contributed some $8.1 billion for the cost of graduate medical education.

Unlike many other aspects of health policy, the federal government's explicit role in training the next generation of doctors was no accident. When it established the Medicare program in 1965, Congress was warned that there might not be enough physicians to treat all the newly eligible beneficiaries. (See BENEFICIARY.) That helped prompt a major subsidy program that still exists. Medicare makes two types of special payments to teaching hospitals. DIRECT MEDICAL EDUCATION PAYMENTS (DME payments) help underwrite the actual salaries and teaching expenses for interns and residents who treat Medicare patients. INDIRECT MEDICAL EDUCATION PAYMENTS (IME payments) help compensate teaching hospitals for the inefficiencies associated with their teaching missions—the need for more supervision and the fact that inexperienced doctors may order more tests, for example. IME payments are calculated under a formula based on a hospital's number of residents and its number of beds and are "added on" to Medicare's per-diagnosis hospital payment. They

also account for the fact that teaching hospitals tend to attract sicker, and thus more expensive, patients because they offer the newest and most cutting-edge treatments and technologies.

But many analysts say Medicare's open-ended financing of graduate medical education has taken what was a potential shortage of physicians and turned it into a glut, particularly of specialists. A 1995 report from the Pew Health Professions Commission predicted that, by the year 2000, the United States would have 150,000 more physicians than it needed and called for the closure of up to 25 percent of the nation's medical schools.

Among the major contributors to the oversupply of specialists, say analysts, are the hospitals, which have more slots for residents than there are graduates of U.S. medical schools each year. Those extra slots—about 26 percent more in 2007—are filled by "international medical graduates," Americans or foreigners who attended medical schools outside the United States. Because, at least in part, of Medicare's generous subsidies, it can cost hospitals less to staff their facilities with residents than with less highly trained personnel. A resident working a twenty-four-hour shift, for example, can take the place of three eight-hour shifts of a NURSE PRACTITIONER (NP) or physician assistant (although recent restrictions on residents' work hours have lessened those savings). (See PHYSICIAN ASSISTANTS.)

Congress, in the 1997 Balanced Budget Act (PL 105–33), attempted to address the medical education issue, although lawmakers vowed that what that measure included was merely a first step. As part of overall efforts to reduce Medicare spending, the bill reduced Medicare's indirect medical education payments by an estimated $7.9 billion over five years. (Subsequent Medicare "giveback" bills in 2000 and 2001 lessened those cuts slightly.) At the same time, however, responding to complaints from teaching hospitals that MANAGED CARE companies were getting subsidies for medical education, then failing to send patients to teaching facilities, the measure carved out Medicare education payments from managed care payments (to the tune of $4 billion over five years) and redirected them back to the teaching hospitals.

The bill also began to address analysts' complaints about the oversupply of physicians, particularly of specialists. It capped the number of residents used to calculate DME and IME payments for individual teaching hospitals at their 1997 levels (adjusted in future years). Although the secretary of the HEALTH AND HUMAN SERVICES DEPARTMENT (HHS) has some authority to make exceptions to the cap, one hospital's increase can be made only if slots are reduced somewhere else. The measure also provided hospitals with incentives to shrink their residency programs by providing additional funds (critics call them bribes) to help hospitals make the transition from resident staffing to more permanent employees. The CONGRESSIONAL BUDGET OFFICE (CBO) estimated that these provisions together would reduce the number of residents being trained by approximately 3 percent.

Over the long term, analysts and interest groups involved in medical education (such as the American Medical Association and the Association of American Medical Colleges) have called for a system that would provide a stable, predictable source of funding for graduate medical education. Because much of medical education is funded by cross subsidies from medical school faculty practice plans that were hard hit by the rise of managed care and because government in general has been looking to decrease its health care spending, many fear that the educational and research missions of the nation's academic health centers could be compromised. As part of the 1995 Balanced Budget Act, passed by Congress but vetoed by President Bill Clinton, Congress proposed establishing a $15 billion per year Teaching Hospital and Graduate Medical Education Trust Fund, from which Medicare medical education payments would have been made.

More recent proposals have called for an "all-payer" system to finance graduate medical education costs, with payments coming from both public and private health insurers, on the theory that the entire health care system benefits from the research and education efforts undertaken at teaching hospitals and academic medical centers. Although such a system would likely increase insurance premiums, taxpayers are paying much of the graduate medical education bill already.

Guaranteed issue

Guaranteed issue, a requirement that insurance companies sell policies to all who agree to pay the required premiums and meet other requirements, can be mandated by states or by the federal government and can apply to different segments of the market (individuals, small groups, or everyone). The HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA) included a modified form of guaranteed issue, requiring that insurers sell policies to all individuals, regardless of their medical condition, who have been continuously covered for at least eighteen months and meet certain other requirements. Guaranteed issue alone, however, does not regulate prices. Thus, as has happened, companies can respond to guaranteed issue rules by selling to all comers but at higher (sometimes much higher) premiums to groups they perceive as likely to be more expensive.

Guaranteed renewability

Although similar to GUARANTEED ISSUE, guaranteed renewability forbids insurers from declining to renew policies because of a change in health status of a group or a member of a group (or an individual in the case of individual coverage). The HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA) of 1996 (PL 104–191) requires that insurers renew policies, except in cases of failure to pay premiums or of fraud, as long as the insurer continues to serve anyone in that market. In other words, an insurer may drop out of the small group or individual market completely but may not renew coverage for some groups or individuals but not others. Legislation in 1990 to tighten federal regulation of the MEDICARE supplement insurance market (MEDIGAP INSURANCE) also required insurers to guarantee renewal of those policies, again, as long as premiums continue to be paid and there is no "material misrepresentation."

H

HCFA

See HEALTH CARE FINANCING ADMINISTRATION (HCFA).

Health and Human Services Department (HHS)

The U.S. Health and Human Services Department (HHS) was officially created on May 4, 1980. Formerly called the Department of Health, Education, and Welfare (HEW), its name was changed after the Department of Education Organization Act in 1979 created a freestanding Department of Education. HEW was created under President Dwight D. Eisenhower, debuting on April 11, 1953. HHS lost a large piece of its portfolio in 1995, when the Social Security Administration became an independent agency.

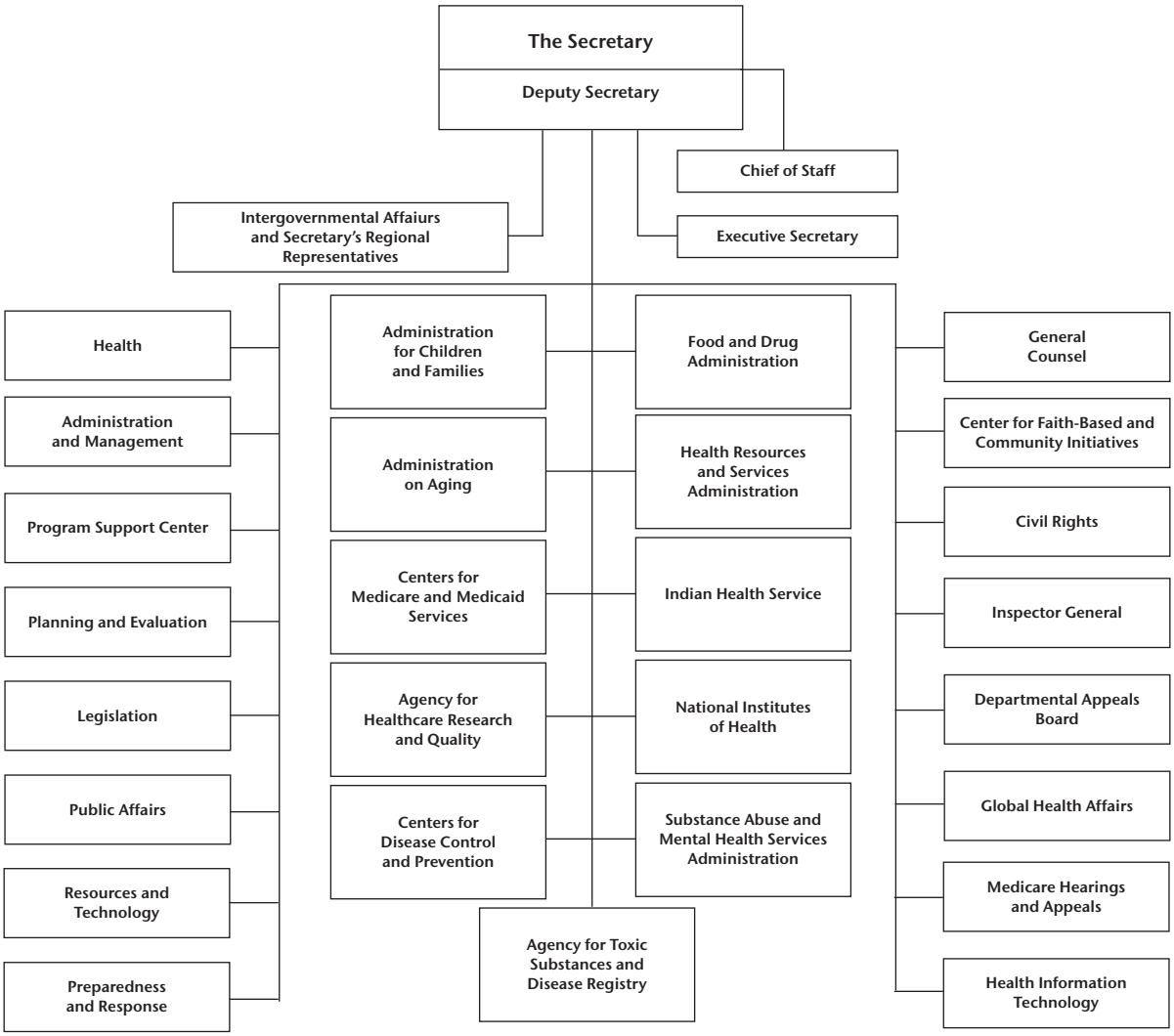
Nevertheless, HHS has the largest budget of any agency in the federal government—nearly $716 billion in fiscal 2008. (By comparison, the Defense Department received an appropriation of approximately $459 billion that same year, although that did not include much of

Secretaries of HEW and HHS, 1953–2008

Secretary	*Department*	*Dates of service*
Oveta Culp Hobby	HEW	April 11, 1953–July 31, 1955
Marion B. Folsom	HEW	August 1, 1955–July 31, 1958
Arthur S. Flemming	HEW	August 1, 1958–January 19, 1961
Abraham Ribicoff	HEW	January 21, 1961–July 13, 1962
Anthony J. Celebrezze	HEW	July 31, 1962–August 17, 1965
John W. Gardner	HEW	August 18, 1965–March 1, 1968
Wilbur J. Cohen	HEW	May 16, 1968–January 20, 1969
Robert H. Finch	HEW	January 21, 1969–June 23, 1970
Elliot L. Richardson	HEW	June 24, 1970–January 29, 1973
Caspar W. Weinberger	HEW	February 12, 1973–August 8, 1975
David Mathews	HEW	August 8, 1975–January 20, 1977
Joseph A. Califano, Jr.	HEW	January 25, 1977–August 3, 1979
Patricia Roberts Harris	HEW/HHS	August 3, 1979–January 20, 1981
Richard S. Schweiker	HHS	January 22, 1981–February 3, 1983
Margaret M. Heckler	HHS	March 9, 1983–December 13, 1985
Otis R. Bowen	HHS	December 13, 1985–January 20, 1989
Louis W. Sullivan	HHS	March 1, 1989–January 20, 1993
Donna E. Shalala	HHS	January 22, 1993–January 20, 2001
Tommy G. Thompson	HHS	February 2, 2001–January 26, 2005
Michael O. Leavitt	HHS	January 26, 2005–

Note: Until May 4, 1980, the Health and Human Services Department (HHS) was known as the Health, Education, and Welfare Department (HEW). Created April 11, 1953, HEW was reorganized in 1979 by authority of the Department of Education Organization Act. In addition to creating a new Education Department, the act renamed HEW the Department of Health and Human Services.

Health and Human Services Department



Source: Department of Health and Human Services

the ongoing cost of the war in Iraq.) Often referred to as the "people's department," HHS and its nearly sixty-five thousand employees administer more than three hundred programs that touch the life of virtually every American. HHS is also the federal government's largest grant-making agency, administering more grant dollars than all other federal agencies combined, according to the department's Web site.

HHS is home to the U.S. PUBLIC HEALTH SERVICE (PHS), which includes eight research and health delivery agencies, including the NATIONAL INSTITUTES OF HEALTH (NIH), the CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC), and the FOOD AND DRUG ADMINISTRATION (FDA). Outside of the PHS purview is the CENTERS FOR MEDICARE AND MEDICAID SERVICES, which runs those programs as well as the STATE CHILDREN'S HEALTH INSURANCE PROGRAM (SCHIP).

Regarding human services, HHS encompasses the Administration for Children and Families, which operated more than $47 billion worth of programs in fiscal

2008, including Head Start for preschoolers and Temporary Assistance to Needy Families (TANF), the successor program to the former federal-state welfare program Aid to Families with Dependent Children (AFDC). HHS also runs programs to provide child care, assist with adoption, help with paying energy bills, and help with collecting child support payments. The Administration on Aging, with a budget of $1.4 billion in fiscal 2008, runs an array of programs for elderly individuals, including Meals on Wheels and counseling services for health insurance and other programs.

Health Care Financing Administration (HCFA)

The Health Care Financing Administration (HCFA) was created by U.S. Department of Health, Education, and Welfare secretary Joseph A. Califano Jr. in 1977 to administer MEDICARE and MEDICAID for the department. Before HCFA's creation, Medicare was overseen by the Social Security Administration; and Medicaid, by the Social and Rehabilitation Services Administration. The agency was renamed the CENTERS FOR MEDICARE AND MEDICAID SERVICES in 2001, in part to try to put its unpopularity with states and health care providers behind it.

Health care fraud and abuse

By some estimates, health care fraud and abuse account for $1 of every $10 spent in the United States on health care each year. Technically, health care fraud, according to the National Health Care Anti-Fraud Association, is "an intentional deception or misrepresentation that an individual or entity makes knowing that the misrepresentation could result in unauthorized benefit to the individual, the entity, or to some other party." The most common type of health care fraud, according to the association, involves billing for services or treatments not supplied or making a false statement, misrepresentation, or deliberate omission critical to the determination of benefits.

Health care abuse includes acts that are not motivated by an intent to commit fraud but are nonetheless not technically necessary for the patient's health. Examples of abuse can include "unbundling," in which, to gain a larger reimbursement, a physician or hospital bills separately for services normally paid as part of a package rate, and "upcoding," indicating a service was more complicated or expensive than what was provided. The line between fraud and abuse is a fuzzy one; often the same act can fall into either category.

As the amounts of money involved have risen, prosecuting health care fraud has become a booming business around the country. MEDICARE and MEDICAID fraud has been a particular emphasis, starting with the Clinton administration's Operation Restore Trust, which began in 1995 as a five-state experiment to coordinate fraud-fighting efforts among federal, state, and private enforcement agencies, focusing on fraud in the HOME HEALTH CARE, nursing home, and durable medical equipment industries. In its first two years, the program identified $188 million owed to the federal government, a return of $23 for every $1 spent on the program. After the program went nationwide in 1997, federal "fraud busters" returned nearly $1 billion to the Treasury Department and expelled twenty-seven hundred providers from the programs. Between 1993 and 1997, the antifraud efforts of the HEALTH AND HUMAN SERVICES DEPARTMENT (HHS) recovered more than $20 billion and increased convictions for health care fraud by 240 percent. In the early 2000s, HHS and Justice Department officials zeroed in on high-risk areas, particularly in South Florida and Southern California. In many cases, drug dealers were turning to Medicare and Medicaid fraud because it was more lucrative and less dangerous than their previous illegal activities.

Despite the stepped-up enforcement activities, fraud and abuse remain a serious problem in Medicare. An audit by the HHS inspector general released in 1998 found that in fiscal 1997 the program made net "improper" payments of about $20.3 billion, representing 11 percent of the total Medicare non–managed care budget. Those payments included not only outright

fraud but also inadvertent mistakes, such as charges not properly documented, and billings for care that was not medically necessary or care not covered by Medicare. The total, however, did represent a decrease of about $3 billion from the previous year. The report for fiscal 2005 spending showed even more progress: the error rate declined to 5.2 percent, representing improper payments of about $9.5 billion.

Congress has revisited the fraud and abuse issue frequently. The current round of fraud-fighting dates back to 1987. Legislation passed that year (PL 100–93) widely expanded the HHS secretary's authority to bar unfit or incompetent health care providers from Medicare and Medicaid, as well as from participation in the MATERNAL AND CHILD HEALTH (MCH) SERVICES BLOCK GRANT and Social Services Block Grant programs.

The legislation required that the secretary exclude from the programs for at least five years any individual or entity convicted of a criminal offense related to the delivery of services under any of the programs, unless a state requested otherwise because the individual or entity was the sole community physician or sole source of essential specialized services in the community.

The secretary could, but was not required to, exclude individuals or entities convicted under federal or state laws of criminal offenses relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or financial abuse if the offense was committed either in connection with the delivery of health care or with respect to a health care program financed in any part by the federal government or any state or local government. Also optionally excludable were individuals or entities convicted of interfering with the investigation of health care fraud or offenses related to controlled substances; individuals whose license to practice was revoked or otherwise lost for reasons bearing on an individual's professional competence, conduct, or financial integrity, or who voluntarily surrendered a license while a formal disciplinary proceeding was pending; individuals or entities suspended or excluded from any other state or federal health care program for reasons related to professional competence, professional performance, or financial integrity; health maintenance organizations that "failed substantially to provide medically necessary services"; or an entity owned or controlled by an individual who had been an officer, director, agent, or managing employee, who was convicted of program-related offenses, or who had had a civil penalty assessed, or who had been excluded from participation in any of the programs. (See HEALTH MAINTENANCE ORGANIZATION [HMO].)

The measure also permitted the imposition of civil penalties of up to $2,000 per item plus twice the amount claimed for services not actually provided and authorized criminal penalties of up to $25,000 in fines or five years in prison for provision of services by an unlicensed physician.

Congress's next major antifraud foray came as part of the 1996 HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA) (PL 104–191). That bill increased penalties for fraud and abuse, and it created a self-funded program to be operated jointly by the Departments of Justice and HHS. The program was to coordinate not only federal antifraud efforts but also state and local efforts aimed at finding misconduct in both public and private health plans. The program was to be funded by the fines, forfeitures, and damages collected.

HIPAA also authorized a separate "Medicare integrity program" to contract with private firms to find Medicare fraud and abuse. The program included provisions allowing "bounties" to be paid to Medicare beneficiaries who identify fraud or misconduct and whose reports result in saving the government money. (See BENEFICIARY.)

HIPAA included a controversial provision some Democrats and the Clinton administration complained could increase fraud. It required the Justice Department to issue advisory opinions on whether certain business arrangements violated federal antikickback laws. The Justice Department complained that because the law is intent-based, advisory opinions could cripple the department's ability to prosecute such cases. The law also called for an expanded list of safe harbor guidelines for acceptable business practices that might otherwise be considered violations.

Among the increased penalties were imposition of mandatory exclusions for some crimes in the voluntary section of the 1987 law, including convictions for any felony related to health care fraud or controlled substances, and an increase in civil fines from $2,000 to $10,000 per violation. Also made explicitly illegal was the dispersal of assets by an individual to qualify for Medicaid.

HIPAA also changed the legal standard for prosecution of health care fraud, from merely knowing the activity was illegal to knowing and acting with "reckless disregard or deliberate ignorance" of the law.

Finally, to make fraud detection easier and to simplify administrative burdens at the federal and state level and in private plans, the law called for every health care provider to be issued a unique identifier. In 1998 HHS proposed an eight-digit alphanumeric code that would allow for twenty billion separate identifiers.

Congress addressed the fraud and abuse issue again the following year. As part of the 1997 Balanced Budget Act (PL 105–33), Congress beefed up penalties one more time, imposing a permanent exclusion of providers from federal health programs after conviction of a third health-related felony ("three strikes and you're out") and requiring a ten-year exclusion for a second conviction. The law gave the HHS secretary authority to bar those convicted of any felony from participation in federal health programs if the inclusion "would be inconsistent with the best interest of program beneficiaries" and to exclude entities controlled by a family member of someone who has been excluded, as well as authority to impose civil fines for persons who contracted with an excluded provider.

To help beneficiaries identify fraud, the law required that providers issue a detailed, itemized bill on request and that a toll-free telephone number for reporting potential fraud be printed on all Medicare beneficiary benefit notices. The measure also broadened the advisory opinion provision from HIPAA to include SELF-REFERRAL CURBS, potential violations of rules against physician self-referrals.

Some say the government has gone too far in its antifraud efforts. Groups representing health care providers, mostly doctors and hospitals, have complained that the government is cracking down so hard it is prosecuting people for making inadvertent mistakes or punishing them for failing to understand highly complex rules and regulations. Even fraud fighters concede that, when done appropriately, antifraud efforts still cannot help but increase paperwork and administrative headaches for those who deliver health care, adding yet another layer of bureaucracy to the system.

Health care spending

Health care spending has been a major source of concern for the past three decades. An aging population, new (and expensive) technology helping people live longer, and an economically comfortable society wanting more and more health care services have combined to put health spending on a trajectory to consume an ever-larger share of the nation's economic output. Although health spending slowed in the mid-1990s, following defeat in Congress of a major health system overhaul in 1994 and the widespread adoption of MANAGED CARE, long-term estimates continue to show health care spending likely to increase faster as the massive baby boom generation reaches its highest health cost years, beginning in the year 2010.

In 2006 the nation's total health care spending rose 6.7 percent from the year before, to $2.1 trillion. That increase was slightly faster than the year before, which had represented the slowest rate of growth since 1999, largely due to a significant slowdown in prescription drug spending combined with a growing economy. Still, health care continued to consume more of the nation's gross domestic product (GDP)—up to 16 percent. Per capita health spending in 2006 was $7,026 for every man, woman, and child in the United States. Public programs (primarily but not exclusively MEDICARE and MEDICAID) paid 40 percent of the nation's health care bill in 2005.

Personal health expenditures (what is spent on actual medical services, not including administration, research, and public health activities) reached $1.76 trillion in 2006.

Compared with other developed nations, the United States spends considerably more and gets considerably

National Health Expenditures (NHE), Aggregate and Per Capita Amounts, and Share of Gross Domestic Product (GDP), Selected Calendar Years 1970–2006

Spending category	*1970*	*1980*	*1990*	*2000*	*2003*	*2004*	*2005*	*2006*
NHE (billions of dollars)	74.9	253.4	714.0	1,353.6	1,732.4	1,852.3	1,973.3	2,105.5
Health services and supplies	67.1	233.4	666.7	1,264.8	1,620.7	1,730.6	1,843.6	1,966.2
Personal health care	62.9	214.8	607.5	1,139.6	1,445.9	1,547.7	1,653.7	1,762.0
Hospital care	27.6	101.0	251.6	417.1	525.4	564.4	605.5	648.2
Professional services	20.6	67.3	216.8	426.7	542.9	580.7	622.2	660.2
Physician and clinical services	14.0	47.1	157.5	288.6	366.7	393.6	422.6	447.6
Other professional services	0.7	3.6	18.2	39.1	49.0	52.4	56.2	58.9
Dental services	4.7	13.3	31.5	62.0	76.9	81.5	86.6	91.5
Other personal health care	1.2	3.3	9.6	37.0	50.3	53.2	56.8	62.2
Home health and nursing home care	4.3	20.9	65.2	125.8	148.5	157.9	168.7	117.6
Home health care	0.2	2.4	12.6	30.5	38.0	42.7	47.9	52.7
Nursing home care[a]	4.0	18.5	52.6	95.3	110.5	115.2	120.7	124.9
Retail outlet sales of medical products	10.5	25.7	74.0	170.1	229.0	244.7	257.3	276.0
Prescription drugs	5.5	12.0	40.3	120.6	174.2	188.8	199.7	216.7
Durable medical equipment	1.6	3.8	11.2	19.3	22.4	22.8	23.2	23.7
Other nondurable medical products	3.3	9.8	22.5	30.2	32.4	33.1	34.4	35.6
Program administration and net cost of private health insurance	2.8	12.2	39.2	81.8	121.0	129.0	133.6	145.4
Government public health activities	1.4	6.4	20.0	43.4	53.8	53.9	56.3	58.7
Investment	7.8	19.9	47.3	88.8	111.8	121.7	129.7	139.4
Research[b]	2.0	5.4	12.7	25.6	35.5	38.8	40.6	41.8
Structures and equipment	5.8	14.5	34.7	63.2	76.3	83.0	89.1	97.6
Population (millions)	210.2	230.4	253.8	282.6	291.1	294.0	296.8	299.7
NHE per capita (dollars)	356	1,100	2,813	4,790	5,952	6,301	6,649	7,026
GDP (billions of dollars)	1,039	2,790	5,803	9,817	10,961	11,686	12,434	13,195
NHE as percent of GDP	7.2	9.1	12.3	13.8	15.8	15.9	15.9	16.0
Implicit price deflator for GDP	27.5	54.0	81.6	100.0	106.4	109.5	113.0	116.6
Real GDP (billions of dollars)	3,772	5,162	7,113	9,817	10,301	10,676	11,003	11,319
Real NHE (billions of dollars)[c]	272	469	875	1,354	1,628	1,692	1,746	1,806
Personal health care deflator[d]	16.0	34.5	70.4	100.0	111.8	116.3	120.4	124.5

Source: Centers for Medicare and Medicaid Services, Office of the Actuary, National Health Statistics Group, and U.S. Department of Commerce, Bureau of Economic Analysis, and Bureau of the Census. Table reprinted with permission from Aaron Catlin et al., *Health Affairs* 27, no. 1 (January/February 2008): 15.

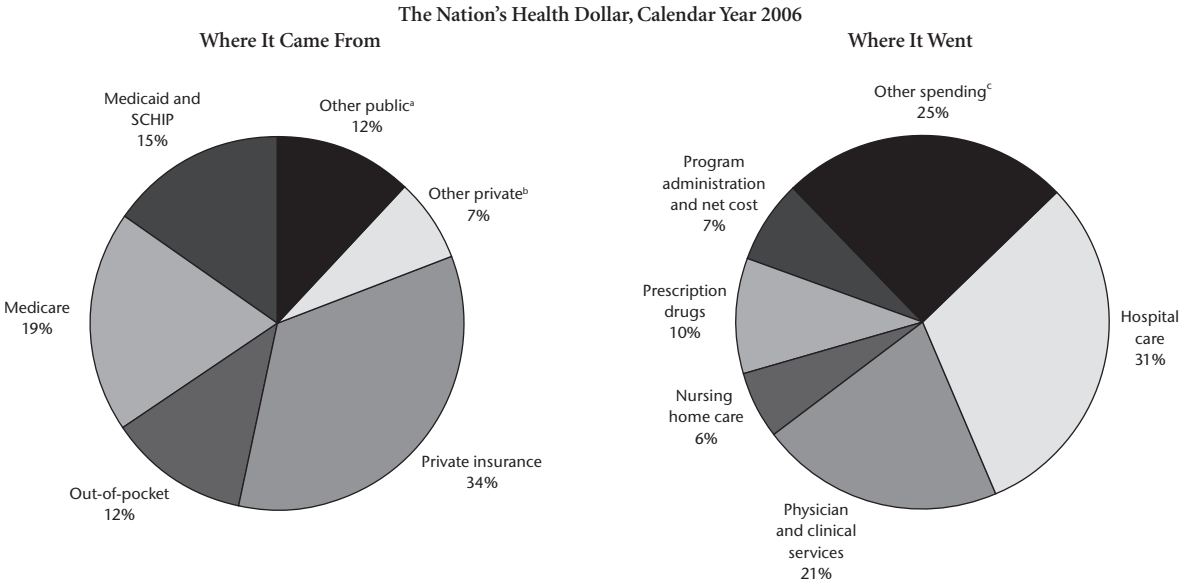
a. Freestanding facilities only. Additional services of this type are provided in hospital-based facilities and counted as hospital care.

b. Research and development expenditures of drug companies and other manufacturers and providers of medical equipment and supplies are excluded from research expend tures but are included in the expenditure class in which the product falls.

c. Deflated using GDP chain-type price index (2000 = 100).

d. Personal health care (PHC) chain-type index is constructed from the producer price index for hospital care, nursing home input price index for nursing care, and consumer price indexes specific to each of the remaining PHC components.

less. According to the Organization for Economic Cooperation and Development (OECD), the United States' 15.3 percent of GDP spent on health care in 2004 was more than six percentage points higher than the 8.9 percent average and nearly four percentage points higher than second-place Switzerland. At $6,100 in 2004, average spending per person in the United States was more than twice the OECD average, even after adjusting for the differences between countries in purchasing power. The 5.9 percent average annual rate of growth in health spending in the United States between 1999 and 2004 also exceeded the OECD average



Source: Centers for Medicare and Medicaid Services, Office of the Actuary, National Health Statistics Group.

Note: Numbers shown may not add to 100 because of rounding. SCHIP is the State Children's Health Insurance Program.

a. Includes, for example, workers' compensation, public health activity, Department of Defense programs, Department of Veterans Affairs programs, Indian Health Service programs, state and local hospital subsidies, and school health.

b. Such as industrial in-plant, privately funded construction, and non-patient revenues, including philanthropy.

c. Includes dentist services, other professional services, home health, durable medical products, over-the-counter medicines and sundries, public health, other personal health care, research, and structures and equipment.

of 5.2 percent per year. While most other OECD countries have universal coverage systems, the United States had an estimated forty-seven million uninsured residents as of 2007. And U.S. life expectancy remained below the OECD average, while the U.S. infant mortality rate was higher than average.

Health Insurance Association of America (HIAA)

The Health Insurance Association of America (HIAA), based in Washington, D.C., was a trade association that represented mostly small and mid-size health insurance companies. Although in the early 1990s the HIAA endorsed the concept of universal coverage to be achieved by requiring employers to cover their workers (the so-called employer mandate), the organization ended up as one of the highest profile opponents of President Bill Clinton's health reform plan, the HEALTH SECURITY ACT. HIAA-funded commercials featured a pair of actors portraying characters named Harry and Louise, who sat around their kitchen table puzzling over the complexities of the proposal and worried about whether it would cost them more. The commercials, which appeared more frequently in news reports about the opposition than in paid spots, were considered emblematic of the problems the plan posed. In 1998 the HIAA became one of the leaders in the fight against legislation to regulate the practices of MANAGED CARE companies. Officials argued such legislation would increase health care spending and, in turn, the cost of insurance.

In 2003 the group merged with the AMERICAN ASSOCIATION OF HEALTH PLANS (AAHP) to create AMERICA'S HEALTH INSURANCE PLANS (AHIP), a single trade group to represent both managed care and traditional health insurers.

Health Insurance Portability and Accountability Act (HIPAA)

On August 21, 1996, President Bill Clinton signed a bipartisan overhaul of health insurance into law. But the Health Insurance Portability and Accountability Act (HIPAA), also known as Kassebaum–Kennedy, for its two principal Senate sponsors, Nancy Landon Kassebaum, R-Kan., and Edward M. Kennedy, D-Mass., was hardly the sweeping overhaul Clinton had in mind when he took office. Although HIPAA (PL 104–191) did represent the most comprehensive federal regulation of private health insurance ever enacted, it addressed only a small portion of the population: those already insured who wished to move from one group plan to another or who wanted to move from a group to an individual plan. And although the measure sought to improve the availability of insurance, it did nothing to make it more affordable—an omission that would come back to haunt the measure only two years later, when analysts reported that insurers were avoiding some of the law's requirements by charging premiums up to six times higher for persons eligible because of HIPAA than they charged other customers.

At the insistence of Republicans in the U.S. House of Representatives and the Senate, who wanted to put their own stamp on the health issue, the measure also went well beyond its original modest intentions. In addition to provisions seeking to reduce the ability of insurers to exclude individuals from coverage because of PREEXISTING CONDITIONS, the final measure included a major antifraud effort and a four-year experiment with the medical savings account (MSA), a tax-preferred account combined with a high-deductible CATASTROPHIC ILLNESS insurance policy that gave individuals much more responsibility for their personal health care spending. It also included several other health-related tax provisions, such as an increase in the percentage of premiums that the self-employed could deduct from their income taxes and new tax deductions for long-term care services and long-term care insurance premiums. The law has probably become best known for its requirement for rules to protect the confidentiality of medical information. (See MEDICAL SAVINGS ACCOUNTS [MSAs] and MEDICAL RECORDS CONFIDENTIALITY.)

Specifically, the measure sought to improve the PORTABILITY of benefits by making it easier for workers to move from job to job without risk of being locked out of insurance or having to wait for coverage of preexisting medical problems. The bill did not permit workers to take their specific health plans with them when they changed jobs (what many people mistakenly thought portability meant), and it did not require employers to offer insurance or to offer any specific benefits if they did provide coverage. But the new law did address the problem of job-lock, the fear many workers had of not being able to reacquire insurance if they gave up their current job—and the insurance that came with it. The General Accounting Office (GAO) estimated that up to twenty-five million Americans could benefit from the measure's portability provisions.

A majority of states had already passed insurance portability laws—forty states acted between 1990 and 1994, according to the GAO. But because many plans that fell under the federal EMPLOYEE RETIREMENT INCOME SECURITY ACT (ERISA) were exempt from state regulation, those state laws could not reach some forty-nine million Americans with employer-provided insurance. For that reason, even though insurance regulation has traditionally been left to states, only a federal law could impose requirements on self-insured ERISA plans.

The bill also prohibited insurers from discriminating against workers based on their or a member of their family's health status or medical history, including mental illness, a history of being a victim of domestic violence, or because genetic tests had detected a likelihood that the person would develop an ailment sometime in the future. (See GENETIC DISCRIMINATION.)

It required insurers to sell insurance to all small groups that seek it if they offer any coverage in the small group market and accept every eligible individual in each group. Members of groups could not be excluded from coverage or denied the chance to renew coverage based on their health status, and individuals in groups could not be charged higher premiums based on health status.

Sens. Edward M. Kennedy, D-Mass., and Nancy Landon Kassebaum, R-Kan., principal sponsors of the Health Insurance Portability and Accountability Act (HIPAA), and others look on as President Bill Clinton signs the measure into law on August 21, 1996. HIPAA represented the most comprehensive federal regulation of private health insurance ever enacted. Source: *AP Images/ J. Scott Applewhite*

Insurers were also prohibited from imposing preexisting condition exclusions exceeding twelve months for conditions for which medical advice, diagnosis, or treatment was received or recommended within the previous six months. For individuals who had been continuously covered for more than twelve months, no preexisting condition exclusions were allowed, and waiting periods were required to be shortened for every month of continuous coverage. For example, if a person had been covered for six months with no break in coverage of more than sixty-three days, the maximum waiting period for coverage of a preexisting condition could be no more than six months.

The measure also sought to guarantee that those leaving group coverage could obtain coverage as individuals. But it benefited only a small subset of individuals: those who were covered continuously under a group plan for eighteen months, who exhausted their extended COBRA continuation coverage, if available, and those who had no other available insurance. (See CONSOLIDATED OMNIBUS BUDGET RECONCILIATION ACT OF 1985 [COBRA].) The law permitted states to establish health insurance coverage "high-risk pools," mandatory group conversion policies, open enrollment of some plans, or other means to accomplish the availability of insurance to these individuals. If the state did not impose some mechanism, however, insurers were required to sell coverage to qualifying individuals. Insurers, though, had significant leeway to offer only certain plans, and the law essentially imposed no limits on what insurers could charge.

The law's medical savings account provision called for establishing up to 750,000 policies combining high-deductible catastrophic insurance plans with tax-preferred accounts from which individuals would pay their own routine and minor medical expenses. MSAs were limited to the self-employed, small employers (those with fifty or fewer employees), and the uninsured. Policies were to be available from January 1, 1997, until January 1, 2001, after which Congress would have to vote to permit the policies to continue their preferred tax status. As part of an economic stimulus bill cleared in early 2002 (PL 107–147), Congress extended the demonstration program through the end of 2003.

On taxes, the measure increased, over ten years, the percentage of premiums the self-employed could deduct. The deduction, at 30 percent when the measure was signed into law, would rise to 40 percent in 1997; 45 percent in 1998 through 2002; 50 percent in 2003; 60 percent in 2004; 70 percent in 2005; and 80 percent in 2006 and thereafter. It also made tax deductible to the same extent as other medical expenses the cost of LONG-TERM CARE services and provided the same tax preferences for long-term care insurance as for other health insurance. (Congress accelerated the rate of deduction increases, up to 100 percent by 2006, in the tax-cut bill that emerged from the 1997 balanced budget negotiations [PL 105–34].)

To curb fraud and abuse, the measure established a joint program between the HEALTH AND HUMAN SERVICES DEPARTMENT (HHS) and the Justice Department, with a dedicated funding mechanism and orders to coordinate with state and local law enforcement efforts. It also called for establishing a "whistleblower" program that would pay "bounties" to MEDICARE beneficiaries who identified fraud or abuse, it increased fraud and abuse penalties, and it provided for mandatory expulsion from Medicare and MEDICAID of individuals convicted of a felony related to health care fraud or misuse of controlled substances. A controversial provision in the measure required the HHS secretary to issue "advisory opinions" to health entities as to whether proposed business plans violated federal antikickback laws.

Finally, the measure included "administrative simplification" provisions calling for the development of uniform standards for the electronic transmission of health information, including health claims, premium payments, injury reports, and enrollment information. The measure called on Congress to pass legislation designed to protect the privacy of medical records by August 1, 1999, or else standards to be proposed by the HHS secretary within six months would take effect. Congress missed its 1999 deadline, and after many delays and revisions, the privacy rules took effect April 14, 2003. (See MEDICAL RECORDS CONFIDENTIALITY.)

The bill's early movement made it look like its passage would be all smooth sailing. On August 2, 1995, the Senate Labor and Human Resources Committee unanimously approved the measure under the stewardship of its sponsors, the committee chair and the ranking member. That the measure proved noncontroversial was no accident—Kassebaum and Kennedy had specifically set out to craft a bill that included only the elements of the failed 1993–1994 health reform effort that were common to both Democratic and Republican bills.

The only naysayer on the measure—at least at the beginning—was the insurance industry. Insurers worried that requiring that policies be provided to individuals who had previously been covered by group plans (a form of GUARANTEED ISSUE) would dramatically increase premiums for everyone in the individual market, because only those most likely to need insurance would purchase it. With poorer risks in the small and price-sensitive individual pool, the companies argued, the premiums would go up, thus driving the healthiest individuals out and making the pool an even poorer risk, until the market would end up so expensive that no one could afford coverage. Sponsors of the measure, however, noted that the provisions were so specific and affected so few individuals (only those who had previously been covered for at least eighteen months) that premiums would be affected only slightly, if at all.

At the behest of insurers, several conservative Republicans in the Senate placed holds on the bill, blocking floor action for the remainder of the year (which was consumed, in any case, by the budget fight that precipitated a major government shutdown). President Clinton attempted to get the issue reignited in his 1996 State of the Union speech, urging Congress to "start by passing the bipartisan bill sponsored by Senator Kennedy and Senator Kassebaum that would require insurance companies to stop dropping people when they switch jobs, and stop denying coverage for pre-existing conditions. Let's all do that."

President Clinton's endorsement spurred Republicans in the House, who decided to proceed with their own bill, which included not only the core of the Kassebaum–Kennedy measure but also other provisions designed to put a "Republican stamp" on health reform efforts, according to House GOP leaders. The resulting measure, passed by the House on a largely party-line vote of 267-151 on March 28, included portability provisions as well as authority for creation of MSAs, limits on

noneconomic damage awards in MEDICAL MALPRACTICE suits, tax-credit provisions, and antifraud efforts. It also would have allowed small groups to band together into ASSOCIATION HEALTH PLANS (AHPs), which would be exempt from state regulation.

Meanwhile, in the Senate, the measure did not get to the floor until April. Despite efforts of the original backers of the Kassebaum-Kennedy measure to fend off unrelated amendments such as those approved by the House, Senate GOP leaders, led by Bob Dole, R-Kan., who was running for president, decided to put together an amendment package including MSAs and health-related tax credits. Although Kassebaum and Kennedy managed to strip from the GOP package the MSA provisions on a 52-46 vote (with Vice President Al Gore present in the chamber to cast his vote in case of a tie), the remainder of the GOP amendment package was added to the bill. The measure ultimately passed the Senate by a rarely recorded unanimous 100-0 on April 23, 1996.

But even with strong support from both the House and Senate and the backing of President Clinton, it still took another three months to iron out the bill's details. President Clinton vowed to veto the measure if it included MSAs, malpractice damage awards, and association health plans, but Republicans, with an eye toward the November presidential election, were eager to call his bluff. Members also had to decide what to do about a surprise amendment added during Senate consideration of the measure that would have required MENTAL HEALTH PARITY—that is, requiring insurance coverage for mental health to be equivalent to that for physical ailments.

In the end, neither Republicans nor Democrats wanted to give up the chance for enactment of a health insurance bill, minimal though it was. President Clinton ultimately accepted the limited MSA experiment, whereas Republicans dropped the association health plans and malpractice provisions. Also dropped was the mental health amendment, although a stripped-down version of that was approved two months later, as part of an unrelated spending bill for the Department of Housing and Urban Development and the Department of Veterans Affairs (PL 104-204). By 82-15, senators approved the language requiring the same annual and lifetime limits on mental health ailments as on all other ailments.

Unfortunately, implementation of HIPAA's requirements did not go as smoothly as lawmakers had hoped. By 1998 five states—California, Massachusetts, Michigan, Missouri, and Rhode Island—had failed to enact legislation necessary to implement HIPAA requirement. That left the federal HEALTH CARE FINANCING ADMINISTRATION (HCFA) as the fallback enforcement agency under the act. HCFA, however, had little expertise as an insurance regulator, and a fiscal 1999 supplemental funding request to hire more personnel was denied by Congress. HCFA did, however, find cases in which insurers were seeking to evade the law's requirement by delaying the processing of applications or by providing commissions to agents artificially low so as to deter them from marketing to HIPAA-eligible individuals or small groups. A February 1998 report from the General Accounting Office (now the GOVERNMENT ACCOUNTABILITY OFFICE) found that some insurers were charging premiums "140 percent to 600 percent of the standard rate" to HIPAA-eligible individuals.

Health jurisdiction in Congress

One reason Congress seems to have such difficulty making health policy is that major responsibility for health issues is divided over seven separate committees in the U.S. House of Representatives and the Senate. (Another dozen committees have limited health jurisdictions—largely over specific populations, such as veterans, federal employees, and Native Americans, or specific subject areas. The House and Senate Judiciary Committees, for instance, oversee antitrust law as it relates to health care, as well as MEDICAL MALPRACTICE.) Divisions among subject areas are relatively common in Congress. For example, responsibility for most subject areas is shared by an authorizing committee and the appropriations committee in each chamber. That is true for health policy, too, with most major annual spending

decisions made by the Labor–Health and Human Services–Education Appropriations subcommittees in the House and Senate. An important exception is the FOOD AND DRUG ADMINISTRATION (FDA). Although it is part of the HEALTH AND HUMAN SERVICES DEPARTMENT (HHS), for historical reasons its funding is contained in the annual appropriations bill for the Department of Agriculture (and decisions about its budget are made by that subcommittee, not Labor–HHS).

Where health policy differs from many other subject areas is that it is also handled by multiple authorizing committees. In the Senate, the Finance Committee has the largest single responsibility over things health-related, with full jurisdiction over MEDICARE, MEDICAID, and the STATE CHILDREN'S HEALTH INSURANCE PROGRAM (SCHIP), authorized in 1997, as well as health-related tax policies. The SENATE HEALTH, EDUCATION, LABOR, AND PENSIONS (HELP) COMMITTEE, known until 1999 as the Labor and Human Resources Committee, oversees most of the other health programs run by HHS, including the vast PUBLIC HEALTH SERVICE (PHS) (which includes such agencies as the NATIONAL INSTITUTES OF HEALTH [NIH] and the CENTERS FOR DISEASE CONTROL AND PREVENTION [CDC]), the FDA, and employee-benefit issues (by virtue of its labor jurisdiction).

In the House, primary jurisdiction over health is divided three ways. The tax-writing Ways and Means Committee has considerably less jurisdiction than the Finance Committee on the Senate side, the result of a 1974 committee overhaul intended to lessen the then vast power of Ways and Means. Although Ways and Means shares Finance's power over health-related tax policies and has exclusive jurisdiction over Part A of Medicare (because it is funded by a payroll tax), it shares jurisdiction over Part B with the Energy and Commerce Committee. Energy and Commerce, in addition to its shared responsibility for Medicare, has exclusive jurisdiction over Medicaid. The committee also has jurisdiction in the House parallel to that of the Senate HELP Committee for the Public Health Service and FDA. Health care issues related to employee benefits, however, are handled in the House by the Education and Labor Committee.

Health maintenance organization (HMO)

Health maintenance organizations, also known as HMOs, are the oldest and most tightly organized type of MANAGED CARE plans. The name is often used synonymously with the term *managed care.* HMOs became less popular during the 1990s as patients demanded more freedom to choose their health care providers and to obtain care outside of their health plans.

Traditionally, there have been four major types of HMOs—staff model, group model, independent practice association (IPA) model, and network model.

The oldest type is the staff model, in which the HMO directly employs the physicians and other health care professionals, who in turn care exclusively for the HMO's patients. In staff-model HMOs, the HMO itself bears risk for the cost of care. Staff-model HMOs offer patients the least choice of provider, and the HMO maintains the most control over costs and care. These HMOs are often referred to as closed-panel systems.

In the group-model HMO, physicians who practice as a group contract with the HMO to provide care. Kaiser-Permanente is probably the best-known group-model HMO. Physicians work for the Permanente group, which in turn provides exclusive services to Kaiser Foundation Health Plans. For the patient, the difference between a group- and staff-model HMO is essentially invisible. The primary distinction is who bears the risk for the cost of care. In group-model HMOs, the physician group is at risk for most of the cost of the care its patients need. It receives a set fee for each patient (known as CAPITATION), intended to cover all the costs of primary and specialty physician care. In some cases the physician group is also at risk for some or all of the cost of hospital care, on the theory that physicians control hospital use.

In an IPA-model HMO, the HMO contracts with a group of physicians who have banded together into an independent practice association, or IPA. Physicians in IPA-model HMOs can assume risk with the HMO by receiving capitation or can be paid a discounted rate for each patient visit, with year-end bonuses for meeting

Henry J. Kaiser (with arm over front seat), founder of Kaiser-Permanente, a group-model health maintenance organization (HMO), accompanies President Franklin D. Roosevelt on a 1942 visit to Kaiser's shipyards. Since 1945, when Kaiser opened his company's health care plan to the public, the plan has grown to become one of the nation's largest nonprofit HMOs.
Source: AP Images/Kaiser-Permanente

cost or other utilization targets. Unlike physicians in staff- and group-model HMOs, physicians in IPA-model HMOs may have contracts with other HMOs or other types of health plans.

Finally, network-model HMOs bring together doctors from different kinds of practices and may combine doctors in a group practice with those in an IPA.

By the mid-1990s, so many managed care plans were adopting so many variations on organization and payment that the term *HMO* was well on its way to being rendered essentially meaningless.

Health plan

Health plan is the umbrella term for an individual insurance product offered to a group of individuals or businesses. Health plans may be types of MANAGED CARE plans (a HEALTH MAINTENANCE ORGANIZATION [HMO], PREFERRED PROVIDER ORGANIZATION [PPO], and the like) or traditional FEE-FOR-SERVICE plans. A single insurance or other company may offer multiple health plans. Distinctions have broken down in managed care plans as many HMOs have adopted practices more typical of PPOs or indemnity (traditional fee-for-service) plans and vice versa. As a result, many analysts and health care companies have adopted the term *health plan,* as did the managed care industry's trade group, the AMERICAN ASSOCIATION OF HEALTH PLANS (AAHP). AAHP in 2003 merged with the HEALTH INSURANCE ASSOCIATION OF AMERICA (HIAA), representing nonmanaged care insurers, to become AMERICA'S HEALTH INSURANCE PLANS (AHIP).

Health Plan Employer Data and Information Set (HEDIS)

The Health Plan Employer Data and Information Set (HEDIS) is a set of measures used by employers and other purchasers of health care to assess the quality of care provided by a HEALTH PLAN. HEDIS was developed by the NATIONAL COMMITTEE FOR QUALITY ASSURANCE

(NCQA) with the input of employers and MANAGED CARE plans to facilitate comparisons between plans. HEDIS measures the effectiveness and availability of care (such as the percentage of children receiving immunizations or the percentage of women screened for breast and cervical cancer), satisfaction (as measured by a survey), health plan stability (as measured by turnover rates for patients and providers), use of services (such as the rate of childbirth by cesarean section and well-child visits), and cost of care (as measured by rate trends). More than 90 percent of health plans use HEDIS, according to NCQA. In 2007 there were seventy-one measures across eight separate domains of care. Previous versions of HEDIS focused more on inputs to care (such as immunization rates) instead of outcomes. New measures in HEDIS proposed for 2008 include whether patients who have suffered a heart attack are given beta blocker drugs and how many of those patients are still taking those drugs six months later. In 2007 NCQA developed HEDIS measures for preferred provider organizations (PPOs), which was an important advance because an estimated 60 percent of all Americans with health insurance are enrolled in a PPO product. (See PREFERRED PROVIDER ORGANIZATION [PPO].)

Health professional shortage area (HPSA)

A health professional shortage area (HPSA) is an area determined by the federal government to have a smaller supply of primary care health care professionals than is needed to maintain the health of the area's population. Although most HPSAs are in rural areas, some are located in inner cities, where residents with low incomes may find it virtually impossible to access health care services. The secretary of the HEALTH AND HUMAN SERVICES DEPARTMENT (HHS) may also designate an individual public or nonprofit private health care facility an HPSA. The Public Health Service Act stipulates that HPSAs "need not conform to the geographic boundaries of a political subdivision" as long as they represent "a rational area for the delivery of health services." HPSAs are eligible for placement of members of the NATIONAL HEALTH SERVICE CORPS, and health professionals practicing within such areas are eligible for special programs to encourage them to remain there. As of June 2008, HHS had designated 5,977 primary care medical HPSAs. More than 20 percent of Americans lived in those designated shortage areas, according to HHS.

Health Resources and Services Administration (HRSA)

The Health Resources and Services Administration (HRSA) is the agency within the U.S. HEALTH AND HUMAN SERVICES DEPARTMENT (HHS) most directly involved with the actual provision of medical services to patients, primarily those who, because of their incomes or where they live, would have little or no other access to health care. With a budget of $6.4 billion in fiscal 2007, HRSA provides primary care services through the Consolidated Health Centers Program, which includes COMMUNITY HEALTH CENTERS, MIGRANT HEALTH CENTERS, the Health Care for the Homeless program, and the Health Care for Residents of Public Housing program. It administers the TITLE X FAMILY PLANNING PROGRAM (of the Public Health Service Act), which provides funds to family planning clinics, and the MATERNAL AND CHILD HEALTH (MCH) SERVICES BLOCK GRANT and Healthy Start programs, which are aimed at lowering infant mortality rates and improving the health of the nation's youngest citizens. HRSA also oversees programs for individuals with specific health conditions. It administers the RYAN WHITE COMPREHENSIVE AIDS RESOURCES EMERGENCY (CARE) ACT, which underwrites treatment and prevention efforts to fight the human immunodeficiency virus (HIV) and ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS) as well as a much smaller federal program to treat those with Hansen's disease (leprosy). It also oversees the nation's organ transplant program. (See ORGAN DONATIONS AND TRANSPLANTS.) In addition, HRSA oversees the federal government's efforts to train future health care practitioners, including doctors, nurses, and other health professionals, with an eye toward expanding the number of PRIMARY CARE providers and improving the geographic distribution of health care professionals. HRSA's NATIONAL HEALTH SERVICE CORPS

combines the agency's missions of delivering services and training practitioners by providing scholarships or loan repayments to primary care practitioners who agree to serve for a period of time in areas with few or no other health care providers.

Health Savings Accounts (HSAs)

Health Savings Accounts (HSAs) are tax-advantaged vehicles that are intended to both help individuals manage and pay for routine medical care and help bring down the cost of medical care. They were created in 2003 as part of the MEDICARE MODERNIZATION ACT (PL 108–173), which added a prescription drug benefit to MEDICARE. The HSAs were a replacement for MEDICAL SAVINGS ACCOUNTS (MSAs), an experiment that had expired several years earlier. They were added to the Medicare legislation, although they had nothing to do with Medicare, in an effort to garner votes from conservative Republicans who were loathe to vote for a bill expanding an entitlement program.

Under the 2003 law, to open an HSA, an individual must have a qualifying high-deductible health plan. For 2008, that deductible had to be at least $1,100 for individuals and $2,200 for families. Individuals in 2008 could contribute up to $2,900 into their HSA tax-free; families, up to $5,800. Both employers and individuals are allowed to contribute money into the HSA, which is a major change from the MSA experiment of the 1990s. The law also limits what individuals and families may be required to pay out-of-pocket before the high-deductible insurance begins covering all remaining health costs for the year. In 2008 that threshold was set at $5,600 for individuals and $11,200 for families.

For advocates of CONSUMER-DRIVEN HEALTH PLANS, HSAs were a dream come true. They had far fewer restrictions than the MSAs they replaced, had even more tax advantages (funds were tax-free going in, built interest tax-free, and came out tax-free if used for qualified medical expenses), and were available to many more people. Backers of market-driven health care hoped that if enough people were to open the accounts and were to begin spending their own money on routine health care (the accounts were required to be combined with catastrophic insurance for major health expenses), they would become more sensitive to the cost of that care and begin to bargain down prices.

Opponents of HSAs, however, were appalled at their approval for the same reasons. The tax advantages

President Bush speaks during a 2007 White House meeting on health savings accounts (HSAs), which were created by the Medicare Modernization Act of 2003. President Bush has been a strong proponent of HSAs and believes that they can help to expand affordable health coverage.
Source: Stefan Zaklin/UPI/Landov

would accrue mostly to the healthy and wealthy, they said. And if the healthiest people were to leave traditional insurance plans, only the sick would be left behind. The cost of those plans then would skyrocket, leaving only HSAs and high-deductible health plans, even for those who could ill-afford them.

Health Security Act

The Health Security Act is the official name of the legislation proposed by President Bill Clinton to restructure the nation's health care system. When Clinton was sworn in as president on January 20, 1993, the country appeared ready for a major overhaul of its health system. Health care spending appeared out of control, in 1993 reaching $903 billion—more than double the amount spent as recently as 1987. The costs were afflicting all health payers, from the federal government via the fast-growing MEDICARE program, to the states, who shared responsibility with the federal government for MEDICAID, to employers, who provided health insurance to their workers. At the same time, the number of Americans with no insurance was rising nearly as rapidly as health care spending. In 1992, on any given day, about 38.5 million Americans were uninsured, about 17 percent of the population under sixty-five.

Even health care providers were ready for a change. In 1990 the AMERICAN MEDICAL ASSOCIATION (AMA), which had helped sink several previous efforts to enact national health insurance, endorsed a requirement that employers provide insurance for their workers. Also backing an "employer mandate" was the HEALTH INSURANCE ASSOCIATION OF AMERICA (HIAA).

But what really put health reform on the agenda was a surprise in a 1991 special Senate election in Pennsylvania to fill the unexpired term of Republican John Heinz, who had died in a helicopter crash that spring. Republican Dick Thornburgh, who had served two terms as Pennsylvania's governor, was a prohibitive favorite to defeat the little-known Harris Wofford, a political neophyte who had been appointed to fill the seat by Gov. Robert P. Casey. But Wofford (whose campaign was run by James Carville, who would go on to advise Clinton) latched onto the health care issue. "If criminals have the right to a lawyer, I think working Americans should have a right to a doctor," Wofford said in what came to be a famous television ad. Wofford went on to defeat Thornburgh, and both Republicans and Democrats set out to do something about health care.

Clinton was not the Democratic candidate in 1992 with the most substantive background in health policy. Clinton was better known in Washington for his work on the 1988 welfare reform bill, the Family Support Act (PL 100–485), and for efforts on education and child care initiatives. During the primaries, Sen. Tom Harkin, D-Iowa, Sen. Bob Kerrey, D-Neb., and former California governor Jerry Brown all were more aggressive than Clinton about spotlighting the need for comprehensive health care reform. But once elected, Clinton quickly elevated health care to the top of his agenda, irritating those who supported Clinton's other major domestic priority, welfare reform.

But the process of turning a campaign outline in favor of a concept called MANAGED COMPETITION into an actual legislative proposal—all while trying to put together the first Democratic administration in twenty-four years—proved a daunting task. Clinton appointed a task force headed by his wife, first lady Hillary Rodham Clinton, who turned out to be a lightning rod for criticism. The task force staff was headed by political neophyte Ira Magaziner, who turned what was already an unwieldy task into a monumental one. Magaziner assembled more than five hundred health policy experts from around the country in various nooks and crannies of the White House and executive office buildings. These experts worked around the clock on what would become the Health Security Act.

Unveiled in a speech on September 22, 1993, the Health Security Act had already earned more than its share of enmity and derision. Groups who should have been inclined to support it, such as the American Medical Association, which had already endorsed an employer mandate, instead felt shut out of the secretive process. In an effort to gain public sympathy, the president and first lady had made another misstep by painting insurance companies and drugmakers as greedy enemies of reform, thus ensuring their opposition. On

Capitol Hill, health policy makers were annoyed that the president was putting together such a detailed proposal, insisting that it was their job to flesh out the specifics.

But for all the grief heaped on the 1,342-page document, Clinton's Health Security Act was a more elegant proposal than many gave it credit for. Although its enormity and complexity made it a hard sell politically, most health policy analysts—even those who opposed it for ideological reasons—conceded that it probably would have worked as intended had it been enacted into law.

The Health Security Act sought to build on the existing health care system by requiring employers to provide most workers and their families with health insurance and to pay most of the costs. To address complaints from small employers that the costs would drive them out of business, the plan proposed generous subsidies. Also subsidized would be low-income families and individuals, who would otherwise have had difficulty paying their share of the premiums. Overall spending would have been controlled primarily by competition between health plans and fallback limits placed on the amount premiums could rise each year. These "premium caps" were a clever device that allowed the Clinton administration to claim (correctly) that it was not imposing price controls on medical services. But the caps would have forced just such eventualities—or else outright rationing—by the insurance companies themselves.

At the heart of the proposal were regional health alliances that would pool premiums from businesses and individuals and negotiate with insurance companies. (These were originally called *health insurance purchasing cooperatives* by those who devised the concept of managed competition, but Clinton administration officials discarded the term as sounding "too communistic," in the words of one aide.)

According to administration number crunchers, because the majority of new costs would be borne by employers, the remainder of the program could have been financed by a combination of a seventy-five cents per pack increase in the cigarette tax; a 1 percent tax on the largest corporations (those with more than five thousand workers) if they opted not to join the alliances; reductions of $124 billion in Medicare, $65 billion in Medicaid, and $40 billion in other federal health programs; and increased revenues that would flow to the federal Treasury through reduced health care costs. Not only would that financing leave a $45 billion cushion in case the subsidies were more costly than anticipated, administration budget officials insisted, but the plan would also produce another $58 billion to lower the deficit.

The CONGRESSIONAL BUDGET OFFICE (CBO) did not share that opinion of the measure. Over the first six years, according to CBO, the plan would add $74 billion to the deficit. CBO also opined that the mandatory employer contributions toward their workers' health coverage should be treated as a tax. Nevertheless, much of the rest of the CBO report on the Health Security Act was favorable. Analysts said the plan would likely cover everyone, as advertised, and, after the year 2004, would reduce national health care spending. The report also defended the plan's scope. "A major reason for its complexity . . . is that the proposal outlines in legislation the steps that would actually have to be taken to accomplish its goals. No other proposal has come close to attempting this. Other health care proposals might appear equally complex if they provided the same level of detail as the administration on the implementation requirements," the report said.

Unfortunately for the administration, its staff proved more skilled at devising the plan than at selling it. In retrospect, though, the battle was probably lost long before it was truly engaged. Democrats were badly split on health reform—a significant minority favored a single-payer plan like Canada's, whereas another faction favored a less sweeping version of managed competition that included no employer mandate, no premium caps, and no guarantee to cover every American. (See SINGLE PAYER.) Republicans, who had early in the debate rallied around a proposal for an "individual mandate," by later in 1993 were emboldened by polls showing declining support for the Clinton plan. They would ultimately back away from support for any far-reaching proposal.

And at center stage were the opponents, led by the NATIONAL FEDERATION OF INDEPENDENT BUSINESS (NFIB),

the small business lobby, which vehemently opposed the employer mandate, and the Health Insurance Association of America, whose "Harry and Louise" ads picturing a couple at their kitchen table puzzling over the complexity of the Clinton plan came to epitomize the opposition.

Congress continued to go through the motions. During the early months of 1994, nearly a dozen committees in the House and Senate worked on various aspects of a health reform plan. The Senate took up a bill on August 9, postponing its traditional summer recess in an attempt to rescue the floundering proposal. (House debate never reached the floor.) But after two weeks of debate with little to show for it, the Senate left for a delayed vacation, and leaders conceded that a comprehensive bill could not be passed. By the end of September, it became clear that even a scaled-back proposal was not in the cards. And in November, voters told Congress what they thought of the entire escapade by giving control of both the House and Senate to Republicans for the first time in forty years.

The fact that no legislation emerged from the wrenching debate of 1993–1994 has colored the fact that Congress came closer to enacting a national health insurance scheme than in any of its earlier tries in the 1930s, 1940s, and 1970s. In 1994 four major congressional committees (House Ways and Means, House Education and Labor, Senate Finance, and Senate Labor and Human Resources) reported five broad bills (House Education and Labor produced two measures, including a single-payer proposal reported to the floor without recommendation). Four of those bills would have guaranteed UNIVERSAL COVERAGE for all Americans. But in the end the Health Security Act, like so many national health insurance proposals before it, was consigned to a historical footnote.

Health services research

Health services research, according to the Association for Health Services Research, is defined as "a field of inquiry using quantitative or qualitative methodology to examine the impact of the organization, financing and management of health services on the access to, delivery, cost, outcomes and quality of services." Like biomedical research, health services research is conducted by university-affiliated researchers, policy research organizations, and health care providers, particularly MANAGED CARE companies, that want to examine things such as technology assessment. Such assessments can help determine if new treatment is more effective or less expensive than an older procedure. Health services researchers also examine the outcomes of various medical interventions to help determine which work best, and they explore health system organizational issues, such as the supply of health professionals, the number of uninsured, and the consequences of being uninsured. At the federal level, the AGENCY FOR HEALTHCARE RESEARCH AND QUALITY (AHRQ) helps coordinate health services research efforts.

HEDIS

See HEALTH PLAN EMPLOYER DATA AND INFORMATION SET (HEDIS).

HELP Committee

See SENATE HEALTH, EDUCATION, LABOR, AND PENSIONS (HELP) COMMITTEE.

HIAA

See HEALTH INSURANCE ASSOCIATION OF AMERICA (HIAA).

Hill-Burton Act

The Hill-Burton Act is the colloquial name of the Hospital Survey and Construction Act (PL 79–725). Passed in 1946 and named for its sponsors,

Sen. (Joseph) Lister Hill, D-Ala., and Harold Burton, R-Ohio, the act was intended to boost the building and rehabilitation of hospitals that had fallen into disrepair during the Great Depression and World War II. Since its inception, the Hill-Burton Act has provided more than $4.6 billion in grants and $1.5 billion in loans to nearly sixty-eight hundred health care facilities in more than four thousand communities. In exchange for the federal aid, facilities must agree to provide free or low-cost care to those without insurance or otherwise unable to pay their bills. In 1972 Congress placed a twenty-year limit on the free care obligations. However, 1975 amendments to the Hill-Burton Act establishing federal grants, loans, and interest subsidies required that uncompensated services be provided in perpetuity. As of 2008, approximately 200 facilities around the country were still obliged to provide free or reduced-cost care under the act.

HMO

See HEALTH MAINTENANCE ORGANIZATION (HMO).

Home health care

Home health care is the provision of health-related services inside a patient's home. Home health care can range from highly technical medical services provided by a registered nurse, to Meals on Wheels deliveries, to help with household chores or such ACTIVITIES OF DAILY LIVING (ADLs) as dressing and bathing. Both MEDICARE and MEDICAID cover the provision of some, but not all, home health services.

Medicare covers services only to those who are homebound or too ill or frail to leave home on a regular basis or without considerable effort (such as requiring crutches or a wheelchair) but not disabled enough to require institutional care. Patients must require either skilled nursing or skilled physical, speech, or occupational therapy services (as opposed to less complex care such as simple bandage changing), as certified by a physician, but only on a part-time or intermittent basis. If a doctor certifies the need for care, Medicare will pay for less skilled care provided by a home health aide in addition to the skilled care.

In the 1990s Medicare spending on home health care rose dramatically. In 1989 it accounted for 2.5 percent of all Medicare spending; by 1996 that had risen to 9.3 percent. Both the number of beneficiaries using the benefit (which required no DEDUCTIBLE or copayment) and the number of visits were rising. In an attempt to stem that rise, Congress in the 1997 Balanced Budget Act (PL 105–33) called for creation of a PROSPECTIVE PAYMENT SYSTEM (PPS) for home care that would base payments on the estimated cost according to a patient's condition, not on what the home health provider spent. Congress imposed an interim system of payments until the new system could be devised and implemented. When the HEALTH CARE FINANCING ADMINISTRATION (HCFA) announced in 1998 that it would not be able to meet the October 1, 1999, deadline for that new payment system, however, Congress was forced to revise the interim system, after beneficiaries and home health providers alike complained that it was forcing some providers out of business. In 1999 the MEDICARE PAYMENT ADVISORY COMMISSION (MedPAC) found that, in 1998, the first year of the new payment system, Medicare spending for home health services declined. MedPAC also found that fewer Medicare beneficiaries were receiving home health services, and the number of agencies participating in the program declined. The General Accounting Office, however, found that despite the payment changes, little evidence existed that beneficiaries' access to home health care was being threatened. Congress boosted funding for home health care providers in Medicare "giveback" bills in both 1999 and 2000, primarily by delaying a planned 15 percent cut. Although agencies continued to insist that the industry was being hurt by the reduced funding, MedPAC in 2003 said Medicare payment was "more than adequate relative to costs" and that access to care was not being compromised. The prospective payment system ultimately implemented for home care pays agencies for sixty-day periods, adjusted for the severity of the needs of the individual patient. Medicare spent $12.6 billion on home health care in 2006.

Hospice

Hospice care is a form of care for dying patients that emphasizes comfort over cure, focusing on managing pain and relieving symptoms instead of on trying to extend a patient's life. Hospice care can be provided in a standalone facility or in a terminally ill patient's home. Hospice services focus on preparing both the patient and the family for an impending death, using an interdisciplinary team of health care and social services providers, including doctors, nurses, HOME HEALTH CARE aides, mental health professionals, and members of the clergy. MEDICARE covers hospice services, provided a physician certifies that a patient is terminally ill—defined as having a life expectancy of six months or less. Unlike traditional Medicare, Medicare's hospice benefit does cover the cost of outpatient prescription drugs (to treat pain and other symptoms) without an additional premium and RESPITE CARE to provide a break for a family member providing care.

Hospital Insurance (HI)

The formal name of Part A of MEDICARE, the Hospital Insurance (HI) program covers not only hospital, but also some home health, nursing home, and HOSPICE care. Although fewer beneficiaries use it, Medicare's Part A is the larger of the traditional program's two parts, with benefit payments totaling $186 billion in 2006. That is because the services Part A covers, particularly hospital and skilled care in a nursing home, are among Medicare's most expensive. About 23 percent of Medicare's forty-one million Part A beneficiaries received services covered by the program in 2003. (See HOME HEALTH CARE and BENEFICIARY.)

Part A is funded by a dedicated portion of the Social Security tax, specifically 1.45 percent of income paid by both employers and workers. Unlike the Social Security tax, however, which is assessed only up to a floating income level ($97,500 in 2007), workers and their employers continue to pay the Medicare tax on all earnings. Congress raised the cap to $125,000 of income in 1990 and eliminated it altogether in 1993 to help boost the ailing financial status of the HI trust fund. Income taxes on Social Security payments that some recipients must pay also go to shore up the Medicare trust fund.

Hospitalist

A recent trend in health care delivery is the use of a hospitalist, a physician who specializes in overseeing care for patients in the hospital, working with, or sometimes in place of, the patient's PRIMARY CARE doctor. According to the Society of Hospital Medicine (SHM), which represents hospitalists and the practice of hospital medicine, an estimated twenty thousand hospitalists in 2006 were practicing in the United States, about the same number as gastroenterologists and neurologists. The specialty has spread rapidly since its inception in the 1990s. As recently as 2003, there were only seven thousand to eight thousand such doctors. More than 75 percent of hospitalists are trained as general internists, according to the SHM, with the remainder specializing in pediatrics and internal medicine subspecialties such as cardiology or working as nonphysicians such as PHYSICIAN ASSISTANTS. Backers of the hospitalist trend say it can benefit both patients and their regular physician caregivers. Hospitalists are more familiar with the workings of their institution and better able to navigate procedural hurdles, are on-site all day (whereas most hospitalized patients' primary care doctors are back in their offices seeing other patients) and better able to respond to emergencies or discharge patients who are ready to go home, and are more accustomed to seeing sicker patients than the average office-based physician. However, some primary care practitioners worry that patients would be better off with a physician who knows them, their families, and their medical histories. Office-based doctors are also worried that if they no longer see hospitalized patients, their skills in caring for the sickest patients may decline.

House Appropriations Committee

The House Appropriations Committee oversees the "discretionary" portion of the federal budget. The

committee writes twelve separate spending bills each year that are required for the government to run. Through the LABOR–HEALTH AND HUMAN SERVICES–EDUCATION APPROPRIATION (Labor-HHS), the committee sets spending levels for most of the HEALTH AND HUMAN SERVICES DEPARTMENT (HHS), with three major exceptions. First, MEDICARE and MEDICAID, as "entitlement" programs, are funded according to estimates of how much they will cost. Legislative changes to affect those costs must be initiated by authorizing committees. Second, for historical reasons, the FOOD AND DRUG ADMINISTRATION (FDA), although part of HHS, is funded by the Agriculture appropriations bill. Third, the Appropriations Committee sets spending levels for other health-related programs, including the INDIAN HEALTH SERVICE (IHS) (funded in the Interior and Environment bill), health care for Veterans (funded in the Military Construction–Veterans Affairs bill), health care and insurance for the military (through the Defense bill), health care for those incarcerated in federal prisons (through the Commerce-Justice-Science bill), and health insurance for federal employees (through the Financial Services and General Government bill).

House Education and Labor Committee

Given back its original name at the start of the 110th Congress (it was the House Education and Workforce Committee for a dozen years under Republican rule), the House Education and Labor Committee has health jurisdiction related to employee benefits. The committee oversees the EMPLOYMENT RETIREMENT INCOME SECURITY ACT (ERISA) as well as legislation that would require employers to provide health coverage. Traditionally populated by liberal Democrats and conservative Republicans (largely for the purpose of pushing or opposing legislation of interest to organized labor), during the health reform debate in 1994 the panel reported legislation (albeit "without recommendation") that would have created a single-payer health system funded by the federal government. (See SINGLE PAYER.)

House Energy and Commerce Committee

After the SENATE FINANCE COMMITTEE, the House Energy and Commerce Committee has the broadest health jurisdiction in Congress and exercises it regularly. The Commerce panel oversees the FOOD AND DRUG ADMINISTRATION (FDA), the PUBLIC HEALTH SERVICE (PHS), and all of the MEDICAID program. The Commerce Committee also shares jurisdiction with the HOUSE WAYS AND MEANS COMMITTEE over Part B of MEDICARE. (Ways and Means has exclusive jurisdiction over Medicare Part A, because it is financed by a payroll tax, and Ways and Means has jurisdiction over taxes in the House.) During the 1980s, under the leadership of committee chair John D. Dingell, D-Mich., and Health and Environment Subcommittee chair Henry A. Waxman, D-Calif., the Commerce Committee led efforts to broaden Medicaid substantially and break its ties with cash assistance programs. The committee also initiated laws to strengthen federal standards for clinical laboratories (see CLINICAL LABORATORY IMPROVEMENT ACT [CLIA]) and to speed up FDA approval of prescription drugs by imposing user fees (see PRESCRIPTION DRUG USER FEE ACT [PDUFA]). Under GOP leadership from 1995 until 2007, the Commerce Committee took the lead on the 1997 FDA Modernization Act and the STATE CHILDREN'S HEALTH INSURANCE PROGRAM (SCHIP) included as part of the 1997 Balanced Budget Act (PL 105–33).

House Ways and Means Committee

The House Ways and Means Committee exercises significant influence over health care policy through its oversight of the MEDICARE program. Ways and Means has exclusive jurisdiction in the U.S. House of Representatives for Medicare Part A, and it shares jurisdiction over Part B with the HOUSE ENERGY AND COMMERCE COMMITTEE. Ways and Means also exercises control over health policy through its jurisdiction over taxes. The U.S. system of employer-provided insurance developed largely because health benefits were made tax-

deductible for employers who gave them and the benefits were excluded from taxation for the workers who received them. In recent years Ways and Means has used its tax power to increase the deductibility of premiums for self-insured individuals, to make private LONG-TERM CARE insurance more financially viable, and to fund a program to compensate children who suffer adverse reactions to required vaccines against childhood illnesses by imposing an excise tax on those vaccines. Ways and Means' health jurisdiction used to be more sweeping still but was scaled back in a 1974 overhaul intended to dilute the panel's vast power. Ways and Means, however, remains so influential that it is still referred to almost reflexively as the "powerful Ways and Means Committee."

HPSA

See HEALTH PROFESSIONAL SHORTAGE AREA (HPSA).

HSAs

See HEALTH SAVINGS ACCOUNTS (HSAs).

Human research subject protection

The 1999 death of eighteen-year-old Jesse Gelsinger during a gene therapy experiment at the University of Pennsylvania renewed efforts to ensure that people who participate in biomedical and behavioral research are adequately protected. Although the Clinton administration took steps to more closely regulate the conduct of potentially life-threatening research and Congress held a series of hearings on the subject, lawmakers were not able to reach consensus on a new statutory scheme to ensure human research participants were acceptably warned of potential risks and benefits and to

President Clinton and Vice President Gore assist Herman Shaw, a 94-year-old Tuskegee Syphilis Study victim, at a news conference May 16, 1997. Clinton apologized to black men whose syphilis went untreated by government doctors during the experiment. Source: *AP Images/Doug Mills*

ensure disclosure of potential conflicts of interests by researchers.

Federal protection of human research participants dates back to the Nuremberg Code, which grew out of the famous trials of Nazi war criminals after World War II. Physicians and researchers had used Jews and other prisoners in a series of medical studies that often resulted in prisoners' death or permanent injury. The centerpiece of the code is that research participants should give voluntary consent for their participation. "This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision," the code said. Other elements of the Nuremberg Code hold that experiments should be designed "to yield fruitful results for the good of society, unprocurable by other methods or means of study"; that research should be conducted to avoid unnecessary physical and mental suffering and injury; that the degree of risk should never exceed the potential benefit to be discovered; that experiments be carried out only by those who are scientifically qualified; and that research participants or researchers should be able and willing to terminate the study at any time if either determines the risks have become too great.

In 1974, following disclosures that federal researchers purposefully withheld treatment from African American servicemen with syphilis to study the effects of the disease (see TUSKEGEE EXPERIMENTS), Congress codified the concept that humans used in research must be protected as part of the National Research Act (PL 93–48). That law required creation of INSTITUTIONAL REVIEW BOARDS (IRBs) to approve, in advance, ethical and scientific plans for research on humans and to monitor such research on an ongoing basis.

In the wake of the Gelsinger death, in the spring of 2000, HEALTH AND HUMAN SERVICES DEPARTMENT (HHS) secretary Donna E. Shalala created a new Office for Human Research Protection to replace and strengthen the former regulatory oversight agency, the Office for Protection from Research Risks. (The former agency also oversaw research on laboratory animals; the reorganization created a new office to oversee animal experimentation.) Although advances in research have brought tremendous benefits, said Shalala, "the explosion in biomedical research has also brought new challenges, as more researchers are becoming involved in commercial ventures that may create new ethical dilemmas. Today's actions are designed to further strengthen government oversight of all biomedical research."

Among the new requirements were for all researchers receiving federal funds to get specific training in bioethics, stricter documentation of the INFORMED CONSENT process, and additional disclosures of financial conflicts of interest by researchers.

The new office made it clear it would act more aggressively to police research than its predecessor. In July 2001 it temporarily ordered a halt to all human research at Johns Hopkins University in the wake of the death of a twenty-four-year-old laboratory worker named Ellen Roche in an asthma experiment a month earlier. Research was allowed to resume several days later, after the office and the university reached agreement on a plan to beef up research oversight.

Hyde amendment

The term *Hyde amendment* refers to a series of amendments on various appropriations bills barring federal funding of ABORTION in most cases. The amendment, which has been altered over the years as abortion-related majorities in Congress and the White House have shifted back and forth, is named for Rep. Henry J. Hyde (R-Ill., 1975–2006), one of the best-known abortion opponents in Congress. But Hyde was not in fact the author of the original Hyde amendment. That distinction belonged to Rep. Silvio O. Conte of Massachusetts, a moderate who was the ranking Republican on the House Labor–Health and Human Services–Education (Labor-HHS) Appropriations Subcommittee.

Congress first engaged the question of whether it should fund abortions in 1974, just a year after the U.S.

Named for Rep. Henry Hyde, R-Ill., one of Congress's best-known abortion opponents, the Hyde amendment sought to bar federal funding of the procedure in most cases. Source: *CQ Photo/Scott J. Ferrell*

Supreme Court legalized the procedure nationwide in the landmark case *ROE V. WADE*. That year the House and Senate took positions opposite of those they would take for the next decade and a half. The House voted no on the first amendment to the fiscal 1975 Labor-Health, Education, and Welfare bill that would have cut off abortion funding (offered not by Hyde but by Rep. Angelo D. Roncallo, R-N.Y.). Meanwhile, the Senate later that year approved an amendment offered by Dewey F. Bartlett, R-Okla., to bar funding for abortions or to encourage abortions "except to save the life of the mother." It was passed by voice vote after a tabling motion failed by 34-50. The amendment, however, was dropped in conference.

The House first passed a funding restriction offered by Hyde on June 24, 1976. As approved by the chamber 207-167, it forbade the use of funds in the bill "to pay for abortions or to promote or encourage abortions." The Senate, however, unlike two years earlier, was not inclined to go along. At the instigation of Sen. Bob Packwood, R-Ore., who would go on to become one of that chamber's leading abortion rights advocates, the Senate voted 57-28 to strike Hyde's amendment from the bill.

The measure was in conference for more than eleven weeks, with both sides refusing to back down and each rejecting dozens of compromise proposals. Finally, on September 15, conferees agreed to a compromise offered by Conte barring abortion funding "except where the life of the mother would be endangered if the fetus were carried to term."

That 1976 agreement, however, left many issues unclear. Conte himself said that, in his view, some psychological factors, such as suicidal tendencies of a pregnant woman, could constitute enough of a threat to a woman's life to justify an abortion. And conferees in their report said they did not intend that the language bar federal funding for the "treatment of rape or incest victims."

The 1976 language did not take effect until August 1977, after the Supreme Court held in three separate rulings that states were not required to use public funds for elective abortions. That prompted a federal judge to lift the injunction on the federal restrictions, and the funding

ban took effect for the first time, reducing MEDICAID abortions from about 300,000 per year to a few thousand.

Meanwhile, even as the funding case continued in the courts, the debate in Congress raged on. The House continued to insist on its no-exceptions funding ban, and the Senate stuck just as steadfastly to exceptions for life of the woman, rape, incest, and abortions considered medically necessary for the woman's health. The standoff persisted for five months, through twenty-five roll-call votes in the two chambers, until a compromise was reached. The final language, crafted primarily by Sen. Edward W. Brooke, R-Mass., and the then House minority whip Robert H. Michel, R-Ill., was seen at the time as a defeat for both sides. It permitted federal funding of abortions in cases of life endangerment, rape, and incest and "in those instances where severe and long-lasting physical health damage to the mother would result if the pregnancy were carried to term when so determined by two physicians." The battle continued through 1978, with the same language ultimately adopted.

For the next three years, abortion-related controversies prevented completion of regular Labor-HHS funding bills, with Congress moving gradually to narrow the exceptions to the funding ban. Buttressed by the Supreme Court's 1980 decision upholding the right of Congress to deny funding and by a right-to-life movement picking up considerable political momentum, Congress stiffened its funding ban in each succeeding year. In 1979 Senate conferees ultimately agreed to drop the exception permitting funding for abortions necessary to prevent severe health damage. The following year, the continuing resolution to keep the departments running required rape victims to report the crime within seventy-two hours and permitted states to ban abortion funding if they wanted to. By 1981 the Senate agreed to drop the rape and incest exceptions altogether, resulting in the language (forbidding all abortion funding except to save the life of the woman) that would be the law of the land for the next twelve years.

After some minor skirmishing from 1982 through 1988, the Hyde amendment in 1989 again took center stage in the nation's abortion debate. Following the Supreme Court's decision in *WEBSTER V. REPRODUCTIVE HEALTH SERVICES,* upholding a series of state restrictions previously considered unconstitutional under the framework of *Roe v. Wade,* abortion rights forces in Congress and in the country mobilized in fear that the Court might overturn the right to abortion entirely. Their principal goal that year was to reinstitute the rape and incest exceptions to the Hyde funding ban. Although the Senate had periodically voted for rape and incest exceptions during the 1980s, the House in October 1989 voted for the first time in eleven years to relax the Hyde restrictions. The 211-206 tally represented a swing of fifty votes from 1988, when members voted 216-166 to maintain the more restrictive language.

The language ultimately did not change. President George H. W. Bush vetoed the Labor-HHS appropriation and the House failed to override the veto by fifty-one votes. In 1990 the issue was barely addressed. The Senate adopted an amendment to grant the rape and incest exception, but antiabortion lawmakers appended to that another amendment, requiring abortion providers who received funds under the bill to notify the parents of a minor forty-eight hours before the abortion could be performed. Because it was procedurally impossible to separate the rape-incest language from the PARENTAL NOTIFICATION requirement, abortion rights advocates dropped the entire matter.

In 1991 and 1992 abortion rights forces focused on other matters, notably unsuccessful attempts to block the GAG RULE barring federally funded family planning clinics from counseling or referring for abortion.

In 1993 it appeared for a time that all abortion funding restrictions would be dropped. But even with abortion rights majorities in both Houses and abortion rights supporter Bill Clinton in the White House, it was not to be. During House floor consideration of the Labor-HHS bill, abortion opponents used a parliamentary maneuver involving a precedent from 1908 to insert into the bill language to ban funding, but because they recognized the reality of the situation, they allowed rape and incest exceptions. "I didn't think the votes were there anymore for a straight ban on abortion funding," Hyde said at the time. The Senate, although traditionally more supportive of abortion rights than the House, nonetheless rejected its Appropriations Committee's recommendation to lift the funding ban entirely and

adopted the House-passed language. Part of the impetus was the odd way the Medicaid statute was drafted. In the absence of language banning funding of abortions, coverage would have been mandatory for the states, thus overturning the laws of at least thirty-one states.

Although the fiscal 1994 Labor-HHS bill, as signed into law, represented the first time since 1977 that Congress had loosened an abortion restriction, that relaxation was seen as a major loss by abortion rights backers, who had hoped to eliminate the Hyde language entirely. It was also seen as a major victory for abortion foes, who found themselves in the odd position of offering as an amendment language that until 1993 they had ardently opposed.

The Republican-controlled 104th Congress attempted to strengthen the Hyde language once again, with the House passing language seeking to make it optional for states to fund abortions in cases of rape and incest. (The previous ban mandated such coverage because of the way the Medicaid law is drafted.) The Senate refused to relent, however, and in the end the language was left unchanged from the previous year. The issue was not engaged in 1996 on the fiscal 1997 Labor-HHS bill.

In 1995 Republicans attempted for the first time to codify the Hyde language into permanent Medicaid law. Because appropriations bills apply only for a single year, the ban had to be renewed each year. But as part of legislation vetoed by President Clinton, the Republican-backed Balanced Budget Act would have written the then existing Hyde language—preventing funding for abortions except for those needed to save the life of the woman or in cases of rape or incest—directly into the Medicaid statute.

In 1997 antiabortion forces decided it was time for an update of the Hyde language to take into account the fact that a significant portion of Medicaid recipients were being moved into MANAGED CARE plans. Worried that plans could offer abortion services without technically running afoul of the funding ban, Hyde wrote language to add that no federal funds could be used to pay premiums for plans that provided abortions. Abortion rights forces, however, complained that Hyde's language was so broad that it could end up forcing managed care plans to drop abortion coverage for their non-Medicaid enrollees. Hyde and Rep. Nita M. Lowey, D-N.Y., negotiated the issue for weeks, finally coming up with a compromise. The new language also refined the "life of the woman" exception, noting that abortions would be allowed to be funded only if the endangerment was "a physical disorder, physical injury, or physical illness, including a life-endangering physical condition caused by or arising from the pregnancy itself." The compromise was included in the fiscal 1999 Labor-HHS bill as well.

Also in 1997, abortion foes again sought to codify the Hyde language during consideration of that year's Balanced Budget Act (PL 105–33), which did become law. That measure wrote into permanent law for the STATE CHILDREN'S HEALTH INSURANCE PROGRAM (SCHIP) Hyde-type language barring federal funding of abortion except in cases of rape or incest or to save the life of the woman. Dropped from the bill, however, was language to rewrite the definition of "medically necessary" to specifically exclude abortion, which would have amounted to a permanent codification of the Hyde amendment for all of Medicaid.

I

ICD-9 codes

The ninth revision of the *International Classification of Diseases,* clinical modification—referred to as ICD-9-CM—is a standardized list of codes to identify specific medical diagnoses. Although the AMERICAN MEDICAL ASSOCIATION (AMA) had developed current procedural terminology codes (known as CPT codes) to standardize the reporting of medical procedures, ICD-9 codes help identify what ailments those procedures are treating. Such information is invaluable in determining which treatments work best for which conditions, a field of medicine known as outcomes research.

The current system is maintained by a joint effort of two agencies of the HEALTH AND HUMAN SERVICES DEPARTMENT (HHS): the National Center for Health Statistics and the CENTERS FOR MEDICARE AND MEDICAID SERVICES. The agencies coordinate annual code revisions, which are published each year in the *Federal Register.* The Central Office on ICD-9-CM, which maintains the system, is itself a public-private partnership that also includes the private sector American Hospital Association and American Health Information Management Association.

Although most other developed nations have long since adopted ICD-10 codes (the next revision, ICD-11, is expected in 2011), the United States has been unable to reach a consensus between health care payers, who want to adopt the ICD-10 scheme with its 200,000-plus codes, and the nation's physicians, who want to stick with what they see as a far more manageable 4,000 codes included in ICD-9-CM.

IME

See INDIRECT MEDICAL EDUCATION PAYMENTS.

Incidence

Often confused with prevalence, which is the total number of people with a disease, incidence is the frequency of new cases of a particular disease.

Income-related premium

The income-related premium is the requirement that wealthier MEDICARE beneficiaries pay more for their coverage. After many years of debate, the scheme was finally adopted as part of the MEDICARE MODERNIZATION ACT in 2003 and first took effect in calendar year 2007. As of 2008 it applied only to the program's Part B, which helps pay physician and other outpatient costs.

Under the original Medicare law, premiums for the Part B program were to cover half the program's costs. In the 1997 Balanced Budget Act (PL 105–33), Congress permanently fixed the premium at 25 percent of the program's cost (after having set it at that level periodically since 1982). That means that 75 percent of Part B costs are subsidized directly from federal general revenues (as opposed to Part A of the program, funded from the 1.45 percent payroll tax paid by both employers and workers). Starting in the late 1980s, a significant minority of lawmakers and other interest groups pressed to lower or eliminate the subsidy for those who could afford it.

Medicare's first experience with an income-related premium came with the passage of the 1988 MEDICARE CATASTROPHIC COVERAGE ACT (PL 100–360). That measure required those beneficiaries with income tax liabilities greater than $150 to pay a supplemental premium (starting at $22.50) along with their income taxes. Although even the top premium ($800) was smaller than

the existing Part B subsidy at the time (which was just over $1,000), beneficiaries rebelled at the new costs for new coverage they said they did not want. Congress repealed the entire program in 1989.

President George H. W. Bush, in his fiscal 1992 budget, proposed to reverse the subsidy for Medicare Part B for individuals with incomes over $125,000 and couples with incomes over $150,000, affecting about 600,000 of Medicare's thirty-four million beneficiaries. For those above the income threshold, their Part B premiums would be three times higher, requiring them to pay 75 percent of their Part B costs, with the government subsidizing only 25 percent. Critics charged that the proposal would undermine Medicare's popularity as a universal program and suggested that such a radical change should be made only if the program was otherwise substantially restructured (presumably to provide more benefits). The proposal was not accepted by Congress, still wary after the catastrophic care legislation debacle two years earlier.

President Bill Clinton next floated the concept. As part of his HEALTH SECURITY ACT, Medicare premiums would have tripled for individuals with incomes over $100,000 and for couples with incomes over $125,000. But in exchange, Medicare beneficiaries would have gotten a much-desired outpatient prescription drug benefit. That proposal died along with the rest of health reform.

Income-related Medicare premiums next surfaced as part of the new Republican Congress's 1995 Balanced Budget Act. That measure, which President Clinton vetoed, would have begun charging beneficiaries higher premiums at income levels of $60,000 for individuals and $90,000 for couples. Unlike previous proposals, which would have cut the Part B subsidy to 25 percent for the wealthiest beneficiaries, the GOP plan would have phased out the subsidy completely for individuals with incomes of $110,000 and couples with incomes of $150,000 or more.

In 1997 the issue arose yet again during consideration of the 1997 Balanced Budget Act (PL 105–33), which did become law. The Senate passed an amendment that would have begun charging higher premiums to individuals with incomes over $50,000 and couples with incomes above $75,000. As with the failed GOP proposal from 1995, those with incomes above $100,000 and couples with incomes above $125,000 would have had to pay the full actuarial cost of Part B, eliminating the federal subsidy altogether. Although President Clinton was careful not to oppose the concept of the income-related premium (because he had himself proposed such an increase only three years earlier), the administration did complain that the structure of the Senate plan would have been administratively unworkable, because the Internal Revenue Service and the HEALTH CARE FINANCING ADMINISTRATION (HCFA) would essentially have had to track each Medicare beneficiary's monthly income to determine the appropriate premium. The administration and advocacy groups for elderly individuals also complained that phasing out the subsidy entirely for those with the highest incomes (as opposed to merely replacing the current 75 percent subsidy with a 25 percent subsidy) could lead more affluent beneficiaries to drop out of Medicare altogether, potentially leaving the program with a sicker risk pool and driving premiums up for everyone left. The provision was ultimately dropped.

The 2003 Medicare law, best known for adding a controversial prescription drug benefit run by private insurance companies, included an income-related premium that became law. The premium affected individuals with incomes over $80,000 and couples with incomes over $160,000, with those thresholds indexed to inflation. The premium phased down the government subsidy for Part B from 75 percent for those under the threshold all the way to 20 percent for those at the highest levels, initially $200,000 for individuals and $400,000 for couples. For 2008, the program's second year, for example, while the basic monthly Part B premium was set at $96.40, an individual with income over $82,000 but not more than $102,000 would pay an addition $25.80 monthly, for a total of $122.20. An individual with an income over $205,000 would pay an additional $142.90 monthly, for a total Part B premium of $238.40. (See also MEANS TESTING [MEDICARE].)

Indian Health Service (IHS)

Established in 1924 and transferred from the Interior Department to the HEALTH AND HUMAN SERVICES

An Indian Health Service nurse treats a Navajo for trachoma, a bacterial infection of the eye that can cause blindness if left untreated. *Source: Indian Health Service/U.S. Department of Health and Human Services*

DEPARTMENT (HHS) in 1955, the Indian Health Service (IHS) provides care to an estimated 1.9 million of the nation's 3.3 million American Indians and Alaska Natives who are members of 561 federally recognized tribes in thirty-five states. The Indian Health Service has approximately 15,800 employees, including 900 physicians, 2,700 nurses, 500 pharmacists, 400 engineers, 300 dentists, and 150 sanitarians. Each year, the IHS provides care for 59,000 hospitalized patients, 9.8 million outpatient visits, and 3.3 million dental visits in forty-eight hospitals, 283 health centers, and 320 health stations and Alaska village clinics. It also offers services purchased from outside the IHS health care system.

The Indian Health Service was established in the Snyder Act of 1921, which authorized funds "for the relief of distress and conservation of health [and] for the employment of . . . physicians . . . for Indian tribes throughout the United States." The Indian Self-Determination and Education Assistance Act (PL 93–638) provided tribes the option of operating their own health care systems or retaining the services of the IHS. The IHS also helps fund sanitation improvements, such as water and sewerage facilities, solid waste disposal systems, and technical assistance for operations and maintenance. Based in Rockville, Maryland, the IHS operated with a budget of $3.3 billion in fiscal 2008.

Indirect medical education payments

The indirect medical education (IME) payment is an additional payment made by MEDICARE to teaching hospitals to compensate them for the costs incurred in caring for Medicare beneficiaries. Indirect costs include the extra demands placed on the hospital staff as a result of teaching activities or additional tests or procedures ordered or performed by physicians-in-training. Teaching hospitals also tend to attract sicker than average patients and maintain higher staff-to-patient ratios, thus increasing their costs. In 2006 Medicare made an estimated $5.9 billion in IME payments to teaching hos-

pitals. Medicare makes separate payments for direct medical education costs, such as the actual salaries paid to training physicians. (See DIRECT MEDICAL EDUCATION PAYMENTS.)

Individual mandate

An individual mandate is the requirement that individuals have health insurance. Although the concept gained political momentum in the early 2000s, the first proposals for an individual mandate date back to the early 1990s. Sen. John H. Chafee, R-R.I., and Rep. Bill Thomas, R-Calif., introduced companion bills in the House and Senate in 1993 with an individual mandate as an alternative to President Bill Clinton's HEALTH SECURITY ACT, which featured an "employer mandate." That was a requirement that employers offer their workers health insurance.

Massachusetts became the first state to enact an individual mandate as part of a sweeping health reform law enacted in 2006. The law was based on the concept of "shared responsibility." The idea was the government would provide subsidies, employers would provide coverage or other payments, and individuals would have a responsibility to purchase coverage unless it was deemed unaffordable. The law also created a "connector" to help match people and businesses in need of insurance with affordable policies. (See MASSACHUSETTS HEALTH PLAN.)

Infertility clinic regulation

Responding to complaints and scandals involving clinics set up to help infertile couples become pregnant, Congress in 1992 enacted legislation (PL 102–624) requiring stricter infertility clinic regulation, including annual publication of individual clinic success rates.

According to the CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC), 12 percent of women of childbearing age have received an infertility treatment in an effort to get pregnant. In 2002, of the sixty-two million women of childbearing age, about 1.2 million women, or about 2 percent, had an infertility-related medical appointment during that year. Yet infertility treatments are both expensive—costing tens of thousands of dollars per cycle—and often not covered by health insurance. Experts in the field charged that to maximize clientele, infertility clinics specializing in fertilization procedures often exaggerated pregnancy success rates, giving couples false hopes.

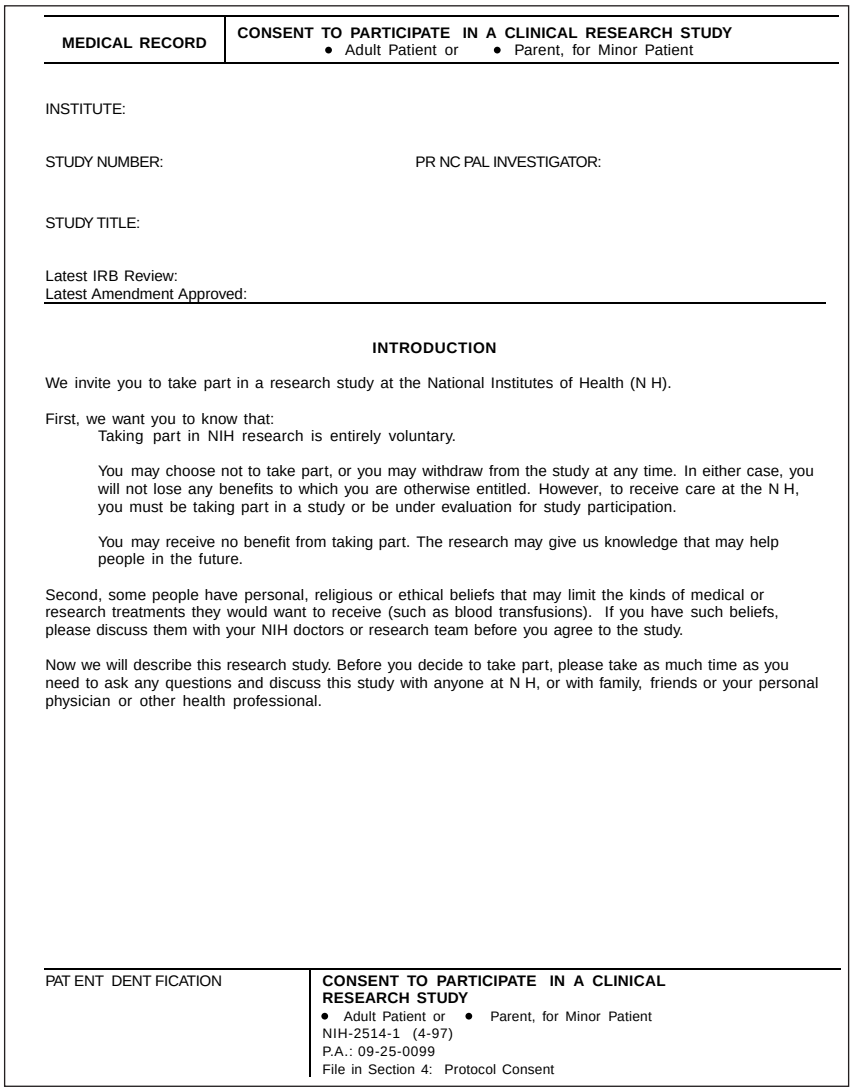
The legislation required that clinics report their pregnancy success rates to the HEALTH AND HUMAN SERVICES DEPARTMENT (HHS) and that the department issue each year a consumer guide noting the rates, which clinics failed to report their success rates, and the names of the embryo laboratories each clinic used. The law also ordered the establishment of a procedure for inspecting and certifying embryo laboratories.

In the first report, the Centers for Disease Control and Prevention found that, in 1995, 11,315 live births resulted from 60,000 cycles of assisted reproductive technology. By 2004, 127,977 cycles of assisted reproduction resulted in 36,760 live births.

Critics, however, have questioned whether the 1992 law had unintended consequences. To ensure success rates, fertility experts have charged, some clinics have impregnated women with high numbers of embryos, resulting in multiple births that endanger both the women and the babies.

Informed consent

Informed consent is the process by which patients are educated to make sure they understand the nature of a treatment or research protocol and its potential risks and benefits. The process arose from the Nuremberg Code, which was developed in response to biomedical research performed by the Nazis. Informed consent ensures that patients (or research participants) understand exactly what is to be done to them, what the potential risks are, what alternatives are available, and what the potential benefit is to that individual or, if research, to society at large.



MEDICAL RECORD	CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY • Adult Patient or • Parent, for Minor Patient

INSTITUTE:

STUDY NUMBER: PR NC PAL INVESTIGATOR:

STUDY TITLE:

Latest IRB Review:
Latest Amendment Approved:

INTRODUCTION

We invite you to take part in a research study at the National Institutes of Health (N H).

First, we want you to know that:

Taking part in NIH research is entirely voluntary.

You may choose not to take part, or you may withdraw from the study at any time. In either case, you will not lose any benefits to which you are otherwise entitled. However, to receive care at the N H, you must be taking part in a study or be under evaluation for study participation.

You may receive no benefit from taking part. The research may give us knowledge that may help people in the future.

Second, some people have personal, religious or ethical beliefs that may limit the kinds of medical or research treatments they would want to receive (such as blood transfusions). If you have such beliefs, please discuss them with your NIH doctors or research team before you agree to the study.

Now we will describe this research study. Before you decide to take part, please take as much time as you need to ask any questions and discuss this study with anyone at N H, or with family, friends or your personal physician or other health professional.

PAT ENT DENT FICATION	CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY • Adult Patient or • Parent, for Minor Patient NIH-2514-1 (4-97) P.A.: 09-25-0099 File in Section 4: Protocol Consent

Participants in National Institutes of Health research projects must sign an informed consent document after they receive all the information about the study. They indicate that they are participating voluntarily and that they understand that they might not obtain any benefit from participating. *Source: National Institutes of Health*

Institute of Medicine

The Institute of Medicine—or IoM, as it is called by health policy makers—is an arm of the National Academy of Sciences, which was chartered by Congress in 1863 to advise the federal government on scientific issues. The National Academy of Sciences in turn chartered the IoM in 1970 "to enlist distinguished members of the appropriate professions in the examination of policy matters pertaining to the health of the public." Congress frequently asks the IoM to study and report on contentious issues in science and health policy. Re-

cent issues addressed by the IoM include a landmark study of MEDICAL ERRORS, one on organ transplant policy, and a multipart examination of the consequences of being without health insurance. (See ORGAN DONATIONS AND TRANSPLANTS.) Members of the IoM are elected based on their professional achievements. Under the institute's charter, to maintain a multidisciplinary focus, one-fourth of the members must be from professions other than those directly related to medicine or health.

Institutional Review Boards (IRBs)

Institutional Review Boards, or IRBs, oversee federally funded research involving the use of humans to ensure that it is carried out ethically and that human research participants are adequately protected. Any university, hospital, or institution that conducts biomedical or behavioral research with federal funding is required to have an IRB. IRBs generally review all research using humans conducted by that institution, whether or not it is federally funded. In addition, independent IRBs exist to review industry-sponsored research for products regulated by the FOOD AND DRUG ADMINISTRATION (FDA). IRBs ensure that human research participants have provided INFORMED CONSENT (an adequate explanation of the risks and benefits of the research and what their participation will entail), that the proposed research protocol has minimized risks, and that unavoidable risks are "reasonable in relation to anticipated benefits."

IRBs must consist of at least five members. At least one member must be a scientist; at least one member cannot be a scientist. In addition, at least one member must be independent. He or she may not be affiliated with the institution or the immediate family member of someone affiliated with the institution.

IRBs review proposed research in advance and can approve it, disapprove it, or require modifications. The boards are also charged with oversight of human research and can step in to stop ongoing studies if they feel it necessary. In recent years, several outside groups have worried that IRBs are getting overloaded with oversight of federal confidentiality and conflict-of-interest rules, as well as ethical considerations. In 2002 the INSTITUTE OF MEDICINE recommended that Congress pass new legislation requiring that IRBs "return to the focused role they were originally intended to serve—reviewing the ethical issues of proposed protocols—because the boards do not necessarily have the expertise, authority, or resources to carry out all of these additional tasks on their own."

Instrumental activities of daily living

See ACTIVITIES OF DAILY LIVING (ADLs).

Intermediary (Medicare)

A Medicare intermediary is a private company (usually an insurance company) that processes claims for Part A services under contract to the CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS). Part A covers inpatient hospital care, care in a skilled nursing facility, and HOSPICE care. Intermediaries also handle hospital outpatient claims that are technically covered by Medicare Part B, assist providers and beneficiaries, determine coverage, make payments according to guidance from CMS, conduct reviews and audits, and help police the program for fraud. Medicare Part B claims are handled by entities called carriers. (See BENEFICIARY and CARRIER [MEDICARE].)

IRBs

See INSTITUTIONAL REVIEW BOARDS (IRBs).

J

JCAHO

See JOINT COMMISSION ON ACCREDITATION OF HEALTHCARE ORGANIZATIONS (JCAHO).

Joint Commission on Accreditation of Healthcare Organizations (JCAHO)

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO, pronounced "jay-co") is a private nonprofit organization that formerly inspected and accredited hospitals. Today it has repositioned itself as an evaluative body for integrated delivery networks, nursing homes, and organizations that provide HOME HEALTH CARE, behavioral health care, laboratory services, and ambulatory care services, in addition to hospitals. In 2002 the organization refocused its accreditation process to focus on systems that most directly affect the quality and safety of patient care. Founded in 1951, JCAHO calls itself the nation's oldest and largest standards-setting and accrediting body in health care, having evaluated more than fifteen thousand health care organizations and programs.

Judicial bypass

The process by which a minor can get permission for an ABORTION from a judge instead of seeking the involvement of her parents is called a judicial bypass. The U.S. Supreme Court in the 1979 decision *Bellotti v. Baird* ruled that teenagers must be able to seek judicial permission instead of involving their parents if they so desire. As part of the proceeding, the minor must either demonstrate to the judge that she is mature enough to make the decision on her own or else the judge must find that the abortion would be in the girl's best interest. If the minor is sufficiently mature to make the decision, according to the Court, the judge must allow the abortion even if the judge does not find the abortion to be in her best interest.

K

Kennedy-Kassebaum law

Kennedy-Kassebaum is the colloquial name for the HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA) of 1996, identified by its principal Senate sponsors, Nancy Landon Kassebaum, R-Kan., chair of the Senate Labor and Human Resources Committee, and Edward M. Kennedy, D-Mass., the committee's ranking Democrat. Technically, the measure should be known as Kassebaum-Kennedy, because Kassebaum was the chair of the committee and the Republicans controlled the Senate at the time the bill was passed. However, the measure enjoyed its strongest support from Democrats, who preferred to use Kennedy's name first. The law, one of the most sweeping health reform measures of the 1990s, made it easier for people to obtain health insurance when they changed jobs, cracked down on HEALTH CARE FRAUD AND ABUSE, and created the first-ever protections for the privacy of personal medical information.

Kerr-Mills bill

A predecessor of the MEDICAID program for the poor, the Kerr-Mills bill (named for its sponsors, Sen. Robert S. Kerr, D-Okla., and HOUSE WAYS AND MEANS COMMITTEE chair Wilbur D. Mills, D-Ark.) was passed in 1960. It created a program called Medical Assistance for the Aged, which provided federal matching funds for states that covered care for "medically needy" aged individuals, those with incomes above the levels required for cash aid but who still required help to pay their medical bills. By 1965, the year Medicaid was established, forty states had established Kerr-Mills programs, and spending on it and a smaller program to pay the medical bills of cash welfare recipients totaled $1.3 billion.

L

Labor–Health and Human Services–Education Appropriation (Labor-HHS)

Typically the largest of the twelve regular spending bills that fund discretionary (as opposed to mandatory) portions of the federal government, the appropriation for the Departments of Labor, Health and Human Services, Education, and related agencies (Labor-HHS) is responsible for funding nearly all of the major federal health agencies. (A major exception is the FOOD AND DRUG ADMINISTRATION [FDA], which, although part of the HEALTH AND HUMAN SERVICES DEPARTMENT [HHS], is traditionally funded through the Agriculture spending bill.) In reality, however, appropriators have almost no say over how more than 70 percent of the total is spent.

The bulk of the bill's funding goes for mandatory programs, such as MEDICARE Part B (Part A is funded via a dedicated portion of the Social Security payroll tax), MEDICAID, and unemployment insurance. Those programs' spending levels can be altered only by making changes to the underlying law that governs them, a task reserved to authorizing committees. In fiscal 2007 the Labor-HHS bill appropriated just under $546 billion, $144.6 billion of which was for discretionary programs for which appropriators determined funding levels and $401.2 billion of which was for mandatory programs.

The Labor-HHS bill has traditionally also been one of the most difficult spending bills to get through Congress each year, and not just because of its enormous size. In the era of tight budgets and spending limits, any increases in popular social programs must be offset by cuts in other, often equally popular programs. Over the years, lawmakers have sparred repeatedly over whether to rob education funds to increase funds for health care or vice versa. "Robbing Peter to pay Paul" is a phrase heard more than once during consideration of the bill nearly every year.

But the measure has also traditionally been hamstrung by fights over some of the most sensitive social issues, particularly ABORTION. Since 1977 the measure has carried what has come to be known as the HYDE AMENDMENT, language prohibiting the use of federal funds to pay for abortion except in limited cases. The Labor-HHS bill has also been the venue for fights over parental involvement in family planning programs, EMBRYO RESEARCH, FETAL TISSUE RESEARCH, and school busing and vouchers. (See PARENTAL INVOLVEMENT LAWS.)

Late-term abortion

Late-term abortion is a widely misused term in the debate over the procedure ABORTION opponents call PARTIAL-BIRTH ABORTION and abortion rights supporters call intact dilation and extraction. The phrase is generally understood to refer to abortions performed after fetal viability—when the fetus can live outside the mother's womb. Others use *late term* to refer to the final trimester of pregnancy, the start of which may or may not be after viability. It is during the final trimester that the U.S. Supreme Court, in *ROE V. WADE,* said states could limit or even ban abortions other than those needed to protect the life or health of the woman. Still others, however, use the term loosely to refer to any abortion after roughly sixteen weeks, the time after which the simplest abortion techniques can no longer be used. Using that definition, it is correct to refer to partial-birth abortion

as a late-term procedure. The vast majority of those abortions, however, both sides concede, occur before twenty-six weeks gestation, too early to be considered "late term" by most definitions.

Lifetime limits

Overall caps imposed by insurers on the amount of medical expenses they will cover are called lifetime limits. An estimated 60 percent of employer-sponsored plans have lifetime caps, typically $1 million to $2 million. Federally qualified health maintenance organizations, however, are not permitted to impose lifetime caps on basic benefits, although they may impose caps on supplemental services such as prescription drugs, dental, vision, hearing, HOME HEALTH CARE services, and durable medical equipment. (See HEALTH MAINTENANCE ORGANIZATION [HMO].) Plans under the FEDERAL EMPLOYEE HEALTH BENEFITS PLAN (FEHBP) are similarly barred from imposing lifetime spending limits. In 1995 an estimated fifteen hundred individuals with catastrophic medical expenses exceeded their lifetime limits, often resulting in their "spending down" to poverty, by using up their savings and liquidating their assets, and thus qualifying for MEDICAID or relying on charity care provided by public hospitals and other facilities.

As health care costs continue to rise with no increase in the limits, it has been estimated that an increasing number of patients will exceed their policy's caps. Starting in 1995 a group of senators, led by James M. Jeffords, I-Vt., the former SENATE HEALTH, EDUCATION, LABOR, AND PENSIONS (HELP) COMMITTEE chair, pushed for legislation to require that lifetime limits be set no lower than $10 million. A cost estimate from the consulting firm Price Waterhouse LLP found such an increased limit would raise premiums on employer-sponsored plans by an average of 1.4 percent. However, insurance companies complained that the increases could be much larger. During debate on the HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA) in April 1996, the Senate voted down the minimum cap on lifetime limits by 42-56. The issue languished in Congress after Jeffords retired in 2007.

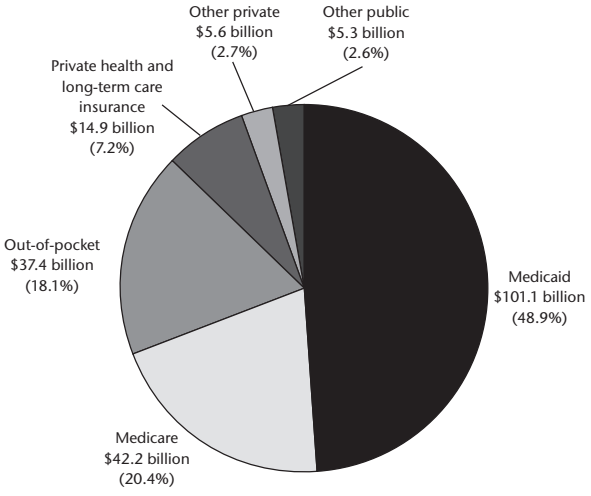
Living wills

A legal document putting an individual's desires for future medical care into writing is called a living will. A living will, which does not take effect until a patient is determined to be terminally ill, may, for example, express the individual's desire not to have his or her life sustained artificially, such as on a mechanical ventilator or feeding tube. Conversely, the individual may express a desire for heroic measures to be taken to keep him or her alive. A living will does not designate a person to make medical decisions for one who cannot. That can be done by other forms of ADVANCE DIRECTIVES, such as a DURABLE POWER OF ATTORNEY FOR HEALTH CARE or a medical power of attorney. The PATIENT SELF-DETERMINATION ACT OF 1990, part of that year's budget reconciliation bill (PL 101–508), required that all hospitals participating in MEDICARE or MEDICAID advise all patients of their right to exercise advance directives, in an effort to encourage their use. (See BUDGET RECONCILIATION LEGISLATION AND HEALTH CARE.)

Long-term care

One of many imprecise terms in health care policy, *long-term care* means different things to different people and can mean different things to the same person, depending on the context in which it is used. Generally, long-term care is the opposite of acute care, or care for an immediate condition. People who need long-term care are generally unable to care fully for themselves (often defined as limited in performing ACTIVITIES OF DAILY LIVING [ADLs]) and need assistance for a relatively long period of time. Long-term care generally takes place outside of a community hospital, in locations ranging from a patient's own home to an assisted living facility, to a nursing home, to a rehabilitation hospital. Long-term care may also consist of different types of services. Long-term care services that are considered primarily medical may include physical or occupational rehabilitation, or nursing care such as changing dressings, giving medications, or monitoring intravenous solutions. Long-term care services can also be primarily custodial,

National Spending for Long-Term Care, by Payer (2005)



Total: $206.6 billion

Source: Harriet L. Komisar and Lee Shirey Thompson, *National Spending for Long-Term Care,* Fact Sheet. Washington, DC: Georgetown University Health Policy Long-Term Care Financing Project, February 2007. http://ltc.georgetown.edu/pdfs/natspendfe07.pdf. Used with permission.

Note: Components may not sum to totals because of rounding.

such as help in dressing, bathing, or going to the bathroom. Long-term care can also consist of providing social services, such as help with shopping or cleaning.

An estimated ten million people over age eighteen received long-term care services in 2005, at a total cost of nearly $207 billion. And as the baby boom generation begins to age, the need for long-term care will only increase, because elderly individuals are more likely to need long-term care services. The population over age sixty-five is expected to double by the year 2030, to nearly seventy million. At the same time, the "old-old" population, those over age eighty-five—of whom more than one in four needs long-term care services—is projected to rise by 143 percent.

As an acute care program, MEDICARE provides relatively meager long-term care benefits. It pays for stays in nursing homes designated as "skilled nursing facilities" (requiring significant copayments and deductibles), as well as home health care services for those with documented medical needs, although payments are not unlimited. MEDICAID does provide coverage for long-term custodial stays in a nursing home, but only after a patient has "spent down" virtually all of his or her income and assets. Together, however, Medicare and Medicaid do pay most of the nation's annual nursing home bill. In 2005 the programs funded 62 percent of that year's $129.8 billion nursing home bill; Medicaid accounted for 49.4 percent and Medicare for 16.6 percent. Individuals paid 24.9 percent of nursing home costs out-of-pocket; private insurance accounted for only 7 percent. Congress sought to make private long-term care insurance more attractive by allowing it, as part of the 1997 Balanced Budget Act (PL 105–33), to be treated the same as other health insurance for tax purposes.

But most long-term care is not delivered in nursing homes. Only about 20 percent of the population requiring long-term care live in a nursing home or other institution; the remaining 80 percent live in the community. In fact, much of the nation's long-term care is not even delivered for money. An estimated thirty-seven million Americans, mostly adult children or spouses, provide long-term care services on an unpaid basis. These caregivers provide all the care for an estimated 60 percent of the elderly long-term care population and for nearly three-fourths of the long-term care population between eighteen and sixty-four.

Long-term care as a political issue has waxed and waned over the past two decades. In the late 1980s and early 1990s, many policy makers suddenly began to look with alarm at the lack of a national policy to help finance the cost of long-term care, particularly given the impending cost explosion that the baby boomers will bring about. A proposal for a new public program to help all Americans with long-term care costs was approved by the bipartisan PEPPER COMMISSION in 1990. But with an estimated cost of $80 billion to fully fund the need for long-term care services, most programs were slow to gather political steam, and other social issues, particularly the plight of the uninsured and the impending financial problems faced by Social Security and Medicare, pushed long-term care as an issue lower on the health care agenda. In the early part of the twenty-first century, many policy makers focused on trying to expand the use and availability of private long-term care insurance, in an effort to get some of the baby boomers to help finance their own long-term care needs in the future.

Loss ratios

A loss ratio is the percentage of premiums paid out by an insurance company for actual medical care. A plan with a high loss ratio pays out most of the money it takes in for care; one with a low loss ratio may spend more money on advertising, administration, and overhead or may keep a larger share of premiums for profits. Legislation passed by Congress in 1990 to regulate private supplemental policies for MEDICARE (known as MEDIGAP INSURANCE) requires plans to maintain loss ratios of at least 65 percent for individual policies and 75 percent for group plans.

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Managed behavioral health care

In an effort to save money and improve care, many insurers, MANAGED CARE and otherwise, have turned to private managed behavioral health care firms to manage the distribution of mental health and substance abuse services to patients. These firms are often referred to as CARVE-OUT ORGANIZATIONS because a specialty company "carves out" a single area of care. In 2007 managed behavioral health care organizations covered more than 170 million Americans.

Managed care

At its most basic level, managed care is any system that integrates the financing and delivery of health care services. But beyond that, definitions diverge.

Managed care includes a broad spectrum of models, from the staff-model HEALTH MAINTENANCE ORGANIZATION (HMO), in which the managed care organization owns all facilities and directly employs all personnel, to the PREFERRED PROVIDER ORGANIZATION (PPO), in which the managed care organization contracts with hospitals and doctors to serve patients for a discounted fee.

Although managed care has been around in some form since the early 1900s, until the 1990s its growth was severely limited by its lack of popularity among both patients and doctors. Many of the early managed care organizations were created by companies to serve patients in areas with severe shortages of medical personnel or by consumers who were attracted by the idea of prepaid medical care. But managed care was slow to take hold. Many patients resisted managed care because (at least in its traditional form) it severely limited their choices of physicians and hospitals. Organized medicine (led by the AMERICAN MEDICAL ASSOCIATION [AMA]) also long opposed the concept of anyone other than physicians making treatment decisions for patients.

A combination of factors, including federal financial incentives in the 1970s and the desire of employers in the 1980s to control their health care costs, pushed managed care from the health system's backbenches to the front row. New and innovative forms of managed care that allowed patients and providers much freer choice helped break down consumer and provider resistance. As a result, managed care enrollment exploded. Between 1986 and 1995 the number of Americans in HMOs more than doubled—from 25.7 million people to 58.2 million. In 2007, 91 percent of people with employer-provided health insurance were covered by managed care plans, according to the annual survey by the Kaiser Family Foundation and Health Research and Educational Trust. Managed care is such a confusing concept, however, that many people do not even know they are in it. A 1998 survey by the Employee Benefit Research Institute found that only 21 percent of those in managed care understood that they were and 56 percent of those enrolled in managed care plans vowed they had never been covered by managed care. Part of the confusion is due to the shift from more restrictive to less restrictive types of plans. In 2007 nearly twice as many workers were in less-restrictive PPOs than in other types of managed care.

But as more people joined managed care—many of them involuntarily, as employers changed the type of coverage they offered—and as more managed care organizations crowded into the marketplace, a backlash developed. Television, radio, magazines, and newspa-

pers were full of managed care horror stories about care delayed or denied, and state legislatures were quick to pass laws aimed at stopping such purported abuses as requiring new mothers and infants to leave the hospital only twenty-four hours following delivery (see DRIVE-THROUGH DELIVERIES). A survey conducted in the fall of 1996 for some of the nation's largest managed care companies found that media coverage of the industry in major national outlets was overwhelmingly negative, with five unfavorable stories for every one favorable report. Even Hollywood got into the act, with movies such as *As Good as It Gets* (1997) and *John Q* (2002), which based plot lines around managed care denials.

Types of Managed Care

In many ways managed care is like a living organism that is continually growing and changing. Labels that mean one thing one time are meaningless months later. Still, some terms are simply used incorrectly. One of the most frequent mistakes is using "managed care" and "HMO" interchangeably. That is like using "fruit" and "apple" interchangeably. An HMO (health maintenance organization) is one of many types of managed care, just as an apple is one of many types of fruit. And just as there are different types of apples, there are different types of HMOs. The easiest way to differentiate between the various types of managed care is to look at them on a continuum, from most to least tightly organized.

HMOS. The HMO is the type of managed care that most closely ties together the financing and delivery of health care services. HMOs may be independent organizations, they may be owned and operated by an insurance company, or (rarely) they may be owned and operated by groups of physicians and hospitals. HMOs typically offer patients the least choice of health care provider. If patients choose to seek care from a doctor or hospital that is not part of the HMO, generally they must pay all of the costs themselves. The hallmark of HMOs is that they offer a comprehensive package of services on a prepaid basis. In other words, the employer or individual pays the HMO a monthly fee, in exchange for which the HMO provides all the care needed by that person or family—with the caveat that the HMO determines what care is "necessary." This type of financing provides the opposite of the incentive offered under the traditional FEE-FOR-SERVICE system, in which the more a doctor (or other health care provider) does, the more he or she is paid. Instead, the HMO has an incentive to provide the least amount of care, because it keeps the difference between the prepaid fee and the cost of care provided. Supporters of managed care note that HMOs have a strong incentive to use preventive care and other ways to keep patients from getting sick (such as offering free nutrition or smoking cessation classes or subsidizing health club memberships), because healthy patients improve the organization's bottom line. Competition with other HMOs, say supporters, keeps HMOs from providing less than the appropriate amount of care.

HMOs also use a variety of formal mechanisms to ensure appropriate use of health care services, both prospectively (such as by limiting the brands of prescription drugs that may be dispensed) and retrospectively (such as by reviewing how often a physician refers a patient to a specialist or admits patients to the hospital.) This is the "management" part of managed care. Rules for patients also are designed to limit care only to that deemed most appropriate according to standards of EVIDENCE-BASED MEDICINE. To obtain care, patients in most HMOs must work through a GATEKEEPER doctor, generally a PRIMARY CARE PHYSICIAN (PCP) such as an internist or pediatrician. That physician decides when and if the patient should see a specialist, enter the hospital, or receive other types of care.

There are four main types of HMOs, categorized by how closely the HMO is tied to those who provide health care services and by who is "at risk" for the costs of patient care. The oldest type is the staff-model HMO, in which physicians are employed directly by the HMO and provide care only to HMO patients. In staff-model HMOs, the HMO itself bears the risk for the cost of care. Staff-model HMOs offer patients the least choice of provider and the HMO the most control over costs and care. They are often referred to as closed-panel systems.

In the group-model HMO, physicians who practice as a group contract with the HMO to provide care. Kaiser-Permanente is the best-known group-model HMO, with its physicians employed by the Permanente

Medical Group. From the patient's point of view the group model is virtually indistinguishable from the staff-model HMO. Physicians care exclusively for HMO patients in a closed panel, with little or no option for patients to seek reimbursed care outside the system. The main difference between the models is in who takes the financial risk for the cost of care. In group-model HMOs, the physician group is at risk for most of the cost of care. It is paid a set fee for each patient (known as CAPITATION), meant to cover costs of all specialty and PRIMARY CARE by physicians. In some cases, the physician group is also at risk for some or all of the cost of hospital care, on the theory that physicians control hospital utilization.

IPAS. In the independent practice association (IPA)–model HMO, the HMO contracts with a group of physicians who practice alone or in small groups and who have banded together into an IPA. Physicians in IPA-model HMOs can assume risk with the HMO by receiving capitation payments or may be paid a "discounted" rate for every patient visit, with bonuses at the end of the year if certain budget targets are met. Physicians in IPA-model HMOs may have contracts with several different organizations as well as serve so-called private pay patients.

Some HMOs mix and match these arrangements, contracting with different groups and even employing some physicians. These are known as network-model HMOs.

POS PLANS. Also known as an open-ended HMO, the POINT OF SERVICE (POS) PLAN gets its name because it allows the patient to choose where to receive service at the time services are desired. Patients are given incentives, in the form of lower deductibles or copayments, to seek care within the HMO network, working through a gatekeeper physician for access to other services. But unlike patients in a traditional HMO, those in POS plans can also seek reimbursed care outside the network, although they will have to pay higher out-of-pocket fees. (See DEDUCTIBLE.)

POS plans have proved popular with patients, giving them simultaneously some of the cost savings associated with HMO membership and the option to seek an outside opinion for serious or rare problems. POS plans, however, have been less popular among insurers because the ability of patients to seek care on their own has made cost control and patient management considerably more challenging and premiums more difficult to calculate.

PPOS. At the least-organized end of the managed care continuum is the most prevalent form of managed care, the preferred provider organization. PPOs are networks of independent physicians (and hospitals and other providers) who contract with insurers to provide care. Physicians in PPOs usually are paid on what is known as a discounted fee-for-service basis. Under this system a physician accepts a fee lower than normal in exchange (theoretically) for a higher volume of patients. The physician, however, still has the same incentive as under traditional fee-for-service insurance—the more care he or she provides, the more he or she is paid. Physicians who operate outside certain parameters, however, can be dropped by the PPO. Patients in PPOs are usually free to seek care in or out of the network and do not need to go through a gatekeeper for access to specialty care, but, as in POS plans, patients are given financial incentives to use physicians who belong to the PPO, usually in the form of lower payments for in-network care and higher ones for care outside the network.

Managed competition

Coined by researchers Alain Enthoven and Paul Ellwood, the term *managed competition* describes a health system in which health plans compete with each other according to ground rules set by the government or other third party. The Clinton administration's failed health reform plan built on the Enthoven-Ellwood model. Although the two terms were often used interchangeably during the 1993–1994 debate, MANAGED CARE and managed competition are entirely different concepts. Under a managed competition model, a new type of entity (Enthoven and Ellwood called it a health insurance purchasing cooperative, or HIPC; President Bill

Clinton called it a health alliance) would act as a purchasing agent for insurance buyers (employers, public agencies, and individuals) and as a quality watchdog for consumers. The central idea of managed competition is that plans, whether managed care or FEE-FOR-SERVICE, would compete on level footing, with consumers more able to compare quality and benefits. As a result, plans would have to compete on service and quality instead of on price alone. (See HEALTH PLAN.)

Massachusetts health plan

On April 12, 2006, Massachusetts GOP governor Mitt Romney, surrounded by such Democratic notables as U.S. senator Edward M. Kennedy, signed into law a first-in-the-nation measure aimed at providing nearly everyone in the state with health insurance.

The measure was the subject of considerable debate and negotiation over the previous months between the Republican governor and the majority Democratic state legislature. But Massachusetts succeeded in forging a compromise when so many others states had failed for one key reason: had they not, state officials were facing the impending loss of nearly $1 billion in federal health funds.

Still, the reform was one that represented a landmark change that, until then, had only been the stuff of academic white papers. The law was based on a concept called shared responsibility, in which government, employers, and individuals all help pay the cost of health insurance.

The government was to provide subsidies to help those with lower incomes, both through MEDICAID and through a system of sliding-scale subsidies for those with incomes up to three times the federal poverty level. Those lower-income individuals not eligible for Medicaid (in Massachusetts called MassHealth) would be able to obtain coverage through a new program called Commonwealth Care.

Employers were expected to participate in a variety of ways. First, those with more than eleven full-time workers were required to either make a "fair and reasonable" contribution to their workers' health insurance or else pay a "fair share" assessment into the Commonwealth Care Trust Fund.

Massachusetts governor Mitt Romney (right) shakes hands with state Health and Human Services secretary Timothy Murphy after signing into law landmark legislation that assured access to health care for nearly all Massachusetts residents. Long-time health care advocate Sen. Edward Kennedy (D-Mass.) (center) was present at the April 12, 2006, ceremony. Source: AP Images/Elise Amendola

Under the law, a "fair and reasonable" contribution was defined as having at least a quarter of full-time workers enrolled in the firm's health plan or offering to pay at least a third of the workers' premiums. The "fair share" assessment initially was set at $295, which was estimated to cover the costs of free care provided to workers whose employers did not offer them health insurance. Employers that did not provide health insurance and whose employees used free care beyond set thresholds could be subject to a "free rider surcharge" of between 10 percent and 100 percent of the cost provided by the state to provide the "free" care.

Governor Romney used his line-item veto authority to reject the employer mandate portions of the law, but he was overridden by the state legislature.

The law also required employers with eleven or more full-time employees to set up CAFETERIA BENEFITS PLANS that allow those employees to pay their health insurance premiums on a pre-tax basis. That alone generally resulted in a savings for those employees of between a quarter and a half of their premium costs, depending on their tax brackets.

Finally, individuals who were unemployed, self-employed, or in jobs without health insurance were required to purchase their own insurance, through an "individual mandate." Only those who were deemed to have incomes too low to afford the lowest-cost plan that met standards for creditable coverage would be exempt from the individual mandate, which took effect July 1, 2007.

The individual mandate was to be enforced through the income tax system. For 2007, the penalty was small—loss of the personal exemption for the state income tax, which was $219 for an individual. Starting in 2008, however, the penalty was to become more painful—a fine of up to 50 percent of the premium of the least costly creditable health insurance plan.

To help facilitate all of that, the law created an independent, ten-member authority called the Commonwealth Connector to undertake the delicate tasks of determining what constituted an adequate insurance policy and at what income level that policy became "affordable." The connector authority also worked with insurers in the state to create a set of unsubsidized, yet affordable, health insurance options, available under the umbrella Commonwealth Choice.

By early 2008, Massachusetts officials reported that an additional 300,000 individuals had gained health insurance, cutting the state's uninsured rate in half. At the same time, the number of people seeking free care had fallen by roughly 10 percent.

Maternal and Child Health (MCH) Services Block Grant

This federal grant to the states provides funding to help improve the health status of low-income pregnant women and children. Created in 1981 in a consolidation of a series of smaller programs, Maternal and Child Health (MCH) Services Block Grant funds may be used for a variety of purposes, including reducing infant mortality, reducing the INCIDENCE of preventable diseases and handicapping conditions among low-income children, increasing the availability of health services to pregnant women, making immunizations and primary care services more available to children, and providing services to children with disabilities or other special needs. Congress appropriated $666 million for the program in fiscal year 2008. States must provide $3 for every $4 allocated by the federal government.

Maternity stays

See DRIVE-THROUGH DELIVERIES.

Means testing (Medicare)

A misnomer used in reference to MEDICARE, means testing is used to determine if a person is eligible for a program aimed at those with limited incomes. For welfare or other programs, a means test is applied to measure an individual's or family's income and assets. If the totals do not exceed a certain level, the person or family is eligible for the program. If the means are too high, the person is not eligible. MEDICAID is a means-tested pro-

gram, as is WIC (SPECIAL SUPPLEMENTAL NUTRITION PROGRAM FOR WOMEN, INFANTS, AND CHILDREN). In Medicare, however, policy makers dating back to the late 1980s discussed the possibility of charging well-off Medicare beneficiaries more for their coverage, specifically by increasing the Part B premium, because 75 percent of Part B costs are subsidized from the general federal Treasury. This is, in fact, not means testing but *income relating,* in which a person or family with a higher income remains eligible for the program but pays more than those who are less affluent. (See INCOME-RELATED PREMIUM.) The MEDICARE CATASTROPHIC COVERAGE ACT (PL 100–360), enacted in 1988, included an income-related premium, but the law was repealed a year and a half later. The 2003 MEDICARE MODERNIZATION ACT (PL 108–173) finally implemented such a scheme. It took effect in 2006.

Under the law, individuals with adjusted gross incomes over $80,000 and couples with incomes over $160,000 pay an additional monthly premium. That premium would increase gradually, until individuals with incomes over $200,000 and couples with incomes over $400,000 would pay premiums equal to 75 percent of Part B costs, thus effectively reversing the federal subsidy for Part B. The income thresholds were set to rise each year with inflation. Thus, in 2007 the income-related premium did not apply to individual unless they had adjusted gross income over $82,000 or to couples with adjusted gross income over $164,000.

Medicaid

Medicaid, which is Title XIX of the SOCIAL SECURITY ACT, is a joint federal-state program that in fiscal 2006 spent an estimated $303.9 billion to provide health care services to an estimated fifty-five million Americans with low incomes. Like MEDICARE, with which it was established in 1965 (by PL 89–97), Medicaid is an entitlement, meaning that those who meet eligibility requirements are legally entitled to benefits and can sue if those benefits are denied. But unlike Medicare, which is a single, federally run program nationwide, Medicaid, as a federal-state partnership, is really fifty-six different programs, one for each state, the District of Columbia, and each of the U.S. territories. Each state and territory, operating within federal guidelines and rules, can set its own eligibility standards and payment rates for medical care, decide what and how much care it will cover, and generally administer the program as it sees fit.

Even in areas in which Medicaid is uniform, though, the program serves three distinct populations with very different health care needs:

- Low-income pregnant women and children who formerly received cash welfare payments through the joint federal-state welfare program, Aid to Families with Dependent Children (AFDC), who currently receive cash payments from the Temporary Assistance for Needy Families (TANF) program, or who qualify through poverty categories.
- Low-income disabled Americans who receive cash welfare payments through the federal SUPPLEMENTAL SECURITY INCOME (SSI) program. (Confusingly, individuals eligible by virtue of disability for the SOCIAL SECURITY DISABILITY INSURANCE [SSDI] program are eligible, after a twenty-four-month waiting period, for Medicare, not Medicaid.)
- Low-income elderly people who require nursing home or other LONG-TERM CARE services or assistance meeting Medicare's cost-sharing requirements.

Although three-fourths of Medicaid beneficiaries are low-income pregnant women and children, they are the least expensive recipients, accounting for about 30 percent of Medicaid spending. Elderly and disabled individuals, who compose about 23 percent of Medicaid's beneficiaries, account for some two-thirds of Medicaid spending, primarily because they require long-term care services, which tend to be far more expensive than the acute and primary care required for healthier, younger individuals.

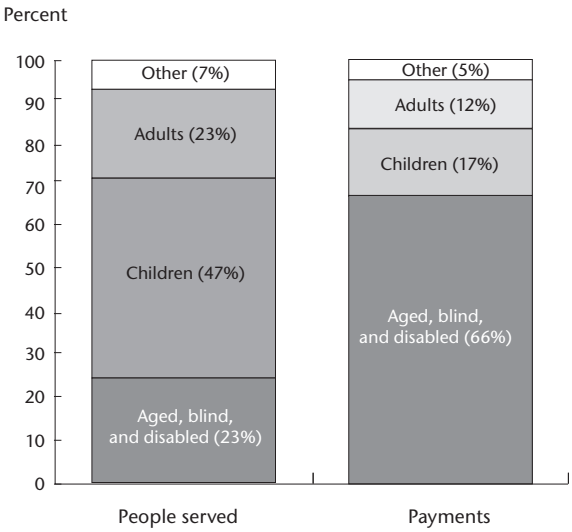
Although everyone on Medicaid has a low income, the program does not cover all poor individuals. Because of its complicated eligibility rules, Medicaid in 2006 covered only about 40 percent of the non-elderly population with incomes under the federal poverty line. And although much has been made of efforts since the 1990s to extend Medicaid coverage to those slightly

higher up the income scale, in 2006 Medicaid provided coverage to only about 23 percent of the "near-poor," those with incomes between 100 and 200 percent of the poverty level. Still, Medicaid's expansion in the 1980s and 1990s, including creation of the STATE CHILDREN'S HEALTH INSURANCE PROGRAM (SCHIP), did help stem the tide of the growing ranks of the UNINSURED.

Medicaid also accounts for a significant portion of medical care delivered in the United States. In 2006 it covered one of every five U.S. residents at some point (including one of every four children). Medicaid each year pays for more than one of every three births and for three of five nursing home residents, and it provides more than half the public funding for individuals with ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS). For more than seven million low-income individuals who are also Medicare beneficiaries, Medicaid acts as MEDIGAP INSURANCE, providing coverage Medicare does not, particularly for long-term care services. These DUAL ELIGIBLES are among the program's most expensive beneficiaries. They consume nearly 40 percent of all Medicaid spending.

Medicaid is also a major payer in the health care system as a whole: its total bill exceeded that of Medicare for the first time early in the twenty-first century (although in 2006 Medicare once again appeared larger due to the transfer of prescription drug spending for those dual eligibles). In 2006 Medicaid paid for 17 percent of all hospital bills, seven percent of physician and other professional services, and 40 percent of home health spending. Medicaid is also the largest single source of funding from the federal government to the states.

Distribution of People Served through Medicaid Payments by Basis of Eligibility, Fiscal 2004



Source: Medicaid Statistical Information System, Centers for Medicare and Medicaid Services.

Note: Fiscal 2004 is the most recent year for which there are complete state data.

Eligibility

Medicaid is not only one of the nation's largest health programs but also one of its most complex. There are some twenty-five separate eligibility categories (sometimes referred to as *pathways*) by which individuals can qualify for Medicaid coverage. A purposeful policy of delinking Medicaid eligibility from eligibility for major cash assistance programs seeks to broaden the universe of low-income Americans who can obtain health insurance. Throughout the 1980s and early 1990s, Medicaid eligibility for pregnant women, children, and elderly individuals was extended beyond those who could get Medicaid by virtue of receiving benefits through the AFDC program or the SSI program. In 1984, 80 percent of Medicaid enrollees were also receiving cash assistance; by 1992 that figure had dropped to 60 percent. The link between welfare and Medicaid was severed completely by passage of the 1996 welfare reform law (the PERSONAL RESPONSIBILITY AND WORK OPPORTUNITY RECONCILIATION ACT, PL 104–193), which ended the fifty-year-old entitlement status of cash welfare payments, eliminating AFDC and replacing it with the TANF program.

In 2007 states were required to extend Medicaid coverage to groups including the following (these individuals qualify for coverage by meeting categorical eligibility requirements):

- Pregnant women, infants, and children up to age six in families with incomes less than 133 percent of the federal poverty level;
- Children through age eighteen in families with incomes under 100 percent of the federal poverty level;

• Adults and children in families that meet the income, resource, and family composition rules that would have qualified them for the AFDC program as of July 16, 1996;

• SSI recipients (in most states);

• Children receiving adoption or foster care assistance under Title IV of the Social Security Act;

• Children and adults in families that lose cash assistance because of increased earnings from work and who may keep Medicaid coverage for a transitional period; and

• Medicare beneficiaries with incomes under 100 percent of the federal poverty level. (Medicare beneficiaries with incomes up to 135 percent of poverty are eligible, on various bases, for more limited aid through Medicaid. See DUAL ELIGIBLES for specifics.)

States had the option of providing Medicaid to members of other groups, including:

• Pregnant women and infants up to age one with incomes between 100 and 185 percent of the poverty level.

• Children under age twenty-one who meet the July 16, 1996, state welfare eligibility standards but are not otherwise required to be covered.

• Institutionalized individuals who meet certain standards set by the states, although they may have incomes no higher than 300 percent of the SSI federal benefits level.

• Individuals who would be eligible if they were in an institution but who are receiving care under waivers allowing Medicaid coverage of home- and community-based care.

• Certain working and disabled individuals with family incomes less than 250 percent of the federal poverty level who would qualify for SSI if they did not work.

• Individuals with tuberculosis who meet the financial eligibility requirements for SSI but who are not members of an SSI eligibility category. Such individuals are eligible only for services related to treatment of their tuberculosis.

• Individuals deemed MEDICALLY NEEDY.

• Families with disabled children who need special services, with incomes up to 300 percent of the poverty level, under terms of the Family Opportunity Act (part of the 2005 Deficit Reduction Act, PL 109–171).

• Other individuals, under terms of several federal waiver programs that permit states to forgo normal requirements for eligibility if they meet certain other restrictions.

Benefits

As with eligibility, states have significant flexibility in the benefits they can offer under Medicaid, with some mandatory and others optional. Required services include:

• Inpatient and outpatient hospital care;

• Prenatal care for pregnant women;

• Childhood vaccinations;

• Physician services;

• Nursing home care for those age twenty-one and over;

• Family planning services and supplies;

• Rural health clinic services;

•HOME HEALTH CARE for those eligible for skilled-nursing care;

• Laboratory and X-ray services;

• Pediatric and family NURSE PRACTITIONER (NP) services;

• Nurse-midwife services;

• Services provided by a federally qualified health center; and

• EARLY AND PERIODIC SCREENING, DIAGNOSTIC, AND TREATMENT (EPSDT; MEDICAID) services for children under age twenty-one.

States can limit the scope and duration of the required services, but only within limits. States must, for example, provide a level of benefits sufficient "to reasonably achieve the purpose of the benefits," and benefit limitations (such as a set number of hospital days or physician visits) may not discriminate among beneficiaries based on their medical conditions. States are also required to provide all "medically necessary" services for children eligible under EPSDT, even if those services are not otherwise covered by the state. (This was altered by the terms of the Deficit Reduction Act of 2005, PL 109–171.)

States can also offer thirty-four separate optional services, including diagnostic, prescription drug, and optometrist services (including providing eyeglasses); care in an intermediate care facility for mentally retarded individuals (ICF/MR); nursing home care for those under age twenty-one; rehabilitation and physical therapy services; and home- and community-based care.

Payments and Financing

Medicaid is what is known as a *vendor payment program,* meaning that states pay providers of care. In turn, the federal government reimburses states for their share according to each individual state's FEDERAL MEDICAL ASSISTANCE PERCENTAGE (FMAP). Overall, the federal government pays about 57 percent of Medicaid costs nationwide, with shares ranging from 50 percent in wealthier states up to 77 percent for the poorest states. In fiscal 2008 the state with the highest FMAP was Mississippi, at 75.84 percent. The federal government matches most administrative costs at 50 percent. Despite Republican-led efforts in the 1980s, 1990s, and 2003 to change it, Medicaid has remained an *open-ended entitlement* in that there is no cap on spending. The federal government reimburses states at their FMAP rates for all mandatory services and optional services the state chooses to offer, as well as for "all necessary and proper" administrative costs. Although beneficiaries whose coverage is optional account for only about a third of the total Medicaid population, an estimated 65 percent of all Medicaid spending is for either those optional individuals or optional benefits for mandatory beneficiaries.

Medicaid spending slowed dramatically in the late 1990s. In 1997 Medicaid spending grew by a mere 3.8 percent from the spending level of the year before, the slowest growth rate in the history of the program and a major turnabout from growth rates in the early 1990s, when Medicaid spending increases routinely ran around 20 percent. (From 1990 to 1992 spending rose by more than 27 percent per year.) But by the late 1990s, with health care costs in general on the rise and state economies sagging, thus making more people eligible, Medicaid increases again reached double-digit rates.

Analysts attributed Medicaid's rapid growth in the late 1980s through 1992 to several different factors. By far the most significant factor was states' use of aggressive financing mechanisms, including targeted provider taxes and DISPROPORTIONATE SHARE HOSPITAL (DSH) PAYMENTS (pronounced "dish") to hospitals that serve large numbers of Medicaid and other low-income patients. DSH payments exploded between 1988 and 1992, rising by 263 percent annually, from $1.3 billion to more than $17 billion. The increases led to an ugly war of words and policies between federal and state lawmakers, with federal legislators arguing that states were shifting serv-

Federal Medical Assistance Percentages, Effective October 1, 2008–September 30, 2009

State	*Federal medical assistance percentages*	*State*	*Federal medical assistance percentages*
Alabama	67.98	Nebraska	59.54
Alaska	50.53	Nevada	50.00
American Samoa	50.00	New Hampshire	50.00
Arizona	65.77	New Jersey	50.00
Arkansas	72.81	New Mexico	70.88
California	50.00	New York	50.00
Colorado	50.00	North Carolina	64.60
Connecticut	50.00	North Dakota	63.15
Delaware	50.00	Northern Mariana Islands	50.00
District of Columbia	70.00	Ohio	62.14
Florida	55.40	Oklahoma	65.90
Georgia	64.49	Oregon	62.45
Guam	50.00	Pennsylvania	54.52
Hawaii	55.11	Puerto Rico	50.00
Idaho	69.77	Rhode Island	52.59
Illinois	50.32	South Carolina	70.07
Indiana	64.26	South Dakota	62.55
Iowa	62.62	Tennessee	64.28
Kansas	60.08	Texas	59.44
Kentucky	70.13	Utah	70.71
Louisiana	71.31	Vermont	59.45
Maine	64.41	Virgin Islands	50.00
Maryland	50.00	Virginia	50.00
Massachusetts	50.00	Washington	50.94
Michigan	60.27	West Virginia	73.73
Minnesota	50.00	Wisconsin	59.38
Missipippi	75.84	Wyoming	50.00
Missouri	63.19		
Montana	68.04		

Source: Compiled by the Department of Health and Human Services. See *Federal Register,* Vol. 72, No. 228, November 28, 2007, pp. 67305–67306 (with later correction).

ices that previously had been exclusively state-funded into Medicaid in an effort to draw down federal funds inappropriately. Congress, in response, cracked down, outlawing most provider taxes and limiting DSH payments in separate legislation in 1991, 1993, and 1997.

But DSH payments alone did not account for the rapid Medicaid increases. Other major factors were enrollment increases, as a result of increased eligibility conferred by legislation, as well as inadvertent increases, such as the growth in the number of disabled children who gained eligibility for SSI (and, hence, Medicaid) following the 1990 U.S. Supreme Court decision *Sullivan v. Zebley.* The Court in *Zebley* found that the Social Security Administration had been inappropriately denying children SSI eligibility.

At the same time enrollment was growing, utilization was rising, because some of the newer Medicaid beneficiaries had expensive medical needs (such as those with AIDS, pregnant women, and seniors in need of significant medical care). It was also during this period that states were required to provide treatment for conditions detected through Medicaid's EPSDT program.

Medicaid spending declined largely because the reasons it escalated so fast reversed themselves. DSH spending dropped by 19.6 percent in 1996, as earlier restrictions imposed by Congress started to take effect. At the same time, the rate of enrollment slowed, because many of the new populations made eligible during the late 1980s and early 1990s had already been incorporated into the program. In fact, in 1996 Medicaid enrollment declined slightly—worrying many analysts, who feared that the 1996 welfare reform bill, although not eliminating Medicaid eligibility for most, might be inadvertently deterring those eligible from signing up. According to the federal AGENCY FOR HEALTH CARE POLICY AND RESEARCH (AHCPR), as many as 4.7 million children who were eligible for Medicaid were not enrolled in 1996.

Analysts attributed the resurgence of Medicaid inflation after 1998 to a major spike in prescription drug spending, as well as higher spending on long-term care services, particularly home health care. Some of the increases were attributed to a financing scheme used by some states known as the UPPER PAYMENT LIMIT (UPL). Congress moved to close down the loophole partially in 2000, and the Bush administration moved to restrict its use further still in 2001.

Medicaid came under severe stress in the early years of the 2000s. As the economy lagged, more people fell into poverty and thereby qualified for Medicaid coverage. From 2001 to 2004, Medicaid enrollment grew by nearly a third. But as state revenues fell, it became more and more difficult for states to pay their share of those rising Medicaid costs. After a prolonged fight, Congress in 2003 gave states an additional $10 billion over two years to help them with Medicaid costs. But many states still were forced to cut back on their Medicaid programs, either limiting benefits, cutting payments to providers, or reducing eligibility.

Medicaid and the 1996 Welfare Reform Bill

The 1996 Personal Responsibility and Work Opportunity Reconciliation Act made significant changes to the nation's welfare system, replacing the permanent entitlement-based AFDC program with the time-limited TANF program. But it also made significant changes to Medicaid, because Medicaid eligibility had always been tied to AFDC for qualifying populations. Although Congress had, since the mid-1980s, been working to weaken the ties between eligibility for Medicaid and eligibility for the cash welfare program, the welfare reform bill severed those ties irrevocably. Anyone who would have been eligible for AFDC benefits as of July 16, 1996 (the date the bill was passed), remained eligible for Medicaid through a newly designated eligibility category known as Section 1931, but the law did not require that those eligible for TANF automatically be enrolled in Medicaid.

The welfare law also barred legal aliens who entered the United States on or after the date of enactment (the date the law went into effect, August 22, 1996) from receiving any "federal means-tested public benefit," including SSI and Medicaid, for five years from their date of entry, affecting an estimated 500,000 immigrants. Congress, however, restored eligibility of some two-thirds of those legal aliens for SSI and Medicaid as part of the 1997 Balanced Budget Act (PL 105–33). Made reeligible for benefits were legal immigrants who were

receiving SSI as of August 22, 1996, based on a disability, those who were receiving SSI on that date because they were elderly but who could requalify based on a disability, and those who were in the United States as of August 22 and subsequently became disabled. Disabled legal immigrants who entered the country after August 22, 1996, but before June 1, 1997, also became eligible for benefits. Remaining legal immigrants who entered the country after August 22 remained ineligible for SSI or Medicaid for five years, and in any case until they became citizens.

Medicaid and the Deficit Reduction Act of 2005

The Deficit Reduction Act of 2005 (PL 109–171), which became law in 2006, changed several key aspects of long-standing Medicaid policy. For example, prior to passage of the act, most cost-sharing was prohibited for Medicaid beneficiaries, except for copayments of up to $3 for prescription drugs. Under the new law, states were given the option of charging unlimited premiums and copayments of up to 20 percent to beneficiaries in families with incomes over 150 percent of the federal poverty level. Copayments for beneficiaries in families with incomes between 100 and 150 percent of poverty were limited to 10 percent. Certain services, such as preventive services for children, emergency services, and pregnancy-related services, were exempt from cost-sharing, and total cost-sharing (copayments plus premiums) could not exceed 5 percent of a family's income over a month or a quarter. The CONGRESSIONAL BUDGET OFFICE (CBO) estimated that one in five Medicaid beneficiaries would be affected by the change by the year 2015.

The Deficit Reduction Act also allowed states to reduce the benefit package for children and certain other beneficiaries. Instead, they could offer benchmark coverage with benefits equivalent to the standard Blue Cross/Blue Shield plan offered to federal workers; health coverage offered to state employees; or coverage offered by the largest HEALTH MAINTENANCE ORGANIZATION (HMO) in the state. States would have to provide additional benefits needed to continue to meet the requirements under EPSDT requirements. States were not permitted to enroll in the alternative benefits packages pregnant women or parents whose coverage was mandatory, the disabled, dual eligibles, and Medicaid beneficiaries who needed long-term care.

Also changed were rules governing the waiting period between the time a person divests his or her assets and when that person can qualify for Medicaid-covered nursing home care. The law changed the "look back" period from three years to five years. But more important, it changed the start of the penalty period from the date of the asset transfer to the date of the application for Medicaid, which CBO estimated would delay Medicaid eligibility by an average of three months for 130,000 beneficiaries by the year 2015.

Finally, in terms of benefit reductions, the act imposed new citizenship documentation rules for people applying for Medicaid coverage. Previously, applicants could "attest" that they were citizens, and investigations and audits had found no evidence of widespread abuse by those not eligible for the program because they were not citizens. Nonetheless, the deficit reduction law required applicants to provide original documents such as a birth certificate or passport, along with valid identification. In the year following implementation of the new rules, several surveys showed that those most likely to be denied coverage under the rules were not illegal immigrants, but rather U.S. citizens who had difficulty obtaining needed documents.

Some of the changes, however, had the effect of boosting access to Medicaid. The Family Opportunity Act, for example, which was included in the deficit reduction measure, allowed states the option of letting families with severely disabled children to "buy in" to Medicaid coverage if their family income was below 300 percent of the federal poverty level. Medicaid coverage was particularly valuable for children with disabilities because it often provided rehabilitation and therapy services private insurance did not cover and families could not otherwise afford. It had been championed on a bipartisan basis for several years on both sides of Capitol Hill before finding its way into the 2005 Deficit Reduction Act.

Another bipartisan proposal included in the measure was the codification of policies known as "money

follows the person" and "cash and counseling," which effectively allowed people with long-term care needs to decide whether to receive that care in an institutional or community setting, or even at home. Previously, Medicaid often covered services only in a nursing home, which both cost more and left patients unsatisfied.

Medicaid and Managed Care

Although MANAGED CARE was slower to catch on in Medicaid than it was in the working population, when states began to enroll their low-income populations in health maintenance organizations and other prepaid plans, the increases were dramatic. In 1991, 2.7 million beneficiaries were enrolled in Medicaid managed care plans, representing 9.5 percent of the Medicaid population. By 1997 enrollment in Medicaid managed care had risen to 15.3 million, representing 47.8 percent of beneficiaries. By 2007 more than 65 percent of beneficiaries were enrolled in managed care plans. Only three states were without Medicaid managed care programs in 2007: Alaska, Mississippi (whose program was terminated after Hurricane Katrina), and Wyoming.

Medicaid managed care comes in two main forms. In fully capitated plans the managed care organization assumes full financial risk for the costs of each beneficiary's care in exchange for a set monthly fee (see CAPITATION). Under primary care case management (PCCM), the state pays a monthly fee to a primary care GATEKEEPER physician who is not "at risk" for the cost of the beneficiary's care but who does control access by the beneficiary to specialists, hospital care, and laboratory tests.

Although conventional wisdom holds that managed care restricts patients' choice of providers, for Medicaid beneficiaries the situation can often be the opposite. Because of Medicaid's traditionally low payment rates, beneficiaries can have difficulty finding providers to serve them. As one analyst put it in 2003, "[T]he Medicaid eligibility card was, in effect, a license to hunt for providers who would accept it." In managed care, however, Medicaid patients often have a broader array of choices than they had when they were in a traditional FEE-FOR-SERVICE plan. Having a PRIMARY CARE PHYSICIAN (PCP) frequently means that Medicaid patients stop seeking routine care in emergency rooms, previously among the few places where they could get medical help. And although many analysts worried that "Medicaid-only" managed care plans would provide substandard care (which had been the case in some instances), many plans have been developed consisting of traditional safety net providers, such as COMMUNITY HEALTH CENTERS, which are attuned to the myriad health and social needs of low-income populations (see SAFETY NET FACILITIES). Evidence, however, is mixed about whether managed care improves access to care for Medicaid beneficiaries.

The 1997 Balanced Budget Act made a number of changes designed to further the spread of managed care in the Medicaid program. Most important, it allowed states to require Medicaid beneficiaries to enroll in a managed care plan. Previously, states had to obtain a federal waiver of rules requiring that beneficiaries be given free choice of medical provider. The measure also permitted states, without waivers, to enroll beneficiaries in plans that serve mostly or exclusively Medicaid beneficiaries. States could also limit the number of managed care organizations serving Medicaid patients in urban areas, thus giving themselves more bargaining leverage with the plans.

Medicaid drug rebate program

Created by the Omnibus Budget Reconciliation Act of 1990 (PL 101–508), the program was intended to force prescription drug manufacturers to provide the same rebates to state MEDICAID programs that they routinely granted to other "bulk" purchasers, such as large MANAGED CARE organizations, hospitals, and the Department of Veterans Affairs.

At $3.3 billion in 1988, drug costs represented a major expense for Medicaid. According to data compiled by the Senate Special Committee on Aging, whose chair, David Pryor, D-Ark., championed the drug discount effort, Medicaid drug outlays for states that offered drug benefits rose 224 percent between 1980 and 1988, a rate three times faster than the inflation rate in the rest of the economy and significantly greater than that in other sectors of health care.

The prescription drug industry vehemently opposed the measure. Medicaid purchases accounted for some 15 to 20 percent of all drug sales, reported the Pharmaceutical Manufacturers Association (PMA, later renamed the Pharmaceutical Research and Manufacturers of America). The industry argued that it was already facing increased price competition as a result of 1984 legislation that made it easier for companies to market "generic" copies after patents expired on brand name products (see GENERIC DRUGS). The PMA also argued that limiting the profits of drug companies would jeopardize research into new drugs that could ultimately reduce health care costs by curing chronic ailments or serving as substitutes for surgery or other expensive procedures.

After a fierce fight, however, Congress decided to require the rebates. Originally, the rebates were set at the lower of 12.5 percent off the average manufacturer price or the "best price" at which the manufacturer sold the drug to any customer except the Department of Veterans Affairs. Discounts on drugs for which generic copies were already on the market were set at 10 percent for the first three years and 11 percent thereafter.

Although the law has been a success, Medicaid's prescription drug costs exploded in the late 1990s, as did costs for virtually every other public or private insurer. Medicaid's discounts, however, drew the attraction of states eager to leverage those required discounts to buy cheaper drugs for UNINSURED citizens not otherwise eligible for the program. One of those state programs, known as "Maine Rx," drew not only complaints from the drug industry that the state was abusing the Medicaid program but also a lawsuit that went all the way to the U.S. Supreme Court. The Court on May 19, 2003, decided in *Pharmaceutical Research and Manufacturers of America v. Walsh* that Maine should be allowed to proceed with the program, but justices left open the possibility that the scheme could still be found to violate Medicaid law.

Medical Device User Fee Act

Congress in 2002 approved legislation aimed at speeding the time it took for the FOOD AND DRUG ADMINISTRATION (FDA) to review the safety and effectiveness of new medical devices by having device manufacturers pay "user fees" to hire additional reviewers. The law (PL 107–250) essentially mirrored the 1992 PRESCRIPTION DRUG USER FEE ACT (PDUFA), which was credited with cutting review times for new medications dramatically.

The legislation nearly got tacked onto another bill cleared earlier in the year (PL 107–188), reauthorizing the drug user fee law for an additional five years, but the deal ended up taking several more months to work out. One key problem was that, unlike drugmakers, which were entirely large firms, many makers of medical devices—including everything from thermometers to high-tech scanning machines—were small businesses for which user fees could pose a serious financial hardship.

In addition to fees on a sliding scale ranging from around $2,200 up to $154,000, the law gave device makers something they had been seeking for several years—authority in some cases for third-party reviewers, people who are not government employees, to inspect device manufacturing facilities. The FDA had fallen badly behind on its inspections, which were supposed to take place at least once every other year. The law also extended a demonstration program allowing third-party review of certain devices. That program was created as part of the 1997 FDA Modernization Act (PL 105–115). Third-party review of facilities would be allowed only if a facility's most recent inspection had shown no problems. Such third-party review had long been controversial. Opponents worried that it could present conflicts of interest that could jeopardize the safety of the public.

The law also addressed the problems posed by the reuse of medical devices originally approved for one-time-only use, such as catheters and biopsy needles. In an effort to save money, "reprocessing" firms had been created to sterilize and repackage such single-use devices so they could be used again. The law increased FDA scrutiny of such reprocessed devices and required that they be explicitly labeled as such.

In 2007, as part of the reauthorization of the Prescription Drug User Fee Act, Congress renewed the medical device user fee provisions. The action lowered most individual fees but added several new classes of

fees to lessen the burden on individual companies. President George W. Bush signed the bill (PL 110–85) on September 27, 2007.

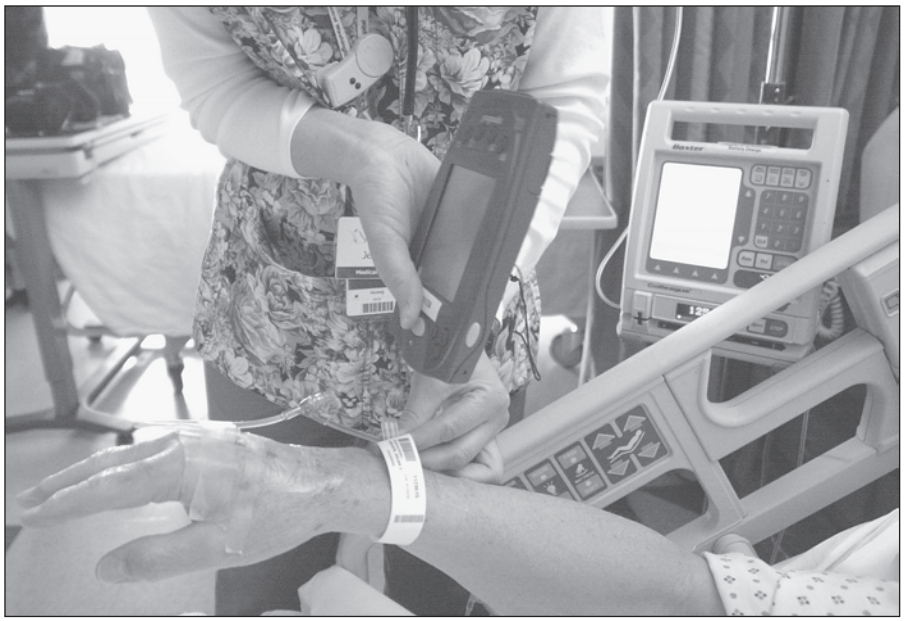
Medical errors

The report issued in November 1999 by the INSTITUTE OF MEDICINE finding that medical mistakes in hospitals killed between forty-four thousand and ninety-eight thousand Americans hit the nation's health policy-making machinery like a ton of bricks. The fact that medical mistakes occur (everything from amputating the wrong limb to giving the wrong medication or the wrong dosage of the right medication) was hardly news. But the reported magnitude of the problem—that, even using the lower estimate, medical mistakes killed more Americans each year than highway accidents, breast cancer, or ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS), according to the researchers—put the issue firmly on the nation's health agenda, with both the private sector and the policy makers vowing to act.

The private sector acted first, as 130 large employers created the Leapfrog Group, dedicated to encouraging changes that would better protect patients by vowing to make their health care purchasing decisions based on patient safety concerns and rewarding employees who choose providers that have instituted policies designed to protect patients from mistakes. The group's first three hospital safety measures were having physicians enter medication orders by computer instead of handwriting; having physicians refer patients who need complex medical procedures to hospitals that have demonstrated better outcomes performing those procedures; and having intensive care units staffed by physicians with specific critical care training.

Lawmakers, who also vowed quick action to reduce medical mistakes, had far more difficulty agreeing on what to do. As part of its report, the Institute of Medicine recommended creation of two separate systems for reporting errors: an anonymous, voluntary system for minor errors and "near misses," to allow experts to examine and correct procedures that lead to mistakes, and a mandatory reporting system for errors resulting in death or serious harm.

But the health care industry launched an immediate campaign to stop mandatory reporting, which they said would create a "culture of blame." Better care, testified a representative of the American Hospital Association before a Senate subcommittee in December 1999, "cannot



A nurse at a Wenatchee, Wash., hospital scans a barcode on a patient's wristband before dispensing medication. Technologies such as this are helping hospitals reduce dangerous and costly medical errors. *Source: AP Images/Wenatchee World/Mike Bonnicksen*

be achieved in an environment of punishment or fear of legal prosecution for doctors, nurses and other caregivers who step forward after an unfortunate mistake is made."

Although several bills were introduced in the 106th and 107th Congresses on ways to prevent medical mistakes, lawmakers generally split along party lines, with Democrats favoring mandatory reporting systems and Republicans voluntary ones. In the end, the only legislative step that became law was language added to the fiscal 2001 spending bill for the HEALTH AND HUMAN SERVICES DEPARTMENT (HHS) (PL 106–554) authorizing creation of a Center for Patient Safety within the AGENCY FOR HEALTHCARE RESEARCH AND QUALITY (AHRQ). The bill provided $50 million for the center to act as a clearinghouse for studies into ways to prevent and address medical errors.

In 2002 two House committees approved bipartisan measures that would have created "patient safety organizations" to which health care professionals could have provided voluntary, anonymous reports. But the two committees could not resolve the relatively small differences in the two bills before Congress adjourned. The House subsequently passed legislation, the Patient Safety and Quality Improvement Act, by 418-6 on March 12, 2003. The Senate passed the measure by unanimous consent on July 22. But lawmakers were unable to resolve their differences, and the measure died.

Finally, in 2005 the House and Senate managed to come together on a bill. The Senate passed its version by voice vote on July 21; the House cleared it 428-3 on July 27. President George W. Bush signed it into law (PL 109–41) on July 29. As envisioned all along, the measure called for the creation of patient safety organizations (PSOs), which were to keep the information reported to them confidential. Under the terms of the compromise reached, the information made available to the PSOs was not "discoverable" in medical malpractice lawsuits, but if it was otherwise available to lawyers, it could be used. In other words, lawyers could not go fishing for information they did not already have. The law also specifically barred employers from taking any retaliatory action against an employee who makes a report to a patient safety organization, and it required HHS to create a database to collect the information from all PSOs and analyze the information nationally and regionally.

More than two and a half years would pass, however, before HHS finally issued regulations to put the new law into effect. Those regulations were released in February 2008.

Meanwhile, MEDICARE was taking advantage of its status as one of the nation's largest payers of health care to push hospitals to reduce errors. In August 2007 Medicare officials announced the program would stop paying hospitals after certain errors occurred, including so-called never events, such as giving patients blood that is the wrong type or leaving surgical instruments inside a patient. Medicare also said it would refuse to pay following certain types of preventable infections or when hospitalized patients fall down.

Medical malpractice

Medical malpractice is one form of *tort,* or wrongful personal injury by one person against another. Patients who believe they have been injured can recover damages in court if they can show that the physician or health care provider had a duty not to harm them, breached that duty by not meeting the community's prevailing "standard of care," and as a result of the breach caused the injury. Most medical malpractice law is at the state level. However, health care providers have been pushing the federal government to get more involved, particularly as malpractice insurance premiums for physicians and other health care providers spiked in 2002 and 2003.

Widespread agreement exists that the system by which doctors who are incompetent or neglectful are punished does not work well. The purpose of medical malpractice laws is twofold: to compensate those who are injured as a result of substandard medical care and to deter health professionals from providing bad or negligent care. Yet a landmark 1991 study by researchers at Harvard University who examined medical records from hospitals in New York City found the system does not accomplish either goal. Researchers examined more than thirty thousand patient records and identified

forty-seven malpractice claims. Only eight of those claims were filed for the 280 patients who the records suggested had been victims of medical negligence. In other words, lawsuits were never filed for the vast majority of cases in which malpractice likely occurred, and most of the lawsuits that were filed were for cases for which no evidence showed that any malpractice took place. A follow-up study found that the size of malpractice awards was determined more by the severity of the injury than by the extent to which the defendant in the case was responsible for that injury. It is little wonder that insurers and doctors refer to the nation's malpractice system as "a lawsuit lottery" in which a few people win multimillion-dollar judgments while the vast majority of those injured receive nothing.

Medical malpractice lawsuits cost the health system money in two different ways. One is through insurance premiums paid by doctors and other health care providers, premiums that are generally passed on to patients and insurers. These premiums may be high for doctors who practice high-risk procedures, particularly obstetrician/gynecologists and surgeons, who are statistically among the most likely to be sued. It is not uncommon for obstetrician/gynecologists to have malpractice premium costs in excess of $100,000 per year, and a 1992 survey conducted during one of the periodic spikes in malpractice insurance premiums found that 12 percent of them had stopped delivering babies because they could not afford the malpractice insurance premiums. Another period of rapid malpractice premium increases in 2002 and 2003, part of a periodic cycle in which premiums rise and fall, had a more dramatic effect, as trauma centers closed temporarily in several cities for lack of specialists to staff them, and doctors in West Virginia, Pennsylvania, and elsewhere effectively went on strike in an effort to force legislative relief. Overall, however, malpractice premiums over time account for about 1 percent of total health care spending.

The other way malpractice affects health care spending is through the practice of "defensive medicine," which occurs when doctors order tests or procedures not because they think they are medically indicated but because of fear of being sued, or to have a defense if they are sued. Although some estimates have put defensive medicine costs as high as 25 percent of all care, a 1994 study by the federal Office of Technology Assessment (OTA) found that defensive medicine more likely accounts for less than 8 percent of diagnostic procedures performed. The OTA study also noted that not all defensive medicine is unnecessary and may be of benefit, even though some of it might not be performed but for physicians' concerns about potential liability.

Physicians say lawyers make too much money off malpractice suits, that patients with minor injuries cannot get compensation because lawyers will not take their cases, and that physicians are unfairly sued too often. One study by the RAND Corporation found that injured patients collect only forty-three cents of every dollar paid in damages and that lawyers take home more than half of each dollar. Provider groups have long urged Congress to impose a "cap" on *noneconomic damages*—those awarded for pain and suffering, as opposed to *economic damages,* which reimburse patients for lost wages and the costs of care, or *punitive damages,* which are intended to punish particularly egregious behavior. California and several other states have imposed such caps as part of malpractice reforms. California's cap, enacted in 1975, was $250,000.

Consumer and legal groups, however, say capping damages would further hurt those already injured by a medical professional. The American Bar Association says that capping noneconomic damages would particularly affect women and low-income individuals, who are likely to have limited direct economic losses, as well as those with severe injuries. Consumer groups also say that the medical profession does too poor a job of policing itself for lawmakers to curb legal recourse. According to the Public Citizen Health Research Group, from 1990 to 2002, 5.1 percent of doctors included in the NATIONAL PRACTITIONER DATA BANK accounted for 54.2 percent of all malpractice payouts. During that same time, the group reported, only 7.6 percent of doctors with two or more malpractice payouts had been disciplined by a state medical board, and only a third of those with ten or more malpractice payouts had been disciplined.

Doctors and lawyers also disagree heatedly over what it is that drives up premiums. Doctors (and insurance companies) say the key culprit is runaway jury awards,

particularly for "pain and suffering." Lawyers (and consumer groups) insist that premiums follow a predictable cycle, rising when insurers' investments do badly and falling when the markets are high. The "crisis of availability" that began in the early twenty-first century, they pointed out, was exacerbated by the withdrawal of key malpractice insurance companies from the market in many states, creating a supply and demand problem on top of what were already expected to be higher than average premiums because of a lagging bond market for insurers' investments.

The malpractice battle between doctors and lawyers, particularly at the federal level, is reflected in campaign contributions made by each side. According to the Center for Responsive Politics, which tracks campaign finance issues, in the 2006 election cycle the American Association for Justice, which represents the nation's trial lawyers, made nearly $2.6 million in contributions to congressional candidates, 96 percent of which went to Democrats. Those contributions ranked the group, which opposes caps on damage awards or attorney fees, number nine among all political action committees (PACs). By contrast, the AMERICAN MEDICAL ASSOCIATION (AMA), the leading proponent of malpractice reforms, gave just over $2.0 million, 69 percent of which was directed to Republican candidates. That donation ranked it eighteenth among PAC givers.

The "crisis of availability" in malpractice insurance in the 1980s prompted federal officials to take a closer look at the issue. In 1991 President George H. W. Bush proposed that states make several malpractice reforms. Included in the proposal, which did not become law, were caps on noneconomic damages and "alternative dispute resolution" mechanisms, such as binding arbitration and mediation, that would keep malpractice cases out of court. President Bush proposed withholding 2 percent in administrative payments made under MEDICAID from states that failed to pass malpractice reforms meeting the requirements.

President Bill Clinton, as part of his HEALTH SECURITY ACT, in 1993 proposed a variety of malpractice reforms, although not a cap on damages. The centerpiece of the act's malpractice proposals was a concept called "enterprise liability," which would have made entire health plans, not individual physicians, liable for malpractice. Physician groups opposed that concept, noting that it would give health plan administrators even more control over doctors' actions. Clinton in his plan also proposed alternative dispute resolution techniques: requiring claims to be awarded a "certificate of merit" from a "qualified specialist" verifying the claim's legitimacy; limiting attorney fees to one-third of awards; and allowing physicians to use as a defense their following of clinical practice guidelines.

After the Republicans took over Congress as a result of the 1994 elections, the House passed legislation to cap noneconomic damages at $250,000 nearly a dozen times before the Democrats retook the majority in 2007. The Senate, however, was never able to follow suit, despite the fervent support of President George W. Bush, who assumed office in 2001.

The GOP-led House first appended its malpractice proposal to three bills that did not become law: the Common Sense Product Liability and Legal Reform Act; the 1995 Balanced Budget Act, which was vetoed by President Clinton; and the 1998 Patient Protection Act, which passed the House but not the Senate. The House included the provisions again in its versions of what would become the HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA) (PL 104–191) and the 1997 Balanced Budget Act (PL 105–33). In both pieces of legislation, the malpractice provisions were dropped in conference at the insistence of the Senate and the White House.

The issue languished for several years while the AMA pursued patient protection legislation in Congress—a pet issue of Democrats—instead of the malpractice proposal that the GOP favored. But the collapse of the PATIENTS' BILL OF RIGHTS (PboR) in 2001, combined with spiraling malpractice premiums in many states, brought the malpractice issue back to the fore in 2002. With the strong backing of President George W. Bush, the House responded by passing a stand-alone malpractice damage awards cap bill, the Help Efficient, Accessible, Low-cost, Timely Healthcare (HEALTH) Act by a near party-line vote of 217-203 in September 2002. The Senate, however, continued its long history of disinterest in the issue. A vote in July 2002 on a far less sweeping malprac-

tice amendment (capping punitive but not noneconomic damages) to an unrelated GENERIC DRUGS bill garnered only forty-two votes.

With the ascent to the Senate majority leader position of physician Bill Frist, R-Tenn., in 2003, backers of malpractice damage awards hoped for a breakthrough in that chamber. The House acted quickly, repassing the 2002 bill, this time by 229-196, with one member voting present, on March 13. But Senate efforts to find the needed votes to overcome stalling tactics foundered early on, and the few Democrats who had expressed interest in a compromise were frustrated by the medical community's unwillingness to budge from the $250,000 cap. A cloture vote on the measure failed by 49-48 on July 9, eleven short of the sixty required.

Frist tried again to bring up the bill the following year in several different guises. First he tried to recast the issue as a matter of health for women and children. New legislation would have shielded only obstetrician/gynecologists and nurse midwives from noneconomic damage awards greater than $250,000, instead of all doctors. A cloture vote on the bill on February 24, 2004, failed by 48-45 as did another effort in April that would have covered emergency room and trauma physicians as well. The April cloture vote was 49-48. Meanwhile, the House passed a measure with the same provisions as the bill it passed in 2003, as part of its actions to commemorate "Cover the Uninsured Week." The vote was 229-197. No further action was taken in the 108th Congress.

The House passed medical malpractice legislation in the 109th Congress, this time by 230-194 on July 28, 2005. The Senate, however, failed to muster the votes to take up a companion bill, falling twelve votes short of the sixty needed for cloture on May 8, 2006. That vote was 48-42.

Medical necessity

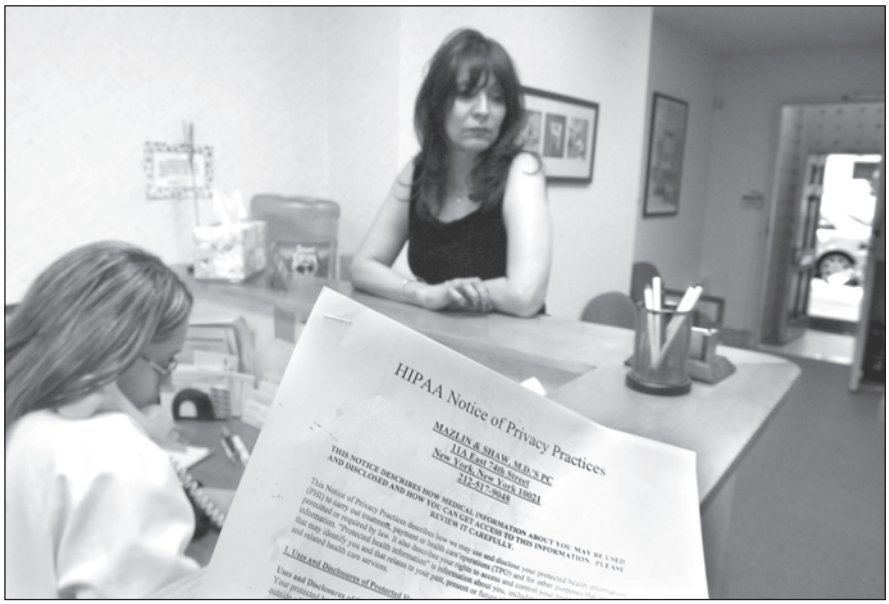
A critical term in MANAGED CARE and health insurance, medical necessity determines what care will and will not be covered. Most insurance policies pay only for medically necessary care. That category of care is intended to exclude things such as cosmetic surgery or other "lifestyle" treatments. But the boundaries of the category often depend less on written definitions and more on who makes the determination of whether care is necessary or not. In the past, anything a physician ordered was generally deemed medically necessary by an insurer. But today, most insurance companies, particularly managed care companies, have their own definitions of medical necessity. Managed care officials say making medical necessity determinations helps them improve care, often by steering a physician toward using a treatment that research has shown to be more effective. But doctors, led by the AMERICAN MEDICAL ASSOCIATION (AMA), say that health plans use medical necessity as a tool to save money, even if it means denying care a patient truly needs. The PATIENTS' BILL OF RIGHTS (PboR) legislation backed by President Bill Clinton would have barred health plans from "arbitrarily interfering with or altering" a treating doctor's judgment if the care in question is otherwise covered and is "consistent with generally accepted principles of professional medical practice."

Medical power of attorney

See DURABLE POWER OF ATTORNEY FOR HEALTH CARE.

Medical records confidentiality

How to protect the confidentiality of medical records is one of the most contentious issues in health policy. On the one hand, the increasing ability to transmit information electronically has an enormous potential to improve health care. For example, emergency room personnel could be able to access critical medical information on an unconscious person who has had a heart attack or was in an automobile accident thousands of miles away from home. And researchers using information in medical records can uncover untold new discoveries, not to mention find which treatments are most cost-effective or have fewest side effects. On the other hand, the increasing dissemination of personal medical information—bits of data are almost continuously traveling between doctors' offices, hospitals, pharmacies,



The Health Insurance Portability and Accountability Act (HIPAA), illustrated center, required keeping medical information private. Barbara Velez, left, manages a doctor's office; she remodeled the small office with high countertops to prevent patients from getting an accidental glance at other patients' records, which could be construed as a federal offense under HIPAA. *Source: AP Images/Bebeto Matthews*

and insurers and other third parties—has its downside. The leaking of sensitive or embarrassing information, such as a history of a mental illness or sexually transmitted disease, can be emotionally devastating. And there is anecdotal evidence that patients are becoming reluctant to share pertinent medical information with their health providers for fear they will suffer job or insurance discrimination (see GENETIC DISCRIMINATION).

On April 14, 2003, the first-ever federal rules to protect the confidentiality of personal medical information took effect, after nearly seven years of struggle and five separate versions.

Congress first addressed the issue as part of the 1996 HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA). In PL 104–191, Congress ordered the secretary of the HEALTH AND HUMAN SERVICES DEPARTMENT (HHS) to make recommendations to Congress on ways to protect "individually identifiable" medical information and to set penalties for wrongful disclosure of such information. In that law Congress set itself a deadline of August 1999 (which it missed) by which to either enact a law governing the confidentiality of medical records or authorize HHS to promulgate its own regulations, the first version of which were presented by Secretary Donna E. Shalala in September 1997.

Privacy advocates, health care providers, insurers, and researchers all wanted federal legislation, not regulations. As health care became increasingly a multistate endeavor, with patients, providers, and insurers frequently living and working across jurisdictional lines from each other, everyone involved in health care struggled to cope with fifty different sets of privacy requirements. But reaching agreement on exactly how to protect personal medical information, who should have access, and what the penalties should be for misuse proved an elusive goal.

In announcing the HHS proposal—which originally applied only to electronic information, not paper records—on September 11, 1997, Shalala said the recommendations "strike a balance between the privacy needs of our citizens and the critical needs of our health care system and our nation." Specifically, the HHS proposal would have imposed confidentiality rules on anyone who provided or paid for health care or who received health information from a provider or payer, either with permission of the patient or as authorized by the rules. Recipients of identifiable patient information would have been required to ensure its confidentiality by creating audit trails, using administrative and management techniques, and leveling sanctions against employees

who used information improperly. Stronger state laws, such as those specifically protecting mental health information or information related to the human immunodeficiency virus (HIV) and ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS), would still apply and would not have been preempted.

Consumers would have been given the right to see their medical records, to copy them, and to propose corrections. Those who collected information would have to inform patients how the information would be used, kept, and disseminated, and patients would have been permitted to see a written history of who had accessed their personal health information. Providers could not condition treatment on a patient's consenting to disclose health information (as was common previously, when patients signed blanket authorizations to receive care) unless the information was required for treatment, coverage, or payment purposes. (Although privacy advocates acknowledged the need for some information to be provided if care is to be covered, they asked that mandatory disclosures be limited as much as possible.) In cases of wrongful disclosure, federal criminal penalties would apply, and patients would have had the right to file a civil suit, known as a "private right of action," against the party who wrongfully disclosed the information.

The original HHS proposal did allow for some exceptions to the confidentiality rules. Information would be available for overseeing the health care system (for conducting audits, fraud investigations, quality assurance activities, and health professional licensing programs). Information would also have been released for emergencies affecting life or safety, for public health purposes, for research, and for state health data systems. Other exceptions to the confidentiality rules concerned medical records requested by law enforcement authorities for court proceedings in which the patient was a party and for other court proceedings in which records had been sought under a specific court order.

Not surprisingly, the HHS recommendations proved controversial. Patient advocates criticized the proposal for not taking stronger measures to protect identifiable medical information from law enforcement authorities—a blanket exception reportedly imposed on HHS by the Department of Justice. Insurance groups argued that allowing stronger state laws to remain in force would undermine the entire concept of creating a single uniform standard.

But by far the most contentious issue was whether patients should have to consent to each use of personally identifiable medical information. Privacy advocates said yes, but researchers said such a requirement could cripple their ability to do their jobs. At one congressional hearing in March 1998, a researcher from the Mayo Clinic said that if a Minnesota privacy law had been in effect two years earlier, Mayo researchers would not have been able to access the information used to demonstrate the relationship between the diet drug combination "phen-fen" and heart valve damage. The Mayo study resulted in the drugs being pulled from the market.

Despite the introduction of more than a dozen bills in Congress in 1998 and 1999, lawmakers proved unable to agree on a final proposal. Three main issues blocked agreement. One was whether or not stronger state laws should be allowed to remain in place. Privacy advocates argued they should; industry and provider groups said setting a single national standard was their primary motivation for supporting legislation in the first place. Democrats and Republicans also fractured over whether parents should have access to their teenaged children's medical information. Both sides said they generally wanted state law to prevail on the sensitive subject, but drafting legislation in a way that would ensure that would be the case turned out to be impossible. Finally, the two sides disagreed about whether there should be a "private right of action" for those whose privacy was violated. Advocates insisted such recourse was needed to ensure enforcement, but Republicans who were busy trying to impose damage award caps on other types of lawsuits were loath to add yet another avenue for litigation.

Passage of the August 1999 deadline triggered the requirement for HHS to act instead. President Bill Clinton himself unveiled the proposed rules on October 29, but in testimony before Congress to explain the proposal, administration officials said they were not fully satisfied with their own proposal. They wanted Congress to act instead, because the proposed rules could

not provide adequate enforcement ability (without a private right of action), they applied only to information transmitted electronically, and they failed to reach many entities that handled identifiable health information, such as life insurers and drug companies.

Fourteen months and more than fifty thousand public comments later, President Clinton unveiled what was intended to be the final version of the rules on December 20, 2000, just weeks before he left office. "It is quite a problem that with the click of a mouse your personal health information can be accessed without your consent by people you don't know who aren't physicians for reasons that have nothing to do with your health care. It doesn't take a doctor to understand that is a prescription for abuse," the president said.

As proposed, the rules allowed patients access to their own medical records, the ability to propose corrections, and the ability to find out who else had seen them. They strictly limited who, other than health care providers, insurers, and health care clearinghouses that turned patient information into electronic form, could have access to identifiable medical information.

The December 2000 version of the rules differed in major ways from the version proposed the year before. Administration officials decided they did have the authority to have the rules apply to written and oral communications, as long as the entity in question transmitted any information electronically. The proposed rules would bar employers from access to health records for any reason not directly related to the provision of health care. And, reversing the earlier version, they required patients to provide written consent before their information could be used for routine treatment, payment, or health care operations.

That last change was more than industry could bear. Hospitals, pharmacy groups, and insurers launched a heated campaign to get the incoming George W. Bush administration to modify the proposal. They claimed the rules would be so unwieldy that they would interfere with patient care. Friends and relatives would no longer be able to pick up prescriptions for others (a charge privacy advocates denied), and doctors would no longer be able to discuss patients with other doctors when making referrals.

Although incoming HHS secretary Tommy G. Thompson reopened the rules for public comment in February 2001, the Bush administration in April announced it would let the rules take effect as scheduled, requiring compliance for all but the smallest health plans on April 14, 2003. But officials said that changes might still be made, and they were. In March 2002 the administration proposed revisions to the rules. The key change dropped the requirement for written consent for routine uses of information, replacing it with a requirement that patients be given a "notice" of privacy practices and their new rights and that providers make "a good faith effort" to get patients to acknowledge receipt of that notice in writing. The revisions also proposed a change to rules barring use of information for marketing without explicit patient permission. Bush officials said the change would make it easier for health plans to make patients aware of new drugs or treatments; privacy advocates said they were a major weakening of the antimarketing provisions.

Meanwhile, industry did not get everything it wanted. Health care providers were upset that the new version failed to drop a requirement that they sign contracts with their "business associates" to ensure those entities, although not officially covered by the rules, agreed to abide by them. Instead, the administration provided model contracts providers could use.

The Bush administration made the revisions to the rules final on August 9, 2002.They took effect, as scheduled, on April 14, 2003.

Medical savings accounts (MSAs)

These tax-preferred vehicles enabled people to self-insure for their own routine medical expenses while simultaneously saving money for themselves. Medical savings accounts (MSAs) were largely replaced by the renamed HEALTH SAVINGS ACCOUNTS (HSAs) created as part of the 2003 MEDICARE MODERNIZATION ACT (PL 108–173). Individuals with MSAs carried a catastrophic insurance policy with a high DEDUCTIBLE (usually $1,500 or more) that kicked in if severe illness struck. The theory behind MSAs was that, by making individuals responsible for

their own routine medical expenses, the savings accounts would make those individuals more price-conscious, thereby holding down overall health spending. Because individuals could keep any money in the MSA that they did not spend on health care (although they must pay taxes on funds not spent for medical care), they had an incentive to spend only for care that was necessary and at the best price possible, the reverse of the situation under FIRST-DOLLAR COVERAGE insurance, in which individuals have no incentive to economize. Political conservatives have been the biggest boosters of MSAs and HSAs, which work the same way, arguing that they return choice and responsibility to individuals.

But MSAs are also among the most controversial entities in health policy. Detractors argue that individuals with MSAs are likely to forgo needed preventive care, because they would prefer to save the money to spend on non–health care items. They also argue that MSAs could undermine the insurance market as a whole. Because they appeal more to healthier people (who are most likely to have money left over at the end of the year in their MSA), MSAs could draw the healthiest people out of the insurance pool, leaving the sick behind and raising premiums. MSAs are also more attractive to wealthy individuals. Because any difference between the amount in an MSA and the amount of the deductible will have to be made up out-of-pocket, they can better afford the risk involved. Higher-income people also benefit more from the tax advantages of an MSA, because their own contributions are tax-deferred, as are amounts deposited by an employer.

Congress in 1996 and 1997 authorized two separate MSA programs. Although federal legislation was not technically needed for MSAs to exist (many employers had been offering them for years), only the federal government could grant the tax advantages needed to make the program attractive to large numbers of people.

As part of the 1996 HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA) Congress authorized a demonstration program, to last until 2001, during which 750,000 policies could be sold. The program was limited to the self-employed and firms with fifty or fewer workers; deductibles for catastrophic insurance coverage were required to be between $1,500 and $2,250 for individuals and between $3,000 and $4,500 for families; and contributions to the MSA could not be more than 65 percent of the deductible for individuals and 75 percent for families. MSA contributions had two tax advantages: no federal taxes were due on the money deposited, and the interest that accumulated in the account was tax-free. Still, the program was slow to catch on. As of June 30, 1998, only 54,702 policies had been sold; only 17,688 had been purchased by people who were previously UNINSURED. MSA advocates argued that the program was structured in such a way as to make MSAs unattractive. However, legislative efforts to lift the enrollment caps, lower the limits on deductibles, and allow both workers and employers to make contributions to the MSA had not been successful as of the end of 2002.

As part of the 1997 Balanced Budget Act (PL 105–33), Congress also authorized an MSA demonstration program for MEDICARE beneficiaries. Under the law, up to 390,000 Medicare beneficiaries could open an MSA and purchase catastrophic coverage until the year 2002. However, no MSAs were ever available under the program because no plan signed up to offer them. Medicare MSA beneficiaries would have been eligible to receive payments equal to those provided to MANAGED CARE plans in their counties. Medicare would have purchased the beneficiary's high-deductible catastrophic policy (with an annual deductible limited to $6,000), then deposited the remainder into the individual's MSA. A BENEFICIARY could use MSA funds without tax penalty for "qualified medical expenses," as defined by the Internal Revenue Service, or to pay premiums for long-term care or other health insurance. Individuals could also have withdrawn funds for nonhealth purposes, paying regular income taxes, as long as the withdrawals left at least 60 percent of the catastrophic insurance deductible in the MSA. Account balances could have been left to heirs under the same tax treatment as that of other tax-preferred retirement accounts.

The Medicare MSAs presented opponents yet another argument—that scarce Medicare dollars could theoretically be used for nonmedical purposes. But many analysts predicted that seniors, being much more risk-averse than younger consumers, would be slow to sign up for MSAs in any case. Even though the 1997

experiment never drew any takers, lawmakers and other MSA backers continued to push the model as one suited to Medicare beneficiaries.

Medical underwriting

This term refers to a process by which insurers determine how much an individual or group is likely to incur in the way of medical bills and thus how much that person or group should pay in premiums. Medical underwriters look at demographic factors, such as age and gender, as well as individual medical histories. In some cases, the underwriting process results in an insurer's declining to offer coverage at all or offering coverage that excludes certain conditions.

Medically needy

This optional federal program allows a state to provide MEDICAID coverage, either in full or in limited form, to certain individuals who have incomes or assets too high to permit them to qualify under the state's eligibility rules but who have "spent down" their income and assets to medically needy eligibility levels by paying for health care services. (See SPEND-DOWN.) In fiscal 2003, 3.5 million medically needy Medicaid beneficiaries received an estimated $27 billion worth of care. Except for their income and asset levels, medically needy individuals must otherwise be members of groups eligible for Medicaid. States may offer fewer benefits to those in its medically needy program than in its regular Medicaid program. However, if they offer coverage to any medically needy populations, they are required to offer it to certain groups and provide coverage for certain services. (In other words, states cannot merely offer LONG-TERM CARE coverage for elderly individuals under a medically needy program.) Mandatory medically needy groups include children under age nineteen and pregnant women, and states must cover prenatal and delivery care for pregnant women and outpatient care for children. In 2005 thirty-four states plus the District of Columbia provided care under a medically needy program. The remaining states provided separate optional Medicaid coverage to institutionalized individuals with incomes up to 300 percent of the level needed to qualify for SUPPLEMENTAL SECURITY INCOME (SSI).

Medicare

The federal program that provided health insurance to 44.6 million elderly and disabled Americans in 2008, Medicare is something of a policy paradox. It is simultaneously one of the most beloved programs run by the federal government and one that provides considerably less in the way of benefits than do most private health insurance plans. It also remains financially unprepared for the impending eligibility of the massive baby boom generation beginning in the year 2010.

History

President Lyndon B. Johnson signed the legislation to implement Medicare (PL 89–97) on July 30, 1965, following a fight that lasted nearly a generation, dating from President Harry S. Truman's failed effort to enact national health insurance in 1949–1950. Johnson signed the bill in Independence, Missouri, Truman's hometown, as a tribute. Backers based their case for creating a government program for health care for elderly people on the low economic status of the over-sixty-five population. In 1962, 47 percent of senior citizens had incomes below the federal poverty line, compared with 13 percent of the rest of the population. At the same time, although older people have more health problems, individual insurance was largely unavailable. Only about 56 percent of seniors had hospital insurance in 1965. And the average senior citizen in 1966, the year Medicare began, spent 15 percent of his or her income for health care services.

Still, President John F. Kennedy was unsuccessful in getting Medicare legislation—one of his top domestic priorities—through a reluctant Congress. It was not until the Democratic landslide in the 1964 elections that Congress was finally willing to make Medicare a reality. But the legislation creating Medicare remained a political compromise.

President Lyndon B. Johnson flips through the text of the landmark legislation that created Medicare at a signing ceremony on July 30, 1965. Former president Harry Truman, pens in hand, had proposed a national health insurance program during his presidency but was unsuccessful in getting it through Congress. *Source: Lyndon B. Johnson Presidential Library/Yoichi R. Okamoto*

Engineered by powerful HOUSE WAYS AND MEANS COMMITTEE chair Wilbur D. Mills, D-Ark., the measure consisted of three parts. One was Medicare's HOSPITAL INSURANCE (HI) program, also known as Part A. This is a "social insurance" program funded by broad-based taxes (in 2008 a 1.45 percent add-on to the Social Security tax paid by all active workers and employers on all of their earnings) and is available to all those eligible for Social Security benefits. This universal program was strongly backed by Democrats and organized labor. The second element was SUPPLEMENTARY MEDICAL INSURANCE (SMI), also known as Part B of Medicare. This optional program, available to all over age sixty-five willing to pay its monthly premiums (originally matched one-for-one by federal dollars) was based on a proposal offered by Republicans and the AMERICAN MEDICAL ASSOCIATION (AMA), mostly in an effort to avoid creation of Medicare's Part A. Finally, the measure created a separate MEDICAID program for poor elderly people and others with very low incomes.

Medicare, which grew quickly, was expanded further in 1972, when certain disabled individuals and those with END-STAGE RENAL DISEASE (ESRD) were made eligible for coverage, although seniors are still Medicare's predominant population. In 2007 the program covered thirty-seven million individuals over age sixty-five and seven million disabled persons (about 400,000 of whom have ESRD).

In 1997 Congress created a Medicare Part C, formally called MEDICARE+CHOICE. This program consisted of private plans (mostly—but not exclusively—MANAGED CARE plans) that provided Medicare beneficiaries with services covered under both Part A and Part B. Many managed care plans, to attract customers, offered benefits Medicare did not normally cover, such as outpatient prescription drugs, foot care, eyeglasses, and hearing aids. Medicare+Choice plans received premiums directly from Medicare under a complex formula based on average spending in the county where the plan is offered. However, because premium increases did not keep up with health inflation in the late 1990s and early 2000s, many plans either cut back on those additional benefits, asked beneficiaries to pay additional premiums, or dropped out of the program entirely.

In 2003 Congress added an outpatient prescription drug benefit to Medicare as part of the MEDICARE MODERNIZATION ACT (PL 108–173). It also replaced the Medicare+Choice program with a revamped (and higher-reimbursed) private plan program known as MEDICARE ADVANTAGE.

Eligibility

Anyone age sixty-five or older who is eligible for Social Security or Railroad Retirement benefits is automatically eligible for Medicare Part A. A worker and spouse become eligible after working forty calendar quarters (ten years) in a qualifying job. Also automatically eligible for Part A are individuals under age sixty-five who have been receiving SOCIAL SECURITY DISABILITY INSURANCE (SSDI) payments for twenty-four months. (Recipients of a related program for the disabled, SUPPLEMENTAL SECURITY INCOME [SSI], are eligible for Medicaid, not Medicare.) Those over age sixty-five who have worked thirty to thirty-nine eligible quarters can purchase Part A coverage if they also enroll in Part B. In 2008 the premium was $233 per month. Those with fewer than thirty quarters could purchase Part A coverage for $423 monthly.

Part B is available on a voluntary basis to anyone who is eligible for Part A and to anyone over age sixty-five

regardless of his or her Part A eligibility. (Those who purchase Part A coverage must also enroll in Part B.) The monthly premium in 2008 was $96.40. For those also receiving Social Security payments, the premium is deducted automatically from their checks. Because it is an excellent buy, and because most supplemental insurance policies require Part B enrollment, the vast majority of Part A beneficiaries (more than 95 percent) also enroll in Part B. Beneficiaries who wish to enroll in a private Medicare Advantage plan must also enroll in Part B and must continue to pay the Part B premium.

Benefits

To overcome initial resistance to Medicare from the medical community—doctors and hospitals—lawmakers designed Medicare to resemble the type of insurance that was typical in the 1960s: insurance that paid for care when people got sick instead of paying for care designed to keep them well. Because most insurance plans of that era did not pay for such items as preventive services, outpatient prescription drugs, or hearing or vision care, neither did Medicare.

Medicare's standard benefit package, typical by 1965 standards, by 2008 looked meager. Although it pays for most "medically necessary care" (see MEDICAL NECESSITY), it excludes most preventive measures, virtually all LONG-TERM CARE expenses (other than rehabilitative care in nursing homes following a hospital stay), most coverage of hearing, vision, dental, and foot care, and, perhaps most important, almost all costs for outpatient prescription drugs. Medicare also includes no "stop-loss" or catastrophic coverage. Most private plans limit the amount a patient must pay for his or her share of covered medical bills each year, often to between $1,000 and $3,000. Congress approved a program to cap Medicare costs in 1988, but it was to be financed by beneficiaries themselves. When beneficiaries objected, the program was repealed in 1989, even before it fully took effect. (See BENEFICIARY and MEDICARE CATASTROPHIC COVERAGE ACT.)

Medicare has improved its benefits somewhat over the years. In the late 1980s and early 1990s, Congress gradually added coverage of annual shots to prevent flu and pneumonia, as well as mammograms to detect breast cancer in women. As part of the 1997 Balanced Budget Act (PL 105–33), Congress beefed up preventive coverage still more, adding more frequent mammograms, pap smears to detect cervical cancer, screening for prostate and colorectal cancer, and coverage of costs for managing diabetes. In 2000, as part of a bill (PL 106–554) to give back to providers some of the deeper than anticipated cuts made in the 1997 measure, Con-

Medicare Premium Amounts for 2008

Hospital insurance (Part A)

- Deductible—$1,024.00 (per benefit period requiring hospitalization)
- Coinsurance—(1) $256.00 a day for the 61st through 90th days each benefit period; (2) $512.00 a day for the 91st through 150th day ("lifetime reserve period"; total of 60 lifetime reserve days, nonrenewable)
- Skilled nursing facility coinsurance—$128.00 a day for the 21st through 100th day each benefit period

Supplementary Medical Insurance (Part B)

- Deductible—$135.00 per year
- Copayment—20 percent of cost of all Medicare-covered services

Part B monthly premium

- $96.40 (standard)

Income-related Part B premium

- Individual beneficiaries with adjusted gross income greater than $82,000 and less than or equal to $102,000 or couples with adjusted gross income greater than $164,000 and less than or equal to $204,000 $122.20
- Individual beneficiaries with adjusted gross income greater than $102,000 and less than or equal to $153,000 or couples with adjusted gross income greater than $204,000 and less than or equal to $306,000 $160.90
- Individual beneficiaries with adjusted gross income greater than $153,000 and less than or equal to $205,000 or couples with adjusted gross income greater than $306,000 and less than or equal to $410,000 $199.70
- Individual beneficiaries with adjusted gross income greater than $205,000 or couples with adjusted gross income greater than $410,000 $238.40

Source: Department of Health and Human Services.

Note: Special rules apply for beneficiaries who are married but file separately if they live with their spouse at least part of the year.

gress added glaucoma screenings and full coverage of outpatient immunosuppressive drugs to prevent rejection in organ transplant patients. And the 2003 Medicare Modernization Act authorized a one-time "welcome to Medicare" physical for those joining the Part B program for the first time, as well as diabetes and cholesterol screenings.

Even with improved benefits, however, Medicare still required beneficiaries to pay a significant amount out-of-pocket for their medical care. In 2008 Part A required a deductible of $1,024 for each benefit period requiring hospitalization. After the first sixty days in the hospital, patients paid $256 per day for days sixty-one through ninety and $512 per day during a "lifetime reserve" period of sixty days. Medicare-covered nursing home stays were fully paid for twenty days; after that, patients were required to contribute $128 per day.

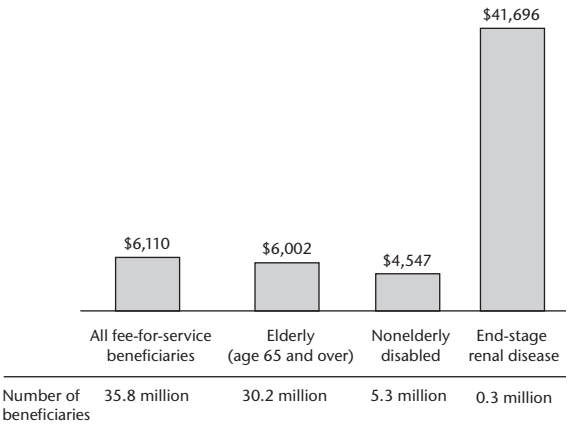
Part B required a $135 annual deductible in 2008 and, after that, a 20 percent copayment for all covered services. For example, if a doctor charged $100 for a service, the patient was responsible for $20 of that amount, assuming Medicare allowed the entire $100 bill under its fee schedule.

Because of Medicare's cost-sharing requirements and the services it fails to cover, beneficiaries in 2003 spent an average of $3,765 per person on health care, about 15.5 percent of the median beneficiary's income. But that was up from under 12 percent only six years earlier. By contrast, nonelderly Americans spend about 8 percent of their incomes on health care. According to a 2007 study published in the policy journal *Health Affairs,* Medicare beneficiaries at every age and income level were far more likely to spend more than 20 percent of their income on out-of-pocket health care cost than their younger counterparts. In 2002 Medicare paid about 52 percent of its beneficiaries' health care costs, ranking it in the bottom 10 percent of health insurance plans.

Cost-Cutting Efforts

Not long after Medicare's inception, its costs began to spiral. Part of the reason was the increase in medical costs overall, particularly as technological advances made more things possible, from organ transplants to joint replacements to new treatments for cancer and other formerly fatal diseases. But a big part, too, was Medicare's "cost-plus" reimbursement, intended to entice providers to serve beneficiaries by paying hospitals, doctors, and other health care purveyors essentially whatever they charged. Between 1975 and 1994 Medicare spending per enrollee grew by an average of 17 percent per year.

Medicare Spending Per Beneficiary, by Eligibility Category, 2002



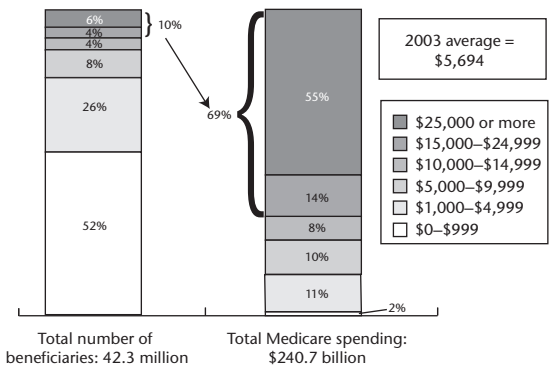
Source: Kaiser Family Foundation analysis of the Medicare Current Beneficiary Survey 2002 Cost and Use File. Reproduced from Henry J. Kaiser Family Foundation, "Medicare Chart Book 2005," no. 7284, July 2005.

Note: Excludes beneficiaries enrolled in Medicare health maintenance organization plans.

Efforts to slow Medicare's rapid spending spiral began as early as 1972, when Congress created Professional Standards Review Organizations (PSROs) to review and control use of Medicare services by beneficiaries. In 1974 Congress imposed the first tentative price controls on Medicare hospital payments.

In 1982 Congress in the Tax Equity and Fiscal Responsibility Act (TEFRA, PL 97–248) imposed a ceiling on hospital payments, prompting outrage from hospitals, which claimed the limits were unfair given their individual circumstances. That paved the way for creation, as part of the 1983 legislation to "rescue" Social Security (PL.98–21), of a new PROSPECTIVE PAYMENT SYSTEM (PPS) for hospitals that based payments on a patient's diagnosis instead of on what the hospital happened to spend to treat that patient. The system created 467 diagnosis-related groups and set a payment according to what the average hospital would spend to treat a

Distribution of Fee-for-Service Medicare Beneficiaries and Expenditures, 2003



Source: Kaiser Family Foundation analysis of the Medicare Current Beneficiary Survey 2003 Cost and Use File. Reproduced from Henry J. Kaiser Family Foundation, *Medicare: A Primer,* no. 7615, March 2007.

patient with that condition. With some allowances for geographic variations and other hospital characteristics (such as whether the hospital has a teaching program), hospitals are paid the same to treat patients with the same condition. The new system reversed the previous incentives, according to which the more services a hospital provided (and the longer a patient stayed), the more the hospital got paid. Under PPS hospitals were given an incentive to become more efficient, because they could keep the excess if care cost less than the predetermined payment, whereas they would have to make up the difference if care cost more.

The new system rapidly brought hospital spending under control, but at the same time, physician spending began to balloon. Throughout the 1980s, Medicare physician spending rose at an average of 15–18 percent per year. That increase led to legislation in 1989 (part of that year's budget reconciliation bill, PL 101–239) to revamp physician spending. Central to the new system was implementation of something called a RESOURCE-BASED RELATIVE VALUE SCALE (RBRVS), devised under 1986 orders from Congress by a group of researchers from Harvard University and refined by the PHYSICIAN PAYMENT REVIEW COMMISSION. The RBRVS measured the time, training, and skill required to perform a given service and was adjusted for overhead costs and geographical differences. It was intended to redress Medicare's tendency to overcompensate for surgery, diagnostic tests, and other procedures and to underpay for primary care services that involved examining and talking to patients instead of performing procedures.

But controlling the price of physician services was only half the battle. To prevent doctors who stood to see lower prices from simply increasing the number of services they provided, the new system also imposed volume controls via an annual Medicare Volume Performance Standard (MVPS), which was to set targets for total spending increases based on the change in the number of beneficiaries, inflation, changes in volume and technology, and other factors. Inflation increases in future years were to be adjusted according to whether the previous year's target was met.

Even with the new hospital and physician payment systems, though, many health care analysts argued that the only way to slow Medicare spending overall was to move away from the program's traditional FEE-FOR-SERVICE orientation and put more beneficiaries into managed care. Congress took the first tentative steps in 1982 budget reconciliation legislation, allowing beneficiaries to join what it called Medicare "risk" plans, health maintenance organizations (HMOs) that agreed to provide all medically necessary care for a preset monthly fee. That fee, known as the Adjusted Average per Capita Cost (AAPCC), was based on 95 percent of the cost incurred by the average Medicare beneficiary in the county where the plan is located. Enrollment grew slowly at first because the plans, like most HMOs, required beneficiaries to give up their free choice of doctors and hospitals and use only providers in the plan's "network." But managed care enrollment took off in the mid-1990s, when plans began to offer attractive new benefits traditional Medicare did not cover, particularly coverage of prescription drugs. By 1998 about 17 percent of beneficiaries had joined managed care plans. (See HEALTH MAINTENANCE ORGANIZATION [HMO]).

In theory, Medicare managed care would appear to save money. Because the payment was 95 percent of the cost of the average beneficiary, the program should have been saving 5 percent for every beneficiary who enrolled. But numerous studies showed that beneficiaries who joined managed care were healthier than average,

thus costing Medicare money over the long run. As part of the 1997 Balanced Budget Act (PL 105–33), Congress moved to slow increases in managed care payments. Among other things, it imposed a 2 percent annual cap on payment increases for most plans. As a result, more than forty plans dropped out of the program for 1999; more than fifty others stopped offering coverage in certain counties. In July 1999 a similar number of plans announced they would leave Medicare in the year 2000. By 2003 a total of 2.4 million beneficiaries had seen their health plans depart the Medicare+Choice program. Although many were able to join other plans, nearly half a million were left no choice but to return to the traditional Medicare fee-for-service program. Most plans that chose to stay in the program found themselves raising premiums and lowering benefits. As a result, Medicare+Choice enrollment dropped to an estimated 4.6 million beneficiaries—about 11 percent of the Medicare population.

In addition to creating the new Medicare+Choice program, the 1997 Balanced Budget Act set in place a series of policies designed to slow Medicare spending dramatically enough to keep the program solvent until the year 2010 (previously the Medicare Part A Trust Fund was projected to run out of money in the year 2001). The success of those efforts, even those only partly implemented, was obvious as early as 1998, when Medicare spending grew by just 1.5 percent, the slowest growth in the history of the program. It also represented the first time Medicare spending had grown more slowly than the federal budget as a whole and the first time in recent years that Medicare had grown at a rate slower than that of private health care spending (which rose by an estimated 4 percent). As a result of the combination of more revenue in payroll taxes, due to the strong economy, and less Medicare spending, Medicare's trustees in March 1999 projected that the Hospital Insurance trust fund would remain solvent until the year 2015.

The spending pendulum, however, would quickly swing back as the century turned. A combination of a weakening economy (producing less in tax revenues), rapid health care inflation in general, and laws passed in 1998, 1999, and 2000 to restore some of the cuts made in the 1997 budget balancing law (see MEDICARE GIVEBACKS) produced another spike in Medicare spending in the early 2000s. Although the trustees reported in 2003 that the program was likely to remain solvent until 2026, that was four years fewer than the trustees projected in 2002.

Medicare's Impending Financial Difficulties

Congress's periodic efforts did succeed in slowing Medicare spending. But Medicare is still financially unprepared for the impending eligibility of the baby boomers beginning in the year 2010. Even after cutting costs, Medicare is consuming an ever-larger share of the nation's health care dollar. In 2006 Medicare spending accounted for roughly 1 of every 5 health care dollars, up from 11 percent in 1970. Even with the savings achieved by the 1997 Balanced Budget Act, Medicare is still growing rapidly, with the program continuing to absorb a growing share of all national resources. According to the CONGRESSIONAL BUDGET OFFICE (CBO), Medicare spending as a share of the nation's total economic output is scheduled to more than double by the year 2035, to more than 7 percent, from its 2007 level of 3 percent.

A major reason for the continuing increase in Medicare spending is the growing number of Medicare enrollees. In 1967 Medicare had 19.2 million beneficiaries; by 2008 that number had more than doubled to 44.6 million. But as the baby boom generation ages, it is threatening to swamp Medicare. The number of elderly beneficiaries is expected to grow to seventy million in 2030 and to eighty-two million in 2050. At the same time, the "graying" of the population means that the percentage of the elderly population will rise from 21 percent in 2003 to 35 percent in 2030. At the same time, the proportion of working Americans who pay the tax that funds Medicare Part A is declining. In 2006, for every Medicare beneficiary, there were 3.9 workers paying the 1.45 percent payroll tax; by 2030 that figure is project to decline to 2.4 workers per Medicare beneficiary.

Medicare is a victim of its own success. Thanks to improvements in medical care, and access to health care made available by the program, Medicare beneficiaries are living longer than ever, with the proportion of

Medicare Data for Calendar Year 2007

		SMI		
	HI or Part A	Part B	Part D	Total
Assets at end of 2006 (billions)	$305.4	$32.3	$0.8	$338.5
Total income	$223.7	$188.7	$49.5	$461.9
Payroll taxes	191.9	—	—	191.9
Interest	16.5	2.2	0.0	18.6
Taxation of benefits	10.6	—	—	10.6
Premiums	2.8	46.8	3.9	53.5
General revenue	0.6	139.6	38.8	179.0
Transfers from states	—	—	6.9	6.9
Other	1.3	0.1	—	1.4
Total expenditures	$203.1	$178.9	49.5	$431.5
Benefits	$200.2	176.4	48.6	425.2
Hospital	128.6	22.9	—	151.5
Skilled nursing facility	22.4	—	—	22.4
Home health care	6.2	9.2	—	15.5
Physician fee schedule services	—	58.7	—	58.7
Managed care	39.0	38.9	—	77.8
Prescription drugs	—	—	48.6	48.6
Other	3.9	46.7	—	50.6
Administrative expenses	$2.9	$2.5	$0.9	$6.3
Net change in assets	$20.7	$9.7	$0.0	$30.4
Assets at end of 2007	$326.0	$42.1	$0.8	$368.9
Enrollment (millions)				
Aged	36.6	34.6	n/a	36.9
Disabled	7.2	6.4	n/a	7.2
Total	43.8	40.9	30.9	44.1
Average benefit per enrollee	$4,573	$4,312	$1,575	$10,460

Source: 2008 annual report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds.

Notes: Totals do not necessarily equal the sums of rounded components. HI is Hospital Insurance; SMI is Supplementary Medical Insurance; and "na" is data not available.

"old-old" (over age eighty-five) rising rapidly. This is important because the oldest beneficiaries need the most medical care and cost the most.

But Congress appeared unlikely to make the changes needed to keep Medicare solvent for the long term much in advance of the impending insolvency. Not only was Congress facing a similar situation for Social Security, but also both programs have proven so politically radioactive in the past that Congress has never been able to impose major changes except in the face of a crisis.

Medicare Advantage

Medicare Advantage is the renamed program of private health plans that serve as an alternative to the traditional MEDICARE program giving patients access to any doctor or hospital, but with a relatively meager benefits package and relatively high cost-sharing requirements. The theory behind Medicare Advantage is that beneficiaries can join a plan that gives them a more limited (in most cases) choice of health care providers in exchange for more generous benefits. Lawmakers who have en-

couraged the growth of private plans in Medicare say that private competition between plans can help hold down Medicare costs, although, in the first years of the Medicare Advantage program, analysts found it cost taxpayers an average of 12 percent more per beneficiary than if those patients had remained in traditional Medicare.

Congress first authorized MANAGED CARE plans to participate in Medicare in the 1970s, although the program did not pick up steam until the mid-1980s. In the early 1990s the program, then known as Medicare Risk, grew in popularity, at least in certain regions, because of the way Medicare paid plans. Those payments, which were based on how much Medicare spent on the average BENEFICIARY in each county, allowed plans to offer extra benefits, often including prescription drugs, and still make a profit in many parts of the country. In other parts of the country, however, those with low average Medicare spending, no health plans offered coverage, because the payments were not high enough. Those were mostly, but not exclusively, rural areas.

As part of the 1997 Balanced Budget Act, Congress tried to fix two problems at once with the Medicare managed care program when it created the MEDICARE+CHOICE program. Congress wanted to offer beneficiaries a greater choice of plan, so it expanded the types of plans that could be offered beyond the traditional HEALTH MAINTENANCE ORGANIZATION (HMO) to other forms of private health plans. And it sought to encourage more of those plans to locate in rural and other underserved areas, by boosting payments.

But in many ways Medicare+Choice backfired. Because the 1997 law was, overall, a budget-cutting measure, and because analysts had long shown that the private plans tended to enroll healthier than average beneficiaries, Congress boosted payments in formerly low-paid areas by cutting them in the formerly high-paid areas. The result was payments that were still not high enough for plans to locate in rural areas, but now too low for plans to remain where they had formerly been profitable. So many plans withdrew from the Medicare market, leaving beneficiaries angry and lawmakers frustrated.

Fast forward to 2003 and creation of the MEDICARE MODERNIZATION ACT. Eager to not have a replay of the exodus of plans that followed the 1997 law, the mostly Republican lawmakers who were convinced that private plans remained the future of Medicare wanted to give a big jump start to the program. So they created Medicare Advantage to make those plans as attractive as possible to both insurance companies and beneficiaries alike.

The new law changed the payment system, allowing plans to submit bids to the government projecting what it will cost the plan to provide Medicare Part A and B services. That bid is compared with a "benchmark" for the area covered. If the bid is above the benchmark, the plan will charge beneficiaries premiums to make up the difference. If the bid is below the benchmark (which most bids through 2008 have been), the government keeps 25 percent of the difference, and the remaining 75 percent is "rebated" back to beneficiaries in terms of reduced cost-sharing or additional benefits Medicare does not normally cover (such as dental or vision care).

In the first three years of the program, Medicare Advantage was successful in enrolling beneficiaries. As of February 2008, some nine million beneficiaries, or roughly one in five Medicare beneficiaries, were enrolled in a Medicare Advantage plan. But Medicare Advantage was not successful in saving the program money. To the contrary, budget analysts worried about the drain it was causing on the program.

According to the GOVERNMENT ACCOUNTABILITY OFFICE, in 2006, the program's first year, Medicare paid $59 billion to Medicare Advantage plans, an estimated $7.1 billion more than it would have spent if those beneficiaries had remained in the traditional Medicare program.

Of particular concern was the rapid growth of PRIVATE FEE-FOR-SERVICE plans. These plans, initially advocated by the NATIONAL RIGHT TO LIFE COMMITTEE (NRLC) as a way to ensure the continued availability of unrationed care, inadvertently became a way for public employee unions and other groups to help their retirees essentially purchase government-subsidized coverage to limit Medicare's cost-sharing. In two years enrollment in the private fee-for-service plans increased eightfold, according to the MEDICARE PAYMENT ADVISORY COMMISSION (MedPAC), to 1.7 million beneficiaries, at a cost of 17 percent more per beneficiary than if that person had remained in the traditional Medicare program.

Medicare Catastrophic Coverage Act

In June 1988 Congress cleared the Medicare Catastrophic Coverage Act (PL 100–360). It was at the time the largest-ever expansion of MEDICARE since its inception in 1965, and it would also prove to be the program's shortest-lived change. Not even a year and a half later, in November 1989, after having been deluged with complaints from angry senior citizens who did not want to pay the bill for the new benefits, Congress repealed the measure in separate legislation PL 101–234).

The catastrophic measure, as it was referred to by lawmakers and lobbyists, was originally intended to fill some of Medicare's most glaring gaps—particularly its lack of any sort of cap on potential out-of-pocket costs. Whereas typical insurance policies (both indemnity and MANAGED CARE) include annual limits beyond which the insurance will pay 100 percent of costs (typically between $1,500 and $5,000 annually), Medicare included no such stop-loss. In fact, Medicare was designed so that the sickest people paid the most, particularly for hospital care, in which the first sixty days are covered (after payment of a deductible, $1,024 in 2008). Thereafter, patients are responsible for an increasing portion of the bill. In 2003 patients were required to pay $210 per day for days sixty-one through ninety and $420 per day during a "lifetime reserve" period of sixty days. After that, Medicare stops paying altogether. In the Part B program for outpatient care, patients are responsible for a 20 percent copayment with no limits. Thus, a $25,000 bill (easily reached for a serious illness) would leave a beneficiary owing $5,000.

The original Medicare catastrophic plan, devised by Otis Bowen, secretary of the HEALTH AND HUMAN SERVICES DEPARTMENT (HHS) and a physician and former Indiana governor, and officially proposed by President Ronald Reagan in February 1987, would have closed only the aforementioned gaps. The plan would have imposed an additional premium of $4.92 per month for unlimited hospital coverage after payment of a single annual deductible and a $2,000 annual cap on Part B out-of-pocket expenses.

But Democrats, having retaken control of the Senate as a result of the 1986 elections, thought the Bowen plan far too meager. They noted Medicare's other major gaps (its lack of coverage of outpatient prescription drugs and paltry coverage of LONG-TERM CARE services) and decided to see if they could build a more ambitious proposal. At the same time, Democrats and some Republicans were worried that merely adding onto Medicare's existing Part B premium—a classic regressive tax, because it is a flat fee paid by all beneficiaries regardless of income—would not help the low-income beneficiaries who most needed the catastrophic coverage. Those were the people too poor to be able to afford private Medicare supplemental MEDIGAP INSURANCE that did fill Medicare's shortcomings for the majority of beneficiaries. Thus, lawmakers wanted not only a broader benefits package (including prescription drug coverage) but also a more progressive financing method.

Some wanted to go further still, most notably House Rules Committee chair Claude Pepper, D-Fla., a longtime crusader for elderly people and much beloved by the nation's senior citizens. Calling the Bowen plan "a pygmy step," Pepper noted—with what would prove great prescience—that Congress ought to expand Medicare as far as it could, even adding hugely expensive long-term care coverage. "If we pass up this opportunity," he said, "we may not come around to this again for another 20 years." (See PEPPER COMMISSION.)

The one thing that held lawmakers back was the consensus requirement that any new benefits had to be fully and openly financed. And Democrats and Republicans agreed that the payers in this case should be those who stood to benefit: Medicare beneficiaries themselves. Although groups representing elderly individuals initially balked at what came to be called "seniors-only" financing, they ultimately made it clear that they would back such a radical change in Medicare financing only if the new benefits were worth it—and that the benefits would be worth it only if they included prescription drug coverage.

The bill signed by President Reagan in a Rose Garden ceremony on July 1 represented what everyone at the time thought would be a workable compromise. It

included an array of new benefits, including unlimited hospital coverage after a single annual deductible, a cap on Part B out-of-pocket costs of $1,370 in 1990 (the first year it would take effect, to be increased thereafter to hold constant the percentage of beneficiaries who would reach the limit at 7 percent), and limited expansions of Medicare's existing nursing home, HOME HEALTH CARE, and HOSPICE benefits. The program also included several benefits new to Medicare, including coverage of outpatient prescription drugs (ultimately Medicare would have paid 80 percent of the cost, after beneficiaries met an annual deductible starting at $600 in 1991); up to eighty hours of RESPITE CARE, paid care to give a break to an unpaid family member or friend who lived with and cared for a chronically dependent Medicare beneficiary; and coverage of mammograms to screen for breast cancer. (After the 1989 repeal of the catastrophic measure, the mammography benefit was added separately to Medicare in 1990 budget reconciliation legislation, PL 101–508.) (See BUDGET RECONCILIATION LEGISLATION AND HEALTH CARE.)

About 37 percent of the cost of the new program was to be financed by a mandatory increase in the Part B premium, starting at $4.90 per month in 1989 (the total premium was $24.80 in 1988), rising to an estimated $10.20 monthly add-on by 1993. The remainder of the program was to be financed by what those who devised the program called a supplemental premium, a surtax assessed on the 40 percent of Medicare beneficiaries wealthy enough to owe federal income taxes of more than $150. In 1989 the supplemental premium (to be paid with 1989 taxes by April 15, 1990) was set at $22.50 per $150 in tax liability, up to a cap of $800 per enrollee.

Although only about 5 percent of Medicare beneficiaries would have had to pay the maximum premium, that message never reached them. A combination of sloppy and incomplete reporting by the news media (one newspaper incorrectly reported that all seniors would have to pay the lower of $800 or 15 percent of their income) and aggressive direct mail campaigns by opponents of the measure (including liberal groups, which disapproved of the seniors-only financing, and conservative, antitax organizations) led to an almost immediate backlash against the new law. Lawmakers' caution in putting the program together also led to another public relations problem. In 1989 all of the financing was being collected to create a contingency reserve for the program, but only the unlimited hospital benefit, which helped the fewest beneficiaries, was in effect. That led many Medicare beneficiaries to feel they were being cheated, and they wasted no time or effort telling their legislators just that.

The iconic moment in the debate came in the summer of 1989, when a protester against the measure, Leona Kozien, separated herself from a throng of sign-waving septuagenarians and draped herself across the hood of HOUSE WAYS AND MEANS COMMITTEE chair Dan Rostenkowski's car after the representative tried to escape a raucous meeting with angry Medicare beneficiaries in his Chicago district. As with much of the protests about the law, the confrontation with Rostenkowski was a set-up—the media had been tipped off in advance. But the pictures of a sweating, obviously uncomfortable, and unabashed defender of the program being harassed by his own constituents had a powerful effect on other members of Congress who were, unlike Rostenkowski, not as clear on the details of the program or its merits.

Ironically, repealing the program proved nearly as difficult as putting it together in the first place. Because the premiums were already being collected, repealing the program would add an estimated $6 billion to the fiscal 1990 deficit, estimated the CONGRESSIONAL BUDGET OFFICE (CBO). Under budget rules, the cost would have to be made up with cuts of that magnitude from elsewhere. And try as they did to find a way to modify the program to make it more acceptable, lawmakers ultimately came up empty-handed. The Senate tried to push a proposal advanced by Sen. John McCain, R-Ariz., that would have eliminated the surtax and left only the expanded hospital benefits. But by November it was clear the entire program had to go. The repeal measure, which waived budget rules so as to not require offsetting cuts, eliminated all of the new Medicare benefits. It left intact only a handful of MEDICAID expansions (including key expansions for pregnant women and

young children, and protection from impoverishment of persons living at home whose spouses were living in nursing homes at Medicaid expense; see SPOUSAL IMPOVERISHMENT) as well as authority for the Pepper Commission, a bipartisan panel charged with devising proposals to cover the uninsured and finance long-term care (the panel was included to pacify the House Rules Committee chair).

Medicare+Choice

Medicare+Choice is the formal name of Part C of Medicare created by Congress in the 1997 Balanced Budget Act (PL 105–33). The theory behind Medicare +Choice was to both save the program money by encouraging beneficiaries to join private health plans, which would accept the risk for the cost of their care, and provide beneficiaries with health care choices that better resembled those available to workers and their families.

Since 1985 Medicare beneficiaries had been able to join a HEALTH MAINTENANCE ORGANIZATION (HMO); as of 1998, about 17 percent of beneficiaries had done so. Moving to MANAGED CARE was attractive to beneficiaries in parts of the country where plans offered additional benefits at no extra cost, including prescription drug coverage, which traditional Medicare did not cover. But Medicare HMOs were largely the old-fashioned type, with enrollees required to seek care only from providers within the plan's network. That requirement deterred many beneficiaries, particularly those with long-standing relationships with doctors, hospitals, or other health care providers.

Medicare+Choice sought to expand the types of choices available to Medicare beneficiaries. It authorized Medicare preferred provider organizations (PPOs) and point of service (POS) plans that permitted enrollees to more easily seek care from outside a health plan's network, although at a somewhat higher cost. To encourage the development of managed care in rural and other areas where Medicare managed care payments were traditionally lower, the measure also authorized creation of PROVIDER-SPONSORED ORGANIZATIONS (PSOs). These were groups of doctors, hospitals, or other health delivery professionals who would band together to offer insurance. (See PREFERRED PROVIDER ORGANIZATION [PPO] AND POINT OF SERVICE [POS] PLAN).

At the urging of conservative members of Congress, Medicare+Choice also included authority for a variety of non–managed care private plans. Among those were PRIVATE FEE-FOR-SERVICE plans that allow enrollees to leave traditional Medicare but continue to see any doctor or use any health facility. Doctors in those plans would not have to abide by Medicare fee limits. The plans were allowed at the urging of the NATIONAL RIGHT TO LIFE COMMITTEE (NRLC), a leading antiabortion group that also worked against euthanasia and health care rationing. The group argued that if the traditional Medicare program continued to see its budget squeezed, providers would drop out rather than accept the lower fees and that beneficiaries would not be able to receive adequate care. In the private plans, patients could continue to obtain unrationed care, albeit at a likely higher out-of-pocket cost.

Also authorized under Medicare+Choice were MEDICAL SAVINGS ACCOUNTS (MSAs). Under the law, up to 390,000 beneficiaries could open the accounts between 1999 and 2002. No companies stepped forward to offer the plans to Medicare beneficiaries, however, and the authority was allowed to expire after 2002.

Not only did the law encourage beneficiaries to join private plans by allowing more types to be offered, but it also encouraged more plans to be offered in more places by altering the payment system. Because Medicare payments to private plans were based on historical costs within each county, payments varied widely. In 1997 they ranged from a low of $221 per beneficiary per month in Arthur County, Nebraska, to a high of $767 in Richmond (Staten Island), New York. The Balanced Budget Act sought to lessen the variation in three ways. First, it imposed a minimum payment for the lowest paid areas (in 2003 the payment was $547.54 per month for counties with populations of twenty-five thousand or more and $495.39 for smaller counties). Then, to prevent plans that had been receiving high payments from dropping out, it guaranteed increases of 2 percent per year for all areas. Finally, to raise payments in relatively low-paying areas not affected by the new floor, the law

called for a "blend" of regional and national payment rates to be phased in gradually.

Altogether, the CONGRESSIONAL BUDGET OFFICE (CBO) estimated that by the year 2005, 34 percent of beneficiaries would be enrolled in a private Medicare+Choice plan, more than double the percentage in 1998. By 2003, however, it was obvious that the changes had backfired. One problem was the payment rates. Because of the required floor and the 2 percent increases, no money was left to implement the blended rate without exceeding the total amount of funds set aside for the program. In the end, the rates in the low-paid areas remained too low to attract many new plans, whereas the constraints in the higher-paid areas (the 2 percent was not only a floor but also a ceiling for rate increases) prompted plans to either drop out of Medicare altogether or reduce the number of counties in which they participated. Between 1999 and 2002, the number of Medicare+Choice plans dropped from 346 to 149, a decline of more than half. Between 1998 and 2003, 2.4 million Medicare beneficiaries found themselves required to find a new HEALTH PLAN, with some 409,000 living in counties with no other managed care plans from which to choose.

At the same time, fewer companies than expected applied to offer the new types of Medicare+Choice plans. By the time the program officially kicked off January 1, 1999, only one PSO had been approved (to offer an HMO product in Oregon), and no MSAs or other types of plans were available. In 2003 the Centers for Medicare and Medicaid Services launched a special program to try to entice PPOs to join Medicare+Choice by offering special financial incentives. The 2007 MEDICARE MODERNIZATION ACT (PL 108–173) largely replaced Medicare+Choice with a new private plan program, MEDICARE ADVANTAGE.

Medicare givebacks

When Congress cleared the Balanced Budget Act in 1997, it was intended to put the MEDICARE program back on firmer financial footing by cutting payments to such providers as hospitals, nursing homes, HOME HEALTH CARE agencies, and MANAGED CARE plans by what was supposed to be a combined $112 billion over five years. But enactment of the bill coincided with an unexpected slowdown in health inflation and new fraud-fighting efforts that depressed spending further. As a result, the formula-based reductions went much deeper than lawmakers planned or expected. By 1999 the CONGRESSIONAL BUDGET OFFICE (CBO) estimated that Medicare spending would slow by $206 billion instead. When providers complained that the cuts were jeopardizing their solvency and, in turn, care for patients, it set off a round of new bills to give back some of the cuts.

The first round of givebacks came in 1998, part of a fiscal 1999 omnibus spending bill (PL 105–277). It restored some $1.7 billion over five years to home health agencies, which complained that an interim payment system put in place while Medicare officials worked to devise a permanent system was cutting too deeply. The fix was expected to provide increases to 65 percent of home health providers and hold the rest harmless.

That bill, however, proved barely an appetizer for the measure Congress would pass in 1999. The Balanced Budget Refinement Act (PL 106–113) restored an estimated $16 billion over five years to hospitals, managed care plans, nursing homes, home health agencies, and HOSPICE and kidney dialysis providers. The BBRA, as it became known, also included new preventive benefits for Medicare beneficiaries, including higher payments for Pap smears to detect cervical cancer in women and broader coverage of immunosuppressive drugs for organ transplant patients.

Providers, however, almost immediately said the funds were not enough. A witness for the AMERICAN ASSOCIATION OF HEALTH PLANS (AAHP) told the HOUSE WAYS AND MEANS COMMITTEE in July 2000 that the 1999 bill "provided only a small fraction of the resources that are needed to fully stabilize the [Medicare managed care] program." Independent analysts, however, disagreed. Despite claims to the contrary from providers, "there is no systematic evidence that access to care is being compromised," the head of the MEDICARE PAYMENT ADVISORY COMMISSION (MedPAC) testified at that same hearing.

Nevertheless, the pleas of providers won out in the end. The Beneficiary Improvement and Protection Act (BIPA, PL 106–554) provided an estimated $35 billion over five years for Medicare providers, new services for

patients, and expansions to MEDICAID and the STATE CHILDREN'S HEALTH INSURANCE PROGRAM (SCHIP).

As with the earlier bill, hospitals were the primary beneficiaries of BIPA, winning approximately $14 billion in increases. Another $11 billion was to boost payments to managed care plans, with an estimated $1.6 billion for nursing homes and $1.7 billion for home health agencies.

To answer a growing chorus of complaints from beneficiary groups that Congress was serving the needs of health care providers at the expense of patients, the measure authorized several new benefits. They included new coverage for preventive screenings for various cancers, nutritional therapy for patients with diabetes, unlimited coverage of immunosuppressive drugs for organ transplant patients, and automatic eligibility for Medicare for patients under age sixty-five suffering from Lou Gehrig's disease. Most patients with that diagnosis died before Medicare's twenty-four-month waiting period to qualify on the basis of disability was up.

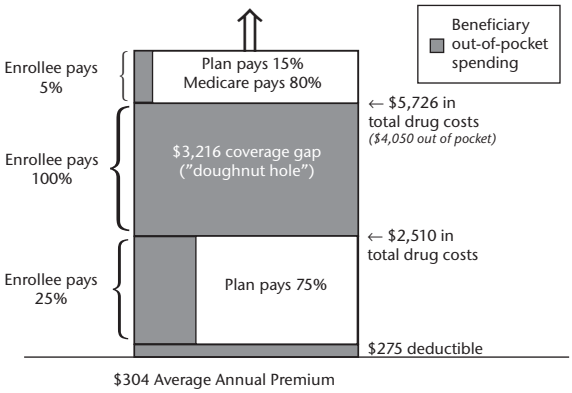
At the insistence of Democrats and President Bill Clinton, who was cool to the idea of another round of givebacks in the first place, the bill also provided roughly $1 billion for Medicaid and SCHIP, including $300 million to make it easier for families to enroll their children in the latter program.

Medicare Modernization Act

The Medicare Modernization Act (PL 108–173), signed by President George W. Bush on December 8, 2003, was at once the largest expansion of MEDICARE since its inception and the most controversial. Passed with largely Republican support, it achieved a goal long sought by Democrats: adding an outpatient prescription drug benefit to Medicare. But it added that benefit in a way aimed at ensuring continued profits for pharmaceutical and insurance companies. And at the same time it made other structural changes to Medicare aimed at bringing more private sector involvement to the program.

Passing the bill with barely a handful of Democratic votes in the House and Senate, Republican sponsors had no easy task keeping together their own majority. Fiscal conservatives balked at adding a new entitlement to

Standard Medicare Prescription Drug Benefit, 2008



Source: Henry J. Kaiser Family Foundation, "The Medicare Prescription Drug Benefit—An Updated Fact Sheet," no. 7044-08, February 2008.

Note: Annual premium amount based on $27.93 national average monthly beneficiary premium (Centers for Medicare and Medicaid Service, August 2007). Amounts are rounded to nearest dollar.

Medicare, particularly the $400 billion, ten-year price tag for the new drug benefit. To win their votes, Republican leaders added provisions authorizing new HEALTH SAVINGS ACCOUNTS (HSAs) and creating fast-track consideration of subsequent legislation to hold down overall Medicare spending.

Sponsors also struggled to keep the support of the senior group AARP, which insisted that the drug benefit provide help to those with low incomes and encourage employers not to drop existing retiree drug coverage; health care providers, who wanted increased Medicare reimbursements; and a drug industry fearful that a government drug benefit would lead to government price controls.

In the end it was somehow fitting that such a controversial bill would pass in a controversial way, with a middle-of-the-night vote in the House that leaders held open for two hours and forty-five minutes beyond the usual fifteen minutes to twist enough arms to muster the majority needed.

Major Provisions

The centerpiece of the legislation was the bill's prescription drug benefit. Instead of simply adding prescription drugs to Medicare's existing benefit package, as Democrats had been urging for years, Republican ar-

Medicare Prescription Drug Benefit Low Income Beneficiary Cost Sharing, 2008

Beneficiary income level	Annual deductible	Monthly premium	Beneficiary out-of-pocket spending for total drug expenditures: ≤ $5,726	> $5,726
≥ 150% FPL (standard benefit)	$275	$25 (average)	25% from $275 to $2,510; 100% from $2,510 to $5,726	Greater of 5% or $2.25–$5.60 copay
135–150% FPL[a]	$56	$0–25	15% from $56 to $5,726	Copayment of $2.25 generic, $5.60 brand name
100–135% FPL[a]	$0	$0[b]	Copayment of $2.25 generic, $5.60 brand name	$0
≤ 100% FPL[a]	$0	$0[b]	Copayment of $1.05 generic, $3.10 brand name	$0

Source: Centers for Medicare and Medicaid Services.

Notes: FPL is the federal poverty level.

a. At these income levels, beneficiaries must also meet an asset test.

b. Monthly prescription drug premium will be $0 if beneficiary enrolls in a basic Part D plan with a premium that is below the low-income premium subsidy amount (or within $1 of the premium subsidy amount).

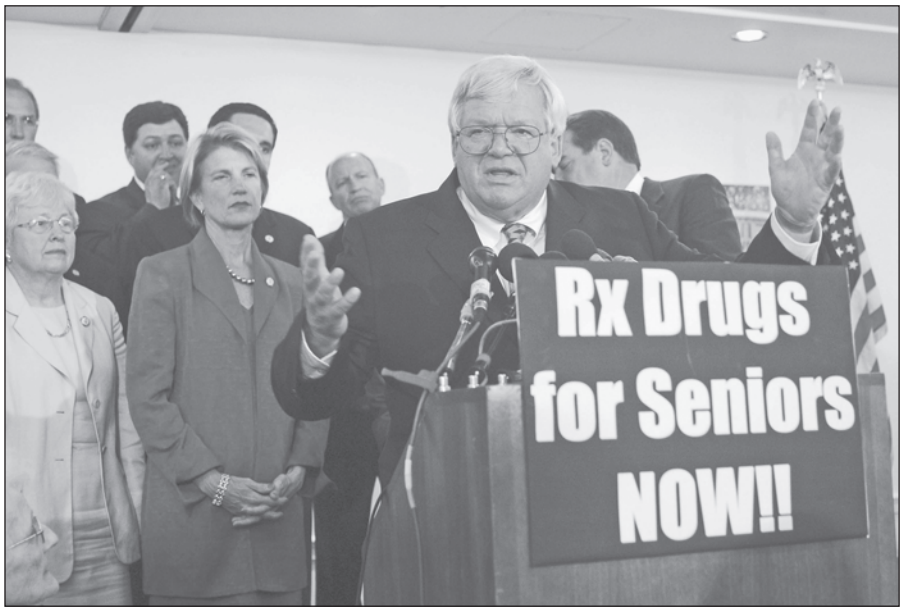
chitects decided to put the benefit in the hands of the private sector. They hoped that by having private plans compete for beneficiaries' business, the overall cost of the benefit would be held down.

Medicare enrollees were given two options for drug coverage: stand-alone prescription drug plans or private MEDICARE ADVANTAGE health plans that offer drug coverage.

Stand-alone drug plans were required to offer either a standard benefit or a benefit equivalent in value. In 2008 the standard benefit had an annual DEDUCTIBLE of $275, then required beneficiaries to pay 25 percent COINSURANCE up to an initial coverage limit of $2,510 in drug costs. After that, beneficiaries fell into a coverage gap referred to as the "doughnut hole," during which they continued to pay monthly premiums but also had to pay the full cost of their medicines. If those beneficiaries incurred more than $4,050 in out-of-pocket drug costs, the coverage would resume and pay 95 percent of drug spending for the remainder of the year.

Special rules were implemented for Medicare beneficiaries with low incomes. Those with the very lowest incomes, who are DUAL ELIGIBLES for Medicare and MEDICAID, had their drug coverage transferred from Medicaid to private Medicare drug plans and were randomly enrolled in plans if they did not choose one themselves. Medicare also automatically enrolled in private drug plans, with special subsidies, low-income Medicare beneficiaries who are enrolled in other so-called Medicare Savings Programs, such as the QUALIFIED MEDICARE BENEFICIARY (QMB) program. Other low-income Medicare enrollees, those with incomes under 150 percent of poverty, were eligible for reduced premiums and copayments, but only if they met both an income and asset test. Those with incomes under 135 percent of poverty would also have to prove they had no more than $7,790 ($12,440 for a couple) in possessions other than a house, car, burial plot, and a life insurance policy worth no more than $1,500 in 2008. Those with incomes under 150 percent could have no more than $11,710 in assets for an individual and $23,410 for a couple.

To appease House conservatives, the final bill included an income-related premium for Part B (replacing the House bill's income-related catastrophic drug



House Speaker Dennis Hastert (R-Ill) speaks at a June 26, 2003, rally supporting the Medicare Modernization Act. *Source: CQ Photo/Scott J. Ferrell*

benefit), with those earning more than $80,000 in 2007 ($160,000 for couples) paying a premium equal to 35 percent of program costs, compared with 25 percent for those under the threshold. Premiums would rise gradually, with those earning more than $200,000 ($400,000 for couples) paying a premium worth 80 percent of program costs.

Also to win conservative votes, the bill included the House measure's Health Savings Accounts provisions, making anyone with a health plan with a deductible greater than $1,000 ($2,000 for family coverage) eligible to open tax-preferred accounts in which funds could be invested before taxes and spent tax-free on medical expenses.

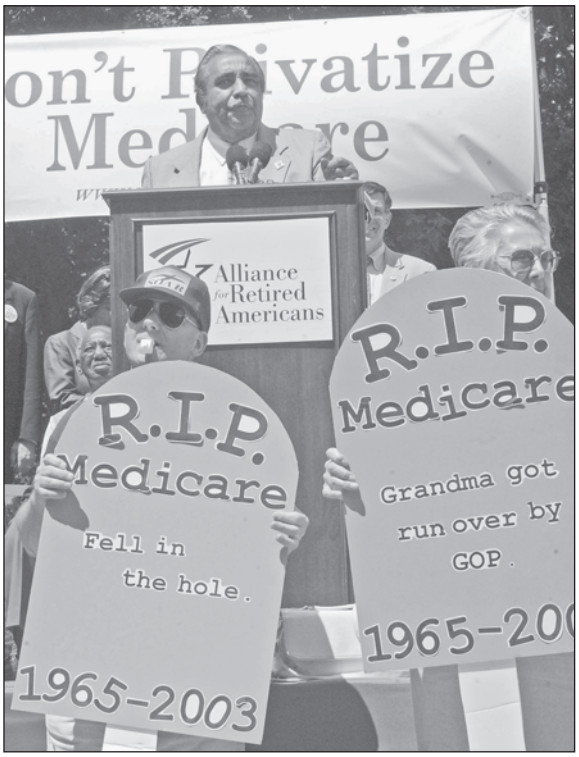
To staunch the flow of employers away from offering prescription drug coverage to their retirees (and to win the critical backing of the AARP), the law provided subsidies to employers continuing such coverage. The subsidies were equal to 28 percent of the costs of qualifying prescription drug coverage above $250, up to $5,000 per retiree. Those thresholds were to be indexed in future years according to the increases in per capita drug spending per Medicare beneficiary.

Health care providers, particularly physicians and hospitals, were brought on board with payment increases.

But probably the biggest change made by the new law, arguably even bigger than the drug benefit itself, was the creation of the Medicare Advantage program. Republican sponsors and President Bush felt strongly that the future of Medicare lay in injecting more private sector competition into the government program. So they changed the payment structure for the then languishing MEDICARE+CHOICE program, made it easier for plans to participate, and, most important, boosted payments to the private plans considerably. The strategy worked. By 2008 Medicare Advantage enrollment had jumped to nearly one in five Medicare beneficiaries. But according to most budget analysts, that came at a steep price to the nation's taxpayers. By 2008, according to the CONGRESSIONAL BUDGET OFFICE (CBO), Medicare Advantage plans were receiving on average 12 percent more per beneficiary than the cost would have been if those individuals had remained in the traditional Medicare program.

Legislative History

Democrats had been agitating to add a prescription drug benefit to Medicare since the 1989 repeal of the short-lived MEDICARE CATASTROPHIC COVERAGE ACT. By the late 1990s Medicare's lack of an outpatient prescrip-



Democrat Charles B. Rangel (NY) speaks at an event on June 24, 2003, with senior citizens blowing whistles in protest of the Medicare Modernization Act. Source: CQ Photo/Scott J. Ferrell

tion drug benefit had once again become a major political issue. Thanks in large part to a 1992 law that speeded up the drug approval process, drugmakers were delivering to market a broad array of new medicines to treat ailments that disproportionately affected elderly Americans, such as arthritis, high blood pressure, high cholesterol, and diabetes. At the same time, drug prices and drug spending were skyrocketing.

Most of the working-age population—at least the majority with health insurance coverage—were shielded from most of the increases. Many Medicare beneficiaries had some drug coverage as well, either through retiree health plans, Medicare+Choice managed care plans, Medicaid, or MEDIGAP INSURANCE supplemental plans. But a third of all beneficiaries had no drug coverage, and many were forced to pay drug costs that often left them choosing between their medicines and their meals or their medicines and their utility payments.

Congress and the Clinton administration hoped that the NATIONAL BIPARTISAN COMMISSION ON THE FUTURE OF MEDICARE, ordered by the 1997 Balanced Budget Act, could reach consensus on a way to add prescription drug coverage and shore up the program's finances for the baby boomers to come. But that group fell a single vote short of the number needed to forward recommendations to Congress, which laid bare a schism that would continue to stymie the efforts. On one side were Republicans and a few moderate Democrats who believed it would be fiscally and morally irresponsible to add an expensive new prescription drug benefit to the program without also making changes intended to put Medicare on a more stable financial footing. On the other side were Democrats and a few moderate Republicans who wanted drug coverage first and other reforms later.

President Clinton proposed a plan in 1999 that would have used 15 percent of the projected budget surplus to underwrite a plan that would have beneficiaries pay a $24 monthly premium in exchange for half the cost of the first $2,000 worth of drugs. When the plan was fully phased in, it was estimated to have cost $44 per month to cover half the cost of the first $5,000 worth of drugs. The proposal also included incentives for employers to maintain prescription drug coverage in existing retiree health plans.

But Republicans in Congress had very different ideas. On June 28, 2000, the House, on a nearly party-line vote of 217-214, passed a bill that would have relied heavily on private companies creating new policies that would provide prescription drug–only coverage. The structure was similar to what would emerge in 2003: after payment of a deductible, the program would have covered half of the next $2,100 in drug costs, then nothing unless the beneficiary spent more than $6,000 in a year, in which case catastrophic coverage would see to the remainder of drug costs in full.

But the insurance industry was skeptical of whether such a scheme would work. Officials feared only those who knew they would need coverage would sign up. And the Senate failed to reach agreement on a bill of its own, leaving the issue to die for yet another Congress.

President George W. Bush tried to shift the focus of the debate in July 2001, when he issued a series of

principles for Medicare reform, including the goal of making subsidized drug coverage available to all beneficiaries. The centerpiece of Bush's plan, however, an immediate "drug discount card" program that would have been provided by private PHARMACY BENEFIT MANAGERS (PBMs) and could have provided discounts to beneficiaries while Congress pursued broader changes, ran into trouble. Pharmacy groups, which feared they, not the PBMs, would be expected to underwrite the discounts, sued. They said that, in establishing the program, Medicare officials overstepped their authority. A federal judge agreed, and the program was scrapped.

The terrorist attacks of September 11, 2001, on New York City and Washington, D.C., delayed the Medicare debate until 2002. As it did two years earlier, the House passed a bill with almost exclusively GOP support. The measure, passed 221-208 on June 28, was only slightly different from the earlier bill. Again, it envisioned drug-only coverage to be provided by private firms, which would have been subsidized by the government. The standard benefit under the plan would have provided more help to those with lower drug costs, in recognition of the criticism of the 2000 measure.

Still, Democrats said the plan was not generous enough. "This is a pitiful, pathetic, puny pretend plan," said Jerrold Nadler, D-N.Y. But Republicans said the Democrats' alternative, on which the Democrats were denied an up-or-down floor vote, would have broken the Medicare bank. That proposal, estimated to cost upward of $900 billion over the ensuing decade, compared with about $300 billion for the GOP plan, would have provided for a $25 monthly premium, $100 deductible, and 80 percent coverage up to $2,000 in out-of-pocket spending. After that, all costs would be covered.

The Democratic-controlled Senate, meanwhile, continued to struggle. In July 2002 Senate leaders brought to the floor a bill intended to help hold down drug costs by making it easier for GENERIC DRUGS to get to market. Leaders hoped that during the debate a deal could be reached to add a Medicare drug plan to the generics bill.

It was not to be, however. Altogether, senators voted down four separate Medicare drug plans, each of which needed sixty votes to prevail because the Senate had failed to pass a budget resolution that year. A bill offered by Sen. Bob Graham, D-Fla., got the most votes: fifty-two. It would have provided, for a $25 monthly premium and no deductible, all drugs for flat copayments: $10 for generic drugs, $40 for "preferred" brand-name drugs, and $60 for nonpreferred brand-name medications. Those with out-of-pocket spending above $4,000 in a year would have the remainder of their costs covered.

When the House refused to take up the Senate's generic drug bill and the Senate opted not to act on the House's Medicare bill, the issue died for the third consecutive Congress.

When Republicans took over the Senate after the 2002 elections, giving the GOP control of both houses of Congress and the presidency, it became clear they would have to deliver on the repeated promise of Medicare reform. The unexpected elevation to Senate majority leader of Bill Frist, R-Tenn., a heart-lung transplant surgeon elected to the Senate in 1994, gave health issues a higher profile still.

The Bush administration in January indicated that it planned to side with those who wanted to make reforms and to add drug coverage. Officials leaked word that the president's plan would provide drug coverage only to those beneficiaries who agreed to join a private managed care plan. But even Republicans who favored reforms found that difficult to swallow. SENATE FINANCE COMMITTEE chair Charles E. Grassley, R-Iowa, spoke for many rural members in expressing concerns about the dearth of private plans in their states and said he would not support a proposal that did not also offer benefits to those in Medicare's traditional government-run program. HOUSE ENERGY AND COMMERCE COMMITTEE chair Billy Tauzin, R-La., concurred, saying it would take "a bulldozer" to get his mother to leave traditional Medicare.

President Bush backed down, unveiling a proposal before the AMERICAN MEDICAL ASSOCIATION (AMA) in March 2003 that called for more generous benefits for those who joined private plans but some coverage for those who remained in the traditional program. That, however, was still not enough for Republicans in Congress. Any Medicare reform bill would have to offer equal benefits to those in public or private plans.

The House and Senate quickly went their separate ways. The fiscal 2003 budget resolution set aside $400

billion over ten years for the effort to extend drug coverage to Medicare, but lawmakers had very different ideas about how to spend the money.

The Senate, mindful of the 2002 standoff and the fact that Democrats could block a bill using delaying tactics, opted for a bipartisan approach. The measure initially crafted by Finance chair Grassley and the committee's top Democrat, Max Baucus, D-Mont., won the important endorsement of Edward M. Kennedy, D-Mass., the chamber's leading liberal on health policy matters. Following a two-week floor debate during which Democrats tried and mostly failed to make the drug benefit larger, the Senate ultimately passed the bill June 26 by 76-21.

The Senate bill called for prescription drug coverage to be provided either through private managed care plans or privately run, free-standing drug-only policies. It envisioned a $35 monthly premium, a $275 annual deductible, and coverage of half of the next $4,225 worth of prescription drugs. After that, beneficiaries would fall into a gap in coverage designed to stretch the $400 billion as far as possible. Beneficiaries with drug spending higher than $5,813 would have 90 percent of their remaining drug costs covered for the year.

The House bill, by contrast, was front-loaded to make the drug benefit as attractive as possible. Like the Senate plan, it envisioned a $35 monthly premium (in both cases, plans would be free to set the premium as they saw fit), a $250 deductible, and coverage of 80 percent of costs up to $2,000. After that would come the same sort of coverage gap as in the Senate bill, with 100 percent coverage of catastrophic drug costs for those with spending above $4,900 a year. The House bill, however, also included an income-related premium for drug coverage, requiring those beneficiaries earning more than $60,000 to pay more of their own drug costs before the catastrophic coverage would begin. Those with the highest incomes, above $200,000, would have to spend $11,600 of their own money before coverage would resume.

Although the drug benefits were similar, other key provisions of the bills reflected deep philosophical divisions about the role of government versus the role of the private sector. For example, the Senate bill included a government-provided fallback prescription drug plan in areas where two private plans failed to offer coverage, a provision demanded by Democrats. Republicans complained that the language could quickly lead to the government-run plan taking over the entire program.

At the same time, to win support of conservatives, the House GOP bill included a variation of the "premium support" structure for Medicare devised by the unsuccessful National Bipartisan Commission on the Future of Medicare in 1999. Under the proposal included in the House Medicare bill, starting in 2010 private plans would compete on price with Medicare's traditional fee-for-service plan, with beneficiaries required to pay more for more expensive plans, but keeping some of the savings if they opted for a less expensive plan. Democrats complained that the premium support mechanism could result in the government plan's premiums rising too high for many beneficiaries to afford, effectively forcing them into private plans against their will.

Even with those provisions designed to appeal to conservatives, however, as well as appending to the Medicare measure the health savings accounts provisions, House GOP leaders still had trouble finding enough support for the measure. With virtually no support from Democrats, the bill passed by the narrowest of margins, 216-215, after a 2 A.M. roll call June 27 (legislative day June 26), which leaders had to keep open nearly forty-five minutes beyond the usual fifteen, while they persuaded enough Republicans to switch votes to ensure the measure's passage.

The House-Senate conference got off to a slow start. By early September, the seventeen members (ten Republicans and seven Democrats) had agreed on only two substantive portions of the massive bill. One incorporated a "regulatory reform" measure passed by the House in previous Congresses to help physicians and other health care providers receive "due process" from Medicare officials fighting fraud and to limit how frequently Medicare could change its voluminous rules. That section of the bill also gave Medicare more authority over the private insurance companies they contract with to process the program's claims.

The other agreement reached by all conferees called for an interim program to provide prescription drug discount cards until the main drug program began in

2006. Those discount cards, to be offered by pharmacies and pharmacy chains, insurance companies, pharmacy benefit management firms, and others, would cost beneficiaries up to $30 per year, in exchange for discounts the Bush administration estimated would be up to 25 percent. Individuals with incomes below 135 percent of poverty would get the cards without charge and would be eligible for a $600 subsidy for each of 2004 and 2005.

By mid-September, however, HOUSE WAYS AND MEANS COMMITTEE chair Bill Thomas, R-Calif., who was leading the negotiations, decided to make a change. He took all ten Republican conferees and two of the seven Democrats—Sens. Baucus and John B. Breaux of Louisiana—behind closed doors to continue the talks in secret. Thomas called the group "the coalition of the willing," implying that the five remaining Democratic conferees, who included Senate minority leader Tom Daschle, D-S.D., would be unwilling to reach any compromise.

For several weeks it appeared that even the relatively like-minded group of twelve would be unable to agree, and a self-set October 17 deadline came and went with little discernible progress. Meanwhile, outside the talks, Democrats in the Senate and conservatives in the House were hardening their positions. A total of forty-four senators, which was more than enough to sustain a filibuster against the bill, signed a letter to conferees vowing not to vote for a final bill if it included the premium support provisions of the House bill. Thirteen of the Republicans who voted for the bill (and provided more than its margin of victory) wrote a similar letter vowing not to vote for the bill unless premium support was part of it.

With time running short before a planned Thanksgiving adjournment for the first session of the 108th Congress, negotiators produced an eleventh-hour compromise. On Saturday, November 15, House and Senate GOP leaders, along with Baucus, Breaux, and the senior group AARP, announced they had agreed on a bill. What sprung the final compromise, they said, was a deal to solve two problems at once. Making employer contributions to retiree health plans tax-free would reduce, from about one-third to one-quarter, the number of employers expected to stop providing that coverage. That would slightly lower the number of Medicare beneficiaries expected to take advantage of the bill's new subsidies, thus freeing up several billion dollars negotiators then used to beef up coverage for those with incomes under 150 percent of poverty. The contentious premium support plan was turned into a six-year demonstration program in six areas around the country, beginning in 2010. The demonstration program would limit potential increases in the traditional program's Part B premiums.

The compromise drug benefit, to begin in 2006 and be offered either as stand-alone plans or as part of broader private coverage, called for a deductible of $250, then 75 percent coverage of the next $2,000 in drug expenses. After $2,250, beneficiaries would have to cover all their own expenses unless their out-of-pocket spending topped $3,600 (meaning consumption of $5,100 of drugs), after which the plan would pay 95 percent of remaining costs for the year. Monthly premiums were estimated to average $35 in 2006, although that was not written into the legislation.

As in the House bill, the estimated six million beneficiaries dually eligible for both Medicare and Medicaid would get the new Medicare benefit, although states would have to return most of the savings to the federal government and would be limited in how much they could use Medicaid funds to augment the new Medicare coverage. That left many analysts predicting those beneficiaries would end up with less generous coverage than they had through Medicaid.

Individuals with income between poverty and 135 percent of poverty would pay no premium, have no deductible, and pay only $2 for each generic drug prescription and $5 for each brand-name drug. Those with incomes between 135 percent and 150 percent of poverty would pay a sliding-scale monthly premium, a $50 annual deductible, and 15 percent cost-sharing up to the out-of-pocket limit, after which they would pay $2 per generic drug and $5 per brand-name medication.

Despite promises made to some moderate Republicans to win their votes needed to get the bill through the House in June, conferees dropped from the final measure a broad House-passed bill making it easier for individuals to "reimport" drugs from Canada and other in-

dustrialized nations. (See REIMPORTATION, PRESCRIPTION DRUG.) But the bill did include changes to make it harder for brand-name drug companies to delay market entry of generic competition.

Even with the backing of the AARP and President Bush, getting the final bill through both houses was no easy feat. The House roll call began around 3 A.M. on November 22, less than two days after the bill's text and final cost estimate ($395 billion over ten years) were made public. As predicted, conservatives balked, saying the bill included too big an expansion of an entitlement program and too little in the way of program reforms. Twenty-six Republicans initially voted against the bill, and the roll call stood at 216 for and 218 against for nearly two hours. Finally, shortly before 6 A.M., after personal calls from President Bush, two Republicans changed their votes. That prompted a flurry of changes on both sides, and Republicans quickly gaveled closed the tally at 220-215, marking the longest roll call in House history.

The Senate vote was less dramatic, but not by much. While opponents of the measure, led by Daschle and Kennedy, failed to mount a filibuster, they tried to block the bill on a technicality, raising a "point of order" that the bill violated the budget because money for health care providers would start flowing in fiscal 2004. The November 24 vote to "waive" the point of order, which required sixty votes, stood at fifty-nine for several minutes, until former Senate majority leader Trent Lott, R-Miss., agreed to switch his vote. The final tally was 61-39, with Ron Wyden, D-Ore., joining Lott. In what amounted to a formality, the Senate approved the bill the next day by 54-44.

Medicare Payment Advisory Commission (MedPAC)

Created by Congress in the 1997 Balanced Budget Act (PL 105–33), the Medicare Payment Advisory Commission (MedPAC) consults Congress on provider payment policies and on general quality of care issues for MEDICARE beneficiaries. MedPAC was formed by merging two previous advisory bodies, the PROSPECTIVE PAYMENT ASSESSMENT COMMISSION (ProPAC), which oversaw Medicare hospital payments, and the PHYSICIAN PAYMENT REVIEW COMMISSION, which monitored Medicare physician payments. Like its predecessors, MedPAC is required to report to Congress each year (by March 1) with recommendations on Medicare payment policies, in light of other changes in the nation's health care system. Congress in 1998 expanded the panel's membership from its original fifteen to seventeen (in that year's omnibus spending bill, PL 105–277).

Medigap insurance

Also known as Medicare supplemental insurance, these are private policies that fill the gaps in basic MEDICARE coverage. In 2003 more than a quarter of Medicare benficiaries had privately purchased Medigap coverage, according to the Kaiser Family Foundation. (Most other Medicare beneficiaries had other forms of protection from high Medicare out-of-pocket costs, either through a plan provided by a current or former employer, a private Medicare plan, or the joint federal-state Medicaid program.) (See BENEFICIARY.)

Congress has regulated the sale of Medigap insurance since 1980, after a 1978 investigation by the House Select Committee on Aging uncovered numerous abuses in the marketing and sale of Medigap policies. In 1988, however, abuses were clearly continuing. A study by the General Accounting Office found that one-third of Medigap insurers failed to meet the 1980 target that plans return 60 percent of premium dollars in benefits for individual policies and two-thirds failed to meet the 75 percent loss ratio for group policies. (Loss ratio is the percentage of premiums paid out by an insurance company for actual medical care. The higher the loss ratio, the more money is spent on actual care and less on administration, overhead, advertising, or profits.) (See LOSS RATIOS.) Medigap insurers also sold policies that duplicated benefits covered by Medicare and that duplicated each other. Congress tightened the restrictions again in 1988 as part of the MEDICARE CATASTROPHIC COVERAGE ACT (when that law was repealed in 1989, the Medigap provisions were left in law). Then, in 1990,

Standardized Medigap Plans and Benefits, 2008

Benefits	*A*	*B*	*C*	*D*	*E*	*F***	*G*	*H*	*I*	*J***	*K*	*L*
Hospital coinsurance Coinsurance for days 61–90 ($256) and days 91–150 ($512) in hospital; payment in full for 365 additional lifetime days	•	•	•	•	•	•	•	•	•	•	•	•
Part B coinsurance Coinsurance for Part B services such as doctor's services, laboratory and x-ray services, durable medical equipment, and hospital outpatient services	•	•	•	•	•	•	•	•	•	•	50%*	75%*
First three pints of blood	•	•	•	•	•	•	•	•	•	•	50%*	75%*
Hospital deductible Covers $1,024 in each benefit period		•	•	•	•	•	•	•	•	•	50%*	75%*
Skilled nursing facility (SNF) daily coinsurance Covers $128 a day for days 2–100 each benefit period			•	•	•	•	•	•	•	•	50%*	75%*
Part B annual deductible Covers $135 per calendar year			•			•				•		
Part B excess charges benefits 80% or 100% of Part B excess charges (Under federal law, the excess limit is 15% more than Medicare's approved charge when provider does not take assignment. Under New York State law, the excess limit is 5% for most services.)						100%	80%		100%	100%		
Emergency care outside the United States Covers 80% of emergency care costs during the first 60 days of each trip, after an annual deductible of $250, up to a maximum lifetime benefit of $50,000			•	•	•	•	•	•	•	•		
At-home recovery benefit Up to $40 each visit for custodial care after an illness, injury, or surgery, up to a maximum benefit of $1,600 a year				•			•		•	•		
Preventive medical care Up to $120 a year for non–Medicare-covered physicals, preventive tests, and services;							•			•		
100% of coinsurance for Part B-covered preventive care services after the Part B deductible has been paid	•	•	•	•	•	•	•	•	•	•	•	•
Hospice care Coinsurance for respite care and other Part A-covered services											50%*	75%*
Outpatient prescription drugs												
***Out-of-pocket maximum** Pays 100% of Part A and Part B coinsurance after annual maximum has been spent											$4,440	$2,220

Source: Medicare Rights Center.

Notes: Medigap plans are standardized by the federal government. Not all plans may be available in any particular area. Consider the benefits offered by each plan and look for one that best meets individual needs.

**Plans F and J also offer high-deductible options. Pay $1,900 in 2008 before coverage begins.

Congress again acted, this time to standardize the marketing and sale of Medigap policies into ten plans, labeled A–J. Congress also required insurers to sell policies to all seniors (but not disabled Medicare beneficiaries) who want them during the first six months after the seniors sign up for Medicare. After that, the federal law limits its exclusions for preexisting conditions to six months, and insurers can turn down seniors for coverage entirely or exclude coverage permanently for certain conditions (although some states have stricter requirements for "open enrollment").

Under the 1990 law all Medigap policies were required to cover certain benefits, including copayments for hospital stays longer than sixty days (in 2008, $256 per day for days 61–90, $512 for "lifetime reserve" days 91–150, and an additional 365 days after all Medicare hospital coverage is exhausted); the 20 percent coinsurance for Medicare Part B services (50 percent for mental health services); and the first three pints of blood required in a year. Plan A, the least expensive, covers only the minimum. Plan B covers the benefits included in Plan A, along with Medicare's annual hospital deductible ($1,024 in 2008). Plan C includes the above benefits plus coverage of the Medicare Part B deductible ($135 in 2008). Other plans offer coverage of coinsurance for care in a skilled nursing facility ($128 per day in 2008), balance billing by physicians (up to 115 percent of Medicare's approved charge), coverage of emergency care outside the United States, HOME HEALTH CARE coverage in excess of what Medicare already provides, up to $120 in preventive benefits not offered by Medicare, and up to 50 percent of the cost of outpatient prescription drugs, to a maximum of $3,000 per year.

In 1997, as part of the Medicare overhaul in the Balanced Budget Act, Congress addressed Medigap again. One quirk of the 1990 Medigap law required insurers to sell policies to seniors without preexisting condition restrictions when they first enroll in Medicare. But if the senior drops coverage to move into a Medicare MANAGED CARE plan, then later leaves the plan, that senior may not be able to repurchase his or her former Medigap plan. Under the 1997 law seniors who left their Medigap plan to enroll in a MEDICARE+CHOICE option and then left again within a year to return to traditional Medicare could reenroll in their former Medigap plan, if it was still available, or in a Medigap plan labeled A, B, C, or F. None of those plans, however, offered prescription drug coverage.

Rules for Medigap changed again in 2003 with passage of the MEDICARE MODERNIZATION ACT, which added an optional drug benefit to Medicare. The new law barred Medigap carriers from selling new plans with drug coverage, but beneficiaries with existing Medigap drug coverage were permitted to keep that coverage if they wished. In most cases, however, that would prove financially disadvantageous, because the new Medicare Part D drug benefit came with a government subsidy, while Medigap drug coverage did not.

Problems in the Medigap market remain, however. For most policies, premiums increase as beneficiaries age, generally a time when their income goes down. Prices have also been increasing rapidly in recent years. Some analysts say part of the problem has been the movement of healthier Medicare beneficiaries to managed care plans. Because those people drop their Medigap coverage, those left behind in the Medigap pool are less healthy, and premiums rise accordingly. As of mid-2008, it was not yet clear what impact the new Medicare prescription drug benefit and the increasing popularity of the new MEDICARE ADVANTAGE private plan program was having on the Medigap market.

MedPAC

See MEDICARE PAYMENT ADVISORY COMMISSION (MedPAC).

Mental health parity

For a variety of reasons, both economic and historic, most HEALTH PLANS offer substantially less coverage for mental health ailments than for those considered strictly physical. One reason is that treatment of those with severe mental illness has historically been funded by states, mostly in asylums and other institutions. Moreover, in the early days of insurance, most mental health treatment for minor ailments was provided on

an outpatient basis, and most insurance did not cover outpatient treatment for mental or physical conditions. But as science has increasingly demonstrated the biological basis for most mental illness, those distinctions have become more and more artificial. Today the reason for less generous mental health coverage is more economic than anything else. Because mental illness is so commonplace, offering full coverage would be prohibitively expensive, insurers say. In any given year, according to the National Institute of Mental Health (NIMH), one in four adults suffers from a diagnosable mental disorder, amounting to an estimated 57.7 million Americans in 2004. According to the Global Burden of Disease project conducted by the World Health Organization, the World Bank, and Harvard University, mental illness accounts for a higher disease burden in major market economies than cancer. Mental disorders, including major depression, bipolar disorder, schizophrenia, and obsessive-compulsive disorder, are the leading causes of disability in the United States and Canada for those ages fifteen to forty-four, according to NIMH.

With new and more effective treatments available, advocates for those with mental illness have been lobbying insurance companies and policy makers for more equitable coverage, not only for the major mental illnesses but also for the less serious ailments (such as anxiety disorders and mood disorders) that, although not totally disabling, can nevertheless interfere substantially with a person's ability to function. Typical mental health coverage might cover no more than thirty days in an inpatient facility or twenty outpatient visits, compared with unlimited hospital and doctor coverage for physical ailments. Often mental health copayments are higher, requiring patients to pay half the cost of an outpatient visit to a mental health professional, compared with only 20 percent of the cost of a visit to a physician.

The resulting pressure for mental health "parity" led thirty-eight states (as of 2007) to pass laws requiring to at least some extent that insurers offer the same coverage for mental illness as for physical incapacity. In September 1996 Congress also cleared a limited mental health parity law that required insurers to provide the same annual and lifetime limits for mental health benefits as for other health care benefits.

The laws had only a small impact, however, according to analysts, primarily because most were so limited in scope. Many of the state laws covered only treatment of serious mental illnesses (excluding coverage of lesser illnesses as well as sickness related to substance abuse). And many excluded small employers.

The federal law came about after the Senate unexpectedly approved a much broader parity requirement during its consideration of what would become the HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA) (PL 104–191). Sponsored by Sens. Pete V. Domenici, R-N.M., a longtime advocate for federal funding of mental health research, and Paul Wellstone, D-Minn., the amendment approved by the Senate 68-30 would have required full mental health parity in most private insurance plans. It was dropped from the final measure after groups representing employers said it would drive premiums up so high that some employers would have to stop providing any insurance.

Instead, Domenici and Wellstone did manage to attach their stripped-down version to an unrelated spending bill for the Department of Housing and Urban Development and the Veterans Administration (PL 104–204). By 82-15 senators approved the language requiring the same annual and lifetime limits on mental health ailments as those on all other ailments. The provision, however, that was kept in the final bill included a series of loopholes. It did not require any plan or employer to offer mental health benefits, applied only to group plans covering fifty-one or more, did not include coverage for illness caused by substance abuse or chemical dependency, and was scheduled to expire after September 30, 2001. The requirement also stipulated that it would not apply if the additional coverage would raise employer premiums by more than 1 percent.

Even in its minimal form, however, many employers still managed to skirt the requirement by changing their plans to replace dollar limits with per-visit or per-day limits. Thus, instead of a $1,000 limit on outpatient mental health visits per year, plans would simply impose a limit of fifteen visits.

When the 1996 law was ready to sunset in 2001, Sens. Domenici and Wellstone set out to replace it with the broader full parity bill. (In the interim, President Bill

Clinton had ordered the FEDERAL EMPLOYEE HEALTH BENEFITS PLAN [FEHBP] to implement a full parity requirement, which it did on January 1, 2001.) On August 1, the SENATE HEALTH, EDUCATION, LABOR, AND PENSIONS (HELP) COMMITTEE unanimously approved the Mental Health Parity Act, and Senate majority leader Tom Daschle, D-S.D., promised to find time on a crowded Senate floor schedule for a full debate before the 1996 law's expiration date of September 30. The attacks of September 11, 2001, however, shoved the mental health bill to the end of the legislative agenda.

Undeterred, Domenici and Wellstone successfully attached their measure to the annual spending bill for the Departments of Labor, Health and Human Services, and Education. The amendment would not have required that mental health coverage be offered as part of a health insurance plan, but if it was, it required that it be equal to coverage for other ailments, including equal copayments and deductibles. The bill did not extend to coverage of substance abuse. Voice-vote approval of the measure came after sponsors agreed to push back the effective date by an additional year and to exempt from the requirements businesses with fewer than fifty workers (up from twenty-five in the original bill). "We can't get everything in one swoop," said Domenici. (See HEALTH AND HUMAN SERVICES DEPARTMENT [HHS] and DEDUCTIBLE.)

Even with the changes, however, the measure ran into heated opposition from the House and the business community. Although the CONGRESSIONAL BUDGET OFFICE (CBO) estimated that the measure would raise premiums by less than a percentage point, even a small increase on top of already escalating premiums could prompt some employers to stop offering coverage altogether, employer groups said.

In the end, House and Senate negotiators agreed to drop the Senate's parity language and replace it with a one-year extension of the 1996 law, thus giving lawmakers another year to negotiate changes.

Early in 2002, President George W. Bush—who had signed a sweeping mental health parity law while governor of Texas—weighed in. In April, at an appearance with Domenici in New Mexico, Bush appeared to endorse the Domenici–Wellstone approach. "Health plans should not be allowed to apply unfair treatment limitations or financial requirements on mental health benefits," he said. But at the same time, he added, "[I]t is critical that as we provide full mental health parity that we do not significantly run up the cost of health care."

As Domenici sought to work out details with the White House, the lobbying increased steadily. The business community continued to insist the parity requirement would be too expensive. "Confronted with 15 percent to 25 percent annual cost increases, employers are already being forced to make very hard decisions about significantly increasing employee contributions," Jane Greenman of Honeywell International told a House Education and Workforce subcommittee. If there had to be a parity law, they said, it should extend only to the most serious "biologically based" illnesses such as schizophrenia and depression. But mental health advocates pointed out that such a limit would fail to cover many serious and treatable conditions, including autism and post-traumatic stress disorder. They also noted that, in the roughly two dozen states that already had full parity laws in effect, costs had generally not risen by more than 1 percent. In fact, testified Henry Harbin of the American Managed Behavioral Health Care Association, in some states costs declined when parity laws were put in place along with MANAGED CARE programs aimed at ensuring that patients got only the appropriate amount of care. "The fact that no state that has enacted parity legislation has repealed it, despite initial concerns about cost, is telling and speaks to the affordability of parity," he told the same House subcommittee.

In the end, however, Domenici and the White House were unable to reach agreement on a consensus bill in 2002. And when Wellstone died in a plane crash in October while campaigning for reelection, the effort collapsed entirely. In November, the House and Senate instead passed a stand-alone bill to again renew the 1996 partial-parity law through 2003. President Bush signed the measure (PL 107–313) on December 2.

At the start of 2007, it seemed the federal law had found new life. First, the Democrats had retaken control of the House and Senate for the first time since 1995, and they were eager to show some accomplishments on health care, particularly on a measure President Bush was considered likely to sign. Mental health parity, long

stalled by the GOP House leadership, seemed almost a slam-dunk. Also working in the bill's favor was the fact that more than a year of closed-door negotiations between business and mental health groups had produced a compromise in late 2006 on a bill that Sens. Edward M. Kennedy, D-Mass., and Domenici quickly introduced at the start of the 110th Congress. The Senate Health, Education, Labor, and Pensions Committee quickly approved the measure by a vote of 18-3 on February 14, 2007. The full Senate passed the measure by voice vote on September 18. But then things stalled. Some mental health groups said the compromise bill gave up too much ground. They backed a bill that would require much broader coverage. It was sponsored by Senator Kennedy's son, Rep. Patrick J. Kennedy, D-R.I., and named for Senator Wellstone. Members of Wellstone's family refused to allow the Senate compromise bill to be named in the late senator's honor because, they said, it gave up too much ground.

Despite efforts by Senate sponsors and the Bush administration to get the House to go along with the Senate bill, House leaders decided to go with the younger Kennedy's bill instead. That measure passed the House by 268-148 on March 5, 2008, thus launching an effort to find a compromise. The May 2008 diagnosis of Senator Kennedy with brain cancer slowed progress, however.

Mexico City policy

First implemented by the Reagan administration at a 1984 United Nations (UN) population conference held in the Mexican capital, and reinstated by President George W. Bush in January 2001, this policy denies U.S. funding for international family planning organizations that use their own funds to "perform or actively promote" ABORTION. At the original Mexico City conference, Reagan administration officials challenged the assumption that population booms deterred economic development in less-developed countries. Whereas for decades U.S. policies had provided aid to international family planning efforts in an attempt to boost economic development, at Mexico City the administration argued that population expansion was inherently a "neutral" phenomenon. Although family planning could contribute to population stability, the White House said, free-market economic policies were the "natural mechanism for slowing population growth."

The Mexico City policy, which, among other things, cut off funding for the International Planned Parenthood Federation, was formally in place from 1984 until it was repealed by President Bill Clinton on his second day in office in 1993. During most of that time, family planning supporters tried but failed to overturn the policy, which they referred to as the "global gag rule." (See GAG RULE [IN ABORTION].) Supporters of the policy insisted that allowing U.S. funds to go to organizations that used non-U.S. monies to perform or advocate for abortion was tantamount to condoning the activities. Because money is "fungible," they noted, using U.S. government funds for allowable activities provided the organizations with more resources for their abortion-related work. But opponents of the ban argued that it represented an unfair restriction on the free speech rights of organizations that worked to change abortion laws in other countries and that it was in particular aimed at defunding International Planned Parenthood, a favorite target of the antiabortion movement.

When Republicans took over Congress following the 1994 elections, they made reimposing the Mexico City policy a top priority. Although the House repeatedly voted to reinstate the policy, the Senate just as steadfastly refused to go along. The fight ultimately produced a complicated and messy compromise that helped reopen the government in early 1996 after the budget standoff in 1995 closed it down. Under the compromise, the Mexico City restrictions were not reimposed, but funds for international family planning programs were reduced by 35 percent from their fiscal 1995 level of $548 million—unless a separate bill reauthorizing those programs became law by July 1 (which did not happen). In the absence of a reauthorization, the family planning programs received $356 million, a reduction of $192 million. At the same time, negotiators stipulated that even the reduced amount could be meted out only at a rate of 8 percent per month.

Mexico City policy again stymied budget negotiators working on the fiscal 1997 budget at the close of 1996.

The policy was not reinstated, and Congress restored some of the funds cut at the start of the year—providing $385 million. But the terms were even more stringent. Under the compromise, none of the money would be available until July 1, 1997 (more than halfway through the year), and it again would be meted out at 8 percent per month. The measure did stipulate that the funds could be made available as early as March 1, 1997, if the president issued a finding that the lack of funding was having "a negative impact on the proper functioning of the population planning program" and if both houses of Congress voted to concur with that finding.

President Clinton issued the finding on February 1, 1997, and, much to the surprise of advocates of the Mexico City policy, both the House and Senate voted to release the funds. The House voted 220-209 on February 13; the Senate officially released the money by 53-46 on February 25. Proponents of family planning successfully argued that it can reduce abortion. In Russia, said Sen. Patrick J. Leahy, D-Vt., contraceptive use increased 5 percent from 1990 to 1994. At the same time, abortions declined by 800,000.

But the fight was not over. Later in 1997, during work on the fiscal 1998 budget, the Mexico City policy was again one of the last issues settled in the entire budget negotiation. The restrictions were not reimposed, and funds for international population aid were restricted—the level was maintained at $385 million. But this time supporters of the policy took hostages. Dropped from the final measure were provisions the Clinton administration badly wanted to pay back dues to the United Nations and $18 billion in loan guarantees for the International Monetary Fund (IMF). Abortion opponents then accused President Clinton of holding important foreign policy initiatives hostage to his prochoice agenda. "We do not believe our disagreement over abortion should block action on national security issues," said a letter to the president from House Speaker Newt Gingrich, R-Ga. "We believe firmly that we should be able to meet our United Nations obligations and strengthen our international financial tools even while we disagree over taxpayer subsidies of organizations that promote abortion."

Despite the vows of Mexico City policy proponents in Congress not to leave in 1998 without getting their policy reinstated, the final result was much the same. But this time there was a different twist. As approved by the House on September 17, the fiscal 1999 Foreign Operations appropriation would have permitted funding for the minority of groups that performed abortions, though the funding would have been reduced from $385 million to $356 million. The measure, however, would still have barred any organization receiving U.S. funds from advocating, lobbying for, or in any way trying to influence the abortion laws of any country in which it operated. But the administration did not bite at what was offered as a compromise. In the end, the program again received $385 million and again meted out at a rate of 8 percent per month. And the administration did finally get its funding for the IMF. But no funds were paid back to the United Nations. Instead, the back UN funding was included in a State Department authorization bill that also included the Mexico City policy language. President Clinton, as promised, vetoed that measure after Congress adjourned for the year.

In 1999, after the House approved conflicting versions of family planning language as part of the fiscal 2000 Foreign Operations appropriation, Mexico City policy advocates finally achieved their goal. As part of a deal with President Clinton to get the back UN dues paid, the final catch-all spending bill (PL 106–113) for the year included the first-ever codification of the Mexico City policy. It barred U.S. aid to groups that performed abortions—except in cases of rape, incest, or where the life of the woman was in danger—or lobbied to change abortion laws or government policies in other countries. Clinton was permitted to waive the restrictions (which he did), but that triggered a shift of $12.5 million of the program's $385 million to an account for child survival and disease prevention.

Clinton vowed not to let the language be included in the bill the following year, and, to an extent, he prevailed. The final language in the fiscal 2001 Foreign Operations bill (PL 106–429) increased funding for the international family planning program to $425 million and dropped the restrictions, although it delayed any spending of the money until February 15. That allowed the next president to reimpose the restrictions if he wanted, which George W. Bush did, eight years to the day after Clinton rescinded them.

The fight, however, continued. In March, a group of senators opposed to the policy announced it would seek to use the Congressional Review Act (CRA) to force an up-or-down vote on whether to rescind the policy. The CRA, a 1996 law that gives Congress sixty days to file a joint resolution of disapproval to cancel certain executive actions, requires only a simple majority in both houses to pass, although the actions can be vetoed and would require the usual two-thirds majority to override. The CRA had been used successfully for the first time only days earlier, when Congress acted to rescind controversial Clinton administration rules on workplace ergonomics.

Bush, however, dodged the threat by reissuing the policy in the form of an "executive memorandum" that is outside the purview of the CRA. That outraged opponents. "Now he's trying to gag the Congress from being heard on this subject," said Sen. Barbara Boxer, D-Calif.

In 2002 the Mexico City policy got entangled with the other major international abortion fight—funding for the UNITED NATIONS POPULATION FUND (UNFPA). As part of a deal to drop from the fiscal 2002 Foreign Operations bill Senate-passed language to rescind the Mexico City policy language, White House negotiators agreed to increase UNFPA funding from $20 million to $34 million.

But Bush signaled in January he might withhold all of the UNFPA funds, after abortion opponents complained that the agency was funding coercive family planning programs in China. Bush followed through on his threat not to spend the money in July, even after a State Department–appointed investigatory committee found no evidence that UNFPA "has knowingly supported or participated in the management of a program of coercive abortion or involuntary sterilization." Although opponents of Bush's abortion policies vowed to continue to work to overturn both the Mexico City policy and the defunding of UNFPA, those efforts remained unrealized by the end of 2007, even after Democrats regained control of both the House and Senate in the 2006 elections. In the end the president's veto threats kept the policy in place for the fiscal 2003–2008 bills.

Mifepristone

Mifepristone is the formal name of the abortion-inducing drug better known as RU486. The drug is sold under the brand-name Mifeprex. *See* RU486.

Migrant health centers

These facilities provide primary care services to migratory and seasonal agricultural workers and their families. Migratory workers are those whose principal employment is in agriculture on a seasonal basis and has been for the past two years. Seasonal agricultural workers are those whose principal employment is in agriculture on a seasonal basis but who are not migratory workers. Migrant health centers are part of the Consolidated Health Centers Program, run by the HEALTH RESOURCES AND SERVICES ADMINISTRATION (HRSA) of the HEALTH AND HUMAN SERVICES DEPARTMENT (HHS). (See COMMUNITY HEALTH CENTERS.)

"Morning after" pill

See EMERGENCY CONTRACEPTION.

N

NAIC

See NATIONAL ASSOCIATION OF INSURANCE COMMISSIONERS (NAIC).

NARAL Pro-Choice America

NARAL Pro-Choice America, better known as simply NARAL, is the nation's best-known abortion rights group. NARAL has had four different names since its founding in 1969 as the National Association for the Repeal of Abortion Laws. After the U.S. Supreme Court legalized ABORTION nationwide in its 1973 ruling *ROE V. WADE,* NARAL changed its name to the National Abortion Rights Action League and adopted a new mission of protecting the rights *Roe* granted. In 1994 the organization changed its name to the National Abortion and Reproductive Rights Action League and added to its mission the encouragement of family planning services that can reduce unintended pregnancies and make abortion less necessary. In 2003 the group changed its name yet again, to NARAL Pro-Choice America.

National Association of Insurance Commissioners (NAIC)

The organization representing the leaders of state insurance departments, the National Association of Insurance Commissioners (NAIC) writes model laws and regulations and consults with Congress and federal agencies on national laws and policies in an effort to establish some uniformity in insurance regulation among states.

National Bipartisan Commission on the Future of Medicare

The National Bipartisan Commission on the Future of Medicare was established by the 1997 Balanced Budget Act (PL 105–33) to develop recommendations for how to shore up Medicare's finances in anticipation of the retirement of the baby boom generation, which was projected to more than double the program's enrollment between the years 2010 and 2030. After a year of work the panel disbanded in March 1999 without reaching agreement on the matter. The group's cochairs, however, Sen. John B. Breaux, D-La., and Rep. Bill Thomas, R-Calif., who did win a majority vote from commissioners for their proposal to transform MEDICARE into a PREMIUM SUPPORT program, drafted the proposal into legislation that they planned to introduce themselves. In 2003 the two worked together to include some elements of the plan into what would become the MEDICARE MODERNIZATION ACT (PL 108–173).

The reason the majority vote for the Breaux–Thomas proposal was not enough for the commission to make a formal recommendation dates back to the origin of the commission itself as part of the 1997 budget bill. When congressional Republicans, Democrats, and the Clinton administration proved unable to resolve during negotiations on that bill provisions to extend Medicare's financial stability beyond the next decade—particularly provisions passed by the Senate but dropped in conference to raise the program's eligibility age from sixty-five to sixty-seven and to require wealthier beneficiaries to pay higher Part B premiums—they decided to refer the problem to a commission.

With each side distrustful of the other, the makeup of the commission was one of the last provisions settled in the Balanced Budget Act. Congress ultimately decided the commission should have seventeen members—eight each appointed by Republicans and Democrats (including the Clinton administration) and a chair jointly appointed by Republicans and Democrats. To ensure that any proposals represented a consensus, negotiators on the budget bill also required that, to receive formal consideration in Congress, the recommendation would have to be approved by eleven of the panel's seventeen members.

The panel got off to a late start when the two sides could not agree on a chair. Breaux, a moderate Democrat who had sided with Republicans in the past on Medicare issues (and a member known for his penchant for deal-making) was finally appointed in January 1998—just fourteen months before the panel's March 1, 1999, termination deadline. In exchange for allowing a Democrat to be appointed chair (giving Democrats a 9–8 majority of the members), Democrats agreed to appoint Representative Thomas as the commission's "administrative chair." But many observers were already predicting the commission could only end in deadlock, as House Speaker Newt Gingrich, R-Ga., made his four appointees promise not to recommend any policies calling for tax increases.

Breaux was clearly leaning toward the premium support concept from the start. He had long advocated making Medicare resemble the FEDERAL EMPLOYEE HEALTH BENEFITS PLAN (FEHBP), which allowed some nine million federal workers and dependents to choose each year from a menu of different health insurance options. By the time Breaux presented the commission with his proposal in January, the partisanship on the commission had become apparent. Although Breaux's proposal was clearly favored by Republicans on the panel, giving him nine of the eleven votes he needed, Democrats held out for including a prescription drug benefit for Medicare, something it lacked. They also urged the commission to consider the proposal offered by President Bill Clinton in his 1999 State of the Union address to reserve 15 percent of the projected budget surplus to help keep Medicare financially solvent. As the commission's termination deadline neared, with Sen. Bob Kerrey, D-Neb., siding with Breaux, the search for the pivotal eleventh vote centered on two Clinton administration appointees, former Clinton economic adviser Laura D'Andrea Tyson and Brandeis University health policy professor Stuart Altman, who had worked on health issues during Clinton's transition and previously had chaired Medicare's PROSPECTIVE PAYMENT ASSESSMENT COMMISSION (ProPAC).

In the end, neither Altman nor Tyson, both of whom had expressed some interest in the premium support strategy, voted for the proposal. They said it did not do enough to shore up the program's finances and the proposed drug benefit did not aid enough beneficiaries. The commission's failure to find eleven votes also led Republicans to charge President Clinton with purposefully attempting to thwart the panel's work. Clinton responded that he would propose his own Medicare reform plan. That plan was unveiled in June 1999. It was not considered formally by either the House or the Senate.

National Committee for Quality Assurance (NCQA)

A nonprofit organization supported by employers, health plans, and health foundations, the National Committee for Quality Assurance (NCQA) assesses and reports on the quality of MANAGED CARE and other types of health plans in an effort to encourage those entities to compete on the basis of quality and service, not cost alone. In 2006, according to NCQA, eighty-two million Americans belonged to 767 health plans that were "accountable" to NCQA in some way, either health maintenance organizations that were subject to the organization's rigorous accreditation program or preferred provider organizations that reported HEALTH PLAN EMPLOYER DATA AND INFORMATION SET (HEDIS) measures that allowed NCQA and the public to examine the way those plans provide care. (See HEALTH MAINTENANCE ORGANIZATION [HMO] and PREFERRED PROVIDER ORGANIZATION [PPO]).

To qualify for accreditation, NCQA examines plans in five separate areas:

1. *Quality management and improvement:* how the plan ensures that patients have access to needed care.

2. *Member rights and responsibilities:* how well the plan responds to member complaints and how clearly it informs members about how to use plan services.

3. *Physician qualifications and evaluation for physicians in the network:* how well the plan researches the credentials of physicians.

4. *Preventive health services:* how well the plan promotes the use of preventive tests and activities.

5. *Utilization management:* how fair, consistent, and prompt the plan is in making decisions.

Plans can receive full, three-year accreditation (for those judged excellent), one-year accreditation (for plans that meet most but not all of the standards), or provisional accreditation (for plans that meet some of the standards), or they may be denied accreditation.

In 2005, for the first time, NCQA began to evaluate not only the quality of care being provided by health plans, but also the value for the premium dollars spent. Its first foray into the value-for-money realm looked at care for patients with diabetes. It found, as did researchers before, that plans spending the most did not necessarily provide the best care (based on how well patients were able to control their disease and avoid complications) and that plans spending the least did not necessarily skimp on care.

National Federation of Independent Business (NFIB)

The largest association representing small business owners, the National Federation of Independent Business (NFIB) has been a major player in health policy since the 1980s. It helped successfully oppose passage of President Bill Clinton's 1993–1994 health care plan and other attempts to mandate that employers provide coverage to their workers. In 1998 it helped lead a successful fight against legislation to impose federal regulations on MANAGED CARE plans. It was a founding member of the Health Benefits Coalition (HBC), which was run out of its offices in Washington, D.C. The HBC, which united business and insurance groups in an effort to block the legislation, argued that requiring patient protections for managed care would raise premiums to the point that employers would be forced to drop coverage.

The NFIB, however, had less success trying to push through Congress legislation to establish ASSOCIATION HEALTH PLANS (AHPs), which it hoped to offer to its members. While the House passed the bill numerous times when Republicans were in the majority from 1995 to 2007 and President George W. Bush strongly supported the effort, the Senate never went along.

National Health Service Corps

Created in 1970 (its founding was chronicled in the popular political science case study *The Dance of Legislation*), the National Health Service Corps places physicians and other health professionals in medically underserved areas, such as rural and inner-city health clinics as well as Indian reservations. Originally the program provided scholarships for medical students who agreed, on completion of their training, to serve for a period of time in the corps, part of the PUBLIC HEALTH SERVICE (PHS) corps of commissioned officers. But by 1987, as the Reagan administration tried to phase out the program, the number of doctors and other health care professionals in the pipeline had dropped so low that Congress instituted a loan repayment program authorizing the federal government to reimburse health professionals already in practice for up to $20,000 (in 1990 raised to $25,000) per year of their educational loans. In the program's first thirty-five years, more than twenty-seven thousand clinicians served in underserved areas. According to the HEALTH RESOURCES AND SERVICES ADMINISTRATION (HRSA), the branch of the HEALTH AND HUMAN SERVICES DEPARTMENT (HHS) that operates the program, a study conducted in 2000 found more than half of all NHSC practitioners continued to serve underserved populations after they satisfied their service requirements.

Congress appropriated $126 million for the NHSC in fiscal 2007, enough to support approximately forty-six hundred health professionals.

National Institutes of Health (NIH)

The nation's preeminent biomedical research institution traces its origin to the 1887 establishment of a bacteriological laboratory in the Marine Hospital at Staten Island, New York, by Dr. Joseph Kinyoun, a physician and bacteriologist who had worked with Louis Pasteur. In 1891 the laboratory was moved to Washington, D.C., and in 1902 was vested by Congress with authority to test and improve vaccines. It officially became the National Institutes of Health (NIH) in 1930, with passage of the Ransdell Act, and in 1938 moved to its current campus in Bethesda, Maryland, just up the road from Washington.

In the past 120 years the NIH has grown from a single laboratory to twenty-seven separate institutes and centers, and from a budget of about $300 to a fiscal 2008 appropriation of $28.9 billion. NIH has been a bipartisan political favorite over the past decade and has enjoyed major budget increases even as other domestic programs have been squeezed. In 1998 Republicans in Congress, eager to challenge Democrats' dominance on health issues, announced a plan to double NIH's funding over the ensuing five years. That task was completed with the fiscal 2003 spending bill, which provided NIH with $27.2 billion. As those increases slowed abruptly, however, scientists complained that the agency became unable to follow through on some of the expansive projects it began when funding was flush.

Although NIH conducts extensive research on its three-hundred-acre campus in Maryland, the vast majority of its funds are used for its "extramural" programs—funding researchers in hospitals, universities, medical schools, and other laboratories around the country. In fiscal 2008 the Bush administration requested enough money for NIH to fund more than ten thousand new and competing grants. However, the agency still can fund only about 30 percent of the projects researchers propose each year.

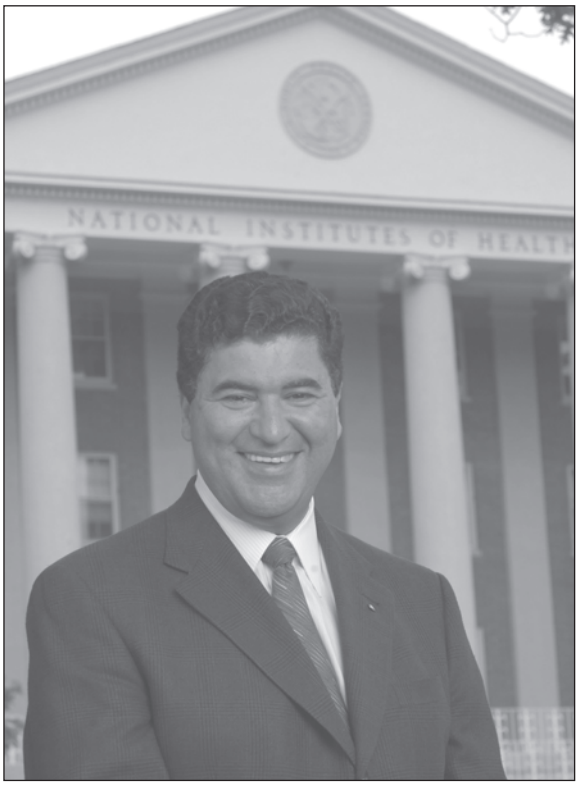
NIH has nineteen separate institutes, plus the National Library of Medicine:

• National Cancer Institute, the oldest and largest institute, which conducts and supports basic and applied research in the detection, diagnosis, prevention, and treatment of cancer and in the rehabilitation of cancer patients.

• National Eye Institute, which studies not only diseases of the eye but also the special needs of those who are blind or have vision impairments.

• National Heart, Lung, and Blood Institute (NHLBI), which supports and conducts research on diseases of the heart, blood vessels, lungs, and blood.

• National Human Genome Research Institute (NHGRI), which in 2000 completed the first part of its mission: to locate and sequence the estimated 100,000 genes that constitute the human genome. (A *genome* is the total of all the genetic material in the chromosomes of an organism.) The institute has now moved into research



Director of the National Institutes of Health Dr. Elias A. Zerhouni began his tenure on May 20, 2002. As director of NIH Dr. Zerhouni oversees 27 institutes and centers and a fiscal year 2008 budget of $28.9 billion. Source: *National Institutes of Health*

involving the use of genomic tools to improve public health. It also conducts and funds research into the ethical, legal, and social implications of the work, given that the project could make possible the prediction of disease well before it strikes or the alteration of human DNA to cure or prevent disease.

• National Institute of Allergy and Infectious Diseases, which has, among other things, pioneered much of the U.S. research on ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS).

• National Institute of Arthritis and Musculoskeletal and Skin Diseases, whose research focus is more than one hundred forms of arthritis, osteoporosis, and other bone diseases, muscle biology and muscle diseases, orthopedic disorders, such as back pain and sports injuries, and skin diseases.

• National Institute of Biomedical Imaging and Bioengineering (the newest institute, created in 2000 by PL 106–580), which supports imaging and engineering research with potential medical applications and the transfer of such technologies to medical applications.

• National Institute of Child Health and Human Development (NICHD), which examines the reproductive, developmental, and behavioral processes that determine and maintain the health and well-being of children, adults, families, and populations. NICHD is also home to the National Center for Medical Rehabilitation Research, which studies better ways to support and aid persons with disabilities.

• National Institute of Dental and Craniofacial Research, which conducts and supports research to improve craniofacial, oral, and dental health.

• National Institute of Diabetes and Digestive and Kidney Diseases, whose research spans the study of diabetes, endocrinology, and metabolic diseases; digestive diseases and nutrition; and kidney, urologic, and hematologic diseases.

• National Institute of Environment Health Sciences, which supports and conducts research into how environmental exposures affect human health.

• National Institute of General Medical Sciences, which conducts and funds the most basic forms of biomedical research, such as research in cell biology, genetics, and biophysics.

• National Institute of Mental Health, which conducts and supports research to improve the prevention, diagnosis, treatment, and overall quality of care for persons with mental illness.

• National Institute of Neurological Disorders and Stroke, whose research seeks to advance understanding of the brain and to improve the prevention and treatment of neurological and neuromuscular disorders, including head and spinal cord injury, epilepsy, multiple sclerosis, and Parkinson's disease.

• National Institute of Nursing Research, whose mission is to foster research to reduce the burden of illness and disability, improve health-related quality of life, and establish better approaches to promote health and prevent disease.

• National Institute on Alcohol Abuse and Alcoholism, which studies the biological causes of alcoholism and why people drink, as well as prevention and treatment strategies.

• National Institute on Aging, which supports biomedical, behavioral, and social research related to aging.

• National Institute on Deafness and other Communication Disorders, which studies human communication issues, including the biomedical and behavioral problems of those with communications impairments or disorders.

• National Institute on Drug Abuse, whose research centers on the causes, prevention, and treatment of drug abuse.

Within the NIH director's office are several other important operating divisions, including:

• Center for Complementary and Alternative Medicine (see ALTERNATIVE MEDICINE);

• Office of AIDS Research, which coordinates the scientific, budgetary, legislative, and policy elements of NIH's AIDS research program;

• Office of Dietary Supplements (see DIETARY SUPPLEMENT RULES);

• Office of Rare Diseases, which coordinates and stimulates research into diseases that affect a relatively small number of patients (see ORPHAN DRUGS) and helps match persons with rare conditions with ongoing or planned clinical research projects; and

National Institutes of Health Appropriations, 1989–2008

Fiscal year	*Appropriation (billions)*
2008	$28.9
2007	28.8
2006	28.5
2005	28.7
2004	28.0
2003	27.2
2002	23.3
2001	20.3
2000	17.9
1999	15.6
1998	13.6
1997	12.7
1996	11.9
1995	11.3
1994	10.9
1993	10.3
1992	9.0
1991	8.3
1990	7.7
1989	7.2

Source: Congressional Quarterly; and *Congressional Record.*

• Office of Research on Women's Health, which ensures the inclusion of women in clinical research and promotes research on conditions that primarily affect women.

In some ways NIH has proven too popular. Congress has sought to micromanage its activities, often in response to lobbying efforts by those afflicted with diseases that, they say, NIH is not paying enough attention to. Members of the HOUSE APPROPRIATIONS COMMITTEE and the SENATE APPROPRIATIONS COMMITTEE, through earmarks in annual spending bills, and members of authorizing committees, through periodic reauthorization legislation (most of NIH is, in fact, permanently authorized), have ordered, at various levels of insistence, that NIH take certain actions. Some of these orders have come in the form of statutory commands, written directly into an appropriations measure (for example, a statute designating a specific amount for a specific purpose). In 1997 Congress used the appropriations bill to order creation of Parkinson's disease research centers. More often, however, Congress's input into NIH activities comes in the form of report language in the conference report (the report resolving disagreements on a bill between the House and Senate) on the appropriations bill or in the House and Senate committee reports. Typically this sort of language urges NIH to devote more resources to a certain disease or condition, or earmarks funding, or asks for a report or study on a certain topic.

A 1998 report by the INSTITUTE OF MEDICINE on NIH's priority-setting process took Congress to task for occasionally ordering NIH to use more than the amount of that year's increase for specific purposes, in essence forcing funding to be reduced for other efforts. In fiscal year 1993, for example, Congress earmarked $77 million of funding within the National Cancer Institute for research on breast, ovarian, cervical, and prostate cancers but provided the institute with only $28 million in additional funding. As a result, NIH was forced to cut basic research on other cancers, including leukemia, non-Hodgkin's lymphoma, and cancers of the colon, bladder, kidney, and brain.

NIH has also been a lightning rod in Congress for all manner of contentious ethical issues in science. For example, Congress, various presidential administrations, and NIH have been arguing over the propriety of research on human fetuses since 1974, when legislation imposed a moratorium on research involving "the living human fetus, before or after ABORTION," unless the purpose was to ensure the fetus's survival. Congress in 1993 NIH reauthorization legislation (PL 103–43) lifted a ban imposed during the Reagan administration on transplants using tissue from aborted fetuses. But the Republican-controlled Congress imposed a new ban on research involving human embryos in 1995, which ultimately helped touch off a major fight over research involving stem cells from human embryos. (See EMBRYO RESEARCH, FETAL TISSUE RESEARCH, and STEM CELL RESEARCH.)

In 2006, however, Congress passed an NIH reauthorization bill for the first time since 2003 that was aimed at giving scientists more ability—and lawmakers less—to determine the biomedical research agenda. President George W. Bush signed the bill (PL 109–482) on January 15, 2007. The measure was an unusually bipartisan, noncontroversial measure, largely drafted in the House.

Lawmakers there agreed that the NIH needed to break out of its traditional "silo" models and to move beyond doing research disease by disease or body part by body part. The bill established a "common fund" to promote research that cut across institutes and scientific disciplines and gave the NIH director considerable authority to channel the use of those funds. The measure also set up a formal process to have scientific experts periodically review the structure of the NIH and recommend changes, if warranted. And the bill called for the establishment of a publicly searchable database of all NIH research grants.

National Practitioner Data Bank

The data bank was created in 1986 to help facilitate the flow of information about physicians and other health practitioners who have been found to have committed malpractice or had adverse actions taken against them. As of 2006, according to the HEALTH RESOURCES AND SERVICES ADMINISTRATION (HRSA), which runs it, the data bank maintains more than 375,000 separate reports and has processed more than thirty-six million queries. Creation of the data bank, which did not get up and running until 1990, was controversial because doctors complained that often malpractice cases are settled even when no malpractice has occurred, because it can be easier and cheaper for the malpractice insurer to settle than to fight a case. In other instances, doctors have had their licenses to practice suspended or revoked not because they did anything wrong but because of administrative mix-ups that were not the doctors' fault. Members of Congress who argued in favor of the data bank cited cases in which doctors who had been convicted of malpractice or had their licenses or hospital privileges revoked because of substandard care merely moved to another state and resumed practice without anyone's knowing until after other medical mistakes had been made.

Currently, medical malpractice payers must report to the data bank and to the appropriate state licensing board within thirty days of making a payment. Hospitals and other health care entities, including professional societies, must report to state medical and dental boards any adverse actions taken against a health care professional (such as license suspension or revocation or loss of hospital privileges) within fifteen days. Those boards then have fifteen days in which to notify the data bank. Access to the data bank is strictly limited—its information is not available to the general public or to medical malpractice payers. Those found guilty of violating the confidentiality of information from the data bank can be fined up to $11,000 per incident. Practitioners themselves may see copies of their own records and may dispute information they think is incorrect or add an explanation. Hospitals are required to check the data bank when a practitioner applies for privileges and again every two years. Information from the data bank may be sought by other health care entities, including state licensing boards, hospitals performing professional review activities, and professional societies or other entities with a formal peer review process. Plaintiffs' attorneys may seek information from the data bank under certain circumstances.

In 2000 House Commerce Committee chair Thomas J. Bliley Jr., R-Va., touched off a fight when he introduced legislation to open the data bank to the public. "Today we know more about the snack foods we eat and the cars we buy than the doctors in whose care we entrust our health and well-being," Bliley said. But representatives of major health provider groups, led by the AMERICAN MEDICAL ASSOCIATION (AMA), said the raw data in the data bank could be misleading to consumers, because it included payments made to settle cases even when no malpractice had been demonstrated. The AMA also accused Bliley of taking up the issue only after the organization endorsed the version of a MANAGED CARE regulation bill supported by President Bill Clinton and most congressional Democrats—and opposed by Bliley and most congressional Republicans. (See PATIENTS' BILL OF RIGHTS [PboR].) "We look at this as retribution for our work on the Patients' Bill of Rights," said AMA president Thomas Reardon. After several high-profile hearings, the bill died without having been acted on in the 106th Congress. Bliley retired at the end of that term.

National Right to Life Committee (NRLC)

Founded in 1973, the year the U.S. Supreme Court handed down its landmark decision legalizing ABORTION nationwide, *ROE V. WADE*, the National Right to Life Committee (NRLC) is the largest (with an estimated seven million members) and best-known antiabortion group. In addition to fighting abortion, the group has a medical ethics division that actively opposes assisted suicide, euthanasia, and health care rationing. (See SUICIDE, ASSISTED.) The NRLC helped spearhead fights to limit STEM CELL RESEARCH using human embryos and to ban human cloning. (See CLONING, HUMAN.) In both instances the group contended that embryos represent individual human lives that should not be destroyed for research.

NCQA

See NATIONAL COMMITTEE FOR QUALITY ASSURANCE (NCQA).

Needle exchange

Needle exchange (sometimes called syringe exchange) programs are aimed at reducing the transmission of the human immunodeficiency virus (HIV) via the sharing of used needles by intravenous drug users. A third of ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS) cases are directly or indirectly (through sexual relations with someone who has used a contaminated needle or has had sexual relations with someone who has) associated with injection drug use, according to 2005 statistics from the CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC), and a quarter (26 percent) of all new infections that year were associated with injection drug use.

Policy makers have been arguing the merits of needle exchange programs—in which drug users trade used needles or syringes for clean ones—for more than a decade. Public health officials say research has shown such programs can and do reduce the spread of not only HIV but also other blood-borne diseases such as hepatitis B, without increasing drug use. But antidrug officials have argued just as vehemently that such programs condone the use of illegal drugs, a position that, some analysts say, the government has no business taking.

Congress first barred federal funding of needle exchange programs in the 1990 RYAN WHITE COMPREHENSIVE AIDS RESOURCES EMERGENCY (CARE) ACT (PL 101–381). That measure explicitly prohibited any of the funds it authorized from being used to distribute hypodermic needles or syringes "so that persons might use illegal drugs."

The ban was broadened in 1992 legislation overhauling substance abuse and mental health programs (PL 102–321). That measure banned any federal funding of needle exchange programs. The ban was reiterated in that year's appropriation bill covering the Labor Department and the HEALTH AND HUMAN SERVICES DEPARTMENT (HHS), barring funding "unless the SURGEON GENERAL [OF THE UNITED STATES] determines that such programs would help prevent the spread of AIDS and would not encourage the use of illegal drugs." That language headed off a more sweeping amendment proposed by Sen. Jesse Helms, R-N.C., that would have barred federal funds from going to state or local governments that used their own money to pay for needle exchange programs.

The ban on federal funding continued in roughly that form until 1997, when the fiscal 1998 Labor-HHS appropriation bill placed a firm six-month ban on funding. The HHS secretary, at that time Donna E. Shalala, was permitted to lift the ban after six months if she could develop criteria to ensure that needle exchange programs prevent the spread of HIV and do not encourage the use of illegal drugs.

By early 1998 such evidence was significant, including several studies commissioned by federal health agencies. One study published by the NATIONAL INSTITUTES OF HEALTH (NIH) found that needle exchange programs reduced high-risk behaviors among injection drug users by 80 percent, with reductions in the transmission of HIV by 30 percent or more. At the same time, the panel concluded that "the preponderance of evidence shows either a decrease in injection drug use among participants or no changes in their current levels of drug use."

An employee of a New Haven, Conn., needle exchange program is shown inside of a bus used to distribute clean syringes to drug users. Although research has shown that needle exchange programs do not encourage drug use, a ban on federal funding for such programs has been in place since 1990. Source: AP Images/Douglas Healey

On April 20, 1998, Shalala announced her finding that "the scientific evidence indicates that needle exchange programs do not encourage illegal drug use and can, in fact, be part of a comprehensive public health strategy to reduce drug use through effective referrals to drug treatment and counseling." President Bill Clinton, however, at the urging of his drug czar, General Barry McCaffrey, declined to allow the funding ban to be lifted. Instead, Shalala announced, "the administration has decided that the best course at this time is to have local communities which choose to implement their own programs use their own dollars to fund needle exchange programs, and to communicate what has been learned from the science so that communities can construct the most successful programs possible to reduce the transmission of HIV, while not encouraging illegal drug use."

Although the administration did not lift the funding ban, the House of Representatives responded to even the possibility the next week, passing by 287-140 legislation to permanently ban federal needle exchange funding. During the debate, proponents of the bill pointed to other studies that did find increases in drug use in areas where needle exchange programs were in operation. The Senate, however, never acted on the measure.

Even in the absence of federal funding, needle exchange programs in the United States have proliferated. In 2002, according to the CDC, 184 programs in thirty-six states, on Indian lands, and in Puerto Rico exchanged more than twenty-four million syringes.

NFIB

See NATIONAL FEDERATION OF INDEPENDENT BUSINESS (NFIB).

NIH

See NATIONAL INSTITUTES OF HEALTH (NIH).

NLEA

See NUTRITION LABELING AND EDUCATION ACT (NLEA).

NRLC

See NATIONAL RIGHT TO LIFE COMMITTEE (NRLC).

Nurse practitioner (NP)

A type of ADVANCED PRACTICE NURSE, nurse practitioners (NPs) have studied and practiced above and beyond the four years required to obtain a bachelor's degree in nursing. In 2007, 120,000 NPs in the United States practiced in a wide variety of settings, from hospitals to physician offices to clinics to nursing homes, performing many of the same functions as a PRIMARY CARE PHYSICIAN (PCP)—conducting physical exams, ordering and interpreting laboratory tests and X-rays, diagnosing common illnesses, managing chronic conditions, and providing health promotion and disease prevention services. NPs may prescribe certain drugs in all but one state, according to the American College of Nurse Practitioners. Twenty-two states and the District of Columbia permit nurse practitioners to practice independently. NPs and PHYSICIAN ASSISTANTS (PAs) are particularly important in rural areas, where they may be the only health professionals for miles around.

Although both NPs and PAs are required to practice under a physician's supervision, frequently that physician is located far away. The AMERICAN MEDICAL ASSOCIATION (AMA), which represents the nation's physicians, has generally supported the spread of NPs but has opposed legislation in many states to expand their scope of practice to equal that of physicians and has continued to insist that all mid-level health professionals practice under a doctor's supervision. Said AMA trustee John Nelson in 1998, "If [nurse practitioners or physician assistants] want to do more, they can go to medical school." Still, the demand for NPs is growing as payers of health care search for lower-cost ways to offer primary care services.

Nursing home standards

In 1986 the INSTITUTE OF MEDICINE of the National Academy of Sciences issued a report noting that care received in too many of the nation's nursing homes was "shockingly inadequate" and "likely to hasten the deterioration of [residents'] physical and emotional health." The report laid much of the blame on a set of 1974 standards for nursing homes that focused too much on the physical ability of each facility to provide required care and not enough on the quality of the care provided. Congress responded in 1987 with a new set of standards for facilities that participate in MEDICARE and MEDICAID, standards enacted as part of that year's budget reconciliation bill (PL 100–203).

Among other things, the new standards for the first time set minimum training and staffing requirements, including at least seventy-five hours for nurse aides, who deliver most of the care in nursing homes. Skilled nursing facilities were required to have a licensed nurse on duty twenty-four hours a day, and intermediate care facilities, which deliver less-advanced care, were required to have staff on duty around the clock, but not necessarily licensed nurses.

The new standards also focused more on outcomes than on the ability of a facility to provide care. For example, facilities were required to develop a standardized assessment and plan of care for each resident on admission. Residents were also guaranteed a patients' bill of rights giving them the ability to choose their own physicians and participate in their own treatment; to be free of inappropriate physical and chemical restraints; to receive visitors, mail, and other communications in private; to be free from physical or mental abuse, including involuntary seclusion; and to reject most involuntary transfers or discharges.

In 1995, at the behest of Republican governors and the nursing home industry, which complained the rules were too burdensome, the Republican-led Congress attempted to repeal the 1987 standards. Implementation of the standards had long been marked by disputes between state and federal officials and nursing home operators, and the rules only became final in 1994. As part of an effort to "block grant" Medicaid, the bill passed by Congress but vetoed by President Bill Clinton would have required states to develop their own standards in eight separate categories. Republicans said their efforts were part of an overall plan to lessen federal "micromanagement" of Medicaid. But backers of the original standards launched an aggressive campaign not to undo the rules. They pointed to several studies, among them

one from the Program on Aging and Long-Term Care at North Carolina's Research Triangle Institute, showing that the new standards had resulted in fewer hospital admissions for nursing home patients, thus saving the Medicare program an estimated $2 billion per year. The Medicare and Medicaid changes ultimately enacted in 1997 as part of the Balanced Budget Act (PL 105–33) did not include the language to repeal the 1987 standards.

In November 2002, the CENTERS FOR MEDICARE AND MEDICAID SERVICES launched "Nursing Home Compare," a Website and toll-free phone line to provide consumers with information directly from government inspection reports. In November 2007, the agency published a list of the nation's worst nursing homes, from its list of "special focus facilities not showing significant improvement." The agency list notes that the facilities included are those "that have a record of persistently poor survey performance, and have been selected for more frequent inspections and monitoring." The initial list included fifty-six facilities in thirty-three states and the District of Columbia.

Nutrition Labeling and Education Act (NLEA)

Passed in 1990 (PL 101–535), the Nutrition Labeling and Education Act (NLEA) was intended to cut down on unsubstantiated health claims manufacturers were making for food products and to provide consumers with more useful nutrition information. Under previous law, food labels had to list nutrition information only if a nutrition claim for the product (such as "low calorie") had been made. Even when information was provided voluntarily, there was no uniformity in labeling. As scientific evidence began to emerge that certain foods could improve health or deter disease, consumer groups found themselves at odds with manufacturers that they said were claiming products were more healthful or beneficial than they were. Those consumer groups pressured Congress to act to police the advertising claims, which Congress did through passage of the NLEA.

As signed into law by President George H. W. Bush on November 8, 1990, the measure required that most processed food products include labels detailing specific nutritional information about a single portion of the product, including the total amount of fat, saturated fat, cholesterol, sodium, sugars, dietary fiber, protein, carbohydrates, and complex carbohydrates. Retailers were also required to provide similarly detailed information for the twenty most frequently consumed types of raw agricultural products as well as for raw fish and shellfish.

To standardize the information, and to free manufacturers from having to package their products differently for sale in different states, the law preempted state nutrition labeling laws. The law did not, however, prohibit states from requiring their own labeled health warnings, such as those alerting consumers to potential toxins or the danger of allergic reactions to products.

To cut down on false or misleading claims, the law required the HEALTH AND HUMAN SERVICES DEPARTMENT (HHS) to define terms such as "natural," "light," and "low-fat." Manufacturers could use the terms on labels or in advertising only if the product fit the government's definition. Manufacturers were also barred from making health claims about their products—for example, saying that high-fiber diets prevented cancer—if the claims had not been fully tested or backed by the FOOD AND DRUG ADMINISTRATION (FDA). The law prohibited manufacturers from making certain nutritional claims about their products on the label—such as promoting a product as "high-fiber" or "low-sodium"—when other equally important nutritional information, such as cholesterol level, had not been mentioned.

Congress has subsequently amended the NLEA. In 1993 legislation (PL 103–80) exemptions from the labeling rules were broadened for small businesses, both retailers and manufacturers. They were given an extra three years to come into compliance with the rules. In 1994, under pressure from a massive campaign by manufacturers of vitamins, minerals, and herbal supplements and by those who used the products, Congress cleared separate legislation (PL 103–417) limiting the federal government's power to regulate those substances. (See DIETARY SUPPLEMENT RULES.)

O

Office for Human Research Protection

See HUMAN RESEARCH SUBJECT PROTECTION.

Office of Research on Women's Health

See WOMEN'S HEALTH, OFFICE OF RESEARCH ON.

Off-label use

The term refers to the prescription by a physician of a product approved by the FOOD AND DRUG ADMINISTRATION (FDA) for a use other than the one for which the product was originally approved. Off-label use has long been legal, and many drugs are used for purposes other than those for which they were first developed and approved. An estimated 50–80 percent of cancer treatments, for example, are off-label.

As part of the 1997 FDA Modernization Act (PL 104–115), Congress tried to make it easier for drug companies to promote off-label uses. Critics had charged that if companies were permitted to advertise or otherwise disseminate information about off-label uses, they would not bother to do the research and testing needed to have the drugs approved for the new purpose. As a result, FDA had banned most promotion of off-label uses since 1991. The compromise reached in the 1997 law permitted companies to distribute information from peer-reviewed journals (see PEER REVIEW) or from reference works such as medical textbooks, but only if the company agreed to conduct the research needed to have the product approved for the new use. (In certain circumstances, such as those involving off-label uses for "orphan" diseases that affect only a small number of patients for whom seeking separate FDA approval would not be cost-effective, the secretary of the HEALTH AND HUMAN SERVICES DEPARTMENT [HHS] could waive that requirement.) Also under the compromise, the FDA was required to review the information before it was disseminated, could demand that "balancing" information be provided along with the journal article, and compel disclosure of conflicts of interest (such as whether the company paid for the research in question).

In July 1999, however, a federal judge struck down the off-label section of the 1997 act as an unconstitutional infringement on the free speech rights of drugmakers. U.S. district court judge Royce Lamberth barred the FDA from enforcing the off-label requirements, calling them "a kind of constitutional blackmail—comply with the statute or sacrifice your First Amendment right to free speech." Lamberth's ruling freed drug companies to distribute any information to doctors about uses for their products.

But the FDA continued to draw a distinction between distributing information and promoting unapproved uses. And in 2004 the drug firm Warner-Lambert paid the price for that distinction. It paid $430 million to settle civil and criminal charges that its Parke-Davis division "illegally and fraudulently" promoted its antiseizure drug Neurontin for a variety of unapproved uses, including bipolar disorder, various pain disorders, amyotrophic lateral sclerosis (Lou Gehrig's disease), attention deficit disorder, migraine, drug and alcohol withdrawal seizures, and restless leg syndrome.

Oregon Health Plan

A first-in-the-nation system of overt rationing for health coverage, the Oregon Health Plan (OHP) was devised by John Kitzhaber, then state senate president (and later governor) and an emergency room physician. It took four years for the state to gain federal permission to institute its landmark system of providing coverage for more people, but for fewer services. Under the system, which Kitzhaber described as a shift "from who is covered to what is covered," MEDICAID in Oregon pays for only a set number of "diagnosis-treatment" pairs on a ranked list of 710 conditions. The list ranks services with a high likelihood of success and a high likelihood of death or disability if they are not performed (such as an appendectomy for appendicitis) near the top of the list and services that are unlikely to work or unlikely to have much of an impact (such as antibiotics for a viral infection) at the bottom.

Oregon launched the rationing debate in 1987, when, at Kitzhaber's urging, the state legislature voted to end Medicaid coverage for organ transplants, an optional service under federal law. (See ORGAN DONATIONS AND TRANSPLANTS.) Instead, it directed more funds to prenatal care for pregnant women and basic care for young children. Legislators knew the new law meant probable death for an estimated thirty Oregonians who would lose their chance for transplants. But the same amount of money would provide basic health and prenatal services to about twelve hundred pregnant women and eighteen hundred children. What the legislature did not foresee was the publicity that would be generated by Coby Howard, a seven-year-old leukemia victim who needed a bone marrow transplant. Because the boy could no longer get Medicaid assistance for the transplant, Howard's family turned to the media to help raise $100,000 to pay for the surgery. Coby died that December, before the money could be raised. Although Oregon's legislature meets only in odd-numbered years, its emergency board convened in 1988 to consider overturning the policy in light of the Coby Howard case. Kitzhaber was labeled "Dr. Death" by critics when he led the charge to maintain the no-transplant policy. Frustrated, Kitzhaber developed the framework for what would become the Oregon Health Plan.

The heart of the proposal, passed by the legislature in 1989, expanded Medicaid to cover every Oregonian with income under the federal poverty line. But to pay for the estimated 120,000 new beneficiaries, Medicaid coverage would be denied for services deemed less important by an eleven-member commission of consumers and health care providers. Using cost-effectiveness data as well as input from public hearings and town meetings, the commission devised a list of 709 (later expanded) medical conditions and their treatments. At the top of the list were fatal but curable ailments, with illnesses best treated by preventive care listed next, and, at the bottom, conditions for which treatment prolongs life without improving its quality or is primarily cosmetic. The last treatment pair as of 2001 was laser surgery to correct vision problems.

After the list was refined to prevent it from violating the AMERICANS WITH DISABILITIES ACT (ADA), the federal government granted Oregon permission to proceed with its program in March 1993 under existing "waiver" authority written into Medicaid law. The program officially began in February 1994, with coverage of the first 606 items on what was originally a 745-item list of diagnosis-treatment pairs. In 1995, when the program began to outstrip its financing, the legislature scaled it back somewhat, imposing premiums on a sliding scale of up to $26 per month, eliminating coverage for full-time college students, requiring individuals to show their incomes have been below the poverty line for three months (up from one), and requiring them to have no more than $5,000 in liquid assets. The legislature also reduced the number of conditions funded to 574 and, as of 2001, was funding to line 566, eliminating, among other things, treatments for poison ivy and genital warts.

As part of the original plan, Oregon also passed an employer mandate proposal to provide coverage to most of the rest of the state's uninsured population. But the proposal was delayed repeatedly by the legislature and was ultimately repealed after the state failed to obtain a needed waiver from the federal government. Instead, the

state enacted a special program to help subsidize employer coverage for individuals with incomes up to 150 percent of poverty.

In 2002 the state got a new waiver essentially to divide the program into two parts beginning January 1, 2003. The first part, called OHP Plus, would provide the existing package of benefits to those who are "categorically" eligible for Medicaid; in other words, those whose coverage is required by the federal government (pregnant women, children, and disabled individuals, among others). The new OHP Standard would provide a somewhat less rich benefit package, including higher premiums and copayments, to those higher up the income scale, including childless adults with incomes up to 180 percent of the federal poverty line. Because the state was strapped for cash at the time, funding for the new OHP Standard would largely come from cutting benefits for those in the OHP Plus program, once again giving the poorest individuals less to provide slightly better-off individuals with something.

Despite Oregon's landmark efforts, however, the program essentially collapsed when the changes were implemented in 2003. Despite the reduced benefits for the very poorest beneficiaries, funding was inadequate to sustain the new OHP Standard program, which was forced to cap enrollment at twenty-four thousand in 2004. Wrote University of North Carolina health policy professor Jonathan Oberlander in the policy journal *Health Affairs* in December 2006: "OHP is now covering both fewer services and fewer people, and the elimination of entire benefit categories and rollbacks in enrolled beneficiaries looks more like the arbitrary cuts common in other states than the rational and equitable model of prioritization to which Oregon aspired."

Organ donations and transplants

Organ donations were officially encouraged by Congress with enactment of the 1984 National Organ Transplant Act (PL 98–507). The measure established a national computerized network, the Organ Procurement and Transplantation Network, which maintains a list of patients waiting for organ transplants as well as a round-the-clock computerized organ placement center that matches donors and recipients. In addition, the act provided funds to upgrade and coordinate local and regional agencies that procured human organs for transplantation. It made selling organs for transplantation a federal crime, subject to fines of up to $50,000. Passage of the bill was delayed by a fight over whether the legislation should include authorization of funding for drugs that can prevent rejection of transplanted organs for those who could not otherwise afford them. To the dismay of its House sponsor, Rep. Al Gore, D-Tenn. (later senator and vice president), the final measure did not include the drug coverage provision, although it was added in subsequent legislation.

Budget reconciliation legislation in 1986 (PL 99–509) expanded the federal organ donor program by requiring that hospitals that participate in MEDICARE and MEDICAID establish protocols for making "routine requests" about potential organs to be donated from the next-of-kin of patients who die in the hospital. That legislation also required that hospitals performing transplants be members of the national network established under the 1984 law. And, for the first time, it provided under Medicare up to one year's coverage of immunosuppressive drugs for the patients who undergo transplants. Legislation cleared in 1988 (PL 100–607) reauthorized the 1984 law and called for creating a bone marrow registry to match donors with recipients. The measure also authorized a block grant to help states provide immunosuppressive drugs to transplant patients without insurance coverage. Fiscal year 1993 budget reconciliation legislation (PL 103–66) gradually expanded Medicare coverage of immunosuppressive drugs, from one year to three years, beginning in 1998. The 2000 Beneficiary Improvement and Protection Act (PL 106–554) made Medicare coverage of immunosuppressive drugs unlimited.

Medical advances, including the use of unrelated living donors, the "splitting" of cadaver livers and lungs to provide transplants to two patients with one organ, and the use of live donors for liver transplants by using only a portion of the organ, all helped make transplants more available. But the number of patients waiting for organs still far outstrips the supply. According to the UNITED

Despite medical advances, including improvements in organ shipment technology, the demand for organs still far outstrips the supply. Source: *Ken Heinen*

NETWORK FOR ORGAN SHARING (UNOS), which runs the national network under contract to the HEALTH AND HUMAN SERVICES DEPARTMENT (HHS), the number of patients on organ waiting lists more than tripled since the 1990s. In the first eleven months of 2007 according to UNOS figures, 21,401 transplants were performed, but more than 97,900 people remained on waiting lists, and, through the end of September, 5,062 people died before receiving a needed organ. The chronic organ shortage has led to political strife. In 1998 HHS proposed rules designed to reduce geographic disparities in the way organs for transplant are distributed. HHS officials argued that scientific advances in shipping organs made obsolete the old system of first offering donated organs in the closest area. Instead, the new rules called for a national waiting list so donated organs would go to those who could most benefit, regardless of where they were located. But states that had been more successful in getting citizens to become organ donors cried foul, as did UNOS. Officials at UNOS charged that the proposed rules would result in too many organs going to the largest transplant centers, possibly forcing some smaller centers to close. In the Labor-HHS portion of the fiscal 1999 omnibus appropriations bill (PL 105–277), Congress imposed a one-year moratorium on the rules. But it also ordered UNOS to provide detailed data, including center-by-center statistics on survival rates, organ waste, and waiting lists. The bill also called for a study by the INSTITUTE OF MEDICINE (IoM) on existing distribution policies and the potential effect of the new rules.

Both sides in the dispute claimed that the IoM report, released July 20, 1999, buttressed their case. UNOS noted the report found that the current system worked relatively well. HHS noted that the report found that larger organ sharing regions "will result in more opportunities to transplant sicker patients without adversely affecting less sick patients" and that larger regions would not result in fewer organs being donated, closure of smaller centers, wasting organs on those unlikely to survive, or making organs less available to minorities and those in rural areas—all charges leveled by UNOS in its fight against the rules.

By that fall, congressional committees with direct oversight of transplant policies began to weigh in. Under the leadership of Thomas J. Bliley Jr., R-Va., in whose Richmond district UNOS was headquartered, the House

Commerce Committee on October 13 approved a bill to reauthorize the National Organ Transplant Program that would have stripped the department of much of its authority to oversee UNOS policies. The Clinton administration argued that the bill was unconstitutional because it would have given "to a private organization regulatory authority unfettered by executive involvement."

On October 18, HHS issued a revised version of the final rules, including language clarifying that organs should not be wasted by giving them to patients unlikely to live. But UNOS and its allies in Congress said the changes did not go far enough, and Congress again stepped in to block the rules from taking effect until the following March.

In 2000 the fight picked up where it left off in 1999. On April 4, the House passed the bill approved by the Commerce Committee the previous October, with an amendment that would cancel the rules outright. Despite a veto threat from President Clinton, it was approved 275-147.

In the Senate, meanwhile, Health, Education, Labor, and Pensions (HELP) Committee Public Health Subcommittee chair Bill Frist, R-Tenn., a heart-lung transplant surgeon before being elected to the Senate, was trying to find a middle ground in the debate. The day after the House acted, Frist, along with UNOS backers Jeff Sessions, R-Ala., and Tim Hutchinson, R-Ark., introduced a bill Frist said "would ensure that organ transplant policies are developed by the medical community while allowing for the appropriate federal oversight of the organ transplant system." Before the bill could be marked up, however, Frist, HHS officials, and HELP Committee ranking member Edward M. Kennedy, D-Mass., reached a deal on changes that finally satisfied both sides. The committee unanimously approved the bill April 12. (See SENATE HEALTH, EDUCATION, LABOR, AND PENSIONS (HELP) COMMITTEE.)

But the legislative process ended there. Wisconsin Democratic senators Russ Feingold and Herb Kohl blocked floor consideration of the bill in deference to their governor (soon to become HHS secretary) Tommy G. Thompson, who had sued HHS to overturn the rules.

In the end the fight was settled not in Congress but by the parties to the dispute. In September 2000 UNOS signed a new contract with HHS to continue to operate the program in which it essentially agreed to most of the provisions of the regulations.

Orphan drugs

These prescription medications are designed to treat rare conditions, generally considered those that affect fewer than 200,000 people alive and living in the United States at any time. According to the National Organization for Rare Disorders, there are more than five thousand such disorders, which together affect approximately twenty million Americans. Among the better known of such rare diseases are amyotrophic lateral sclerosis (Lou Gehrig's disease), cerebral palsy, and ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS).

Because drug development is so expensive (costing an average of $500 million and taking from twelve to fifteen years, according to Pharmaceutical Research and Manufacturers of America), drugs that will be used by a relatively small number of patients are not cost-effective for companies to pursue. One drug approved in 1997, for example, was estimated to benefit only an estimated four hundred patients worldwide. In 1982 Congress cleared the Orphan Drug Act (PL 97–414; signed into law January 4, 1983), which provided a series of incentives for companies to develop drugs to treat orphan diseases. The most significant of the incentives granted companies that developed orphan drugs an additional seven years of "exclusivity," or the right to sell the drug in a market free of competition from generic copies. (See GENERIC DRUGS.) A drug's patent life is normally seventeen years, although, as a matter of practice, much of that has been consumed by the time the drug completes the approval process and is first offered for sale. As of 2007, the FOOD AND DRUG ADMINISTRATION (FDA) had approved 245 orphan drugs and biologic products, with another 1,150 in the approval pipeline.

Companies can also receive tax incentives for clinical research they have performed or funded. In the 1997 Taxpayer Relief Act (PL 105–34), Congress made permanent the tax credit for orphan drug research, which reimburses companies for up to 50 percent of qualified clinical testing expenses.

In 2002 Congress approved two new bills to further encourage the development of products to treat rare diseases. The Rare Diseases Act (PL 107–280) authorized in law the NATIONAL INSTITUTES OF HEALTH (NIH) Office of Rare Diseases, which was created administratively in 1993 to act as a clearinghouse for the public and medical professionals for information about treatment of rare disorders. The Rare Diseases Orphan Product Development Act (PL 107–281) proposed to double funding for the FDA's orphan drug program that provides funding for clinical trials and other expenses involved in gaining approval for drugs or devices to treat rare diseases.

Outcomes

In medical parlance, outcomes are the results of a medical intervention. The ultimate "bad outcome" is a patient's death. But good outcomes can be measured in various ways, including not only a lengthened lifespan but also an improvement in the quality of life even if the lifespan is not lengthened. The measurement of outcomes has been a focus of HEALTH SERVICES RESEARCH for only the past few decades, but, in the age of MANAGED CARE, it has taken on a new importance and prominence as a proxy for the question "What works in medicine?" Measuring outcomes can be as specific as charting the number of complications suffered by patients of an individual surgeon or as general as looking at the childhood immunization rates of an entire metropolitan area after implementing a new public health campaign. More and more health plans and government agencies are also measuring patient satisfaction under the broad umbrella of "outcomes research," on the theory that even if a patient is successfully cured of a condition, if the experience was unsatisfactory, there is likely room for improvement.

P

PACE program

See PROGRAM OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE).

Parental consent

Parental consent is a legal requirement that health care professionals obtain the permission of one or both parents before rendering treatment to minors. When parental consent is applied to ABORTION, the U.S. Supreme Court has required that states employ a JUDICIAL BYPASS allowing a judge to consent to the procedure if the minor does not wish to consult her parents. Twenty-eight states had parental consent laws on the books in 2007, according to the PLANNED PARENTHOOD FEDERATION OF AMERICA (PPFA). In twenty-four of those states the laws were being actively enforced (in four others, laws were blocked by courts). Some of the states also allowed a minor to seek consent from an adult family member other than a parent in certain situations. (See PARENTAL INVOLVEMENT LAWS.)

Parental involvement laws

Parental involvement laws are one of the most contentious issues surrounding the issue of ABORTION. Proponents of such laws point out that minors need a parent's permission to go on a school field trip, to get their ears pierced, or to be given an aspirin by a school nurse. Yet, according to the U.S. Supreme Court, parents do not necessarily need to be told, much less give permission, for their daughters to have an abortion—a surgical procedure. They also say the government has no business—and no authority—to interfere in the raising of children. Foes of consent and notification requirements, however, say that such laws can put some minors at risk, particularly those who are victims of incest or who fear violent reactions from parents if they tell them they are pregnant. Requiring minors to tell parents (or, for that matter, having to seek permission from a judge) also makes it more likely teenagers will delay seeking medical care. Adolescents are twice as likely as other women to have second-trimester abortions, which are considerably more dangerous than abortions performed earlier. Teenagers frightened of telling their parents about an unplanned pregnancy may also seek even more dangerous options—illegal abortions.

In fact, a majority of teenagers who have legal abortions do tell a parent. According to the Alan Guttmacher Institute, 61 percent undergo the procedure with at least one parent's knowledge; 45 percent of minors who have abortions tell both their parents.

In 2007 thirty-five states enforced PARENTAL CONSENT or PARENTAL NOTIFICATION laws for minors seeking an abortion, according to the PLANNED PARENTHOOD FEDERATION OF AMERICA (PPFA). Eight other states had laws on the books that were not being enforced, in some cases because they were blocked by court orders.

The Supreme Court has made its position clear on the issue of parental involvement laws for abortion. In the 1979 decision *Bellotti v. Baird,* the Court struck down a Massachusetts law that required minors to seek parental consent before approaching a judge for a waiver and that permitted the judge to deny the petition if he or she found that the abortion would be against the minor's best interests. The Court said that a minor

must be given an opportunity to approach a judge on a confidential basis instead of going to her parents and that a judge must grant a "mature minor's" request for an abortion, regardless of whether the judge feels it would be in the minor's best interest or not.

The Court expanded on its requirements for parental involvement laws in two cases decided in 1990. In *Hodgson v. Minnesota,* a 5-4 majority ruled that a state can require both parents to be notified, but only if the law also includes a judicial bypass. In a companion case, *Ohio v. Akron Center for Reproductive Health,* the Court similarly upheld a one-parent notification law, but also only if it had a judicial bypass. The cases represented the first time the Court extended its requirement for minors to seek a judge's permission for an abortion from consent laws to those merely requiring parental notice.

Parental notification

Parental notification is the legal requirement that health care professionals treating minors notify one or both parents before treatment is rendered. In 2007, according to the PLANNED PARENTHOOD FEDERATION OF AMERICA (PPFA), sixteen states had parental notice laws on ABORTION on the books. All but one of them required notification of one parent, while Minnesota's law required notice to both parents. Of the sixteen state laws, eleven were being enforced. In three states, minors had the option of notifying specified adults other than their parents in certain circumstances. In 2006, according to the Center for Reproductive Rights, no state required parental consent or notice for minors seeking contraceptive services, prenatal care, sexually transmitted disease services, or treatment for alcohol or drug abuse. Many states explicitly authorized minors to receive such services on their own, in confidence. (See also PARENTAL INVOLVEMENT LAWS.)

Fights over parental notification for both abortion and family planning services have been a major factor in Congress's failure to reauthorize the federal government's TITLE X FAMILY PLANNING PROGRAM of the Public Health Service Act.

The issue first emerged in 1983, when the Reagan administration issued regulations to require parental notification for minors seeking prescription contraceptives through Title X clinics. Opponents of the regulations called them the "squeal rule." That effort fizzled when a federal appeals court threw out the rule and the administration declined to appeal.

In 1985 the HOUSE ENERGY AND COMMERCE COMMITTEE, by voice vote, rejected an amendment by Rep. William E. Dannemeyer, R-Calif., to require parental notification for minors seeking contraceptives. When Dannemeyer was not allowed to offer a similar amendment during floor debate, his objections helped kill the reauthorization bill. In the Senate, a compromise engineered by Labor and Human Resources Committee chair Orrin G. Hatch, R-Utah, won a special demonstration program for his home state, whose parental consent requirement for contraceptive services rendered it ineligible for Title X funding. That bill, however, never made it to the Senate floor.

In 1987, with Democrats having taken the Senate back, Hatch was rebuffed in his attempt to get special treatment for Utah, with the Labor Committee voting 11-5 against the exception. But that reauthorization bill died, too.

The full Senate took up the issue in September 1990, when members by voice vote adopted an amendment that would have required Title X recipients who perform abortions with nonfederal funds to notify parents of minors seeking an abortion forty-eight hours before the procedure. But it was unclear exactly what the Senate's sentiment was, because the amendment was appended to an unrelated amendment on the strategic petroleum reserve. That bill, too, failed to become law after members were unable to cut off a filibuster against it. Two weeks later, abortion rights advocates failed to beat back another parental notification amendment, this time on the LABOR–HEALTH AND HUMAN SERVICES–EDUCATION APPROPRIATION (Labor-HHS) bill, which would have applied to all recipients of federal funds, on a 48-48 tie. The amendment, however, was dropped in conference.

That amendment, drafted by Sen. Nancy Landon Kassebaum, R-Kan., was notable in that it was equally opposed by those on both sides of the abortion debate.

Kassebaum's proposal would have required that at least one parent consent to an abortion or be notified forty-eight hours in advance. It also included numerous exceptions, such as allowing a pregnant teenager to obtain permission from a judge, physician, or professional counselor with no financial interest in the abortion.

The House, through various parliamentary sleights of hand, managed never to vote on parental involvement—at least until 1993. That year, as part of yet another bill to reauthorize Title X that would not become law, members rejected a motion to recommit the bill with instructions to report it back with a restrictive federal parental notice requirement for those family planning clinics affiliated with abortion facilities. The vote, however, seemed to turn less on the issue of parental involvement than on whether the federal government or the states should be the ones to determine how much involvement, if any, was appropriate. Many who rejected federal intervention said they were strong supporters of state parental notice or consent laws.

In 1996 the issue of parental notification or consent for receipt of contraception, dormant since the Title X "squeal rule" was struck down in 1983, again reemerged. Rep. Ernest Istook, R-Okla., pushed an amendment to the Labor-HHS appropriations bill that would have required minors to have parental consent for receipt of prescription contraceptives or else to wait five business days for the provider of the services to notify a parent or legal guardian of the intent to provide contraceptive drugs or devices. The House instead adopted a substitute amendment that required clinics to provide counseling to minors on how to discourage coercion to have sex and that required them to encourage parental involvement. The year 1997 proved to be a replay of 1996. In 1998 Istook's insistence on a straight up-or-down vote on the House floor on his amendment effectively prevented the bill from ever coming up. On October 8, just days before adjournment—and after conferees on the measure had agreed among themselves not to include Istook's amendment in the final measure—House leaders brought the bill to the floor long enough to give Istook his vote. The amendment was adopted by 224–200, but it was not included in the final measure.

Part A (Medicare)

See HOSPITAL INSURANCE (HI).

Part B (Medicare)

See SUPPLEMENTARY MEDICAL INSURANCE (SMI).

Partial-birth abortion

In 2007 the U.S. Supreme Court upheld a 2003 federal law that, for the first time since the high court legalized ABORTION nationwide in 1973, banned a specific abortion procedure. The Court's ruling in *Gonzales v. Carhart* allowed to stand the ban of the dilation and extraction (D&X) procedure referred to by its opponents as "partial-birth abortion." Controversy had raged over the procedure since it first rose to national attention in 1995. Both sides disputed how often the procedure was used and at what point in pregnancy, as well as what procedures the law would actually ban.

The Partial-Birth Abortion Ban Act of 2003 criminalized abortions in which "the person performing the abortion deliberately and intentionally vaginally delivers a living fetus until, in the case of a head-first presentation, the entire fetal head is outside the body of the mother, or, in the case of breech presentation, any part of the fetal trunk past the navel is outside the body of the mother for the purpose of performing an overt act that the person knows will kill the partially delivered living fetus; and . . . performs the overt act, other than completion of delivery, that kills the partially delivered living fetus."

Doctors who performed abortions complained that the definition was broad enough to encompass not only the D&X procedure abortion opponents said they intended to ban, but also the dilation and evacuation (D&E) procedure that was the most common method of terminating pregnancies after the first trimester. Three appeals courts agreed with them. The Supreme

Sen. Rick Santorum (R-PA) (center), flanked by Republican House and Senate members, speaks during a news conference following Senate passage of the Partial-Birth Abortion Ban Act of 2003. In 2007 the Supreme Court upheld the constitutionality of the law in Gonzales v. Carhart. *Source: CQ Photo/ Scott J. Ferrell*

Court, however, in *Gonzales v. Carhart* essentially reversed its 5-4 position in *Stenberg v. Carhart* (2000), in which it found a nearly identical Nebraska law unconstitutionally vague and lacking an exception to protect the health of the pregnant woman.

The fight over D&X began because abortion opponents hoped focusing on the procedure would help draw attention to the practices used in abortion. "We would hope that, as the public learns what a 'partial-birth abortion' is, they might also learn something about other abortion methods and that this would foster a growing opposition to abortion," Douglas Johnson of the NATIONAL RIGHT TO LIFE COMMITTEE (NRLC) told the *New Republic* magazine in 1996.

Adding to the confusion was that there was no medical procedure officially termed "partial-birth" abortion. The phrase was coined by antiabortion activists to describe a procedure devised independently by a physician in Ohio and one in California. The Ohio physician, Martin Haskell, wanted to find a way to perform second-trimester abortions without an overnight hospital stay, because local hospitals did not permit most abortions after eighteen weeks. Haskell's procedure was a variation on the more common D&E method, in which the physician dismembers the fetus still in the womb, and then removes the pieces through the woman's dilated cervix. Haskell's procedure involved pulling the fetus intact through the cervix, feet first, until only the head remained in the womb. Using scissors or another sharp instrument, the head was then punctured, and the skull compressed, so it, too, could fit through the dilated cervix. Haskell called his procedure "dilation and extraction." California physician James McMahon, who died in November 1995, referred to his variation as "intact D&E."

Abortion opponents learned of the procedure after Haskell presented it at a conference of the National Abortion Federation in 1992. Appalled, they dubbed it "partial-birth abortion" and set about to see it banned. The NRLC commissioned drawings to illustrate the procedure and published them in booklet form as well as placing them as paid advertisements in newspapers to build public opposition. Haskell's home state of Ohio passed the first ban on D&X abortions in 1995, but it was struck down by a federal district court, which ruled it was so vague that it would also ban more common procedures used earlier in pregnancy. In 1998 the Supreme Court refused to hear Ohio's appeal of the decision.

Lawmakers on Capitol Hill also joined the debate. The original bill introduced in Congress in 1995 would have banned a procedure defined as "an abortion in which the person performing the abortion partially vaginally delivers a living fetus before killing the fetus and completing the delivery." It would have barred prosecution of the pregnant woman but would have imposed fines and prison terms of up to two years for those performing such an abortion and permitted the woman, her husband, or the parents of a minor to sue the abortion provider for damages.

From the beginning, the federal measure enjoyed more than a two-thirds majority support in the House, which first passed it by a vote of 288 to 139 on November 1, 1995. The Senate, long more supportive of abortion rights than the House, passed the bill, 54-44, on December 7, only after adding to the measure an exception to the ban for situations in which the life of the woman was endangered "by a physical disorder, illness or injury and no other medical procedure would suffice." The Senate refused to adopt a separate amendment allowing the procedure to protect the woman's health, by a vote of 47 to 51.

That failure to include a health exception, abortion rights proponents and President Bill Clinton argued, made the measure unconstitutional under the tenets of *ROE V. WADE* and its 1973 companion case, *Doe v. Bolton,* in which the Court held that abortion could not be banned before viability and only after that point if exceptions were allowed to protect the woman's life or health. Abortion opponents, however, pointed out that the Supreme Court had defined *health* so broadly as to encompass psychological as well as physical threats. Thus, they said, adding a health exception would "gut" the measure.

President Clinton kept his promise not to sign the bill without a health exception, and he vetoed it on April 10, 1996, surrounded by women who had undergone the procedure and who told heart-rending stories of their badly deformed fetuses who were almost certain to die soon after birth. The procedure, they argued, not only saved their lives but also their future ability to bear children.

Republicans waited to hold the override vote until September, as close to the November elections as they could manage. But even that added pressure was not enough to enact the measure over the president's objections. Although the House voted 285-137 to override on September 19, the Senate tally of 57-41 was nine votes short of the needed two-thirds majority. Three senators who had voted against the bill in 1995 switched sides to support the override: Patrick J. Leahy, D-Vt.; Arlen Specter, R-Pa.; and Sam Nunn, D-Ga.

In 1997 proponents of the measure picked up where they left off. In the Senate, leaders designated the measure S 1, denoting its importance. The House again voted first, passing the measure in March, by its biggest majority yet: 295-136. Just days before the Senate vote in May, the AMERICAN MEDICAL ASSOCIATION (AMA) unexpectedly endorsed the measure.

Even the AMA's imprimatur, however, was not enough to put the measure over the top. Although the tally was the Senate's highest yet, the 64-36 vote was still three votes short of the number needed for an override. President Clinton vetoed the bill in October 1997. As before, Republican leaders waited until closer to the election to mount their override effort. The House overrode the veto on July 23, 1998, by 296-132. The Senate fell short, again voting 64-36, on September 18, ending the effort for the 105th Congress.

Backers of the measure hoped the 1998 elections would add the needed three votes to their side, but that did not happen. After the elections, both sides estimated that the net change on the partial-birth abortion issue for the 106th Congress in the Senate would be zero or one.

The debate continued to rage at the state level. By the end of 1998, twenty-eight states had passed various procedure bans—many, but not all, based on the proposed federal law. However, in twenty of those states, courts or the state attorney general had blocked enforcement.

By far the biggest source of dissension about the issue—other than what a partial-birth abortion is—has been the number of such abortions and at what stage of pregnancy they are performed. A 1998 study by the Alan Guttmacher Institute (AGI), an abortion rights research group, found that in 1996 D&X procedures accounted for just 0.03–0.05 percent, or about 650 procedures, of 1.37 million abortions performed. The large majority of procedures occurred between twenty and twenty-four

weeks of pregnancy. According to AGI and the CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC), only 320 abortions took place after twenty-six weeks, accounting for 0.0002 percent of all abortions. Further, only three physicians in the United States were known to perform third-trimester abortions. By 2000, according to AGI, the number of D&X procedures had risen to an estimated 2,200 of the 1.3 million abortions performed that year, still less than 0.2 percent of the total.

Although the NRLC claimed that the number of such abortions was more likely in the thousands than the hundreds, the organization did not dispute that healthy babies aborted in the ninth month were the exception, not the rule. The NRLC vehemently opposed proposals offered as an alternative to the partial-birth procedure ban that would have banned all abortions after the start of the third trimester. Such a bill, said the NRLC, "means that the vast majority of partial-birth abortions would continue without any limitation, because they occur *before* the third trimester" (its emphasis).

Even the medical community could not agree on whether the procedure should be banned. The American College of Obstetricians and Gynecologists (ACOG) firmly opposed the legislation from the beginning. "The College finds very disturbing that Congress would take any action that would supersede the medical judgment of trained physicians and criminalize medical procedures that may be necessary to save the life of a woman," the organization wrote in a letter to then Senate majority leader Bob Dole, R-Kans. "Moreover, in defining what medical procedures doctors may or may not perform, [the legislation] employs terminology that is not even recognized in the medical community—demonstrating why Congressional opinion should never be substituted for professional medical judgment."

Until 1997 the nation's leading medical organization, the AMA, shared ACOG's opinion. In December 1996, the AMA's policymaking House of Delegates, noting that "ethical concerns have been raised by the intact dilatation and extraction," concluded that "the physician must . . . retain the discretion to make that judgment, acting within standards of good medical practice and in the best interest of the patient." But after negotiating with congressional sponsors of the measure to make what both sides conceded were "cosmetic" changes to protect physicians from wrongful prosecution, the AMA endorsed the legislation in May 1997, just days before the Senate vote was scheduled. "Although our general policy is to oppose legislation criminalizing medical practice or procedure, the AMA has supported such legislation where the procedure was narrowly defined and not medically indicated. [The House bill] now meets both those tests," wrote the AMA's executive vice president, P. John Seward, in a letter to the bill's Senate sponsor, Rick Santorum, R-Pa. A 1998 audit of the AMA, however, found that trustees had "blundered" in endorsing the bill, contradicted longstanding AMA policy, and "set itself up for accusations of playing politics." The audit, by consulting firm Booz Allen Hamilton, came after the AMA replaced most of its leadership in the wake of an unrelated scandal.

In 1999 lawmakers in Washington took up the measure again. This time, the Senate acted first, passing legislation on October 21, by a 63-34 margin. Although no senator changed his or her vote from the year before, backers of the ban picked up a vote because of the Senate membership changes resulting from the 1998 elections. The bill lost the AMA's backing, however. "The current version . . . subjects physicians to criminal prosecution. For this reason we do not support the bill," said a statement from AMA trustee John C. Nelson, officially reversing the organization's previous position.

The bill also picked up some language that dismayed its supporters. By 51-47, senators voted to add a "sense of the Senate" amendment offered by abortion rights supporters Barbara Boxer, D-Calif., and Tom Harkin, D-Iowa, that said the 1973 Supreme Court ruling *Roe v. Wade* was "appropriate" and should not be overturned. Sponsors said it marked the first time Congress had ever taken a vote on whether to endorse the historic ruling.

The House waited to vote until the next year, approving a slightly different bill 287-141 on April 5, 2000. But a final measure never emerged from the 106th Congress because the Supreme Court, on June 28, struck down a substantially similar Nebraska law. By a 5-4 ruling, the majority in *Stenberg v. Carhart* held that Nebraska's ban was unconstitutionally vague and lacked a needed exception allowing the procedure to be used to protect the health of the pregnant woman.

The election of George W. Bush in 2000—who vowed on the presidential campaign trail to sign a "partial-birth abortion" ban if presented with such a measure—changed the arithmetic. Congress would no longer need a two-thirds majority to overcome a presidential veto. Overcoming the Supreme Court's ruling in the Nebraska case would prove to be a more difficult task.

It was not until June 2002 that ban supporters unveiled their solution. The new measure included a more specific definition of the procedure that supporters said would pass Supreme Court scrutiny. Rather than adding a health exception, sponsors included fifteen pages of congressional "findings" holding that no exception was needed because the procedure "is never medically necessary" to protect a pregnant woman's health.

The Republican-controlled House passed the new version of the bill on July 24 with a 274-151 vote and one member voting present. The Senate, in Democratic hands at that point, took no action on the bill.

With the Senate restored to Republican control in the 108th Congress, the upper chamber acted first on the bill in 2003. It passed the bill, designated S 3, 64–33 on March 13. But sponsors' hopes that the House could quickly pass the Senate bill and send it to President Bush for his signature were dashed when the Senate again passed the Harkin-Boxer language expressing support for *Roe v. Wade.* That amendment passed 52-46.

The House passed the bill 282-139 on June 4, setting up what turned out to be a months-long conference, even though the only difference between the two bills was the Senate's nonbinding language supporting *Roe.* Senate Democrats, led by Boxer, managed to use procedural tactics to tie up the bill, although in the end the *Roe* language was dropped and the final bill was sent to President Bush, who signed it into law (PL 108–105) on November 5, 2003.

The law did not take effect at that point, however. Abortion rights groups filed three separate lawsuits for which they received almost immediate injunctions. Planned Parenthood filed on behalf of its providers in federal district court in San Francisco, the American Civil Liberties Union filed on behalf of the National Abortion Federation in federal district court in New York, and the Center for Reproductive Rights filed on behalf of a handful of individual abortion providers—including LeRoy Carhart, the Nebraska physician on whose behalf the Supreme Court had struck down a similar state ban three years earlier—in federal district court in Nebraska.

Judges in all three cases found for the abortion rights plaintiffs, and those holdings were upheld on appeal. On July 8, 2005, the Eighth Circuit Court of Appeals unanimously affirmed the judgment in the case filed in Nebraska, noting that the federal government's lawyers presented "no new evidence which would serve to distinguish this record from the record reviewed by the Supreme Court in Stenberg" in 2005, and therefore finding the new version of the bill unconstitutional for its failure to include a health exception.

The government petitioned *Gonzales v. Carhart* to the Supreme Court in September 2005, even before the appeals courts in New York and San Francisco also upheld the lower court rulings striking the law down.

Meanwhile, new evidence emerged on the medical front. In June 2004 the *American Journal of Obstetrics and Gynecology* published a study that found women who had D&X abortions experienced no more complications than those who had more traditional D&Es, even though the D&X procedures were performed later in pregnancy, when the complication rate would be expected to be higher. Thus, the study's authors concluded, in some cases D&X could be considered as safe as—and safer than—D&E. What was almost equally surprising about the study was that the 383 abortions after twenty weeks gestation examined were performed by doctors at Cornell University's medical school in New York City.

Lead author Stephen Chasen, a Cornell obstetrician/gynecologist who specialized in care of women with high-risk pregnancies, was one of the plaintiffs in the suit filed in federal district court in New York. He said in a 2006 interview that the 2004 study, which was entered into evidence at the trial, not only disproved the congressional finding that the procedure was "never medically necessary," but also the finding that it was a "disfavored procedure" in the medical community. "I learned it here at an Ivy league medical school where I teach it," he told National Public Radio. "My other plaintiffs and experts testifying in these cases come

from some of the top hospitals in the U.S. and come from some of the top medical schools. The ACOG, which represents more than 90 percent of all practicing ob/gyns has come out forcefully in stating that this ban is not consistent with health and safety of women."

On April 18, 2007, the Supreme Court in *Gonzales v. Carhart* ruled the law constitutional by a 5-4 vote, overturning *Stenberg v. Carhart* (2000), which had also been decided by a margin of 5-4. Many observers attributed the changed outcome to changes in the Court's membership; Chief Justice John G. Roberts Jr. and Justice Samuel A. Alito Jr. had been appointed to the bench by President Bush since the *Stenberg* decision.

Although Justice Anthony M. Kennedy, who wrote the majority opinion, acknowledged that Congress had erred in finding that the procedure was never medically necessary, he said that Congress remained within its rights—and within the framework of abortion rights allowed under *Roe v. Wade,* as constrained by *PLANNED PARENTHOOD OF SOUTHEASTERN PENNSYLVANIA V. CASEY* in 1992—to pass the law. "The government may use its voice and regulatory authority to show its profound respect for the life within the woman," Kennedy wrote. "The Act's ban on abortions involving partial delivery of a living fetus furthers the Government's objections. Congress determined that such abortions are similar to the killing of a newborn infant."

In a dissent signed by the remaining four justices and delivered from the bench, Justice Ruth Bader Ginsburg vehemently disagreed. "Today's decision is alarming," she said. "It refuses to take *Casey* and *Stenberg* seriously. It tolerates, indeed applauds, federal intervention to ban nationwide a procedure found necessary and proper in certain cases by the American College of Obstetricians and Gynecologists (ACOG). It blurs the line, firmly drawn in *Casey,* between previability and postviability abortions. And, for the first time since *Roe,* the Court blesses a prohibition with no exception safeguarding a woman's health."

Participating physician (Medicare)

"Participate" is a term of art in MEDICARE parlance. It does not mean any physician who accepts Medicare payments. Instead, it pertains to a specific program in which physicians agree to accept Medicare's rate as payment in full for all Medicare patients for all Medicare-covered services (patients remain responsible for Medicare's required 20 percent coinsurance). In exchange for agreeing not to balance bill, or charge more than Medicare's set fee, physicians receive incentives, including a 5 percent payment bonus, speedier payment of their bills, and publication of their names in a special directory, thus, theoretically, bringing them more business. (See BALANCE BILLING [MEDICARE].) The participating physician program was first established in 1984 budget reconciliation legislation (PL 98–369) and revised in the 1986 Omnibus Budget Reconciliation Act (PL 99–509). In 2007, 596,340 physicians who billed Medicare had signed up as participating physicians, representing 94.9 percent of those who billed the program. More than 99 percent of physician services under Medicare were assigned in 2006, meaning physicians agreed not to bill more than Medicare allowed. (See BUDGET RECONCILIATION LEGISLATION AND HEALTH CARE.)

Patient "dumping"

This is jargon for hospital emergency rooms denying care or inappropriately transferring to another facility patients with medical conditions requiring emergency treatment, usually because the patient does not have insurance. As part of its 1986 budget reconciliation legislation (PL 99–272), Congress passed the Emergency Medical Treatment and Active Labor Act (EMTALA), which required hospitals, as a condition of participation in MEDICARE and MEDICAID, to screen all patients seeking emergency care and to provide treatment needed to stabilize patients with emergency conditions. Patients in unstable condition cannot be transferred unless the benefit of the transfer outweighs the risk (such as transferring a trauma patient to a facility with a trauma center). Hospitals found to transfer patients inappropriately or refuse treatment because of an inability to pay (or, in some cases, because the hospital cannot get the patient's MANAGED CARE plan to authorize care) can be expelled from the Medicare program (a serious penalty,

because most hospitals get a significant portion of their revenues from the federal program for elderly and disabled individuals), and hospitals and doctors are subject to fines of up to $50,000 for each offense. (See BUDGET RECONCILIATION LEGISLATION AND HEALTH CARE.)

Advocacy groups for poor people have charged that the law is underenforced, although the government has been reticent to release statistics on the subject. Between 1995 and 2001, according to the General Accounting Office, the federal government investigated about four hundred hospitals per year for EMTALA violations and cited about half of those. Since the law was passed, however, only four hospitals were terminated from the Medicare and Medicaid programs, and two of those were later reinstated.

Doctors and hospitals have complained that they are being squeezed unfairly by the EMTALA requirements, on the one hand, and managed care plans' refusing to pay for legitimate emergency treatment, on the other. In 1997 Congress required health plans to pay for emergency room care for Medicare and Medicaid beneficiaries if a PRUDENT LAYPERSON deemed it necessary. But legislation to extend the requirement to privately insured individuals had not been enacted as of mid-2008. In December 1998, however, the HEALTH AND HUMAN SERVICES DEPARTMENT (HHS) issued an order to hospitals to see patients presenting for emergency care without waiting for approval from a managed care plan. As part of that order, it issued guidelines recommending that hospital emergency rooms should not even ask patients about health insurance coverage until the patient's condition has been evaluated and the patient stabilized.

More recently, hospitals have complained that EMTALA puts an undue burden on them to care for uninsured, undocumented immigrants. Yet several studies have found that illegal immigrants are, in fact, lower users of emergency room care than legal immigrants or other uninsured individuals. For example, one study published in November 2007 in the *Archives of Internal Medicine* found that illegal immigrants from Mexico and other Latin American countries were less than half as likely to use hospital emergency rooms in California than Latinos born in the United States.

Patients' Bill of Rights (PboR)

Patients' Bill of Rights (also known by the shorthand PboR) is both the name of several bills passed variously by the House and Senate since 1998 as well as a concept that gained substantial political support in the late 1990s—that members of MANAGED CARE and other health plans should not have to sacrifice needed care in the name of cost-containment. (See HEALTH PLAN.) Despite polls showing broad public support for restrictions on such alleged managed care practices as denying emergency room care and limiting access to specialists, and support from Presidents Bill Clinton and George W. Bush, by 2008 Congress had still failed to reach agreement on a measure. At issue was less the specific protections in question (many of which had been added voluntarily anyway by health plans in response to the backlash against managed care) than the way those rights would be enforced. Democrats and a handful of key Republicans wanted to make it clear that patients could sue their health plans over injuries resulting from care denials. Most Republicans and President Bush were loath to extend any new right to sue and wanted to cap damages to the greatest extent possible. The battle also pitted doctor and patient groups, which wanted access to care legally guaranteed, against insurance and business groups, which feared that the new requirements would add so much to health care costs that many employers would stop providing coverage.

Ultimately, the issue largely faded from the scene as most Americans either opted out of managed care plans that imposed the type of restrictive rules the proposed legislation would have regulated or else the plans reduced restrictions on care in favor of increased cost-sharing for patients.

By far the leading proposal to address a growing backlash against managed care, what came to be known formally as the Patients' Bill of Rights in 1998, was hardly the first such measure. As far back as 1994, several lawmakers introduced their own bills. They were backed by the AMERICAN MEDICAL ASSOCIATION (AMA), which was locked in a life-or-death struggle with man-

aged care, not only for money but also for whether doctors or administrators would exercise autonomy over the nation's health care system. The Patient Protection Act, introduced in 1994 by Sen. Paul Wellstone, D-Minn., one of the most liberal members of the Senate, and Sen. Conrad Burns, R-Mont., one of the most conservative, would have required that patients receive "clear statements about services that are covered and not covered, patient out-of-pocket costs, and financial incentives that restrict or require the use of specific physicians or services." It also would have provided appeals processes for denied claims, required plans to respond to practitioner requests for "prior authorization" within two business days, and required health care provider participation in the development of "utilization review" standards. The bill was never acted on.

Dozens more bills were introduced in the 104th Congress, most of them seeking to address a single issue, such as required coverage of emergency room care, mandatory minimum hospital stays for childbirth and for mastectomies for breast cancer, or barring gag clauses in managed care contracts limiting communications between physicians and patients. But the only provisions that became law required coverage for childbirth. (See GAG CLAUSES [IN MANAGED CARE] and DRIVE-THROUGH DELIVERIES.)

In 1996, during his campaign for reelection, President Clinton sought to delay the growing managed care debate by announcing creation of a commission to examine quality issues in health care. In November 1997 the Advisory Commission on Consumer Protection and Quality in the Health Care Industry proposed a Consumer Bill of Rights and Responsibilities. It included requirements for information disclosure, choice of providers and health plans, access to specialists, access to emergency room care, patient participation in treatment decisions, confidentiality of medical information, nondiscrimination in receipt of health care services, and "an independent system of external review." The commission issued its final report in March 1998, after its members disagreed only about whether patients should be able to sue their health plans for injuries resulting from benefit denials.

The panel ultimately called for a national dialogue "regarding the current state of existing remedies for individuals in public and private plans who are injured as a result of inappropriate healthcare decisions." The panel also came to no consensus on whether its bill of rights should be implemented through legislation or voluntarily.

President Clinton and congressional Democrats had no such doubts. About six weeks after the commission issued its final report, Democrats introduced their Patients' Bill of Rights. Among the provisions in the bill were requirements that:

• Patients injured as a result of being denied care be permitted to sue in state courts. This would amend the EMPLOYEE RETIREMENT INCOME SECURITY ACT (ERISA), which bars those in an employer-sponsored health plan from seeking remedies other than in federal court, where they can recover only the cost of the actual treatment denied.

• Physicians, not health plans, have the final say over what care is "medically necessary" and that health plans not impose gag clauses or any other limitations on communications between physicians and patients (see MEDICAL NECESSITY).

• Health plans permit patients to see specialists who are not part of the plan if the plan has no qualified practitioner to deliver the needed care.

• Health plans provide drugs ordered by physicians even if the drugs are not on the plan's list of approved medications.

• Health plans provide "standing referrals" to see specialists to patients with chronic conditions, so they do not have to go back through their primary care doctor every time they need to see a specialist who is caring for them regularly. (See REFERRAL.)

• Health plans permit patients to participate in approved CLINICAL TRIALS to test new drugs or treatments.

• Health plans permit women to designate their obstetrician/gynecologist as their PRIMARY CARE PHYSICIAN (PCP).

• Health plans cover the costs of emergency room care in situations in which a PRUDENT LAYPERSON would

deem such care necessary and that health plans pay for post-stabilization care provided by a hospital if a patient went to a non-network hospital for an emergency medical condition.

• Health plans allow women in their last trimester of pregnancy or those undergoing an active course of treatment to continue seeing their physician even if the employer changes to an insurance plan that does not include the doctor in that network.

• Health plans not retaliate against doctors, nurses, or other health professionals who advocate for their patients' care and that plans not provide financial incentives to providers to limit care.

• Patients have access to a POINT OF SERVICE (POS) PLAN (at their own expense), allowing them to see doctors outside the plan's network if an employer offers only a closed-panel plan.

• Patients be given uniform, comparable information on what is and is not covered by the plan and the plan's rules and procedures.

• Health plans have in place appropriate safeguards to protect the confidentiality of patients' medical records.

• Health plans maintain internal grievance procedures and provide access to an external, independent body to decide disputes. Plans would have to pay the cost of the "external appeal," and the decision would be binding.

• Health plans pay for minimum hospital stays for women undergoing mastectomies for breast cancer and for reconstructive breast surgery after breast removal. (The latter provision became law in 1998 as part of the year-end omnibus appropriations bill, PL 105–277.)

The bill supported by President Clinton and Democrats, however, was not the one that passed the House in 1998. Instead, House Republicans were forced to act when one of their own, retired dentist Charlie Norwood, R-Ga., gathered 218 cosponsors for his Patient Access to Responsible Care Act, or PARCA, a bill even more sweeping than the Democrats' measure. Faced with mounting horror stories from patients denied care by their HMOs, House GOP leaders put together the Patient Protection Act, which included many of the patient protections common to PARCA and the PboR but, notably, no new right for patients to sue their health plans. The bill also included provisions that were anathema to many Democrats, including a $250,000 cap on damages in MEDICAL MALPRACTICE lawsuits and provisions allowing small businesses to band together to offer health insurance to their workers and to avoid state consumer protection laws. After bypassing the committee process—where the measure would have been open to amendment not only by Democrats but also by Republicans loyal to the American Medical Association, which had surprised GOP allies by endorsing the Democrats' bill—leaders brought the measure directly to the House floor. It passed 216-210 on July 24, after the chamber turned back, 212-217, the Democrats' version. Senate GOP leaders, however, held off Democratic efforts to bring up the bill before the end of the 105th Congress.

Although both the House and Senate managed to pass patients' rights bills in 1999, the 106th Congress ultimately proved no more successful at reaching an agreement on the still high-profile issue than its predecessor.

In 1999 it was the Senate that acted first. Republicans pushed their version, called the Patients' Bill of Rights Plus Act, through the SENATE HEALTH, EDUCATION, LABOR, AND PENSIONS (HELP) COMMITTEE in March, then through the full Senate on July 15, by 53-47. (Two Republicans, John H. Chafee of Rhode Island and Peter G. Fitzgerald of Illinois, joined all forty-five Democrats to vote against the bill.) Democrats complained that although the bill included many of the same headings as their measure, it would have covered fewer people and provided fewer protections. For example, although the Democrats' bill would have covered all 161 million Americans with private health insurance, the GOP bill would have extended its protections only to the estimated 49 million people in "self-insured" plans that were, under ERISA, exempt from state regulation.

While the Senate managed to muscle through a bill favored by its GOP leaders, the House, unlike the year before, lost control of the process. After two key Republican health professionals, Norwood and plastic surgeon Greg Ganske, R-Iowa, joined with Democrats to support their version of the bill, House leaders found them-

selves on the defensive. In the end, the House on October 7 passed the Democratic-backed bill, named for Norwood and House Commerce Committee ranking Democrat John D. Dingell of Michigan, by a resounding 275-191. Sixty-eight Republicans crossed party lines to defy their leaders and vote for the Dingell-Norwood bill. GOP leaders, however, had one remaining trick up their sleeves. A day earlier, leaders pushed through, 227-205, the Quality Care for the Uninsured Act, a series of GOP-favored health-related tax changes and pooling mechanisms opposed by most Democrats. After the managed care bill passed, leaders appended the patients' rights measure to the access bill and sent them as one to a House-Senate conference. That allowed leaders to sidestep a rule that required a majority of conferees to have supported the underlying bill, because the underlying bill was at that point the access measure, not the patients' rights measure. In fact, only one of the thirteen GOP conferees on the measure had voted for the patients' rights bill.

Not surprisingly, the conference was unable to reach agreement through six months of negotiating in 2000, and the fight continued into the administration of George W. Bush.

In 2001 it appeared the dynamic had changed. As Texas governor, Bush had signed a broad patients' rights bill and allowed a separate bill permitting limited lawsuits against health plans to become law without his signature. Although business and insurance groups were worried the president would seek a bill along the lines of the ones backed by Democrats and doctors, that would not be the case. By spring Republicans had basically split into three groups. One group, led by Ganske in the House and John McCain, R-Ariz., in the Senate, was siding with Democrats, doctors, trial lawyers, and consumer groups in pushing for the broadest possible bill. A second group, led by conservatives such as Don Nickles, R-Okla., in the Senate and John A. Boehner, R-Ohio, in the House, sided with business and insurance groups wanting no new right to sue and the most limited expansions of rights achievable. But a third group, which included the president and two more physician-lawmakers, Sen. Bill Frist, R-Tenn., and Rep. Ernie Fletcher, R-Ky., tried to find a middle ground with bills that would extend relatively broad patient protections and a limited new right to sue.

In a stunning move, Vermont senator James M. Jeffords switched from Republican to Independent in June 2001, giving control of the chamber back to Democrats for the first time since 1995 and bringing the patients' rights issue back to the forefront. Democrats made it their first order of business, calling the bill sponsored by McCain, Senate HELP Committee chair Edward M. Kennedy, D-Mass., and former trial lawyer John Edwards, D-N.C., to the floor in June.

The bill did include a few compromises compared with earlier versions. For example, it included a $5 million cap on punitive damages in federal court and, in most cases, required patients to exhaust other remedies before filing suit. But President Bush still vowed to veto it. The bill, said the administration in a June 21 statement, "encourages costly litigation by providing no effective limitations on frivolous class action suits and allows trial lawyers to go on fishing expeditions to seek remedies under other federal statutes."

The Senate, however, ignored the president's threat. The McCain-Kennedy-Edwards bill passed 59-36 on June 29, with nine Republicans crossing party lines to approve the measure, which included some last-minute compromises limiting attorney fees and class action suits and shielding employers from most lawsuits over denied care.

For several weeks, it appeared that the House would pass the Senate version of the bill, and President Bush would have to decide whether to follow through on his veto threat. But at the eleventh hour, Norwood, in a private meeting with the president, abandoned his longtime allies and cut a deal to limit damages in lawsuits. "I argued long and hard with almost every friend I have against putting caps in a bill for four years because we had a president who said he would veto a patient protection bill with caps," Norwood said, referring to President Clinton. "Now we have a president who says he will veto a bill without caps. This compromise is a simple recognition of political reality."

With Norwood's support, the House passed the GOP-backed measure, 226-203, thus forcing a House-Senate conference. But with the impasse looking

unlikely to be broken, and the September 11, 2001, attacks dramatically altering the agenda for the rest of the year, the conference was never formally convened. Instead, Kennedy, Edwards, and McCain set out to try to negotiate a deal with the Bush administration in private, much as Kennedy had worked out a deal on a broad education bill. The negotiations, however, were officially abandoned in August 2002. "At the end of the day, the White House sided with the [health maintenance organizations] and we sided with the patients," said Edwards.

While several bills were introduced in subsequent Congresses, no serious legislative effort was mounted after that. Rep. Norwood, who tried to keep the issue alive, died of lung cancer in 2007.

Patient Self-Determination Act of 1990

The Patient Self-Determination Act of 1990 is the formal name of language enacted as part of the fiscal 1991 budget reconciliation act (PL 101–508) requiring hospitals participating in MEDICARE and MEDICAID to provide written information to all patients about their rights to accept or refuse medical care and to exercise ADVANCE DIRECTIVES about their desire for care in the event they become incapacitated. Such directives include LIVING WILLS, which express a person's desire about being kept alive by artificial means at the end of life, and the DURABLE POWER OF ATTORNEY FOR HEALTH CARE, which permits a patient to designate a person to make medical decisions in his or her stead. The 1990 law also requires medical personnel to document in the patient's written record whether the individual has completed an advance directive. The 1997 Balanced Budget Act (PL 105–33) required that the actual advance directive be placed in the patient's permanent medical record.

Payers

Payers can refer to anyone who pays for medical care, but the word is usually shorthand for employers, insurers, and federal, state, and local governments, which pay the majority of the nation's $2 trillion-plus annual health care tab. As health care costs began to spiral upward in the 1980s, payers began to play a more active role in health care. Instead of routinely and unquestioningly paying bills, payers began urging providers of health care (which can also include insurers) to be more attentive to both costs and quality. In some cases, payers banded together into buying groups to increase their bargaining power.

Pay for performance

Pay for performance (known as "p4p" in health care circles) refers to the practice of basing payments on the outcome of a health care service, not simply its delivery. While p4p has been discussed for decades, only relatively recently have actual pay-for-performance schemes been put into effect, largely because they require the collection of massive amounts of information. That has been mostly theoretical until the recent rise of ELECTRONIC MEDICAL RECORDS. Pay-for-performance programs have also encountered pushback from provider groups fearing that measurements will be inaccurate or unfair.

Medicare has been a leader in experimenting with the beginnings of p4p efforts. In 2007 Medicare officials announced that starting October 1, 2008, hospitals would no longer be paid following certain avoidable medical errors, including injuries resulting from falls, four common hospital-acquired infections, and three "never" events, including leaving a surgical instrument inside a patient and operating on the wrong site.

Pay or play

See PLAY OR PAY.

PboR

See PATIENTS' BILL OF RIGHTS (PboR).

PCP

See PRIMARY CARE PHYSICIAN (PCP).

PDUFA

See PRESCRIPTION DRUG USER FEE ACT (PDUFA).

Pediatric exclusivity

Concerned that drugmakers were too reluctant to test their products on children, Congress in 1997 enacted legislation providing an incentive—an additional six months of exclusive marketing without generic competition. In the five years leading up to the program's inception, which came as part of a broader law (PL 105–115) revising much of the authority of the FOOD AND DRUG ADMINISTRATION (FDA), fewer than a dozen drugs were formally tested for safety and efficacy in children. By contrast, in the program's first five years of operation, some four hundred drugs were studied for use in pediatric patients. In late 2001, just before the program was set to expire, Congress reauthorized it through 2007 in a separate bill (PL 107–109). In 2007, as part of the reauthorization of the PRESCRIPTION DRUG USER FEE ACT (PDUFA), Congress renewed the pediatric exclusivity law. President George W. Bush signed the bill (PL 110–85) on September 27, 2007. (See GENERIC DRUGS.)

Pediatric and parent groups had long worried that too little was known about the effect of prescription drugs in children, whose bodies often reacted to medications differently than adults did. Doctors said they were often guessing when they prescribed medications for children, in terms of dosage and in terms of impact. Drugmakers, however, were reluctant to mount clinical trials in children that could cost a couple of million dollars, both because of liability concerns—children by definition cannot give INFORMED CONSENT—and because they feared the pediatric market might not be lucrative enough to recoup their investment.

Despite the documented success of the program, during the debate in 2001 on whether to renew the program, some lawmakers said the increased testing came at too high a price—that some drugmakers were reaping windfalls from the additional six months without competition. The additional six months of exclusive marketing time for the blockbuster heartburn drug Prilosec alone, they noted, netted its maker, AstraZeneca, an estimated $1.4 billion from a pediatric study that cost approximately $4 million. And during those six months, they said, Prilosec users had to pay dramatically higher prices, because the introduction of generic competition tends to cut prices almost immediately.

Still, those who wanted to change the program, largely by limiting the incentive to some multiple of the actual cost of the pediatric trials, were beaten back by supporters of the program. "This incentive has been tested, and we know that it works to the benefit of children," said the Coalition for Children's Health, whose members included groups fighting for more research funding for a wide array of diseases. "The six month period of exclusivity assures priority of pediatric studies, and helps to justify establishing infrastructure necessary for doing pediatric studies," the coalition said. Those who wanted to cut back on the incentive found that argument less than convincing. "Giving the drug industry the keys to the federal treasury would also work," said Rep. Sherrod Brown, D-Ohio. "Does that mean it's a good idea?"

One change to the program those on both sides of the debate did agree to was creation in the 2001 legislation of a fund to encourage pediatric testing of drugs with patents that had already expired. Makers of those drugs could not take advantage of the added exclusive time, but many had not yet been tested in children. The legislation called for funding of pediatric studies in those drugs through a joint public-private foundation.

In 2007, when the program was again up for reauthorization, the Democrats were in charge. And this time they vowed to scale back the program. The Senate version of the bill would have cut the exclusivity period for blockbuster drugs (those with more than $1 billion in annual sales) from six months to three months. But the provision was ultimately dropped in conference,

after it drew objections from congressional Republicans and the Bush administration.

Pediatric Rule

Put forth in 1998 to accompany a 1997 law (see PEDIATRIC EXCLUSIVITY) that provided drugmakers with incentives to test their products on children, the Clinton administration issued what came to be known as the Pediatric Rule. Unlike the pediatric exclusivity program, which was voluntary for drugmakers, the 1998 rule allowed the FOOD AND DRUG ADMINISTRATION (FDA) to order drugmakers to test new products on children. Drugs covered by the rule included ones that were expected to provide a "meaningful therapeutic benefit" to children over and above existing treatments or those expected to be used frequently by children.

Unlike the voluntary program, however, which enjoyed broad support, the mandatory testing program proved highly controversial, was opposed by the drug industry, and was struck down by a federal district court judge in October 2002.

Even as the lawsuit—which charged that the FDA overstepped its authority in issuing the rule—was working its way through the judicial process, efforts were underway in Congress to write the rule into law. The controversy erupted into public view in March 2002, when the Bush administration offered to settle the lawsuit by suspending the rule for two years. The administration said the renewal of the voluntary testing program "potentially duplicates the intent of the rule."

Lawmakers and children's health groups were furious. "At the time the final rule was issued, FDA stated that there was 'an important need' for it because the exclusivity provision was likely to leave many drugs and age groups unstudied," three Democratic House members wrote President George W. Bush the day the proposed settlement was announced.

The Bush administration pulled back, and in June HEALTH AND HUMAN SERVICES DEPARTMENT (HHS) secretary Tommy G. Thompson told a Senate subcommittee that the proposal to revoke the rule was a "wrong decision" that had not been cleared through his office. At the time, however, Thompson told lawmakers he did not think it necessary to write the rule into law.

That did not stop backers of the policy, who tried and failed to add the rule's codification to legislation renewing the popular PRESCRIPTION DRUG USER FEE ACT (PDUFA). The SENATE HEALTH, EDUCATION, LABOR, AND PENSIONS

Damon Rawls plays with prescription drug bottles that contain the medication that his brother, Rontrell Windham, center, takes to help his body accept a new kidney. Windham takes the same medication that is given to adults. Congress-created incentives have prompted drug companies to study pediatric dosages for prescription medications, including the immunity-suppressing drug that Windham takes. Source: AP Images/Will Shilling

(HELP) COMMITTEE approved a stand-alone bill in August but failed to get it passed before Congress adjourned in October. On October 18 U.S. district court judge Henry H. Kennedy ruled that "the Pediatric Rule exceeds the FDA's statutory authority and is therefore invalid."

In December, the Bush administration reversed course again. It decided not to appeal the court's ruling. Instead, Thompson said in a statement, the administration would urge Congress to write the rule into law.

That happened in 2003. The Senate passed legislation to codify the rule, retroactive to the date in 2002 the court originally struck it down, on July 23; the House passed it November 19; and President Bush signed it into law (PL 108–155) on December 3. Rep. James C. Greenwood, R-Pa., who helped spearhead efforts on both the rule and the pediatric exclusivity program, said passage of the codification "makes a nice, full circle of an effort to make sure we do everything humanly possible to make drugs available to kids in dosages that are appropriate for them."

Peer review

The practice of peer review, common in science and medicine, is that of having other experts review a study before it is published or otherwise released to the public, thus increasing its credibility. Most important medical journals, including the *New England Journal of Medicine* and the *Journal of the American Medical Association,* are "peer reviewed" in that studies proposed for publication are not accepted or printed until they have passed muster with a peer review panel.

Peer review organization (Medicare)

See QUALITY IMPROVEMENT ORGANIZATIONS (QIOs).

PEPFAR

See PRESIDENT'S EMERGENCY PLAN FOR AIDS RELIEF (PEPFAR).

Pepper Commission

Officially the Bipartisan Commission on Comprehensive Health Care, the commission was created at the behest of and named for its first chair, Rep. Claude Pepper, D-Fla., a crusader for elderly people, who died in 1989, before the panel could complete its work in 1990. The commission, stacked with influential members of Congress from both houses and both parties, was charged with devising proposals to address the dual problems of individuals needing LONG-TERM CARE services and those lacking health insurance. But it was one of many such commissions that started out with great hopes and ended essentially in failure, with members badly divided and recommendations that never saw the legislative light of day.

Pepper, who chaired the influential House Rules Committee, essentially blackmailed the commission into existence by threatening to attach to a fast-moving measure written to provide catastrophic cost protections to MEDICARE a larger and more expensive program guaranteeing long-term care services. Pepper was ultimately persuaded to drop his long-term care proposal from the bill in exchange for the commission being created. When the rest of the catastrophic coverage bill was repealed in 1989, the commission's authorization was left intact. (See MEDICARE CATASTROPHIC COVERAGE ACT.)

The fifteen-member commission was divided from its outset, initially unable to decide whether to prioritize its task to address long-term care or UNINSURED individuals. (Pepper's initial plan was to give the group six months to devise a long-term care plan, then another six months to look at coverage issues.) Pepper was finally prevailed on to allow both reports to be issued together in November 1989, but the commission's work was ultimately set back further by Pepper's death on May 30 of that year. Members elected as their new chair Sen. John D. Rockefeller IV, D-W.Va., and the commission's deadlines were officially extended to March 1, 1990, as part of the fiscal 1990 budget reconciliation bill.

Members did manage to agree on proposals. By 11-4, members approved a $42.8 billion plan to create a

largely federal program to provide long-term care services to all Americans who required them, regardless of age. The program would have helped pay for HOME HEALTH CARE for all severely disabled individuals and would have paid for three months of nursing home care as well.

The more controversial proposal to address the problem of uninsured people passed 8-7. It called for various tax incentives and subsidies over the following five years to encourage businesses to provide health insurance coverage to their employees. It also called for changes in private insurance to prevent companies from refusing to cover those most likely to need care, provisions ultimately enacted as part of the 1996 HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA). Finally, the plan urged expanded federal health coverage of the poorest Americans. If, after five years, at least 80 percent of previously uninsured workers and dependents in small businesses still lacked health insurance coverage, the plan called for a PLAY OR PAY system requiring employers either to provide workers with health insurance or else to pay into a special fund from which insurance would have been provided.

The commission's major failing, however, was its inability to reach any semblance of a consensus on how to finance its initiatives. "I don't think we've done our job. We didn't figure out how to pay for it," said Rep. Pete Stark, D-Calif., a commission member who was then chair of the House Ways and Means Subcommittee on Health. "There is no tax fairy out there who's going to pull it out from under a pillow."

Personal Responsibility and Work Opportunity Reconciliation Act

The Personal Responsibility and Work Opportunity Reconciliation Act (PL 104–193) is the 1996 welfare reform law that ended both welfare as an open-ended entitlement and one of the main "automatic" eligibility pathways for MEDICAID, the joint federal-state health program for those with low incomes. The law also restricted Medicaid eligibility for many immigrants.

Pharmacy benefit managers

Pharmacy benefit managers (PBMs) are firms that specialize in operating employers' or insurance companies' benefits programs for prescription drugs. Originally these companies were simply claims processors, paying the bills as a subcontractor to an insurance company or MANAGED CARE organization. But as prescription drug prices began to rise sharply in the late 1980s, the PBMs began to act as "prudent purchasers," cutting deals with drug companies and otherwise urging doctors and patients to use certain medications and not to use others, based on both cost and effectiveness. In the early 1990s, large drug companies began to purchase the PBM companies. In 1993 Merck bought Medco Containment and Eli Lilly bought the PBM market leader PCS Health Systems (and sold it in 1999 to the Rite Aid pharmacy chain). Drugmakers' purchases of PBMs led to conflict-of-interest charges on the grounds that the PBMs would favor the medications made by their parent companies. PBMs, however, continue to be a major player in the health care industry. In 2007 they managed drug benefits for an estimated 210 million Americans with drug coverage through self-funded employer plans, health insurers, labor unions, and MEDICARE prescription drug plans.

PHS

See PUBLIC HEALTH SERVICE (PHS).

Physician assistants

Physician assistants (PAs) are part of a relatively new breed of mid-level health care providers who specialize in PRIMARY CARE services, frequently in areas with a shortage of doctors. The first PA class was organized in 1965, composed of mostly navy corps members who had received training and experience in Vietnam but whose civilian employment prospects were bleak. As of Sep-

tember 2007, 63,609 physician assistants were in clinical practice, according to the American Academy of Physician Assistants. Just under 60 percent worked in primary care medicine, including family practice, internal medicine, obstetrics/gynecology, emergency medicine, and pediatrics. Another 24.9 percent specialized in surgery or surgical subspecialties.

Like doctors, PAs are licensed to practice, although only with physician supervision (which may or may not have to be on-site). PAs perform many functions also done by physicians, including conducting examinations and ordering and interpreting lab and other tests, diagnosing and treating illnesses, and counseling patients. In 2007 all fifty states and the District of Columbia granted PAs drug-prescribing privileges. PAs must graduate from an accredited physician assistant program and pass exams to qualify for a license. PA training is similar to that received by medical students, except that it lasts two years instead of the four required for medical school, and PA candidates are required to have only two years of college, instead of the four needed for medical school admission. In addition, PAs, unlike physicians, do not have to complete an internship and residency before starting practice. The majority of PA students have both bachelor's degrees and more than four years of previous health care experience before beginning their studies. A 1986 Office of Technology Assessment report found that PAs "perform better than many physicians in supportive care and health-promotion activities." The PA profession is growing quickly. The Bureau of Labor Statistics projected the number of PA jobs would grow by 53 percent between 2000 and 2010, compared with 15 percent for all other jobs.

Physician Payment Review Commission

The Physician Payment Review Commission (PPRC) was a group created by Congress in 1986 to advise lawmakers on physician reimbursement issues under MEDICARE. PPRC and a parallel advisory commission for hospitals, the PROSPECTIVE PAYMENT ASSESSMENT COMMISSION (ProPAC), were merged into a single entity, called the MEDICARE PAYMENT ADVISORY COMMISSION (MedPAC) as part of the 1997 Balanced Budget Act (PL 105–33).

Physician self-referrals

See SELF-REFERRAL CURBS.

Plan B

Plan B is the name under which the "morning after" emergency contraceptive pill is marketed by Barr Pharmaceuticals. Plan B consists of two pills—high doses of regular birth control pills, which, if taken twelve hours apart, the first within seventy-two hours of unprotected intercourse, can prevent pregnancy nearly 90 percent of the time. After a heated, several-years-long fight, Barr in 2006 won permission from the FOOD AND DRUG ADMINISTRATION (FDA) to sell Plan B without a prescription to women age eighteen and older. (See EMERGENCY CONTRACEPTION.)

Planned Parenthood Federation of America (PPFA)

The Planned Parenthood Federation of America (PPFA) is the nation's oldest, largest, and one of its most controversial reproductive health organizations. Founded in 1916 by birth control pioneer Margaret Sanger, PPFA in 2007 provided reproductive health care and sexual health information to some five million women and men at 860 local health centers operated by the organization's 108 affiliates in every state except North Dakota. Planned Parenthood clinics performed 265,000 abortions in 2005, making it the nation's single largest provider of the service. But its contraception and family planning programs prevent an estimated 630,000 unwanted pregnancies each year, nearly half of which would likely have ended in ABORTION. Planned Parenthood clinics also provide much more than abortions

and contraceptive services. The clinics provide basic PRIMARY CARE to women and girls with no other access to health care, infertility screening, and testing and counseling for HIV (human immunodeficiency virus) and other sexually transmitted diseases for women and men, as well as a wide array of educational services aimed at preventing disease and unwanted pregnancy and fostering reproductive health.

Planned Parenthood says it is "dedicated to the principles that every individual has a fundamental right to decide when or whether to have a child, and that every child should be wanted and loved." Sanger herself was a controversial figure. A trained nurse, she founded what is today's Planned Parenthood, and her single-minded writing and lobbying helped strike down the "Comstock law" in 1936 that banned the distribution of most birth control information. But her advocacy of smaller families, particularly for poor immigrants, and her support of sterilization for those with hereditary diseases have led critics to charge her with supporting eugenics, the practice of improving humanity through selective reproduction. Family planning advocates say some of the more inflammatory statements attributed to Sanger were actually said or written by others and that they are being spread purposefully by those opposed to contraception.

In recent years, however, the organization's advocacy of legalized abortion has made it a major target of antiabortion activists. Although Planned Parenthood does not use federal funds to provide abortion services, abortion opponents have sought to cut off funding it receives for providing family planning and other health care services. A set of regulations proposed in 1987 to bar abortion counseling and referrals in federally funded clinics (as well as barring abortion-performing facilities from being "colocated" with family planning clinics) was clearly aimed at driving Planned Parenthood clinics from the federal TITLE X FAMILY PLANNING PROGRAM, abortion opponents said (see GAG RULE [IN ABORTION]). In the 1990s, abortion opponents turned their efforts toward seeking to end family planning funding through the U.S. Agency for International Development for international organizations that "perform or promote" abortion, particularly the International Planned Parenthood Federation, of which PPFA is a member. (See MEXICO CITY POLICY.)

Planned Parenthood of Southeastern Pennsylvania v. Casey

Planned Parenthood of Southeastern Pennsylvania v. Casey was a pivotal 1992 U.S. Supreme Court case that simultaneously upheld the core right to abortion set forth in *ROE V. WADE* (1973) while making it significantly easier for states to impose restrictions on the procedure. Chief Justice William H. Rehnquist in the plurality opinion issued on June 29 wrote that the decision "retains the outer shell of *Roe v. Wade,* but beats a wholesale retreat from the substance of that case. . . . *Roe* continues to exist, but only in the way a storefront on a Western movie set exists; a mere facade to give the illusion of reality."

At issue in the case was a Pennsylvania law imposing a series of requirements—many of them struck down by the Court in earlier cases (see ABORTION). But this time the Court decided that it was permissible to allow Pennsylvania to require a twenty-four-hour waiting period and to require women seeking an abortion to be given state-sponsored material about fetal development and abortion alternatives. That expressly overturned two earlier cases: *Thornburgh v. American College of Obstetricians and Gynecologists* (1986) and *Akron v. Akron Center for Reproductive Health* (1983).

Unlike the 1989 case *WEBSTER V. REPRODUCTIVE HEALTH SERVICES,* in which the Court did not openly address the continuing viability of the framework established in *Roe,* in *Casey* the plurality opinion did address the fundamental question of a woman's right to abortion. And, much to the surprise of those on both sides, it affirmed it. But Justice Sandra Day O'Connor's opinion made it clear that the right she was embracing was not nearly as unlimited as the one for which *Roe* became known. The trimester framework, said the opinion, "undervalues the State's interest in potential life, as recognized in *Roe.*" Thus, the decision discarded the trimester system and, in its place, substituted a rule under which only state regulation that imposed "an undue burden" would

be invalidated. Using that new standard, the justices proceeded to overturn one of the Pennsylvania law's provisions that would have required a married woman to notify her husband before obtaining an abortion.

Play or pay

A health reform option that enjoyed significant popularity in the early 1990s, play or pay was initially endorsed by then presidential candidate Bill Clinton. The concept, intended to produce UNIVERSAL COVERAGE, would require that employers either provide their workers with health care coverage (play) or contribute to a government fund from which insurance would be provided (pay). The idea lost popularity after several studies predicted that most employers would pay instead of play, with the system thus devolving into a SINGLE PAYER program.

Point of service (POS) plan

In general, a point of service (POS) plan is a HEALTH MAINTENANCE ORGANIZATION (HMO) that permits patients to seek care outside the HMO's network for an additional fee. A POS plan is different from a PREFERRED PROVIDER ORGANIZATION (PPO). Although in both cases enrollees can seek care within a network at a lower fee or outside for a higher cost, in a PPO, care is generally less managed in the first place. In a POS plan, the underlying coverage is generally an HMO, with its requirements for primary care physicians to provide referrals for specialty or other care. POS plans may or may not require referrals for patients to seek covered out-of-network care. (See PRIMARY CARE PHYSICIAN [PCP] and REFERRAL.)

Portability

Portability refers to the ability to maintain insurance coverage without having to undergo waiting periods or other exclusions. Often portability is mistakenly thought to be the concept of moving from employer to employer while remaining in the same insurance plan. Rather, the type of portability promised by the failed Clinton health reform plan (the HEALTH SECURITY ACT) and the 1996 HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA) (PL 104–191) permits those in employer-sponsored plans to maintain coverage, but not necessarily the same coverage. In the case of job-to-job portability, if both the old and new employers offer coverage, the law requires that the new coverage not impose waiting periods or preexisting condition exclusions if the worker was covered for at least eighteen months (and waiting periods must decline on a sliding scale for previous coverage of less than eighteen months). For job-to-individual coverage, the law has similar requirements. Another form of portability is so-called COBRA continuation, which guarantees those with employer-provided plans the ability to continue in that plan for eighteen months if they pay the full premium (plus a 2 percent administrative fee) themselves.

POS

See POINT OF SERVICE (POS) PLAN.

Poverty statistics

Poverty statistics are used by the federal government to determine not only how many poor people there are but also eligibility for programs aimed at those with low incomes, including health programs such as MEDICAID and the STATE CHILDREN'S HEALTH INSURANCE PROGRAM (SCHIP). The government has two separate poverty measures. The federal poverty threshold is the official measure. It is updated each year by the U.S. Census Bureau based on a formula developed in 1963 by Mollie Orshansky, an economist with the Social Security Administration. Orshansky estimated how much money it would take to feed a family using the U.S. Department of Agriculture's economy food plan, the lowest cost of four nutritionally adequate diets developed by the department. The department said the economy plan was "designed for

Health and Human Services Department Poverty Guidelines, 2008

Persons in family or household	*48 contiguous states and Washington, D.C.*	*Alaska*	*Hawaii*
1	$10,400	$13,000	$11,960
2	14,000	17,500	16,100
3	17,600	22,000	20,240
4	21,200	26,500	24,380
5	24,800	31,000	28,520
6	28,400	35,500	32,660
7	32,000	40,000	36,800
8	35,600	44,500	40,940
For each additional person add	3,600	4,500	4,140

Source: Department of Health and Human Services. See *Federal Register,* Vol. 73, No. 15, January 23, 2008, pp. 3971–3972.

Note: The Health and Human Services Department has listed separate poverty guidelines for Alaska and Hawaii since the 1966–1970 period.

temporary or emergency use when funds are low." Based on a finding that a family of three spent about one-third of its after-tax income on food, Orshansky estimated that income under three times the price of the economy food plan was by definition less than subsistence level, and that became the original poverty level. That original calculation was modified to develop thresholds for families of other sizes and has been updated ever since, based on the year 1963. The Orshansky formula was formally adopted by the federal government in 1969.

The thresholds, which lag by a year because they are based on inflation from the previous year, are used mostly for statistical measures, including calculating the percentage of the population that lives below the poverty line.

Each year the HEALTH AND HUMAN SERVICES DEPARTMENT (HHS) also publishes poverty "guidelines," which are used for administrative purposes, such as to make eligibility determinations for means-tested programs. The guidelines are by necessity based on cost increases from the previous year, but they are dated for the year in which they appear. The poverty guidelines are often referred to as the federal poverty level, or FPL.

The poverty numbers have been controversial since their inception. Those who think they understate poverty argue that they do not account for differences in costs in different parts of the country (although there are separate, higher guidelines for Alaska and Hawaii). They also argue that the original research showing that an average family spends a third of its income on food is from the 1950s and that spending patterns have changed considerably. Those who think the numbers overstate poverty complain that they do not take into account the value of noncash income, particularly housing subsidies or MEDICAID health insurance coverage.

PPFA

See PLANNED PARENTHOOD FEDERATION OF AMERICA (PPFA).

PPO

See PREFERRED PROVIDER ORGANIZATION (PPO).

PPRC

See PHYSICIAN PAYMENT REVIEW COMMISSION.

PPS

See PROSPECTIVE PAYMENT SYSTEM (PPS).

Practice guidelines

See CLINICAL PRACTICE GUIDELINES.

Preexisting condition

This refers to a medical condition, physical or mental, that existed before the date of health insurance coverage. Insurers frequently deny coverage for costs associated with preexisting conditions or impose waiting

periods (typically a year), although various laws have put significant limitations on insurers' ability to do that. The HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA) barred insurers from imposing preexisting condition limitations on members of group plans who had been continuously covered by another group plan for at least eighteen months and on individuals who were previously covered by a group plan. Similarly, during seniors' first six months of enrollment in MEDICARE, sellers of private MEDIGAP INSURANCE may not impose preexisting condition limitations on those wishing to purchase such coverage.

Preferred provider organization (PPO)

A preferred provider organization, or PPO, is a type of MANAGED CARE health plan that tries to limit costs by steering patients to physicians and other health care providers who have agreed to accept discounted prices in exchange for larger patient volumes. PPOs are the most prevalent form of managed care in the United States, enrolling an estimated 57 percent of all Americans with employer-provided health insurance in 2007. Patients are typically given an incentive to use providers in the plan's network in the form of lower copayments. Unlike those in a HEALTH MAINTENANCE ORGANIZATION (HMO), however, patients in a PPO can obtain covered care outside the network, usually after paying an annual DEDUCTIBLE and a higher copayment. PPOs also typically do not require patients to select a GATEKEEPER or PRIMARY CARE PHYSICIAN (PCP) who must approve all other care, including visits to specialists.

Premiums

Premiums are fees, usually paid monthly, for health insurance (or other insurance) coverage. Until the mid-1980s, premiums were invisible to most workers, with employers paying the entire monthly fee and employees responsible only for copayments and an annual DEDUCTIBLE. As premiums rose in the 1980s, however, more employers began charging workers at least a portion, usually deducted from their paychecks. MEDICARE has always charged a premium for its optional Part B coverage ($96.40 in 2008), withheld from the Social Security checks of most Medicare beneficiaries. MEDICAID law bars charging premiums for most of its low-income enrollees, although in some cases Medicaid patients can be asked to participate in cost-sharing.

Premium support

Premium support is a concept developed by academics and modified as a proposal for reforming MEDICARE by the NATIONAL BIPARTISAN COMMISSION ON THE FUTURE OF MEDICARE in March 1999. The commission failed by one vote to formally recommend its premium support plan to Congress, but the concept was drafted into legislation by the panel's cochairs, Sen. John B. Breaux, D-La., and Rep. Bill Thomas, R-Calif. The idea was for Medicare to encourage competition between private health plans by paying a portion of each plan's premium. Beneficiaries who wanted to purchase more expensive plans would have to pay more out of their own pockets; those who opted for plans with lower premiums could save both themselves and the federal government money. (See BENEFICIARY.) The federal government would also pay a portion of costs for Medicare's traditional FEE-FOR-SERVICE program, making it compete against private plans on the same footing. The premium support concept was similar to MANAGED COMPETITION, the failed concept on which President Bill Clinton's proposed HEALTH SECURITY ACT was based.

Prescription Drug User Fee Act (PDUFA)

The Prescription Drug User Fee Act (PDUFA, pronounced "padoofah"; PL 102–571) was enacted swiftly in 1992 after years of dissension over the issue among GOP presidents Ronald Reagan and George H. W. Bush, Democrats in Congress, and the prescription drug industry. With appropriations for domestic spending in general being increasingly squeezed by the growing federal budget deficit, a perennial suggestion in administration

budgets sent to Capitol Hill had been to require drug companies to pay user fees to have their drug applications considered by the FOOD AND DRUG ADMINISTRATION (FDA). And, at least until 1992, the suggestion had been just as perennially ignored by Congress.

What changed the situation was the realization by the drug companies that although the FDA's workload was increasing, there was little prospect of new funds to help clear the backlog of drugs waiting for review. In 1992 it took an average of twelve years to bring a drug from initial discovery to market. At that time, the FDA spent an average of twenty months to review and approve new drug applications, FDA commissioner David Kessler told Congress, and forty months to review applications for new biologics, such as vaccines or blood products. And the backlog appeared likely only to get worse. In 1980 companies filed 66 applications to begin clinical trials on potential new drugs; by 1991 that had grown to 504 applications. The other half of the compromise was the agreement by the Bush administration that any funds raised by the user fees go back to the FDA to speed up the approval process. Earlier administration user fee proposals would have returned at least some of the fees to the Treasury, prompting drugmakers to label it a "tax on innovation."

As signed into law by President Bush, the measure required makers of prescription drugs and biologics to pay both annual "facilities" fees and fees every time they submitted a drug for approval to the FDA. The facilities fees began at $60,000 and rose to $138,000 by the fifth year. The application fees started at $100,000 and rose to $233,000 in five years. Drugmakers also had to pay a separate fee for each drug marketed, starting at $5,000 and rising to $14,000. Small and start-up companies were allowed to pay reduced or no fees.

The FDA kept its promise to speed up its approvals. In 1996 the FDA took an average of 15.4 months to approve new drugs, down from 30 months in the late 1980s. The percentage of approvals made within the statutory time limits was 95 percent in fiscal 1995, compared with 40 percent before passage of PDUFA. That exceeded the measure's goal for that year, which was 70 percent.

Congress reauthorized PDUFA in 1997 as part of a broader overhaul of the FDA in the FDA Modernization Act (PL 105–115).

The program's third reauthorization, in 2002, came as part of an unrelated broader bill to authorize programs to better prepare the nation's public health system for BIOTERRORISM (PL 107–188). Under a deal worked out between HEALTH AND HUMAN SERVICES DEPARTMENT (HHS) secretary Tommy G. Thompson and the prescription drug industry, the measure dramatically increased user fees (from $313,320 per application requiring clinical data to $533,400) and allowed for the first time a portion of the fee to be used for "postmarket surveillance," or problems that develop with a drug after its initial approval. Democrats in particular wanted stronger postmarket follow-up on drugs that were being approved more quickly, because there was less time during the initial testing phase for problems to show up.

The 2007 reauthorization of the program came in the wake of several large-scale problems with prescription drugs—most notably the withdrawal from the market of Vioxx, a popular pain drug that was shown to have serious cardiovascular risks. As a result, the final version of the legislation, signed by President George W. Bush (PL 110–85) on September 27, 2007, boosted user fees by some $225 million over five years to underwrite a new program to increase drug safety activities at the FDA.

President's Emergency Plan for AIDS Relief (PEPFAR)

PEPFAR is the acronym for the President's Emergency Plan for AIDS Relief, the $15 billion, five-year program to combat ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS) and HIV (human immunodeficiency virus) overseas, which President George W. Bush unveiled in his 2003 State of the Union address. Congress cleared legislation to implement the program May 21, 2003, and it was signed into law (PL 108–25) May 27.

The bill allowed, but did not require, the administration to contribute up to $1 billion to the Global Fund to Fight AIDS, Tuberculosis, and Malaria in fiscal 2004. Just over half of the remaining funding was to go for the purchase of anti-retroviral drugs to treat those already infected with AIDS or HIV, and 20 percent was to go for prevention programs; 15 percent, for palliative care; and 10

President George W. Bush, with Tanzania's President Jakaya Mrisho Kikwete, greets patients at the Amana District Hospital in Dar es Salaam, Tanzania. Tanzania has received funding under the President's Emergency Plan for AIDS Relief (PEPFAR) for HIV/AIDS prevention and treatment programs.
Source: Reuters/Jim Young/Landov

percent, for aid to orphans and children made vulnerable by the epidemic. Among its more controversial provisions were those requiring recipients of U.S. prevention funds to support the so-called ABC program: A for abstinence, B for be faithful, and C for condom distribution. The measure also allowed faith-based groups to accept funding while rejecting aspects of the program they disagreed with, such as condom distribution. Congress reauthorized the program in 2008 with an increase of $48 billion.

Prevalence

In health policy, prevalence refers to the total number of people with a particular disease or condition. Prevalence is different from INCIDENCE, which is the rate of new cases of a disease or condition.

Primary care

The term *primary care* is used to describe basic medical services provided to patients and to differentiate it from specialty care. Primary care physicians include internists, family practitioners, pediatricians, and geriatricians. Many obstetrician/gynecologists also provide primary care, as do such mid-level practitioners as PHYSICIAN ASSISTANTS and nurse practitioners. (See PRIMARY CARE PHYSICIAN [PCP] and NURSE PRACTITIONER [NP].)

Primary care physician (PCP)

Originally a term that referred to any physician who is not a specialist, in the age of MANAGED CARE the concept of primary care physician (PCP) has shifted somewhat. Internists, general practitioners, pediatricians, and doctors who have completed residencies in family practice are all primary care physicians. But because in many managed care plans the primary care physician also acts as a GATEKEEPER—coordinating all of a patient's medical care and deciding whether and when a patient undergoes tests, enters a hospital, or sees a specialist—some specialists are also acting as primary care physicians, oxymoronic as that seems. In particular, many

plans permit a woman to designate her obstetrician/gynecologist as her primary care physician for purposes of coordinating her care.

Prior authorization

Prior authorization is a tool used by MANAGED CARE plans to control the use of services. It generally refers to any treatment for which a physician must receive permission before prescribing. Hospital and emergency room care commonly require prior authorization, although the latter can sometimes be obtained directly by the patient, instead of the doctor. Prior authorization is also used commonly if a physician wants to prescribe a patient a drug that is not on the plan's FORMULARY, or list of approved medications.

Private contracting (Medicare)

Private contracting for MEDICARE is an agreement between a physician and a Medicare BENEFICIARY in which the patient agrees to pay the doctor out of his or her own pocket for Medicare-covered services, at whatever rate the doctor wants to charge, with no reimbursement from either Medicare or, in most cases, supplemental MEDIGAP INSURANCE. Private contracting was explicitly authorized by Congress for the first time as part of the 1997 Balanced Budget Act (PL 105–33). But some who advocated for the change almost immediately sought to alter the language, arguing that the limitations placed on the practice—particularly the requirement that physicians who want to make private payment arrangements with patients opt out of Medicare entirely for two years—made the situation worse than it was before. Previously, the HEALTH CARE FINANCING ADMINISTRATION (HCFA), which ran Medicare, had held it impermissible for a physician to privately contract with a Medicare beneficiary to provide a Medicare-covered service, because provisions of the 1989 Omnibus Budget Reconciliation Act (PL 100–239) required physicians to file claims on Medicare patients' behalf for such services.

The 1997 change was championed by Sen. Jon Kyl, R-Ariz., who argued that it was needed to allow patients who became eligible for Medicare to continue existing relationships with physicians who do not take part in the program. Kyl was worried about highly sought after specialists or generalist physicians in areas with few health care providers who, if they did not accept Medicare, would no longer be legally allowed to see patients who became Medicare beneficiaries. But consumer advocates, as well as the Clinton administration, worried that allowing doctors to determine for which patients, or even for which services, they wanted to accept Medicare payment would undermine the program's beneficiary cost protections. In other words, allowing doctors to pick and choose not to accept Medicare's payment rates in certain cases could expose beneficiaries to unlimited costs.

The compromise enacted in the 1997 budget law required that physicians and patients sign a written contract in advance of the treatment in question, with both agreeing not to bill Medicare for the services and the patient agreeing to pay the full amount of the doctor's bill. Patients would also have to be informed in writing that the service would be covered by Medicare if it were provided by another doctor. Private contracts are not allowed in emergency medical situations, to prevent doctors from coercing patients into paying higher than Medicare rates. HCFA (later renamed the CENTERS FOR MEDICARE AND MEDICAID SERVICES), argued that requiring doctors to drop out of Medicare entirely for two years was the only way to preclude unscrupulous physicians from billing both Medicare and patients simultaneously.

But some conservative groups, led by the 600,000-member United Seniors Association, charged that the law could prevent Medicare beneficiaries from paying out-of-pocket for services Medicare did not cover, such as annual physicals, or from paying for services Medicare covers in some cases, but not others, such as laboratory tests performed every three months instead of every six months. Critics also worried that the law could restrict people from paying for sensitive services—particularly mental health care—themselves to avoid notifying a third party. HCFA, however, said that

nothing in the new law or old rule prevented a patient from paying privately for services Medicare does not cover or for more frequent uses of Medicare-covered services than Medicare allows. HCFA also notified doctors that it would not penalize them for not filing claims for patients who failed to provide sufficient information, thus protecting patients who wished to keep their medical affairs confidential.

HCFA also said that doctors who wanted to perform a service they were uncertain that Medicare would cover would not need a private contract and would not be required to drop out of Medicare for two years. Instead, they could provide patients with an advance beneficiary notice that the service might not be paid for and ask that the patient agree to pay the claim if Medicare did not.

Unsatisfied with HCFA's interpretation, the United Seniors Association sued in federal court to overturn the 1997 law, charging that the private contracting provisions unconstitutionally limited Medicare beneficiaries' access to medical care. On April 14, 1998, U.S. district court judge Thomas Hogan dismissed the case, noting that "[t]he plaintiffs have not demonstrated that they have a constitutional right to privately contract with their physicians." The association appealed the ruling to the District of Columbia Court of Appeals, which upheld the lower court ruling on July 16, 1999.

Meanwhile, relatively few physicians availed themselves of the private contracting option through 2008.

Private fee-for-service (Medicare)

Private fee-for-service plans were authorized by Congress in the 1997 Balanced Budget Act (PL 105–33) as one of the private plan options available to beneficiaries under the MEDICARE+CHOICE program. Allowing the plans came at the urging of the NATIONAL RIGHT TO LIFE COMMITTEE (NRLC), an antiabortion group that also worked to prevent health care RATIONING. The NRLC was concerned that if Congress continued to ratchet down on MEDICARE payments to doctors, hospitals, and other health care providers, those providers would begin to stop accepting Medicare patients. That would leave beneficiaries with no choice but to join one of the traditional managed care plans, which overtly ration care.

The concept behind the private fee-for-service plan is that beneficiaries would be allowed to pay a premium to a private entity that would set prices for providers high enough to entice them to participate. The private fee-for-service plan would also have to allow any provider to participate who agreed to accept the plan's fee schedule, thus giving beneficiaries essentially unfettered access to the provider of their choice. Plans would not be allowed to provide incentives for providers to limit care or to otherwise seek to control use of health care services. Beneficiaries, in addition to having to pay a premium to join the plan, could be subject to higher cost-sharing than in the government-run fee-for-service plan. Consumer advocates worried that, in rural areas or others with a limited number of providers, virtually all the providers could join together in a private fee-for-service plan and drop out of traditional Medicare, potentially leaving low-income beneficiaries with limited or no access to health care services.

Initially the plans were slow to establish themselves. As of April 2003, four plans operating in thirty-three states had a combined enrollment of 22,344 beneficiaries, out of an estimated 4.6 million in the Medicare+Choice program.

But that changed after 2003, when the MEDICARE MODERNIZATION ACT replaced the Medicare+Choice program with the MEDICARE ADVANTAGE program. In an effort to entice more private health plans to participate in Medicare, Congress purposefully boosted payments to those plans beyond what it cost to provide the standard package of benefits to the average Medicare BENEFICIARY. In fact, by 2007 the CONGRESSIONAL BUDGET OFFICE (CBO) estimated that private plans were paid, on average, 12 percent more per beneficiary than it cost to provide the standard package of Medicare benefits. That suddenly made private fee-for-service plans more attractive to insurers to offer, and they began to proliferate rapidly.

Enrollment began to grow, too. The Congressional Budget Office reported in mid-2007 that private fee-for-service plan enrollment was driving increases in enrollment in Medicare Advantage. Enrollment in the

non-managed private plans grew from about 200,000 at the end of 2005 to more than 1.6 million in June 2007.

But allegations arose that at least some, and possibly much, of that rapidly increasing enrollment was the result of inappropriate sales pressure or outright fraud. Because sales agents got paid higher commissions for signing up beneficiaries for private fee-for-service plans than for stand-alone prescription drug coverage, many seniors who thought they were merely signing up for a new drug plan suddenly found themselves in a private plan that they did not understand and that their doctors and hospitals would not accept, potentially leaving them liable for thousands of dollars in copayments. As a result, in June 2007, under pressure from Medicare regulators, seven insurers who sold the majority of private fee-for-service plans voluntarily suspended marketing activities to retrain sales staff and revamp beneficiary education efforts. By the end of September 2007, all seven companies were approved to resume marketing efforts, after vowing to meet a series of new protections, including confirmatory phone calls by individual plans to make sure beneficiaries understood how the private fee-for-service plans differ from traditional Medicare. Meanwhile, Democrats and some Republicans in Congress vowed to try to reduce payments for the plans, but they managed only a small reduction in Medicare legislation enacted over President Bush's veto in July 2008 (PL 110–275).

Program of All-Inclusive Care for the Elderly (PACE)

The Program of All-Inclusive Care for the Elderly (PACE) was created as a demonstration program in 1986 budget reconciliation legislation (PL 99–509) and was made permanent in the 1997 Balanced Budget Act (PL 105–33). An optional program for states, PACE represents a multidisciplinary, comprehensive program of health and social services that integrates acute and LONG-TERM CARE services in an effort to keep those who are age fifty-five or over and in frail condition out of nursing homes. PACE providers receive a capitated monthly payment from the state, for which they are responsible for all care required by PACE enrollees, twenty-four hours a day, seven days a week. PACE programs use adult day care, private homes, hospitals, and nursing homes to help manage health and social service needs, with teams providing preventive, rehabilitative, curative, and support services. PACE operates through both the MEDICARE and the MEDICAID programs, and providers must contract with PACE programs and not charge deductibles, copayments, or other cost-sharing. (See DEDUCTIBLE.)

Project BioShield

Project BioShield was a mostly unsuccessful effort by Congress and the George W. Bush administration to spur the development of countermeasures (vaccines, treatments, and means of detection) to potential bioterror agents such as anthrax, smallpox, and botulinim toxin. Because such products have little commercial value, companies have little financial incentive to pursue them. The idea behind Project BioShield, enacted in 2004 (PL 108–276), was to create a government-guaranteed market for such products. The law also allowed products not yet approved by the FOOD AND DRUG ADMINISTRATION (FDA) to be used in cases of declared national emergency.

President Bush originally announced the effort in his 2003 State of the Union address. Members in both chambers generally agreed that shortcuts in regulatory procedures were justified in light of the potential catastrophe of a biological attack. The anthrax attacks in the fall of 2001 brought bioterrorism directly to Capitol Hill. The 2003 outbreak of severe acute respiratory syndrome (SARS) further reminded Congress that deadly afflictions are capable of spreading quickly.

While the House acted relatively quickly—approving a $5.6 billion authorization over ten years for the effort in July 2003—the measure bogged down in the Senate over whether to provide guaranteed funding.

President Bush said the government needed mandatory, open-ended funding to get the program started. The administration also asked for expedited review and procurement procedures to get research, development, and production going on high-priority drugs and vac-

Mei Li, a scientist at Hollis-Eden Pharmaceuticals, works in the laboratory of the small San Diego firm researching a promising anti-radiation drug. Despite the promise of significant funding for research and development of countermeasures to acts of biological and chemical terrorism, Project Bioshield has yet to attract significant interest from the private sector.
Source: AP Images/Lenny Ignelzi

cines; a permanent funding stream to guarantee companies a market for the new products; and the authority to allow emergency use of promising, but unapproved, drugs and treatments for bioterrorist attacks.

The SENATE HEALTH, EDUCATION, LABOR, AND PENSIONS (HELP) COMMITTEE approved a bill in March 2003 that reflected the administration request. However, Robert C. Byrd of West Virginia, ranking Democrat on the Senate Appropriations Committee, blocked further action, saying that putting the funding outside the annual control of the appropriators would undermine Congress's ability to oversee the program.

The impasse on the authorization was not broken until the following spring, when Senate Budget Committee chair Don Nickles, R-Okla., worked out a funding compromise with Byrd. The Senate approved the compromise in May. After a couple more false starts, the House cleared the bill and sent it to President Bush, who signed it July 21.

In the end the program proved relatively ineffective at achieving its goal of luring new products to the market. Despite the availability of funding, firms worried about a lack of liability protections and, in particular, about a funding "gap" between start-up research funding provided by the NATIONAL INSTITUTES OF HEALTH (NIH) and procurement funding provided by BioShield, but no funding in between for costly clinical trials and other testing.

That led Congress to make some changes to the program as part of a 2006 bioterrorism bill. The new measure (PL 109–417) essentially replaced Project BioShield with a new government agency. The Biomedical Advanced Research and Development Authority, or BARDA, was charged with coordinating all federal efforts to research, develop, and produce bioterror countermeasures. It was to be modeled after DARPA (Defense Advanced Research Projects Agency), the Defense Department agency credited with helping spur the development of supercomputers and nanotechnology, among other things.

ProPAC

See PROSPECTIVE PAYMENT ASSESSMENT COMMISSION (ProPAC).

Prospective Payment Assessment Commission (ProPAC)

An advisory body created by Congress in 1983 to oversee the implementation of the new MEDICARE prospective payment system for hospitals and to recommend changes, the Prospective Payment Assessment Commission (ProPAC) also proposed the amounts by which hospital payments should be adjusted annually. In the 1997 Balanced Budget Act (PL 105–33), ProPAC and the parallel advisory commission for physician payments, the PHYSICIAN PAYMENT REVIEW COMMISSION, were merged into a single, fifteen-member entity called the MEDICARE PAYMENT ADVISORY COMMISSION (MedPAC).

Prospective payment system (PPS)

In 1983, in legislation to shore up the ailing Social Security trust fund (PL 98–21), Congress put the HOSPITAL INSURANCE (HI) trust fund of MEDICARE on firmer financial footing by creating a new way to pay hospitals. The need was acute. Even though most of the attention was focused on Social Security, whose insolvency was imminent, the CONGRESSIONAL BUDGET OFFICE (CBO) had projected that the HI trust fund would run out of money as soon as 1987. Hospital spending was an obvious target, accounting for two-thirds of the program's costs. Although Congress had since the early 1970s been imposing limits on what hospitals could charge the program, they were still paid essentially what they charged, and they had a built-in incentive to provide more rather than less care.

The prospective payment system (PPS) turned that incentive around. The law originally created 467 diagnosis-related groups (DGRs) of common conditions requiring hospitalization. (By 2007 those conditions had been refined to adjust for severity, and the total number increased to 745.) Payment would be based on the average cost of treating those conditions. If it cost the hospital less than the predetermined payment, it could keep the difference. But if it cost more, the hospital would have to make it up. Not every hospital receives the same payment for the same DRG. Payments are adjusted according to the cost of labor in a particular area, whether the hospital is located in a large city or rural area, whether a hospital serves a disproportionate share of low-income patients, and whether it has a teaching program. But the idea was to provide an incentive for hospitals to improve their efficiency. (See DIAGNOSIS-RELATED GROUP [MEDICARE] and DISPROPORTIONATE SHARE HOSPITAL [DSH] PAYMENTS [MEDICARE AND MEDICAID].)

Although hospitals complained and considerable fine-tuning was required, the PPS system overall has been considered a major success. (It has been so successful, in fact, that Congress in the 1997 Balanced Budget Act [PL 105–33] ordered the creation of prospective payment systems for outpatient hospital care, HOME HEALTH CARE, and nursing home care.) Medicare's hospital costs, which had been climbing at rates approaching 20 percent annually in the 1970s and early 1980s, quickly slowed. The average length of stay for Medicare patients in the hospital declined from 10 days in 1983 to 7.6 days in 1994. This raised accusations that patients were being discharged too early in some cases (referred to by critics as "sicker and quicker"). Among the protections imposed by Congress to address that complaint is a requirement that patients who feel they are being sent home before they are ready be able to appeal their discharge to a Medicare peer review organization and stay in the hospital an extra day at no cost to them. More surprisingly, the number of hospital admissions declined sharply as well, although at least some of that decline may have been attributable to a cost-cutting movement throughout the health system of performing more services on an outpatient basis. In the case of Medicare, hospitals had an incentive to shift patients from inpatient to outpatient status, because Medicare reimbursement for outpatient care remained cost-based, at least until 1997.

Providers

Any person or entity that delivers medical care is called a provider. The term *providers* generally refers to physicians and hospitals, but it also encompasses mid-

level practitioners such as PHYSICIAN ASSISTANTS, nurse practitioners, and physical therapists as well as entities such as nursing homes, HOME HEALTH CARE agencies, and kidney dialysis facilities. (See NURSE PRACTITIONER [NP].)

Provider-sponsored organizations (PSOs)

Provider-sponsored organizations (PSOs) are health plans owned and operated by hospitals, doctors, or other health care providers. (See HEALTH PLAN.) At the strong urging of hospital and physician groups, which were fighting a losing battle for primacy in running the health care system with insurance companies, Congress in the 1997 Balanced Budget Act (PL 105–33) authorized PSOs to serve MEDICARE beneficiaries under the MEDICARE+CHOICE program. (See BENEFICIARY.) In that legislation, Congress provided PSOs with the ability to circumvent state regulations if states refused to grant the organizations an operating license (physician and hospital groups argued that they were discriminated against because insurance regulators in many states were biased in favor of insurance companies). Insurers argued that if doctors and hospitals wanted to run insurance companies, they should have to meet the same requirements as any other insurer. Health care providers countered that they did not need the same level of financial reserves as insurers, because if they ran into financial difficulties, they could provide care for free, whereas insurers would still have to pay providers. Lawmakers who backed the PSO concept said they hoped PSOs would form in areas of the country where Medicare MANAGED CARE payments were too low to attract managed care organizations from outside the area. With the doctors and hospitals already in place, start-up managed care costs would be expected to be lower. PSOs got off to a slow start, however. By the end of 1998, only one PSO, Clear Choice Health Plans of Bend, Oregon, had been approved by the HEALTH CARE FINANCING ADMINISTRATION (HCFA) to offer coverage through Medicare+Choice. It later converted to a standard Medicare+Choice plan, leaving no PSOs in the program as of early 2003. The MEDICARE MODERNIZATION ACT, which established a prescription drug benefit for the Medicare program, also created significant incentives for managed care plans to locate in rural areas, thus lessening the need for PSOs. As of 2007, there were six PSOs in the now renamed MEDICARE ADVANTAGE program.

Prudent layperson

Use of hospital emergency room (ER) care ballooned during the 1980s and early 1990s, much of it for care that did not constitute medical emergencies. Often patients who were sick but did not want to miss work to see their own doctor, or who had no insurance, or no regular doctor or source of medical care, took advantage of the 24–7 availability of the local emergency room. One 1994 survey found that more than half of all hospital ER visits could have been handled better in another setting.

One of the tenets of MANAGED CARE is that patients should get the most appropriate care in the most appropriate—and least expensive for their needs—setting. As a rule, care in a hospital emergency room other than for a life- or health-threatening emergency is rarely appropriate or cost-effective. Emergency room physicians are by definition unfamiliar with individual patients' medical histories, thus potentially missing important clues as to a patient's underlying problem, and the equipment and staff required to run an emergency room makes it among the most expensive forms of care. As a result, most managed care plans put strict limits on the use of hospital emergency rooms, requiring PRIOR AUTHORIZATION before a patient can seek ER care or limiting patients to care in particular ERs, which may or may not be a convenient distance from a patient's home or office.

As a result of new restrictions, inappropriate ER use did begin to fall in the mid-1990s. It did so, however, at a price: many patients who went to emergency rooms with what they considered emergency conditions found their insurers refusing to pay the resulting bills. In many cases decisions to pay were based on the diagnosis at discharge, not the presenting symptoms. Thus, the person who had chest pain and thought he was having a heart attack might not be covered when the pain turned out to be acute indigestion, or the person who had

fallen and thought she had broken an ankle would see her claim denied because her injury turned out to be only a sprain. In other cases, patients seeking urgent care were advised to go to emergency rooms far from their homes so they could be cared for by practitioners in their health plans' networks. In some cases those delays resulted in catastrophic consequences.

Angry patients began to complain to lawmakers, who quickly responded. By 2002, thirty-two states had passed laws requiring insurance plans to cover care in an emergency room—in or out of the plan's network—if a prudent layperson would deem that care warranted. Definitions varied, but in general a prudent layperson was described as someone with an average knowledge of medicine who thinks his or her symptoms could pose an immediate threat to life or health without medical treatment. Those state laws, however, did not apply to the estimated forty-nine million Americans in plans that were self-insured and thus not subject to state regulations under the 1974 EMPLOYEE RETIREMENT INCOME SECURITY ACT (ERISA). As part of the 1997 Balanced Budget Act, Congress applied the prudent layperson standard to MEDICARE and MEDICAID beneficiaries in managed care plans. (See BENEFICIARY.)

Public Health Service physicians were required to examine all immigrants entering the United States for possible health problems. Eye exams such as this one at Ellis Island were common as inspectors looked for signs of the infectious disease trachoma. Source: *Library of Congress*

Public health

A phrase with a continually shifting definition, *public health* is, in its broadest sense, the effort to improve health and prevent disease in a community or population, not in individual patients. Originally public health focused on sanitation, particularly on obtaining clean water, proper disposal of human waste, and eradication of rats and other vermin. But as these goals were achieved more or less, and as the modes of transmission of disease became clear, public health began to interact more with the practice of medicine (the act of healing individuals), including reporting and quarantines of those with infectious diseases and, later, efforts to immunize populations against preventable ailments. Today public health efforts look at the roles of nutrition, substance abuse, accident prevention (such as seat belts and bicycle helmets), and pollution, among other things, in determining health status. Public health workers may be medical professionals, but they may also be statisticians, health educators, food and drug inspectors, toxicologists, or environmental scientists. Today health policy work is also an important part of public health.

Public Health Service (PHS)

The U.S. Public Health Service (PHS) dates back to 1798, with the creation of the fledgling federal government's first marine hospital, under the Department of the Treasury. The Fifth Congress established the Hospital to Care for Merchant Seamen, who were critical to the security of the nation for both commerce and defense purposes. Marine hospitals ultimately spread up and down the East Coast and along other shipping routes, caring for American sailors and British prisoners in the War of 1812 and for combatants on both sides in the Civil War. (The PHS hospitals would later be turned over to the Veterans Administration.)

The Public Health Service was reorganized in 1870, under the first SURGEON GENERAL OF THE UNITED STATES, John Maynard Woodworth, who reshaped it more along military lines, complete with uniforms and tenure and promotional opportunities based on merit. Congress officially established the Commissioned Corps of the Public Health Service in 1889 (see PUBLIC HEALTH SERVICE, COMMISSIONED CORPS).

In 1912 Congress formally founded the Public Health Service, with a mandate to study "the diseases of man and conditions affecting the propagation and spread thereof." The PHS spent much of the early part of the century combating diseases such as malaria, smallpox, and yellow fever, improving sanitation and other environmental causes of disease, caring for veterans, and manufacturing and distributing vaccines.

In 1939 the service was transferred from the Treasury Department to the Federal Security Agency, later to become the Department of Health, Education, and Welfare, which in turn would become the present-day HEALTH AND HUMAN SERVICES DEPARTMENT (HHS). In 1944 Congress passed the Public Health Service Act (PL 78–410), which codified the agency's authority.

By 1998, two hundred years after it began, the PHS included eight health research and delivery agencies. In fiscal 2008, they had a combined budget of just over $45 billion. The PHS is nominally headed by the surgeon general. However, the surgeon general's line authority was eliminated in 1966, with most of the PHS put under the direction of the HHS assistant secretary for health (ASH). In 1995 the position of assistant secretary for health was downgraded as well, giving the heads of the PHS agencies a direct conduit to the HHS secretary. Ironically, Dr. Philip Lee, who served as the first ASH, as the position is known, under President Lyndon B. Johnson, also served as the last ASH before the position was reconfigured in 1995.

PHS agencies include:

• The NATIONAL INSTITUTES OF HEALTH (NIH), the nation's premier biomedical research establishment. The NIH consists of twenty-seven separate institutes, centers, and divisions. With a 2008 budget of $28.9 billion, NIH funds research both at its campus in Bethesda, Maryland, and around the nation.

In an attempt to control the spread of yellow fever in New Orleans, workers from the U.S. Public Health and Marine Hospital Service fumigate against mosquitoes in 1905. *Source: National Library of Medicine*

• The FOOD AND DRUG ADMINISTRATION (FDA), which regulates a quarter of all products sold in the United States. Its functions include determining the safety and efficacy of prescription drugs, medical devices, and biologic products. The FDA's 2008 budget was $2.27 billion.

• The CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC), based in Atlanta, Georgia, which surveys and monitors outbreaks of communicable diseases, funds research into prevention strategies, and runs the nation's childhood immunization program. CDC's fiscal 2008 budget was $6 billion.

• The AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY (ATSDR). With a fiscal 2008 budget of $745 million, the agency conducts public health assessments, health studies, surveillance activities, and health education training in communities around waste sites designated as Superfund sites by the U.S. Environmental Protection Agency. The newest of the Public Health Service agencies, the agency was established in 1980 and is based in Atlanta, Georgia.

• The INDIAN HEALTH SERVICE (IHS). Established in 1924, the IHS provides comprehensive health services for an estimated 1.9 million members of 561 recognized tribes of American Indians and Alaska Natives

through a network of 48 hospitals, 283 health centers, and 320 health stations and Alaska village clinics, as well as services purchased from outside the IHS health care system. The IHS received an appropriation of $3.32 billion in fiscal 2008.

• The HEALTH RESOURCES AND SERVICES ADMINISTRATION (HRSA). Established in 1982, HRSA funds health care for medically underserved populations through its network of community and migrant health centers, administers the RYAN WHITE COMPREHENSIVE AIDS RESOURCES EMERGENCY (CARE) ACT, the MATERNAL AND CHILD HEALTH (MCH) SERVICES BLOCK GRANT program, and the National Organ Transplant System. (See ORGAN DONATIONS AND TRANSPLANTS.) HRSA also provides funds and assistance to help train the next generation of health professionals, including operating the NATIONAL HEALTH SERVICE CORPS. HRSA's fiscal 2008 appropriation was $6.9 billion.

• The SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION (SAMHSA). Created in 1992, SAMHSA is the successor agency to the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA). SAMHSA provides funds for prevention and treatment services for those with substance abuse or mental health problems. The agency also funds research and demonstration projects on prevention and treatment and, with a budget of $3.4 billion in fiscal 2008, monitors the incidence and prevalence of substance abuse and mental health problems.

• The AGENCY FOR HEALTHCARE RESEARCH AND QUALITY (AHRQ). Established in 1989 as the AGENCY FOR HEALTH CARE POLICY AND RESEARCH (AHCPR), AHRQ studies cost, quality, and effectiveness issues associated with the nation's health care system. AHRQ (pronounced "ark") is the federal government's home for HEALTH SERVICES RESEARCH, which examines how the health care system functions. AHRQ received a fiscal 2008 appropriation of $335 million.

The assistant secretary for health, as the position was reconfigured by the Clinton administration's "reinventing government" initiative in 1995, is the senior adviser to the HHS secretary on public health and science issues and oversees the Office of Public Health and Science (OPHS). Included in the OPHS are the surgeon general's office (in 1999 Dr. David Satcher, for only the second time in history, served simultaneously in both posts; in 2003 Bush administration surgeon general Richard Carmona was also appointed acting assistant secretary for health) and a series of smaller offices. Those include the Office of HIV/AIDS Policy, the Office on Minority Health, the Office of Research on Women's Health, the Office of Disease Prevention and Health Promotion, the Office of Emergency Preparedness, the Office for Human Research Protections, the Office of Population Affairs, the Office of Research Integrity, the Office of International and Refugee Health, and the President's Council on Physical Fitness and Sports. (See ACQUIRED IMMUNE DEFICIENCY SYNDROME [AIDS] and WOMEN'S HEALTH, OFFICE OF RESEARCH ON.)

Public Health Service, Commissioned Corps

The Commissioned Corps of the U.S. Public Health Service is headed by the SURGEON GENERAL OF THE UNITED STATES and is made up of approximately six thousand uniformed health care professionals who serve in the eight agencies of the PUBLIC HEALTH SERVICE in all fifty states and around the world. The corps is one of seven uniformed services of the United States (along with the army, navy, Marine Corps, air force, Coast Guard, and Commissioned Corps of the National Oceanic and Atmospheric Administration). As such, in times of national emergencies the corps can be designated as a military service. The corps's mission, according to the HEALTH AND HUMAN SERVICES DEPARTMENT (HHS), is "to provide highly-trained and mobile health professionals who carry out programs to promote the health of the Nation, understand and prevent disease and injury, assure safe and effective drugs and medical devices, and deliver health service [sic] to federal beneficiaries, and furnish health expertise in time of war or other national or international emergencies."

The Commissioned Corps, as it is known, was founded by the nation's first surgeon general, John Maynard Woodworth, who was appointed to the post in

1871. Most members of the Commissioned Corps work in the INDIAN HEALTH SERVICE (IHS), but they also help staff the NATIONAL INSTITUTES OF HEALTH (NIH), the CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC), and the FOOD AND DRUG ADMINISTRATION (FDA) and serve outside HHS in providing health services to the Coast Guard, the Bureau of Prisons, the Environmental Protection Agency, and the U.S. Citizenship and Immigration Services. Members of the Commissioned Corps include not only physicians and nurses but also scientists, dentists, engineers, pharmacists, veterinarians, dietitians, therapists, and health services officers.

Q

QIO

See QUALITY IMPROVEMENT ORGANIZATIONS (QIOs).

QMB

See QUALIFIED MEDICARE BENEFICIARY (QMB).

Qualified Medicare Beneficiary (QMB)

A Qualified Medicare Beneficiary (QMB, pronounced "quimbee") is a MEDICARE beneficiary with income and assets too high to qualify for full coverage under the MEDICAID program but still under 100 percent of the federal poverty line ($10,400 for an individual and $14,000 for a couple in 2008). QMBs are eligible to have Medicaid pay all of their Medicare cost-sharing requirements, including monthly premiums for Part B coverage ($96.40 in 2008) and all required deductibles and copayments. (See DEDUCTIBLE.) Although the program has been in existence for more than two decades, enrollment has remained relatively low. Advocates hoped that creation of additional subsidies for Medicare's new prescription drug program, established in 2003 as part of the MEDICARE MODERNIZATION ACT, would draw more people into the QMB program as well.

Qualifying Individual Program (QI-1 and QI-2)

Created as part of the 1997 Balanced Budget Act (PL 105–33), the Qualifying Individual Program was intended to build on the QUALIFIED MEDICARE BENEFICIARY (QMB) program to help low-income MEDICARE enrollees who cannot afford private supplemental insurance pay the cost-sharing Medicare requires. The law provided up to $1.5 billion for states through the end of 2002 to operate the QI-1 and QI-2 programs. The QI-1 program paid Medicare Part B premiums (but not other cost-sharing) for beneficiaries with incomes between 120 and 135 percent of the federal poverty line (individuals with incomes between $12,252 and $13,783 and couples with incomes between $16,428 and $18,481 in 2007). In 2007, with the Medicare premium at $93.50, the program provided a benefit of about $1,122 per year to an estimated 1.5 million beneficiaries. The QI-2 program allowed states to pay only the increased portion of the Part B premium attributable to the transfer in the Balanced Budget Act of Medicare's HOME HEALTH CARE program from Part A to Part B for beneficiaries with incomes between 135 and 175 percent of the federal poverty line. In 2002 the program paid $3.91 monthly for QI-2 beneficiaries. Congress has continually renewed the QI-1 program on a year-to-year basis but allowed the less-used QI-2 program to lapse at the end of 2002. (See BENEFICIARY.)

Quality Improvement Organizations (QIOs)

Quality Improvement Organizations (QIOs), formerly known as peer review organizations (PROs), are independent private organizations that contract with the MEDICARE program to ensure and improve the quality of care provided to the program's more than forty-

one million beneficiaries. QIOs are also charged with investigating complaints from Medicare beneficiaries about potential quality problems. Originally created in the 1982 Tax Equity and Fiscal Responsibility Act of 1982 (PL 97–35), PROs subsumed Medicare's former quality watchdog program, the Professional Standards Review Organizations.

The job of the fifty-three entities (which cover all fifty states, the District of Columbia, and U.S. territories) has changed over the years. Today they are also known as Quality Improvement Organizations in recognition of the changes made in 1992 to orient them away from the traditional FEE-FOR-SERVICE setting in which care was delivered and more toward a health care system that is primarily MANAGED CARE. The reconfiguration of the PROs into the Health Care Quality Improvement Program was an attempt to shift the organizations' activities away from reviewing records after care has been provided and more toward community-based quality improvement and consumer education. Currently, QIOs, using detailed clinical information on providers and patients, focus on nationally uniform criteria to examine patterns of care and outcomes. In addition to working on a state-by-state basis, the organizations are working together on national quality improvement projects.

The QIO program ran into controversy in the early 2000s, with questions being raised about the program's effectiveness; beneficiaries facing increasing difficulty getting information from QIOs about quality reviews; and members of Congress criticizing what they called profligate spending by QIO officials on travel and other activities. Independent reports by both the INSTITUTE OF MEDICINE and the GOVERNMENT ACCOUNTABILITY OFFICE called for an overhaul of the way the QIOs operate, particularly given Medicare's new emphasis on attempts to tie payment to quality outcomes.

Quarantine

In public health, quarantine refers to the practice of isolating a person who is potentially infected with a communicable disease to prevent its spread. The word comes from the Latin for the number forty—a reference to the practice of preventing sailors from disembarking in ports for that many days during the Middle Ages to prevent the spread of plague. The concept of quarantine is frequently confused with that of isolation, which is used to separate and restrict the movement of those who are already known to have a specific illness. Isolation is commonly used in hospitals for patients with tuberculosis and certain other infectious diseases. The widely publicized case of Andrew Speaker, an Atlanta attorney who flew to Europe in May 2007 to get married despite a diagnosis of drug-resistant tuberculosis, was frequently mischaracterized as having been the subject of a federal quarantine order. In fact, having already been diagnosed, Speaker was the subject of a federal isolation order.

In the United States, most legal quarantine and isolation authority rests with state and local public health officials, an extension of state authority to ensure the safety, health, and well-being of its citizens. When Andrew Speaker was put under the federal isolation order, it was the first time such federal power had been used since 1963 (when a person exposed to smallpox had been quarantined). The federal government, primarily through the CENTERS FOR DISEASE CONTROL

The CDC director of the Division of Global Migration and Quarantine, Dr. Martin Centron, speaks to the press about the CDC's response to a patient with drug-resistant tuberculosis. The patient's international travel while the subject of a federal isolation order made headlines in 2007. Source: *Centers for Disease Control and Prevention/James Gathany*

AND PREVENTION (CDC), is charged with preventing the spread of communicable diseases from state to state, or from other countries into the United States. The list of communicable diseases for which federal isolation and quarantine are authorized is limited. They include cholera, diphtheria, infectious tuberculosis, plague, smallpox, yellow fever, and viral hemorrhagic fevers (such as ebola). Severe acute respiratory syndrome (SARS) was added in 2003.

Qui Tam

See FALSE CLAIMS ACT.

R

Rationing

A loaded word in health policy parlance, rationing is merely the way health care resources are distributed within a population. The United States currently rations health care by default—those with the most money or best insurance coverage get the most (and usually, but not always, the best) care. In other countries, care is rationed in other ways, frequently through "queues," or waiting lists, for expensive surgery or high-tech treatments, or by limiting the spread of technology. For example, some countries limit the number of magnetic resonance imaging (MRI) machines or positron emission tomography (PET) scanners that are available to the population. Other countries impose age limits for certain procedures, refusing, for example, to transplant kidneys into those over sixty-five years of age. When Oregon proposed its novel (for the United States) rationing program for MEDICAID recipients, critics charged that it was antithetical to American values (see OREGON HEALTH PLAN). Proponents of the program, however, argued that Medicaid was already rationed—those who met eligibility standards got "everything," whereas those who were poor, but not poor enough, or who did not fall into one of Medicaid's eligibility categories, got nothing. Better to give more people some care than some people no care, they argued (and ultimately prevailed, although no state since has emulated Oregon's example). Most health policy analysts predict that when the huge baby boom population reaches its high health cost years beginning around the year 2010, the United States will have no choice but to implement some sort of overt rationing system.

Referral

Originally an informal method by which patients in need of specialized care were sent to a more advanced practitioner by their personal physician, today *referral* indicates a technique by which MANAGED CARE plans seek to control the use of medical services by their members. Many plans require that to obtain any care except that provided by a patient's PRIMARY CARE PHYSICIAN (PCP), the patient must obtain a written referral from that physician (who is sometimes called a GATEKEEPER). Referrals frequently limit visits to specialists to one or two appointments, after which, if more care is needed, another referral must be obtained. Referrals are also required for laboratory tests, physical therapy, or other ancillary medical services and for admission to a hospital or other treatment facility. Many patients and physicians, however, find referrals needlessly bureaucratic and even intrusive on a patient's preexisting relationship with another physician. By the early 2000s, many health plans had relaxed rules about referrals, and a majority of states passed laws requiring that women be able to "directly access" their obstetricians/gynecologists without a referral from their primary care physician, regardless of that plan's rules. (See HEALTH PLAN.)

Regenerative medicine

Using the human body's own mechanisms to repair damaged tissues and organs is known as regenerative medicine. Largely still theoretical midway through the first decade of the twenty-first century, researchers involved in the field anticipate using information derived

from the mapping of the human genome, manipulating both adult and embryonic STEM CELLS, and using existing genes and proteins to repair and ultimately replace nonworking parts. Early examples of regenerative medicine include growing new skin for burn victims and new cartilage to repair damaged joints. Some researchers claim regenerative medicine can ultimately produce perpetual youth by replacing tissues and organs as they age, a prospect raising ethical as well as scientific questions.

Reimportation, prescription drug

Bringing back U.S.-made prescription drugs from countries to which they have been sent for sale is known as reimportation. Congress explicitly made the practice illegal in 1988 legislation (PL 100–293) for anyone except the drug's manufacturer. The law, known as the Prescription Drug Marketing Act, was an effort to ensure that outdated, misbranded, or tainted medications would not end up in the hands of unwitting consumers. But with drug prices in other countries largely lower than in the United States (sometimes because of overt price controls, sometimes for competitive reasons), consumer groups—and sometimes lawmakers themselves—began sponsoring drug-buying bus trips to Canada and Mexico, where medications could often be purchased at a fraction of the price charged at home.

Eager to make such discounts available to people who lived further from the border, and frustrated at their inability to agree on a prescription drug benefit for MEDICARE, Congress in 2000 voted to relax the reimportation ban. The measure, part of the fiscal 2001 spending bill for the Department of Agriculture, which included funding for the FOOD AND DRUG ADMINISTRATION (FDA) (PL 106–387), allowed pharmacists and wholesalers to bring back drugs from a list of nations with advanced drug regulatory regimes. That list included Canada and most of Europe, but not Mexico.

But the law included several elements that cast doubt on whether it would have reached its goal of offering U.S. buyers lower prices. The first—and ultimately most important—was language added by the Senate stipulating that the entire provision not take effect unless the secretary of the HEALTH AND HUMAN SERVICES DEPARTMENT (HHS) certified "that the implementation . . . will pose no risk to the public's health and safety, and result

Drug importation supporters, from left to right, Gil Gutknecht, R-Minn., Rahm Emanuel, D-Ill., Bernard Sanders, I-Vt., and Jo Ann Emerson, R-Mo., celebrate the bill's passage in July 2003.
Source: CQ Photo/Scott J. Ferrell

in a significant reduction in the cost of covered products to the American consumer."

During the House-Senate conference on the bill, Republicans also added provisions that Democrats charged cut the heart out of the legislation, allowing drugmakers, for example, to refuse to provide labeling needed to sell the reimported drugs in the United States. Democrats said Republicans were doing the bidding of the drug industry, which opposed any relaxation of the reimportation ban. Ten former FDA commissioners, both Democratic and Republican, also opposed making it easier to bring drugs back from other countries, arguing that the agency was ill-equipped to ensure the continuing safety of the nation's drug supply.

President Bill Clinton signed the spending bill, but only after complaining that, with the changes, the reimportation provisions "clearly will provide less help to seniors and others who need but can't afford drugs." HHS secretary Donna E. Shalala announced on December 26 that she could not certify that the program would both save money and protect patients "because of serious flaws and loopholes in the design of the new drug reimportation system."

Sponsors of the provision hoped that the Bush administration would see things differently. But HHS secretary Tommy G. Thompson said he agreed with his predecessor. "Opening our borders . . . would increase the likelihood that the shelves of pharmacies in towns and communities across the nation would include counterfeit drugs, cheap foreign copies of FDA-approved drugs, expired drugs, contaminated drugs, and drugs stored under inappropriate and unsafe conditions," he wrote in a July 2001 letter to Sen. James M. Jeffords, I-Vt., who spearheaded the effort in the Senate.

The Senate in 2002 approved a provision that would have made it easier to reimport drugs from Canada, but it was part of a bill intended to speed generic copies of brand-name drugs to market that the House never considered. (See GENERIC DRUGS.)

In 2003 it was the House's turn to lead the reimportation fight. As part of a bill to add prescription drug coverage and make other changes to the Medicare program, both the House and Senate included provisions that would have allowed drugs to be purchased from Canada. But both versions also included what reimportation backers referred to as "poison pill" language, requiring approval by the Health and Human Services Department before such trade would be allowed—approval Bush administration officials had made clear would not be forthcoming.

Backers would get another chance, however. When House Republican leaders found themselves a handful of votes short of being able to pass the Medicare bill just after 2 A.M. June 27, they cut a deal with reimportation leader Jo Ann Emerson, R-Mo. In exchange for Emerson agreeing to cast the deciding vote on the Medicare bill, Republican leaders agreed to allow an up-or-down vote on the version of reimportation Emerson preferred. That was a bill sponsored by Gil Gutknecht, R-Minn., which allowed reimportation from some two dozen industrialized nations, with no requirement for HHS preapproval. Under the deal, if the Gutknecht bill passed, it would replace the more limited reimportation language in the Medicare bill as the House's official position.

Republican leaders promised officially not to work against the bill, but the drug industry and the Bush administration launched a furious lobbying campaign as the vote, scheduled for July 24, neared. The industry ran its own advertisements and bankrolled those of other groups. Food and Drug Administration commissioner Mark McClellan wrote a scathing letter to lawmakers, charging that the Gutknecht bill "creates a wide channel for large volumes of unapproved drugs and other products to enter the United States that are potentially injurious to public health and pose a threat to the security of our Nation's drug supply."

But an unlikely coalition of conservative Republicans, liberal Democrats, and moderates of both parties united in their belief that something had to be done to lower drug prices, and the Gutknecht bill was at least a part of the answer. Despite what both sides predicted would be a close vote, the Gutknecht bill passed by a resounding 243-186 on July 25, just before 3:00 A.M.

The final version of the Medicare legislation (PL 108–173) included the language allowing drug importants from Canada along with the "poison pill" language, but it required the secretary of health and human

services to conduct a study on the safety and trade issues associated with drug reimportation. The due date of that study was set for December 2004, a month after the upcoming presidential election.

As many expected, the administration concluded in that report that reimportation was unlikely to be made safe or, if it could be made safe, was unlikely to save consumers money. Reimportation backers said the report would trigger a backlash in Congress, because it proved that the Bush administration would never ease restrictions on its own. Even though bipartisan majorities in the House and Senate clearly supported reimportation legislation, GOP leaders managed to keep most importation legislation bottled up for the entirety of the 109th Congress.

In 2007, with the Democrats in charge of Congress for the first time in a dozen years, the Senate passed a sweeping drug importation bill in May as part of legislation to reauthorize the FDA PRESCRIPTION DRUG USER FEE ACT (PDUFA). But in a surprise move, senators also approved the same language added under Republican rule, requiring that the HHS secretary first certify that such reimportation would be both safe and cost-effective. The language was subsequently dropped from the FDA bill.

Report cards

"Report cards" is jargon for tools that can be used by health care consumers, providers, and payers to compare the performance of health plans. The NATIONAL COMMITTEE FOR QUALITY ASSURANCE (NCQA) has developed an online report card that allows consumers to compare health plans in their area according to measures of access, number of qualified providers, wellness, and other measures. Report cards, however, have yet to live up to their promise of providing patients and other purchasers of health care with adequate information to make informed choices. Next generation report cards hope to measure everything from health care quality and use to cost control, consumer satisfaction, administrative efficiencies, and financial stability. (See HEALTH PLAN.)

Residency review committees (RRCs)

Residency review committees (RRCs) are composed of groups of physicians who set standards for training and evaluate medical training programs in each of twenty-six recognized medical specialties. The RRCs report to the ACCREDITATION COUNCIL ON GRADUATE MEDICAL EDUCATION (ACGME), a nonprofit group charged with the responsibility of overseeing the quality of physician training in the nation's roughly one thousand medical teaching facilities.

Resource-based relative value scale

The resource-based relative value scale (RBRVS) measures the time, training, and skill required to perform a given medical service. The RBRVS, devised for MEDICARE by researchers from Harvard University in 1986, is the basis for the program's physician fee schedule. It has three main factors: physician work (time, skill, and intensity involved in the service), practice expenses, and malpractice costs. The relative values are then adjusted for geographic variations and converted into payment by multiplying the resulting figure by a "conversion factor." Thus, if the relative value for a particular service is 0.75 and the conversion factor is $50, the payment for that service would be $37.50. The RBRVS was devised as a way to redress Medicare's tendency to overpay for surgery and other medical procedures and to underpay for so-called cognitive services such as counseling and performing a physical examination. In the early years it was in place, Medicare's new physician fee schedule increased incomes for primary care physicians such as internists and decreased them for "proceduralists," such as surgeons. But other changes to the way Medicare paid doctors, including volume controls, had the impact of reversing the gains made by the RBRVS, once again leaving primary care physicians behind in terms of pay in the mid-2000s. (See PRIMARY CARE PHYSICIAN [PCP].)

Respite care

Respite care is a service that provides a paid caregiver to relieve a family member providing support or other care to a family member. Respite care, which is most frequently used for those caring for individuals with Alzheimer's disease, may be provided in the ailing person's home or in an outside facility (including a hospital, nursing home, or adult day care center). MEDICAID allows respite care as an optional service; MEDICARE covers it only as part of its HOSPICE benefit for terminally ill patients. The 1988 MEDICARE CATASTROPHIC COVERAGE ACT (PL 100–360) included the first-ever respite care benefit for Medicare generally, authorizing up to eighty hours per year for unpaid family members or friends who lived with and cared for a chronically dependent Medicare BENEFICIARY. But that benefit was repealed before it ever took effect, along with the other new benefits in the law, in 1989.

Congress did create a program to provide some limited federal funding for respite care as part of the 2000 reauthorization of the Older Americans Act (PL 106–501). The National Family Caregiver Support Program was funded at $153 million in fiscal 2008. The program helps pay for respite care and for information, referrals, counseling, and other services.

Retiree health insurance

Many, particularly large, firms offer this health coverage for free or for a fee to workers who are retired from the company. About a quarter of MEDICARE beneficiaries—about 10.3 million individuals in 2006—had some sort of health insurance provided through a former job. That represented the single largest source of coverage to fill Medicare's many benefit gaps. (See BENEFICIARY.)

Retiree coverage, however, once widespread, has been on the decline. Between 1988 and 2006, the percentage of large firms offering retiree health benefits fell from 66 percent to 35 percent, according to a survey by the Henry J. Kaiser Family Foundation and the Health Research and Educational Trust. (Large employers are more likely than small firms to offer retiree coverage.) The study also found that many employers who were not dropping coverage were cutting back in other ways. In 2006 nearly three-quarters of firms raised premiums for retirees under age sixty-five, while 58 percent raised premiums for retirees eligible for Medicare.

Most analysts say the trend toward less generous retiree benefits comes mostly from increasing health care costs in general. But another important factor was the 1992 imposition of a rule by the Financial Accounting Standards Board requiring companies to show on their current books the estimated future costs of retiree health insurance. The rule is known as FAS 106.

Lawmakers were concerned that adding prescription drug coverage to Medicare in 2003 would accelerate the trend of employers dropping retiree coverage. To try to prevent that, the law included subsidies for employers who maintained retiree health plans. At least in the early years of the new benefit, those subsidies appeared to work. According to the 2006 Kaiser–Hewitt survey, an annual study of large firms conducted by the Kaiser Family Foundation and business consultants Hewitt Associates, 82 percent of the firms surveyed took the subsidy and continued to offer coverage in 2006, the first year of the new benefit. For 2007, 78 percent of employers said they planned to continue coverage and take the subsidy.

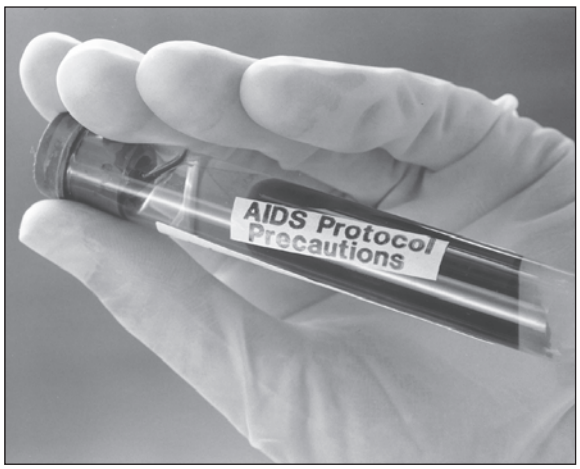
Ribicoff children

So-called for Sen. Abraham Ribicoff, R-Conn., who sponsored the legislation to authorize coverage, this is an optional category of children that states may cover under MEDICAID. Originally, Ribicoff children were those under age twenty-one who would have been eligible for benefits under the Aid to Families with Dependent Children (AFDC) program if they met the definition of a dependent child. The program permitted coverage of children in low-income families not living at home (such as those in intermediate care facilities for

the mentally retarded, those in foster care, and those in psychiatric institutions). The program has largely been superseded by mandated coverage of children in families with incomes under 100 percent of the poverty level born after September 30, 1983.

Ricky Ray Hemophilia Relief Fund Act

This legislation was cleared by Congress in 1998 to authorize "compassionate" tax-free payments of up to $100,000 for hemophiliacs (and their families) who contracted HIV (human immunodeficiency virus) from contaminated clotting factor before blood tests for ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS) were in wide use. The measure (PL 105–369) was the culmination of five years of lobbying by the hemophilia community, an estimated half of whose members became HIV-positive from using the contaminated clotting factor. Unlike the blood used in regular blood transfusions, the clotting factor was derived from thousands of donors, which thus substantially increased the recipients' risk of contracting HIV. Ricky Ray was a Florida hemophiliac and the oldest of three brothers, all of whom contracted AIDS through contaminated clotting factor. Ray and his family were shunned by their community in the mid-1980s, before AIDS and its modes of transmission were well understood. He died in 1992 at age fifteen. In 1997 manufacturers of the clotting factor reached a legal settlement with some seventy-two hundred hemophiliacs with HIV and survivors of those who already died to pay them $100,000 each. But because HIV-positive hemophiliacs already spent $100,000 a year on clotting factor alone, and another $10,000 to $50,000 on AIDS-related treatment, Congress decided to match the settlement monies. The measure almost did not become law in 1998—its passage in the Senate was one of the last legislative acts of the 105th Congress—because some senators wanted to extend coverage beyond the hemophilia community to all of those who contracted HIV from tainted blood transfusions. That, however, would have more than doubled the bill's cost.



Passed by Congress in 1998, the Ricky Ray Hemophilia Relief Fund Act authorized compensation for the more than seven thousand hemophiliacs who contracted HIV from contaminated clotting factor in the mid-1980s, before blood tests for AIDS were in wide use. *Source: National Institute of Allergy and Infectious Diseases, National Institutes of Health*

Risk adjustment

Risk adjustment is a mechanism for spreading the cost of very high users of medical care among the rest of an insured population. The existence of a well-working risk adjuster would eliminate the incentive for insurers to seek to cover those who are least likely to need care and to shun those likely to get sick. The distribution of health care costs among the population makes it obvious why insurance companies would like to cover the healthy: the sickest 1 percent of the population incurs 30 percent of all health care spending in a year; and the sickest 10 percent of the population accounts for 72 percent of health spending. Meanwhile, the healthiest 50 percent of the population incurs only 3 percent of annual health care costs. There are two basic types of risk adjustment—prospective and retrospective. Prospective risk adjustment looks at likely risk factors (age, gender, medical history) and sets payments in advance based on anticipated costs that are distributed among insurers. Retrospective risk adjustment looks at the actual claims experience of individuals and redistributes payments based on patients who cost more than expected, who

suffer from certain conditions, or whose costs exceed a certain threshold.

In the 1997 Balanced Budget Act (PL 105–33), Congress ordered the HEALTH CARE FINANCING ADMINISTRATION (HCFA) to develop a risk adjustment mechanism for the Medicare managed care program by the year 2000. HCFA announced the first phase of its proposed methodology on January 15, 1999. It based risk-adjusted payments on whether or not beneficiaries had been hospitalized for certain conditions in the previous year, which could indicate those patients will have higher than average health costs in the future. Medicare managed care plans complained vociferously about the risk adjuster, claiming that they did such a good job keeping sick patients out of the hospital, they would end up being hurt, not helped, by the new payment adjustments. (See MEDICARE, MANAGED CARE, and BENEFICIARY.)

Risk adjusters have proven simpler to theorize than to develop and implement. They generally require more, and more detailed, data than most plans have available. It took Medicare officials several tries to come up with a way to collect the needed outpatient data that did not swamp Medicare managed care plans with paperwork.

Roe v. Wade

Roe v. Wade is the landmark case that legalized ABORTION nationwide. The ruling, written by Justice Harry A. Blackmun and issued on January 22, 1973, declared that the guarantee of liberty in the Fourteenth Amendment to the U.S. Constitution extends a right to privacy "broad enough to encompass a woman's decision whether or not to terminate her pregnancy."

But *Roe* also recognized that states have a legitimate interest in protecting both the woman's health and the potential life represented by the fetus. Said the decision: "[A]ppellant and some [friends of the court] argue that the woman's right is absolute and that she is entitled to terminate her pregnancy at whatever time, in whatever way, and for whatever reason she chooses. With this we do not agree. . . . The court's decisions recognizing a right of privacy also acknowledge that some state regulation in areas protected by that right is appropriate. . . . We, therefore, conclude that the right of personal privacy includes the abortion decisions but that this right is not unqualified and must be considered against important state interests in regulation."

The heart of the decision is the so-called trimester framework—dividing the nine-month pregnancy into three equal parts—which Blackmun described as follows:

> For the stage prior to approximately the end of the first trimester the abortion decision and its effectuation must be left to the medical judgment of the pregnant woman's attending physician. For the stage subsequent to approximately the end of the first trimester the State, in promoting its interest in the health of the mother, may, if it chooses, regulate the abortion procedure in ways that are reasonably related to maternal health. For the stage subsequent to viability, the State in promoting its interest in the potentiality of human life, may, if it chooses, regulate, and even proscribe, abortion except where it is necessary, in appropriate medical judgment, for the preservation of the life or health of the mother.

In the companion case *Doe v. Bolton,* handed down the same day as *Roe,* the U.S. Supreme Court made clear that it took a liberal view of what "health" meant: "[T]he medical judgment may be exercised in light of all factors—physical, emotional, psychological, familial, and the woman's age—relevant to the well-being of the patient. All these factors relate to health."

A literal reading of *Roe* would seem to allow states considerable leeway to regulate abortion. But under the original holding, a woman had a "fundamental right" to terminate a pregnancy before fetal viability, and any state efforts to regulate that choice had to survive "strict scrutiny" and demonstrate a "compelling state interest." Under that rubric, the Court in subsequent cases struck down a wide array of abortion restrictions, including twenty-four-hour waiting periods, requirements that all abortions be performed in hospitals, and so-called INFORMED CONSENT laws requiring women seeking abortions to be given information about fetal development and abortion alternatives.

Until the 1989 case *Webster v. Reproductive Health Services of Missouri,* the only major restrictions allowed by the Court were PARENTAL NOTIFICATION and consent

laws, as long as minors could seek permission from a judge if they feared involving their parents (*Bellotti v. Baird,* 1979; *Hodgson v. Minnesota,* 1990; among others), and state and federal laws barring public funding for abortions not needed to save the woman's life (*Harris v. McRae,* 1980, upholding the so-called HYDE AMENDMENT barring federal funding for abortions except in life-threatening situations).

Then, in 1992, the Court discarded the trimester framework altogether in *PLANNED PARENTHOOD OF SOUTHEASTERN PENNSYLVANIA V. CASEY.* In its place, it substituted a rule under which only state regulations that impose "an undue burden" on a woman's ability to obtain an abortion would be found unconstitutional.

RRCs

See RESIDENCY REVIEW COMMITTEES (RRCs).

RU486

Formally known as mifepristone, RU486 is a pill that can induce early ABORTION without surgery. Taken after pregnancy is established, RU489 differs from Plan B, which prevents ovulation or implantation of a fertilized egg (see EMERGENCY CONTRACEPTION). Since the drug was first approved in France in 1988, abortion rights and antiabortion groups have fought a nearly nonstop battle over whether RU486 should be available in the United States. The fight even continued after the FOOD AND DRUG ADMINISTRATION (FDA) formally approved it for sale under the brand name Mifeprex in September 2000. Abortion rights supporters see the "abortion pill" as a salvation, allowing women to terminate unwanted pregnancies in the privacy of their own homes and thus moving the procedure away from abortion clinics, which have become targets of sometimes violent protesters. They also say availability of this "medical abortion" increases the likelihood that more doctors will provide abortion services, reversing a decline in access. And unlike surgical abortions, which cannot generally be done until a pregnancy is in its seventh week, RU486 works only in the earliest stages of pregnancy. At forty-nine days, the outer limit for using the drug most effectively, the embryo is roughly the size of an aspirin. Abortion opponents fear RU486 for much the same reasons proponents want it, including the fact that the highest public support for abortion is at the earliest stages of pregnancy.

The drug is what is known as an antiprogestin. By blocking the action of the hormone progesterone, which prepares the lining of the uterus for pregnancy, RU486 interrupts pregnancy in its early stages (up to seven weeks after a missed menstrual period). To work best, RU486 must be combined with a prostaglandin, typically misoprostol, an ulcer medicine that causes uterine contractions. By itself, RU486 works 65 to 80 percent of the time to end a pregnancy; combined with a dose of prostaglandin, the effectiveness jumps to 95 percent. Women who take the drugs and do not abort must undergo the typical surgical procedure.

Medical abortion is not without its difficulties. First, it requires three separate visits to a health professional. The first visit includes an examination, counseling, determination of gestational age. If everything checks out, the woman takes three 200 mg tablets of RU486 and remains under observation for a half-hour. Two days later, the woman returns to take two 200 mcg tablets of misoprostol to induce contractions and remains at the clinic for up to four hours. About half of the women have their abortions at the clinic during the second visit; 75 percent abort within twenty-four hours after taking the prostaglandin. The combination of drugs can also cause some significant side effects, including sometimes severe cramping and bleeding, as well as nausea, headache, weakness, and fatigue.

Overall, however, the procedure is considered very safe—far safer than carrying a pregnancy to term. Since 1981 women in twenty-three countries have used RU486 combined with various prostaglandins to induce early abortions. In Europe alone, more than 700,000 women have used the procedure. In 1998 the *New England Journal of Medicine* published the results of the U.S. clinical trials, in which the drug was found safe and effective, when combined with a prostaglandin, in terminating pregnancies of forty-nine days or less. Of 2,015 volun-

teers with pregnancies up to forty-nine days, 2 percent experienced complications severe enough to require hospitalization or surgical intervention; 4 percent of those with pregnancies between fifty and sixty-three days experienced serious side effects.

Through the first half of 2001, an estimated thirty-seven thousand medical abortions were performed in the United States, according to statistics gathered by the Alan Guttmacher Institute, although a quarter of those were performed not with mifepristone but rather methotrexate, a long-approved drug used to treat rheumatoid arthritis and some cancers that also caused early abortions. The use of the regimen was increasing rapidly, according to the PLANNED PARENTHOOD FEDERATION OF AMERICA (PPFA), approaching the 20 percent level common in Europe. By late 2002, more than 100,000 women in the United States had used RU486 to obtain a medical abortion, according Danco Laboratories, the firm created to manufacture and market the drug in the United States. Still, fewer practitioners were offering the procedure than had been predicted before its approval. A survey by the Kaiser Family Foundation a year after its approval found that only 6 percent of obstetrician/gynecologists and 1 percent of general practitioners were offering RU486 to their patients.

The fight over introduction of RU486 into the United States was a heated one. From 1988 to 1993, Americans could not even bring RU486 into the country. The FDA under Presidents Ronald Reagan and George H. W. Bush issued an "import alert" instructing customs agents to confiscate any pills from Americans returning from outside the country. President Bill Clinton lifted the alert on his second full day in office in 1993, along with a raft of other abortion restrictions from the eras of Reagan and Bush.

In 1994 the French maker of the drug, Roussel-Uclaf, donated the U.S. rights to the medication to the Population Council, a nonprofit organization based in New York. The Population Council conducted U.S. clinical trials, applied to the FDA for approval, and arranged for a manufacturer for the drug.

In September 1996, the FDA issued a letter calling the drug "approvable," pending receipt of more information on the drug's manufacturing and labeling. Final approval was delayed, however, when the person the council contracted with to raise money to manufacture and distribute the drug was found to have committed fraud.

In June 1998, abortion opponents in Congress made an attempt to stop RU486 legislatively. During consideration of the Agriculture appropriations bill (which includes funding for the FDA), the House voted 223-202 for an amendment offered by Rep. Tom Coburn, R-Okla., to bar the FDA from granting final approval to any drug "for the inducement of abortion," including RU486. "Should we be in the business of spending federal tax dollars to facilitate the death of children?" Coburn asked on the House floor. "We should be seeking alternatives to abortion rather than making abortion easier." The amendment, however, was dropped in a House-Senate conference, as was a subsequent amendment added at Coburn's instigation in 1999.

Following a series of manufacturing and labeling negotiations with the FDA by Danco, the FDA granted its formal approval on September 28, 2000. But that did not end the matter. Coburn in the House and Tim Hutchinson, R-Ark., in the Senate introduced the RU-486 Patient Health and Safety Act, which would have strictly limited those who could prescribe the drug to physicians who are able to perform dilation and curettage (D&C) abortions, are certified to date a pregnancy through ultrasound, and have admitting privileges at a hospital less than an hour away. "General family practitioners who cannot perform a D&C should not be giving this pill," said Coburn, himself a family practitioner who also delivered babies.

The bill, however, did not move, and abortion opponents pinned their hopes instead on the incoming administration of abortion foe George W. Bush. During his confirmation hearing to become secretary of the HEALTH AND HUMAN SERVICES DEPARTMENT (HHS) just months after FDA's approval of the drug, Wisconsin governor Tommy G. Thompson, also an abortion foe, said he was inclined to revisit the question. But both Bush and Thompson came to understand that an administration cannot reverse an FDA approval without new evidence showing the drug was somehow not safe or effective. In 2002 three antiabortion groups filed a formal petition with the FDA to have the approval

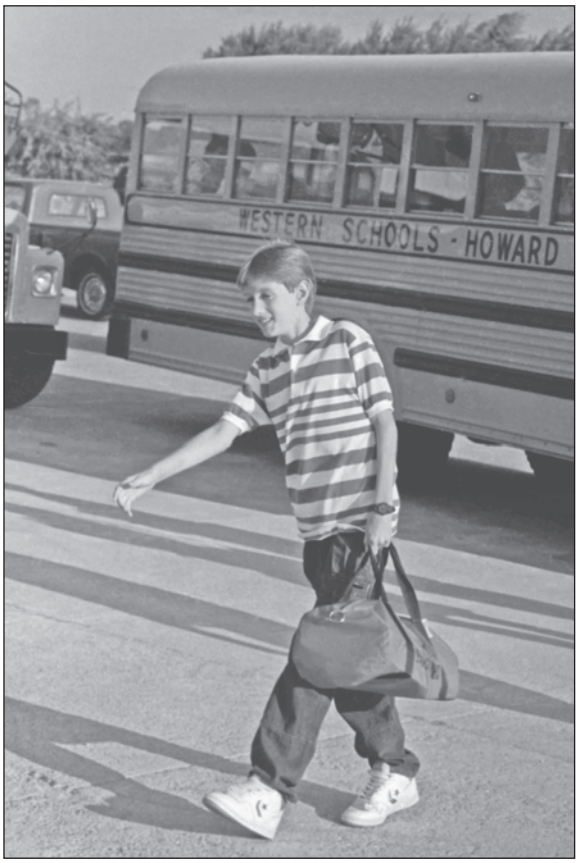
revoked, claiming that the trials were "undeniably deficient." As of 2003, however, the FDA had not acted on the petition. In December 2002, Thompson appointed one of the doctors who worked on the petition, David Hager, to the FDA Advisory Committee on Reproductive Health Drugs, over the objections of abortion rights and other women's groups.

Opponents mounted another effort to have the drug's approval pulled after several deaths were reported from a rare bacterial infection after women had taken the drug. In most of the cases it turned out the women had taken the second drug in the two-drug combination, misoprostol, vaginally, rather than orally, as stipulated by the FDA. Planned Parenthood officials said the vaginal route caused fewer side effects, but in March 2006 after a total of seven deaths they banned vaginial administration of misoprostol in their clinics.

Ryan White Comprehensive AIDS Resources Emergency (CARE) Act

Cleared by Congress in 1990 and signed reluctantly by President George H. W. Bush (PL 101–381), the Ryan White Comprehensive AIDS Resources Emergency (CARE) program rapidly became the major source of funding for treatment and detection of ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS) and HIV, the human immunodeficiency virus or AIDS virus. In fiscal 2008, Congress appropriated $2.2 billion for the Ryan White program, named for an Indiana teenager who contracted AIDS from contaminated clotting factor he took for hemophilia and whose struggle attracted national attention early in the epidemic. White died at age nineteen on April 8, 1990, a little more than a month before the Senate passed the measure and four months before it became law. By 2006 more than 530,000 people per year were receiving funds from a medical, health, or support service provider funded by the act.

The program has five major parts. Title I provides emergency relief grants to cities with demonstrably high rates of AIDS and HIV-positive citizens. Grants can be used to provide health care and support services, prescription drugs, transportation, and counseling to low-income and uninsured individuals. When the measure was passed originally in 1990, fifteen cities qualified for the emergency grants; as of 2003, fifty-one cities were eligible. Title II provides grants to all fifty states, the District of Columbia, and U.S. territories to improve "the quality, accessibility and organization of health care and support for those with AIDS and HIV." Services that can be provided with Title II money are similar to those allowed in Title I. Title III provides grants to states to provide early intervention and comprehensive primary health care services for people liv-



Ryan White, who contracted HIV through a blood transfusion, was barred from his school after it was learned that he had AIDS. A court order later overturned the ban and White was allowed to return to school. The 1990 legislation that bears his name provides federal funding for AIDS education, support, and treatment programs. Source: AP Images/Michael Conroy

ing with AIDS as well as for at-risk populations, including women, intravenous drug users, and homeless individuals. Title III grants fund such activities as education, counseling, testing, and treatment. Title IV provides grants for coordinated HIV services and access to research for children, youth, women, and families. The final section of the act, which in the 1996 five-year reauthorization measure (PL 104–146) combined several programs from the original measure, includes authorized funding for fifteen AIDS education and training centers to educate health professionals in early diagnosis and treatment of HIV-positive individuals; a grant program to reimburse dental schools for the additional, uncompensated costs of providing services to those with AIDS and HIV; and special projects grants that fund innovative programs to deliver care to special populations with HIV disease.

Although the original measure passed with overwhelming support in both the House (where it was approved 408-14) and the Senate (where the vote was 95-4), heated arguments over AIDS policy held it up for months. The arguments focused particularly on issues related to the confidentiality of AIDS testing and whether the federal government should fund NEEDLE EXCHANGE programs to deter the spread of HIV among intravenous drug users by providing them with clean needles. (The final bill barred funding of such programs.) Some conservative lawmakers, particularly Sen. Jesse Helms, R-N.C., and Rep. William E. Dannemeyer, R-Calif., opposed the bills outright, calling them a payoff to the politically active homosexual lobby. President George H. W. Bush also expressed disapproval of the measure, noting in an official administration statement that the bill's "narrow, disease-specific approach sets a dangerous precedent, inviting treatment of other diseases through similar ad hoc arrangements." Nonetheless, Bush signed the measure on August 18, 1990.

Although the issue of treating AIDS was hardly as controversial when the act was due for reauthorization in 1996, the final measure was held up for several months by a debate over whether testing of all newborn infants for HIV should be mandatory. With evidence having accumulated that treating pregnant women with the drug AZT (zidovudine) could reduce the chances of transmission to newborns, some members of the medical community (including the CENTERS FOR DISEASE CONTROL AND PREVENTION [CDC] and the AMERICAN MEDICAL ASSOCIATION [AMA]) argued that testing efforts should be aimed at mothers, not at babies. In the end, a compromise was worked out that would make HIV testing for newborns mandatory if states did not accomplish by other means a reduction in perinatal (pregnant mother to child) transmission of the disease. To continue receiving Ryan White funds, states would have to show a 50 percent reduction by March 2000 in the rate of new perinatal transmissions, compared with 1993; show that at least 95 percent of mothers who had received prenatal care during their pregnancy had been tested; or implement mandatory testing for newborns whose mothers had not been tested. AIDS organizations opposed the compromise as a waste of resources, noting that of an estimated 4.5 million live births annually, only about seven thousand were to HIV-infected women, resulting in only about two thousand infected infants.

The 2000 reauthorization made fewer changes to the program, but it was also held up over efforts to base funding on cases of HIV instead of full-blown AIDS. Sponsors said that the ability of drug regimens to postpone the onset of AIDS made the change a logical one, but California lawmakers were concerned the change would deprive the hard-hit San Francisco Bay area of funding. A compromise limited San Francisco's loss of funds to no more than 15 percent.

Disputes over how funds should be distributed also delayed the 2006 authorization, which ended up passing only on the final day of the 109th Congress. The fight pitted parts of the country that had traditionally received the lion's share of the funding against those areas where caseloads were growing more rapidly, but remained smaller. In the end the measure did direct more funds to areas with fast-growing caseloads but stipulated that no state would lose more than 5 percent of the funds it received in fiscal 2006 and shortened the reauthorization period from five years to three. President George W. Bush signed the measure (PL 109–415) December 19, 2006.

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Safety net facilities

Technically, safety net facilities are health care providers who are legally required to provide health care services free or at reduced rates to those who cannot otherwise afford them. In practice, however, the safety net is much larger, including a network of some of the approximately eleven hundred public hospitals owned and operated by states, cities, or counties; one thousand community and migrant health centers supported by the federal and local governments; and other clinics and practitioners that provide health services to those with low incomes, no insurance, or other access problems. Also considered safety net providers are maternal and child health clinics, local PUBLIC HEALTH departments, veterans hospitals, and INDIAN HEALTH SERVICE (IHS) facilities.

Although many of the nation's large, urban public hospitals provide more than two-thirds of their services to patients on MEDICAID or without insurance altogether, they are also important to those who are better off. Frequently, public hospitals operate an entire region's only burn unit or neonatal intensive care unit or other specialized but money-losing forms of care. Safety net providers have been under stress in recent years. At the same time the number of uninsured has continued to grow, Medicaid patients, who have traditionally been safety net providers' primary source of revenue, are moving into MANAGED CARE plans, which do not necessarily send them to the safety net providers. Some safety net providers have responded by forming their own managed care plans, usually a combination of hospitals and COMMUNITY HEALTH CENTERS, which can provide both inpatient and outpatient services.

Safety net providers have also been affected by federal budget cuts. As part of the 1997 Balanced Budget Act (PL 105–33), Congress reduced Medicaid payments for hospitals that serve a "disproportionate share" of low-income patients by $13 billion over five years (see DISPROPORTIONATE SHARE HOSPITAL [DSH] PAYMENTS [MEDICARE AND MEDICAID]). That law reduced reimbursement for many federally supported clinics that serve UNINSURED and poor individuals. Safety net providers also saw caseloads rise as a result of the effects of the 1996 welfare reform law (the PERSONAL RESPONSIBILITY AND WORK OPPORTUNITY RECONCILIATION ACT, PL 104–193), which eliminated Medicaid coverage for many immigrants.

SAMHSA

See SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION (SAMHSA).

SCHIP

See STATE CHILDREN'S HEALTH INSURANCE PROGRAM (SCHIP).

Secondary care

Secondary care is care provided by a medical specialist. It is the intermediate step between PRIMARY CARE (the first point of contact with the medical system for most

patients) and TERTIARY CARE (highly specialized care, normally provided in a hospital). (See SPECIALTY CARE.)

Secondary Payer (Medicare)

The MEDICARE Secondary Payer program is a set of provisions to help determine which insurance policy pays first for Medicare beneficiaries who have other insurance. (See BENEFICIARY.) In most situations, Medicare is the "primary payer," meaning that it covers care to the extent of its benefits, with other insurance covering some or all of the gaps. In some cases, however, Medicare is the secondary payer, meaning that other insurance must pay to the extent of its coverage, with Medicare paying uncovered bills, if any. For example, employers of more than twenty workers must offer workers age sixty-five and over (and their spouses age sixty-five and over) the same coverage offered to other workers. If the Medicare-eligible worker accepts the employer's coverage, that coverage becomes the primary payer, and Medicare the secondary payer. Plans offered by large employers (with more than one hundred employees) are also primary payers for employees or dependents who receive Medicare on the basis of disability, as long as the employee is considered to be in "current employment status." And employer-sponsored plans of any size are the primary payer for eighteen months for persons who become eligible for the END-STAGE RENAL DISEASE (ESRD) program. That leaves employers as the primary payers for a maximum of twenty-one months (eighteen months plus the three-month waiting period for ESRD coverage). The Medicare Secondary Payer program also authorizes a "data match" program, using Internal Revenue Service and Social Security Administration records to determine if working Medicare beneficiaries may have employer-based coverage that should be a primary payer. The Medicare Secondary Payer program was temporary throughout the 1980s and 1990s, with periodic extensions, producing periodic savings to the Medicare budget baseline. In the 1997 Balanced Budget Act (PL 105–33), Congress made the program permanent.

Self-insurance

Self-insurance is the practice of (usually) large companies using their own funds to pay health benefits to employees. Self-insured firms often hire an insurance company as a third-party administrator to process claims and other paperwork, but the company, not the insurer, pays for the cost of medical care for those covered by the plan. Self-insured companies often purchase "stop-loss" coverage to protect themselves against unexpectedly large expenses. Such coverage limits the total amount a company would have to pay in claims. Self-insurance can be financially attractive to companies because self-insured plans are exempt from most state insurance laws (including costly benefit mandates) under the federal EMPLOYEE RETIREMENT INCOME SECURITY ACT (ERISA).

Self-referral curbs

Congress twice, first in 1989 and again in 1993, sought to crack down on MEDICARE reimbursement for laboratory tests, X-rays, and other services provided at facilities owned in whole or in part by physicians who made the referrals. The first set of restrictions, made in the fiscal 1990 budget reconciliation bill (PL 101–239), grew out of a report by the inspector general of the HEALTH AND HUMAN SERVICES DEPARTMENT (HHS) that found that Medicare patients of physicians who owned or invested in clinical laboratories received 34 percent more lab services than the average Medicare patient in 1987, costing the federal government an extra $28 million that year. The reconciliation bill barred Medicare payments to clinical laboratories when the referring physician had an ownership interest or other financial arrangement with the facility. But the measure included several exceptions. Not covered by the ban were laboratory services provided directly by the physician or his or her employee or by an employee under the physician's direct supervision; services provided as part of a group practice; services within prepaid health plans; and services provided in any rural area or in Puerto Rico.

Selling of patient referrals was already illegal. In 1977 legislation (PL 95–142) Congress made it a felony to accept kickbacks for services paid for by the federal Medicare or joint state-federal MEDICAID programs. A 1987 law (PL 100–93) instituted civil penalties to make prosecution easier and sought to close some of the loopholes left in the earlier statute. But most of the ventures the 1990 law sought to block were crafted to get around those earlier laws by not basing direct payments on referrals. Many of the ventures were in the form of "limited partnerships" that provided the doctor-owners a percentage of any profits.

Organized medicine, led by the AMERICAN MEDICAL ASSOCIATION (AMA), opposed the new restrictions, noting that, in many areas, facilities owned by doctors were the only ones available. But even the editor of the prestigious *New England Journal of Medicine* argued in favor of the self-referral curbs, noting in testimony before Congress that such arrangements "inevitably encourage unnecessary duplication and overutilization of facilities and services, and thereby add significantly to the cost of health care."

Rep. Pete Stark, D-Calif., then chair of the House Ways and Means Subcommittee on Health and sponsor of the limitations (which have come to be known as the Stark I and Stark II restrictions), was disappointed that the curbs enacted in 1989 applied only to laboratory services. He was rewarded in 1993, when, as part of that year's budget reconciliation bill (PL 103–66), the self-referral curbs were extended to cover not only laboratory services but also physical and occupational therapy services; radiology or other diagnostic services; radiation therapy services; durable medical equipment; parenteral and enteral nutrients, equipment, and supplies; prosthetics, orthotics, and prosthetic devices; HOME HEALTH CARE services; outpatient prescription drugs; and inpatient and outpatient hospital services. The bill revised and added a series of exceptions to the ban, including ones for services provided to rural residents in rural areas, those provided by group practices, and those provided by or under the direct supervision of a physician or group of physicians. It also clarified circumstances in which ownership of investment securities constituted a relationship that triggered the referral ban, and it clarified permissible compensation arrangements and definitions of group practices.

As part of the 1997 Balanced Budget Act (PL 105–33), Congress required that the Justice Department issue binding "advisory opinions" to physicians who submit business plans as to whether the plan would violate the self-referral restrictions.

Senate Appropriations Committee

The Senate Appropriations Committee oversees the "discretionary" portion of the federal budget. The committee writes twelve separate spending bills each year that are required for the government to run. Through the LABOR–HEALTH AND HUMAN SERVICES–EDUCATION APPROPRIATION (Labor-HHS), the committee sets spending levels for most of the HEALTH AND HUMAN SERVICES DEPARTMENT (HHS), with three major exceptions. MEDICARE and MEDICAID, as "entitlement" programs, are funded according to estimates of how much they will cost. Legislative changes to affect those costs must be initiated by "authorizing" committees. (Appropriators do have authority over some limited portions of the Medicare budget, primarily how much to allocate for Medicare contractors, the private insurance companies that process Medicare claims.) In addition, for historical reasons, the FOOD AND DRUG ADMINISTRATION (FDA), although part of HHS, is funded through the Agriculture appropriations bill. The appropriations committee also sets spending levels for other health-related programs, including the INDIAN HEALTH SERVICE (IHS) (funded in the Interior bill), health care for veterans (funded in the Military Construction, Veterans Affairs, and related agencies bill), health care and insurance for the military (through the Defense bill), health care for those incarcerated in federal prisons (through the Commerce-Justice-Science and related agencies bill), and health insurance for federal employees (through the Financial Services and General Government bill).

Senate Finance Committee

The Senate Finance Committee has the broadest health jurisdiction of any committee in Congress. Whereas the HOUSE WAYS AND MEANS COMMITTEE shares its health jurisdiction with the HOUSE ENERGY AND COMMERCE COMMITTEE, Senate Finance has complete and exclusive jurisdiction over all health programs included in the Social Security Act. That gives it authority over MEDICARE, MEDICAID, the MATERNAL AND CHILD HEALTH (MCH) SERVICES BLOCK GRANT, and the STATE CHILDREN'S HEALTH INSURANCE PROGRAM (SCHIP) created in the 1997 Balanced Budget Act (PL 105–33). Of the committees that oversee health programs, the Senate Finance Committee has always been the most closely divided between Republicans and Democrats (traditionally the majority party has had only a two-vote advantage over the minority, meaning that a single defector could produce a tie vote). As a result, the panel tends to act in a more bipartisan manner than other health committees, and, for that reason, among others, its bills tend to be taken seriously by both the Senate and the House.

Senate Health, Education, Labor, and Pensions (HELP) Committee

Formerly the Labor and Human Resources Committee, the panel was renamed the Committee on Health, Education, Labor, and Pensions (HELP) at the start of the 106th Congress. The HELP Committee has the second broadest health jurisdiction in that chamber, after the Finance Committee. The Senate HELP panel oversees most of the health programs run by the HEALTH AND HUMAN SERVICES DEPARTMENT (HHS), among them the vast PUBLIC HEALTH SERVICE (PHS), which includes the NATIONAL INSTITUTES OF HEALTH (NIH), the CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC), and the FOOD AND DRUG ADMINISTRATION (FDA); it does not oversee MEDICARE and MEDICAID, which are under the Finance committee's purview. The committee also oversees employee-benefit and worker-safety issues by virtue of its labor jurisdiction and aging and disability issues under its human resources purview. The Senate HELP panel has had a reputation for being more liberal than the Senate as a whole. In 1995 and 1996 the committee's chair, Sen. Nancy Landon Kassebaum, R-Kan., and its ranking

Senate Finance Committee chair Max Baucus (D-Mont.) (right), and ranking member Charles E. Grassley (R-Iowa), preside over the markup of funding for the State Children's Health Insurance Program (SCHIP) in the summer of 2007. Their committee has the broadest jurisdiction over health policy issues in Congress. Source: *CQ Photo/ Scott J. Ferrell*

Democrat, Edward M. Kennedy, of Massachusetts, developed a bipartisan measure that would become the HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA) (PL 104–191). Kennedy also worked closely with Kassebaum's successor, James M. Jeffords, R-Vt. (Jeffords in 2001 left the Republican Party and became an Independent, giving Senate control back to the Democrats.) In 2003, with the GOP again in control of the chamber, Judd Gregg, R-N.H., became the most conservative member to run the panel since Orrin G. Hatch, R-Utah, in the early 1980s. In 2007, when the Democrats retook the chamber, Kennedy resumed the chairmanship for the third time. Kennedy was diagnosed with brain cancer in May 2008 but continued to serve during his treatment.

Single payer

"Single payer" is the term used to refer to a health care system in which all the bills are paid by a single entity, generally the government. Single-payer systems, however, are not the same as government-run medical care. MEDICARE is a single-payer system, with the federal government responsible for paying for all Medicare-covered services, which are provided by private health care entities. By contrast, the Department of Veterans Affairs (VA) health system is a government-run enterprise: the hospitals are owned by the federal government, and health care professionals are paid a government salary to provide services. Internationally, Canada has a single-payer system, in which the government finances care provided by private doctors and hospitals, whereas Great Britain's system (although it has evolved considerably over the years to reflect more private influences) is more in the mold of the VA, with government-owned facilities and doctors on salary.

Single-payer advocates in the United States note that it has many advantages over the existing public–private patchwork system. It is fundamentally simple, easy enough for everyone to understand. It would, by definition, provide UNIVERSAL COVERAGE, insuring everyone. A single-payer system would also significantly reduce costs associated with administering more than fifteen hundred private insurance plans. An estimate of one single-payer proposal offered during the health reform debate of 1993–1994 said it would have reduced national health spending by 6 percent in the year 2003. Even a significant subset of doctors supported the single-payer concept, based on the theory that it would be better to be hassled administratively by a single entity than have to deal with multiple sets of rules imposed by dozens of payers.

But critics complained that adopting a single-payer system would be catastrophically disruptive, essentially putting out of business the entire private health insurance industry. It would entail a huge tax increase—and even though most people would pay no more under a single-payer system than they paid before in premiums and other out-of-pocket health care costs, taxes remained anathema to many, if not most, Americans. Other opponents worried that government control of the health care system, particularly price controls, could suppress critical innovations in new treatments or therapies, or even lead to overt rationing of new or expensive technologies.

During the 1993–1994 debate over health reform in the United States, significant—although not majority—support arose for proposals to convert the nation's private health insurance system to a single-payer program. The proposal, sponsored by Rep. Jim McDermott, D-Wash., and Sen. Paul Wellstone, D-Minn., would have imposed a new payroll tax to fund all health care and imposed strict price controls on health care goods and services. The proposal at one point enjoyed the support of nearly one hundred House members, as many cosponsors as signed onto President Bill Clinton's HEALTH SECURITY ACT. Support for the plan on the HOUSE EDUCATION AND LABOR COMMITTEE (traditionally a liberal stronghold) was so strong that the only way the panel could find enough votes to report out a bill favored by the Clinton administration was by also reporting out (without recommendation for passage) the single-payer proposal. In the end, neither bill was acted on by the full House.

SLMB

See SPECIFIED LOW-INCOME MEDICARE BENEFICIARIES (SLMBs).

Small market variation

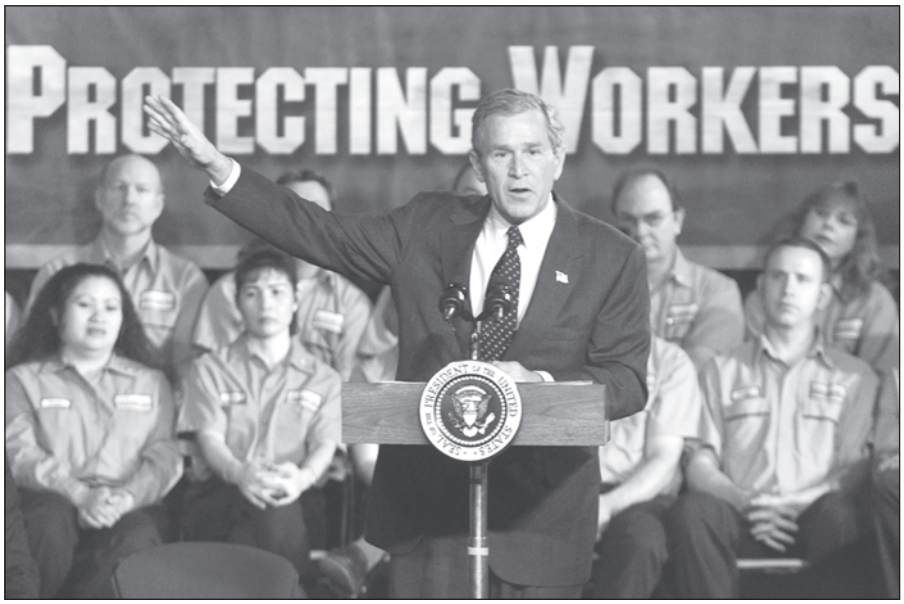
Research over the past two decades has shown conclusively that doctors in different parts of the country practice medicine in different ways. What is less clear, however, is whether the patients who receive more care are getting better care, or whether those receiving less care are being undertreated. The phrase *geography is destiny*—meaning that the medical care patients receive is determined by where in the country they live—is associated with John Wennberg, a physician and researcher at Dartmouth University in Hanover, New Hampshire, who pioneered research into variations in medical practice. Wennberg's early research demonstrated that the rates of procedures performed in Boston were vastly different from those performed in Providence, Rhode Island, less than one hundred miles away. In 1996 Wennberg produced the first *Dartmouth Atlas of Health Care,* which used data from the Medicare FEE-FOR-SERVICE program to document different practice patterns of physicians and different delivery capacities in 306 separate areas of the United States. For example, on a per-person basis, MEDICARE spending is more than twice as high in Miami, Florida, as in Minneapolis, Minnesota. Wennberg's analyses also showed that although health care use is generally higher in areas with a greater capacity (that is, more hospitalizations in areas with more hospital beds), care also varies depending on how physicians tend to practice. Thus, an area may have a higher than average rate of some surgical procedures, but a lower than average rate of others. More recent research performed by Wennberg and his associates at Dartmouth has shown that areas with the highest numbers of doctors have worse medical outcomes than areas with fewer doctors, suggesting that more care is not necessarily better.

SMI

See SUPPLEMENTARY MEDICAL INSURANCE (SMI).

Social Security Act

This law governs the best-known U.S. retirement program and a broad range of other social programs. It was originally passed in 1935, as one of the centerpiece accomplishments of President Franklin D. Roosevelt's



President George W. Bush used a speech in Des Moines, Iowa, to promote his 2002 proposal to create private retirement savings accounts within the Social Security System. *Source: Reuters/Larry Downing*

New Deal, although it has been amended many times since, to add additional programs and benefits. MEDICARE is Title XVIII of the Social Security Act, and MEDICAID is Title XIX. Other programs authorized in the Social Security Act include Survivors and Disability Insurance (Title II), Unemployment Insurance (Title III), the MATERNAL AND CHILD HEALTH (MCH) SERVICES BLOCK GRANT (Title V), the SUPPLEMENTAL SECURITY INCOME (SSI) program (Title XVI), and the Social Services Block Grant (Title XX). The STATE CHILDREN'S HEALTH INSURANCE PROGRAM (SCHIP), authorized in the 1997 Balanced Budget Act (PL 105–33), is Title XXI of the Social Security Act.

Social Security Disability Insurance (SSDI)

Social Security Disability Insurance (SSDI) is the program under Social Security that protects workers from loss of income due to disability by providing them with monthly cash payments. Disability insurance represents the "DI" portion of Social Security's core OASDI program (the remainder is the "old age" and "survivors" insurance). Insurance for the DI portion of Social Security is 0.6 percentage point of the 7.65 percent Social Security payroll tax (1.45 percentage points are for MEDICARE; the remaining 5.6 are for old age and survivors insurance). Congress created SSDI in 1956 to aid workers who retire after age fifty but before age sixty-five because of disability. Coverage of younger workers was added later.

To qualify for SSDI benefits, an individual must have worked the requisite number of quarters in Social Security–covered employment (generally twenty quarters, unless the person is blind or under age thirty-one) and must have a severe impairment rendering him or her unable to perform his or her previous job or any other "substantial gainful activity" as a result of a medically determinable physical or mental impairment that can be expected to result in death or which has lasted or can be expected to last for at least twelve continuous months. SSDI recipients who are certified as "permanently and totally disabled" after a twenty-nine-month period (five months before cash benefits begin and twenty-four months of receiving benefits) are eligible for MEDICARE coverage.

As of December 2007, an estimated 8.9 million disabled workers and dependents were receiving SSDI benefits, accounting for about 15 percent of total Social Security benefits paid.

Somatic cell nuclear transfer

Somatic cell nuclear transfer is the scientific name for the first step involved in cloning a human being or other animal. The procedure involves removing the nucleus from a female egg cell and replacing it with the nucleus of a cell from the person (or animal) to be cloned. The egg is then electrically stimulated, which, if successful, prompts it to begin to divide as if it were fertilized. When the resulting blastocyst is approximately five days old and consists of between 100 and 150 cells, it can be destroyed to harvest embryonic STEM CELLS for research or, some researchers theorize, to grow new tissues for transplantation into the person who donated the cell. Because the initial cell is from the person receiving the transplant, theoretically the new tissues will not be rejected, unlike organs or tissues from other people. The embryo created using somatic cell nuclear transfer can also, theoretically, be implanted into a woman and grown into a baby that would be the genetic twin of the original cell donor. (See CLONING, HUMAN.)

Special Supplemental Nutrition Program for Women, Infants, and Children

See WIC (SPECIAL SUPPLEMENTAL NUTRITION PROGRAM FOR WOMEN, INFANTS, AND CHILDREN).

Specialty care

Specialty care is that provided by a medical "specialist," generally a medical doctor who has undergone additional training and passed an examination given in one of twenty-six disciplines regulated by the American

Board of Medical Specialties. Surgeons, psychiatrists, obstetrician/gynecologists, and cardiologists are all specialists. In many MANAGED CARE plans, patients may not obtain care from a specialist without a written REFERRAL from their PRIMARY CARE PHYSICIAN (PCP).

Specified Low-Income Medicare Beneficiaries (SLMBs)

Specified Low-Income Medicare Beneficiaries (SLMBs, pronounced "slim-bees") are MEDICARE beneficiaries with incomes between 100 and 120 percent of the federal poverty line. Such incomes are too high to qualify SLMBs for full MEDICAID coverage or for Medicaid coverage of all their Medicare cost-sharing requirements. SLMBs do qualify, however, for a program enacted in 1990 that requires state Medicaid programs to pay their Medicare Part B premium ($96.40 in 2008). The SLMB program is significantly underused. Only about 13 percent of those eligible were enrolled as of 2007. (See also DUAL ELIGIBLES.)

Spend-down

Spend-down is the name for the process by which an individual qualifies for MEDICAID coverage by virtue of exhausting his or her income and assets. States have considerable flexibility to determine the level at which a person has spent down to Medicaid eligibility, but, generally, federal law requires states that operate optional MEDICALLY NEEDY programs to take into account the cost of health insurance premiums and other required cost-sharing, as well as other medical expenses the person has, in determining if the remaining financial situation would qualify the individual for Medicaid coverage.

Spousal impoverishment

Spousal impoverishment refers to a situation under MEDICAID in which a person living in the community is impoverished by the program's requirements for payments to augment Medicaid coverage of his or her spouse in a nursing home. Until passage of the 1988 MEDICARE CATASTROPHIC COVERAGE ACT (PL 100–360), Medicaid required not only that an individual spend down virtually all of his or her income or assets before qualifying for Medicaid coverage of a nursing home stay but also that virtually all of the institutionalized individual's income go toward the cost of the care. (See SPEND-DOWN.) After a person had been institutionalized for more than one month, spouses were no longer considered to be living together, and only the income of the institutionalized spouse was considered for determining Medicaid eligibility. If the wife was in an institution and the husband remained at home, the husband could keep any income in his own name. The problem arose most often, however, when it was the husband in the nursing home and the wife at home. If the wife had no income in her name, as was frequently the case, she had to subsist on a welfare-level maintenance allowance from the husband's income while the rest went toward the cost of his nursing home care, giving rise to the term *spousal impoverishment.*

Under provisions of the Medicare Catastrophic Coverage Act that were not repealed with the rest of the measure in 1989, in any month in which a married person was in a nursing home, no income of the at-home spouse was to be considered available to the institutionalized spouse, and income paid solely to one spouse was to belong to that spouse alone. Income paid in both names was to be considered available in equal portions to both spouses. At the beginning of a continuous period of institutionalization, a couple's total assets would be counted and split in two, with half considered available to each spouse, exempting the couple's house, household goods, and personal effects. If, after division of the assets, the at-home spouse was left with less than $12,000 (indexed to general inflation beginning in 1989), the institutionalized spouse could transfer an amount sufficient to allow the at-home spouse to hold $12,000 worth of assets in his or her own name. In 2008 the minimum asset amount was $20,880. However, amounts greater than $60,000 (also indexed to inflation) would be attributed to the institutionalized spouse and thus become available to pay the nursing

home bill. In 2008 the maximum asset limit was $104,400. States could, at their option, raise the minimum to any level below the maximum.

Beginning on September 30, 1989, states also had to permit the at-home spouse to keep a "maintenance needs allowance" from the other spouse's income sufficient to bring total income to at least 122 percent of the monthly federal poverty threshold for a two-person household, rising to 150 percent by 1992. In 2008 the cap on the maintenance allowance was $2,610.

SSDI

See SOCIAL SECURITY DISABILITY INSURANCE (SSDI).

SSI

See SUPPLEMENTAL SECURITY INCOME (SSI).

Stark I and Stark II restrictions

See SELF-REFERRAL CURBS.

State Children's Health Insurance Program (SCHIP)

Created in 1997 as part of the Balanced Budget Act (PL 105–33), the State Children's Health Insurance Program, or SCHIP (sometimes referred to as CHIP), represented the largest one-time expansion of public health insurance coverage since the inception of MEDICARE and MEDICAID thirty-two years earlier. The program provided $48 billion over ten years to states to help insure an estimated one-half of the eight million to ten million children who lacked coverage.

The "kids first" concept of extending health care coverage began in the late summer of 1994 as it became increasingly clear that legislation to guarantee insurance for all Americans was not going to pass. But only as the economy began to improve did the concept take on political and economic feasibility. Covering children was not even President Bill Clinton's top health care priority in 1997. Instead, he had been pushing hard for a plan to provide short-term coverage for those temporarily unemployed. But a coalition of mostly senators, including Sen. John D. Rockefeller IV, D-W.Va., a longtime crusader both for children's and health care issues, and Sens. Edward M. Kennedy, D-Mass., and Orrin G. Hatch, R-Utah, who had teamed up successfully to push through Congress both child care legislation and a bill to provide treatment funds for ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS), brought the issue front and center.

It helped that states were already moving to cover children on their own. Pioneering programs in Florida, New York, and Pennsylvania were singled out and grandfathered in the legislation, not only to permit them to continue and expand but also to encourage other states to copy them.

In retrospect it should have been obvious to policy makers that children's coverage should be expanded. Children are generally healthy and, hence, inexpensive to insure, and they are politically popular with politicians from both parties. Kennedy and Hatch made their plan more irresistible still by proposing to finance the majority of the increased coverage through a boost in the cigarette tax. That plan would have the doubly beneficial effect, they noted, of deterring smoking in general and deterring it particularly among younger smokers, who are most sensitive to price increases.

But the program still nearly did not come about, as lawmakers sparred over how it should be structured and how much flexibility states should be given in spending the money. Democrats and some moderate Republicans favored funneling much of the money through the existing Medicaid program, because each state already had an administrative mechanism in place and the program guaranteed a comprehensive package of benefits. More conservative Republicans, however, wanted states to be allowed to offer less generous packages in an effort to cover more children. They also noted that many states were not enamored of Medicaid and its myriad rules and regulations.

In the end Congress split the difference, allowing states to choose between expanding Medicaid or creat-

ing (or expanding) new, stand-alone programs to cover uninsured children under age nineteen who are not eligible for Medicaid and who live in families with incomes generally under 200 percent of the federal poverty line. States with Medicaid coverage already extended above 150 percent of the poverty threshold (including Hawaii, Tennessee, and Vermont) would be permitted to provide coverage to those in families with incomes fifty percentage points higher than their existing Medicaid limits.

States choosing to create new programs could offer plans with benefits either identical to those of one of three types of benchmark plans—the Blue Cross/Blue Shield plan available to federal employees, any plan broadly available to state employees, or the HEALTH MAINTENANCE ORGANIZATION (HMO) plan offered in the state with the largest commercial enrollment—or a plan "actuarially equivalent" to one of those plans. States were also allowed either to provide a plan with the same benefits as those offered in the Florida, New York, or Pennsylvania plan or to devise their own plan and apply to the federal government for approval. Generally, the insurance had to cover inpatient and outpatient hospital care, physician care, laboratory and X-ray services, and well-baby and well-child care, including immunizations. Plans were also required to include at least 75 percent of the actuarial value of four additional benefits—for mental health, vision, hearing, and prescription drug services—but only if the benchmark plan offered any of those benefits.

Although the federal government was providing funds at a more favorable rate under the new program than it did under Medicaid, states were required to come up with a significant share of the funding for the program. Generally, states were provided funds at rates fifteen percentage points higher than their Medicaid matching rates, up to a ceiling of 85 percent federal funds. For example, if under Medicaid a state had received sixty-five cents from the federal government for every thirty-five cents it spent, under SCHIP it generally took in eighty cents from the government for every twenty cents spent. Although the program was optional for the states, the vast majority were quick to jump at it. As of January 1999 the HEALTH CARE FINANCING ADMINISTRATION (HCFA) had approved plans from fifty-two states and territories. By January 2003, twenty-one states were operating Medicaid expansion plans, nineteen were operating separate SCHIP plans, and sixteen were using a combination of the two. In fiscal 2002 SCHIP covered an estimated 4.2 million children.

By 2007, the program's final year of its original ten-year authorization, more than six million children were enrolled. By nearly every measure SCHIP was considered a major success. It had brought down the rate of uninsured children by roughly a third, provided states with much-needed funding at a time when they were being continually squeezed by rising health costs, and its tax on tobacco products had deterred the use of cigarettes, thus reducing health costs even more.

While unanimous support existed in Washington, D.C., for the program's renewal, it was clear early on that getting that reauthorization would not be easy.

The first warning signal came when President George W. Bush proposed a total increase of only $4.8 billion over five years for the program in his fiscal 2008 budget. Given the rate of health care inflation, that would not have even been enough to cover those children currently enrolled. The president also proposed to effectively limit SCHIP's attractive federal funding match (fifteen percentage points higher than that for Medicaid) to children with incomes at or below 200 percent of the federal poverty line. As of January 2007, seventeen states covered children in families with incomes higher than that threshold.

Democrats, meanwhile, who had retaken the House and Senate as a result of the November 2006 elections, were eager to renew the program and to expand it to cover a total of ten million children.

By late spring of 2007 House and Senate Democrats were moving in different directions on efforts to reauthorize SCHIP. While the fiscal 2008 budget resolution approved by Congress called for a total of $50 billion to be spent on SCHIP reauthorization and expansion, the reinstatement of "pay-as-you-go" budget rules meant that an equal amount of funds had to be cut from other programs or raised in new taxes. Lawmakers in both chambers felt relatively comfortable raising a majority of the new funds from a boost in tobacco

Sen. Edward M. Kennedy (D-Mass), speaks in favor of a Senate bill to reauthorize and expand SCHIP. The program's future funding was hotly debated in Congress in 2007. Ultimately, the Democrats' efforts to expand the program were thwarted by two presidential vetoes.
Source: CQ Photo/Scott J. Ferrell

taxes, which had funded the original program a decade earlier. But legislators from tobacco states began to balk seriously after that levy reached sixty-one cents per pack of cigarettes—raising $35 billion over ten years—leaving a $15 billion gap to be filled.

In the House, with its relatively comfortable Democratic majority with firm control of the floor, it was simple to see where the additional money would come from. Democrats were still steaming about the huge subsidies for the MEDICARE ADVANTAGE program Republicans had granted private insurance companies as part of the 2003 Medicare prescription drug law (PL 108–173, the MEDICARE MODERNIZATION ACT). Trimming those back would win votes from liberals, as well as help pay to fend off a scheduled cut in fees for physicians under Medicare.

In the Senate, however, Finance Committee chair Max Baucus, D-Mont., had a harder row to hoe. The need for sixty votes—the threshold required to block a filibuster—took Medicare Advantage cuts off the table. Republicans were simply adamant on that subject. So in the end the bill spent only $35 billion, instead of the full $50 billion allowed by the budget resolution. Republicans in the Senate who supported a far broader bill than President Bush wanted also insisted on gradually eliminating coverage of adults in the SCHIP program, including parents, and capping income levels in most cases at three times the federal poverty level. Liberals grumbled, but on August 2 the 68-31 tally on passage of the bill was enough to break a filibuster and to override a promised presidential veto.

The House's more partisan measure, meanwhile, with its full list of Medicare changes and much larger price tag, passed by a much narrower 225-204 on August 1.

Even before the two chambers could start to reconcile the measures, the Bush administration dropped a bombshell into the fight. On August 17, while Congress was in recess, the administration issued a "dear Medicaid director" letter that sought to do administratively what it had failed to get Congress to do in legislation—basically force states to cover lower-income children before adding those from higher-income families. Governors and members of Congress from affected states were furious and vowed to overturn the policy in the bill they would send to the president's desk.

That did not happen, though. Given that the Senate had a veto-override majority for its bill, House leaders decided to move closer to that version. And on September 27—just days before the program was set to ex-

pire—the measure arrived on the president's desk, having fallen just a handful of votes short of achieving an override majority in the House as well. Still, despite its strong bipartisan support in both chambers, President Bush vetoed it, saying it expanded the program "beyond its initial intent."

The veto infuriated not only Democrats, but also moderate Republicans, who feared that they would be painted as antichild in the 2008 elections. Sen. Charles E. Grassley, R-Iowa, who led the negotiations on the bipartisan Senate bill, complained that the funding increase the president supported would not even have been large enough to cover those children currently enrolled in the program.

A multimillion-dollar lobbying and advertising campaign followed the veto. It was aimed at House Republicans considered potentially vulnerable in the upcoming elections. Despite these efforts, the 273-156 override vote held October 18 was just over a dozen votes short of the two-thirds needed, and it produced not a single additional Republican who had not also voted for the measure the first time around.

After a week of negotiations, House Democratic leaders brought to the floor a new, slightly tweaked bill they hoped would win over enough votes for the override. But the 265-142 tally included one fewer Republican than voted for the previous version. The Senate passed the measure 64-30 on November 1. Congressional leaders delayed sending it down Pennsylvania Avenue in hopes of finding a last-minute compromise. When that did not happen, they sent it, and President Bush on December 12 vetoed SCHIP legislation for the second time in two months.

Meanwhile, the program had been kept running on temporary funding at fiscal 2007 levels since its authorization expired October 1, 2007. After one more round of negotiations, Democrats gave up and agreed to extend the program at current funding levels for the remainder of the fiscal year. With time running out on the session, however, Republicans in the Senate had the upper hand. They forced Democrats to swallow an extension not until October 1, 2008, just before the election, but until April 1, 2009, instead, to take the politically potent SCHIP program off the table until after the next president and Congress were safely in office. That short-term bill, which President Bush signed December 29 (PL 110–173), also postponed the cut in Medicare fees for doctors until June 30, 2008.

In what amounted to a formality, the House failed to override Bush's second SCHIP veto, on January 23, 2008. The vote was 260-152, fifteen votes short of the two-thirds majority required.

Stem cell research

The fight over federal funding of stem cell research eclipsed nearly all other science issues in the final years of the twentieth century. On one side were scientists who claimed that stem cells, particularly those taken from early embryos, could revolutionize medicine, giving rise to individually customized cell transplants to treat or cure as many as 128 million Americans with chronic or debilitating ailments. On the other side were religious and antiabortion groups, who claimed that the potential benefit did not exceed the actual cost of extracting embryonic stem cells—destroying the embryo from which the cells are taken. They claimed that adult stem cells showed at least equal promise in treating disease and that more resources should be directed toward less ethically charged types of stem cell research. In late 2007 it seemed the controversy might be defused when scientists announced they had devised a way to manipulate skin cells to give them the same properties as embryonic stem cells. But those same scientists cautioned that their discovery was still preliminary and no type of research should be forestalled.

The controversy was ignited when two groups of researchers, working separately at the University of Wisconsin and at Johns Hopkins University in Baltimore, announced they had isolated embryonic stem cells in late 1998. In January 1999, NATIONAL INSTITUTES OF HEALTH (NIH) director Harold Varmus announced his agency would provide federal funds for research on pluripotent stem cells. Varmus based his announcement on an interpretation by the general counsel of the HEALTH AND HUMAN SERVICES DEPARTMENT (HHS) that such research did not violate a congressional ban on EMBRYO RESEARCH as

On July 19, 2006, President Bush exercised his veto power for the first time when he vetoed the Stem Cell Research Enhancement Act of 2005. At the White House ceremony pictured on the left, the president discussed the vetoed legislation and signed into law the Fetus Farming Prohibition Act. He was surrounded by so-called snowflake babies: children conceived from embryos remaining after in vitro fertilization treatments.
Source: UPI Photo/Kevin Dietsch/Landov

long as federal funds were not used to destroy the embryos from which the stem cells were derived. HHS general counsel Harriet Rabb concluded that because the stem cells themselves had no ability to develop into a human being, they were not embryos under the statutory definition.

In September 1999 the National Bioethics Advisory Commission (NBAC), asked by President Bill Clinton to review the scientific and ethical considerations involved in stem cell research, recommended that embryonic stem cell research—including the destruction of embryos to derive those cells—be eligible for federal funding if the cells were derived from embryos leftover from in vitro fertilization attempts and if the donors of those embryos provided INFORMED CONSENT.

Three months later, the NIH issued draft funding guidelines laying out the types of research that would be eligible for federal funding. The guidelines tracked the recommendations of the NBAC. Research not eligible for funding included projects intended to create or contribute to a human embryo, to combine human cells with an animal embryo, to use cells for reproductive cloning of a human being, or to create human embryos specifically for research purposes. (See CLONING, HUMAN.) The NIH made those guidelines final in August 2000. The Clinton administration's claims notwithstanding, opponents of embryonic stem cell research said the guidelines violated both the spirit and the letter of the embryo research ban. "To say as the NIH now does, that it cannot legally and morally fund the actual destruction of embryos to obtain their stem cells, but it will fund research that depends directly on such destruction is disingenuous," said a coalition of groups, called Do No Harm, opposed to embryonic stem cell research.

Because the guidelines stipulated several levels of review, no grants were awarded before President Clinton left office in January 2001. When President George W. Bush was inaugurated, those on both sides of the debate wondered how the new administration would handle the issue. As a candidate, Bush had sided with antiembryonic stem cell research forces. "The governor opposes federal funding for stem cell research that involves destroying a living human embryo," said a Bush campaign spokesperson when the final NIH guidelines were issued the previous August. But Bush's HHS secretary Tommy G. Thompson had been a strong supporter of the research as governor of Wisconsin, one of the states where embryonic stem cells were first isolated. In March 2001, during testimony on Capitol Hill, Thompson told two separate congressional committees that the policy

on funding of embryonic stem cell research was "currently under review."

As President Bush tried to find a middle ground in what was becoming an increasingly polarized debate pitting Republican friends in the biomedical research community against Republican friends in the Catholic Church and antiabortion movement, Republicans in Congress began taking sides. Sen. Strom Thurmond, R-S.C., a longtime abortion opponent, was an early backer of embryonic stem cell research. Thurmond, whose daughter had diabetes, had broken with antiabortion forces in supporting federal funding for research using tissue from aborted fetuses in the early 1990s (see FETAL TISSUE RESEARCH). In June, antiabortion senator Orrin G. Hatch, R-Utah, also came out for the research. In a nine-page analysis, Hatch declared that the research using embryos likely to be destroyed in any case should be allowed to proceed. "In my view, research on stem cells derived from embryos first created for, but ultimately not used in, the process of in vitro fertilization, raises questions and considerations fundamentally different from issues attendant to abortion," Hatch wrote Thompson. "As I evaluate all these factors, I concluded that this research is consistent with bedrock pro-life, pro-family values."

But the senator whose opinion was among those most widely watched was that of Bill Frist, R-Tenn., a former heart-lung transplant surgeon who had become a leader in the party on health and science issues. In what turned out to be a preview of President Bush's ultimate position, Frist in July announced he would support funding research on embryonic stem cells, but only under strict conditions, including banning the creation of embryos for research; continuing the funding ban on removing stem cells from embryos while funding only the actual stem cell research; banning human cloning; and limiting the number of embryonic stem cell lines available for research.

President Bush built on Frist's conditions in a nationally televised speech to announce his decision on August 9, 2001. He said that, as of 9 P.M. that night, private researchers had already created more than sixty "genetically diverse stem cells lines," enough to determine whether the research was viable and thus avoid any further embryo destruction. "I have concluded that we should allow federal funds to be used for research on these existing stem cell lines, where the life and death decision has already been made," he said.

Reaction to the decision was mixed. Backers of the research were stunned by the announcement of the existence of more than sixty embryonic stem cell lines. Leading stem cell researchers said they were aware of only a handful and expressed concerns about whether such potentially commercially valuable cells would be made available to other researchers. At the same time, abortion opponents split over the decision. The NATIONAL RIGHT TO LIFE COMMITTEE (NRLC) supported it, noting that the embryos already killed cannot be brought back. But the U.S. Catholic Conference disagreed. President Bush "has crossed an important moral line here," said the Catholic group's Richard Doerflinger.

President Bush's announcement, however, did little to end the debate. By September, HHS secretary Thompson began to back away from earlier estimates on the number of available cell lines. Although the administration had been able to verify sixty-four "derivations," he told the SENATE HEALTH, EDUCATION, LABOR, AND PENSIONS (HELP) COMMITTEE, only twenty-four or twenty-five of those had been developed into usable cell lines.

The debate moved off center stage after the September 11, 2001, terrorist attacks and to some extent was subsumed by the debate over whether to ban human cloning, including the cloning of embryos to produce stem cells. But by late 2002, researchers started to complain that their work was being hindered by a lack of availability. "More than a year after the president's announcement, I am still waiting to receive my first stem cell line," Dr. Curt Civin of Johns Hopkins School of Medicine told the Senate Appropriations Subcommittee on Labor, Health and Human Services, and Education in October. Also testifying at the hearing was Roger Pederson, a stem cell researcher who left the University of California, San Francisco, in 2001 to move to the University of Cambridge in England to pursue his research because of questions over the funding and legality of stem cell research in the United States.

Although a few states, most notably California and New Jersey, took steps to fund the controversial research

using their own public funds, the situation at the federal level remained unchanged until 2005.

That was when a group of moderate Republicans in the House, led by Michael N. Castle, R-Del., forced leaders to allow a vote on long bottled-up legislation to expand research funding in exchange for their vote on that year's annual budget resolution. The stem cell bill would have continued to allow funding only on embryos leftover from in-vitro fertilization efforts, and only if they were otherwise to be destroyed. The House passed the bill on May 24, 2005, by 238-184. That same day, in an effort by the GOP leadership to give opponents of the bill something they could vote for, the House also passed, 431-1, a bipartisan measure to expand research into and create a registry for stem cells from umbilical cords. Cord blood stem cells were considered particularly promising scientifically.

It was unclear after the House action how or whether the main embryonic stem cell bill would get a vote in the Senate, but then and with virtually no warning, Sen. Frist, recently elevated to Senate majority leader, changed his position. On July 29, just hours before the Senate was scheduled to leave for its month-long summer recess, Frist took to the Senate floor to announce that he no longer believed that the president's 2001 policy provided enough cell lines to allow needed research to proceed. "While human embryonic stem cell research is still at a very early stage, the limitations put in place in 2001 will, over time, slow our ability to bring potential new treatments for certain diseases," Frist said. "Therefore, I believe the President's policy should be modified."

It would be nearly a year, however, before the Senate would get to the stem cell bill. Hurricane Katrina, two Supreme Court confirmation battles, and a budget standoff delayed the debate.

Finally, in July 2006, Frist brokered a deal that brought three separate bills to the Senate floor. (The cord blood stem cell bill had passed the Senate by unanimous consent and been signed into law [PL 109–129] by President Bush the previous December.) In addition to the House-passed bill, which the Senate passed July 18 by a vote of 63-37, the Senate passed by identical 100-0 votes bills to increase funding into stem cell research that did not involve the destruction of embryos and to prohibit so-called fetus farming, the practice of implanting embryos into women or animals to further their development so they could then be removed and their stem cells extracted. There was no evidence that such farming was taking place or was being contemplated.

As was the thinking by House leaders a year earlier, Senate GOP leaders hoped that passing the three bills together would give President Bush something he could sign as well as veto, thus minimizing the political impact of using his first veto on a measure polls showed enjoyed significant popular support. Those plans were complicated, however, when the House unexpectedly rejected the research alternatives bill. House backers of the embryonic stem cell research bill, such as Diana DeGette, D-Colo., called the measure a "fig leaf" for the president to hide behind and successfully urged colleagues to vote it down.

Thus, on July 19, President Bush used his veto pen for the first time to veto the stem cell funding bill. The House tried and failed to override the veto that same afternoon. The vote was 235-193, well short of the two-thirds required. Bush signed the fetus farming measure.

In 2007, with Democrats in charge of both chambers for the first time in a dozen years, they made the stem cell research bill a top priority. But the outcome was not much different. The House on January 11 passed a bill, 253-174, virtually identical to the one it passed in 2005. The Senate passed its version, 63-34, on April 11. The House cleared the measure on a final vote of 247-176 on June 7, and President Bush vetoed it again on June 20.

Stem cells

Cells that can duplicate themselves indefinitely and have the ability to develop into more specialized cells are called stem cells. Scientists have isolated stem cells from various sources, including adult blood, bone marrow, and dental pulp; from placentas and umbilical cords of newborn infants; from fetal tissue; and from four- to seven-day-old embryos known as blastocysts. Researchers say they hope that teasing out what makes stem cells develop into other types of cells could lead to treatments or cures for such previously intractable diseases as

Parkinson's, Alzheimer's, diabetes, and spinal cord injuries. Although most stem cells can develop into other types of cells, it appears that only embryonic stem cells, first isolated in 1998, are capable of developing into any cell in the body. Such cells are also known as pluripotent stem cells.

Substance Abuse and Mental Health Services Administration (SAMHSA)

Created in 1992, the Substance Abuse and Mental Health Services Administration (SAMHSA) is the successor agency to the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA). SAMHSA provides funds to help with the costs of treatment for those with substance abuse problems or mental illness, and it funds research into the causes and prevention of these ills. The agency, with a budget of $3.2 billion in fiscal 2008, also monitors the incidence and prevalence of substance abuse and mental health treatment. SAMHSA has three main branches: the Center for Mental Health Services, which helps disseminate information on treatments for mental illness; the Center for Substance Abuse Prevention, which spearheads federal efforts to prevent alcohol and substance abuse; and the Center for Substance Abuse Treatment, which studies ways to improve treatment services and make them more available.

Substitution

See CROWD OUT.

Suicide, assisted

Defined generally, assisted suicide is the practice of helping someone, usually someone with a terminal illness, end his or her own life. From the perspective of health professionals, the term means taking "affirmative steps" to end someone's life instead of merely withholding treatment or nourishment. But the difference between assisted suicide and murder or euthanasia (the affirmative "mercy" killing of a suffering individual) is a fine line, as Dr. Jack Kevorkian, a Michigan pathologist who said he helped more than 130 people kill themselves between 1990 and 1998, has demonstrated.

Kevorkian frequently provided a carbon monoxide machine to allow patients with terminal illnesses to end their lives. Between 1994 and 1996 Kevorkian, whose license to practice medicine was revoked by Michigan and California authorities, was tried and acquitted three times on assisted suicide charges. A fourth trial ended in a mistrial. But in 1998 Kevorkian was arrested for first-degree murder after he appeared in a videotape broadcast on the newsmagazine *60 Minutes*. The videotape showed him delivering what he said was a fatal injection of potassium chloride to fifty-two-year-old Thomas Youk, a Michigan man suffering from Lou Gehrig's disease, a uniformly fatal muscle malady. A Michigan jury convicted Kevorkian of second-degree murder in March 1999.

Kevorkian said he wanted to force Americans to debate the issue of assisted suicide and euthanasia. But even without him, the debate over end-of-life issues was already well underway.

In anticipation of two forthcoming U.S. Supreme Court rulings, Congress in early 1997 moved to outlaw federal funding for assisted suicide. The Assisted Suicide Funding Restriction Act of 1997 (PL 105–12), signed by President Bill Clinton April 30, barred the use of federal funds "to provide any health care item or services furnished for the purpose of causing, or for the purpose of assisting in causing, the death of any individual, such as by assisted suicide, euthanasia, or mercy killing." The measure, however, specifically exempted from the ban the withdrawing of medical care, withholding of food or water, and providing of pain relief "even if such use may increase the risk of death."

The Supreme Court, however, in the two cases testing the issues, did not find any constitutional right to assisted suicide in the decisions it issued in June 1997. In *Vacco v. Quill* and *Washington v. Glucksberg,* the Court upheld assisted suicide bans in New York and Washington, respectively. But at the same time, the Court did not find any reason that states could not permit assisted suicide if they so chose.

So far, Oregon is the only state to test that side of the assisted suicide equation. In 1994 voters used the initiative process to approve the Death with Dignity Act, which permitted state residents who were determined to be mentally competent and to have less than six months to live to request prescriptions for lethal doses of drugs. After a protracted court fight that culminated in the Supreme Court's rejecting a challenge to the law on October 14, 1997, voters in November 1997 reaffirmed their support for the measure by a 60-40 margin, and it took effect later that month. In the measure's first year of operation, ten state residents used the law to obtain lethal doses of barbiturates to kill themselves. Eight of them committed suicide; the other two died of their ailments. In subsequent years, the number of residents using the law grew, but not by much. By the end of 2006, the law's ninth year, a total of 292 terminally ill people had used the law to hasten their deaths.

Meanwhile, some lawmakers in Washington, D.C., tried to overturn the Oregon law. Before the measure took effect in 1997, the respective chairs of the House and Senate Judiciary Committees, Henry J. Hyde, R-Ill., and Orrin G. Hatch, R-Utah, wrote to the federal Drug Enforcement Administration (DEA) asking if Oregon physicians could legally provide drugs for assisting death that were included on the federal government's list of "controlled substances." So as not to interfere with the Oregon vote, the DEA waited until the day after the election to respond to the letter. Its determination was that physicians could not fulfill the requirements of the Oregon law without running afoul of the federal Controlled Substances Act. That law permits physicians to prescribe drugs only for "legitimate medical purposes," DEA administrator Thomas Constantine wrote, and assisted suicide or euthanasia was not a legitimate medical purpose.

In June 1998, however, Attorney General Janet Reno overruled the DEA's interpretation. "The state of Oregon has reached the considered judgment that physician-assisted suicide should be authorized under narrow conditions and in compliance with certain detailed procedures," acting assistant attorney general L. Anthony Sutin wrote in a letter to Oregon Democratic senator Ron Wyden advising him of Reno's decision. "Under these circumstances, we have concluded that the [Controlled Substances Act] does not authorize DEA to prosecute, or to revoke the DEA registration of, a physician who has assisted in a suicide in compliance with Oregon law."

In response to Reno's overturning of the DEA opinion, anti-assisted-suicide legislators immediately set out to overturn Reno. In June 1998 they introduced the Lethal Drug Abuse Prevention Act, which would have barred physicians from prescribing drugs on the federal list of controlled substances "with the purpose of causing, or assisting in causing, the suicide or euthanasia of any individual." The measure was sponsored in the Senate by Assistant Majority Leader Don Nickles, R-Okla., and in the House by Judiciary chair Hyde.

By September the bill had been approved by both the House and Senate Judiciary Committees and was set for floor action in both chambers. But neither house ended up voting on the measure. That was because a coalition of health professionals and patient groups, many of which opposed assisted suicide, launched an intense—and ultimately successful—lobbying campaign to defeat the measure.

They argued that giving the DEA the affirmative authority to police cases of suspected assisted suicide or euthanasia would make it less likely that doctors would use appropriate levels of medication to control intractable pain for terminal patients, thereby taking an already bad problem and making it worse. "We're concerned that using the federal government, the DEA, as a watchdog over physicians will have a very chilling effect on physicians treating patients at the end of life with heavy doses of pain medication," said Thomas Reardon, president-elect of the AMERICAN MEDICAL ASSOCIATION (AMA). "So we're concerned that this will really negatively impact the quality of care for many terminally ill patients." (The AMA was on record as opposing assisted suicide, noting that "physician assisted suicide is against the Code of Medical Ethics and incompatible with the physician's role as healer and caregiver.") The bill was also blocked by Senator Wyden, who said he personally voted against the Oregon assisted suicide law but did not believe the federal government should act to overturn what the voters of the state twice endorsed. Wyden

also opposed the bill on the grounds it would interfere with pain relief efforts.

In 1999 Nickles and Hyde returned with the Pain Relief Promotion Act, which would still have overturned Reno's interpretation of the Controlled Substances Act but would have authorized a broad array of provisions aimed at improving the use of "palliative care" for terminally ill and other pain patients. The changes won the measure the endorsement of several medical groups that opposed the earlier version, including the National Hospice Organization and, notably, the American Medical Association.

The House passed the bill on October 27, 1999, by a vote of 271-156. But its path in the Senate was complicated by the steadfast opposition of Wyden, who managed to delay committee consideration for several weeks and pushed a final debate late into 2000. The House again tried to force the Senate's hand, in October 2000, including the bill it passed in 1999 into a year-end package of tax and MEDICARE changes.

But that earned the measure not only a filibuster threat from Sen. Wyden but also the opposition of President Clinton, who threatened to veto the measure. "Whatever your opinions about assisted suicides and whether the people ought to have a right to vote on it in a given state, we certainly don't want to do anything that would in any way undermine the willingness of physicians to write pain relief medication for fear they'll later be prosecuted if the patient dies," Clinton said in late October. In the end, proponents of the bill dropped their efforts when it became clear that George W. Bush had won the 2000 election.

Instead, they counted on Bush's attorney general, former senator John Ashcroft, to reverse Reno, which he did on November 6, 2001. In a memo to the DEA, Ashcroft wrote that the use of federally regulated drugs to assist a suicide is not a "legitimate medical purpose" under the Controlled Substances Act and that doctors who did so could be subject to losing their federal prescribing privileges.

Oregon's attorney general sued Ashcroft, and in April 2002 a federal district court judge overturned Ashcroft's ruling, finding that the Oregon law did not conflict with the federal drug control law and that Oregon physicians who wrote prescriptions under the law could not have their federal prescribing privileges revoked.

The Bush administration formally appealed the ruling in September 2002, but in May 2004 a three-judge panel of the Ninth Circuit Court of Appeals in San Francisco upheld the lower court ruling. The judges ruled, among other things, that Ashcroft had overstepped his authority in issuing the ruling.

Ashcroft, however, was still determined to fight on. He appealed to the full court of appeals and was turned down. On the same day he announced his resignation as attorney general that November, he appealed to the Supreme Court. On February 22, 2005, the high court agreed to hear the case. Oral arguments were held on October 5, 2005.

The Court handed down its ruling in what by then was *Gonzales v. Oregon* on January 17, 2006. By a 6-3 ruling, it agreed with the lower courts that Ashcroft had overreached in trying to block the Oregon law. Justice Anthony M. Kennedy wrote for the majority that the "authority claimed by [Ashcroft] is both beyond his expertise and incongruous with the statutory purposes and design."

Supplemental Security Income (SSI)

Supplemental Security Income (SSI) is a federal entitlement program that provides cash assistance to low-income aged, blind, and disabled individuals. Although it is run by the Social Security Administration, SSI is not the same as the SOCIAL SECURITY DISABILITY INSURANCE (SSDI) program. SSDI requires qualifying individuals to be fully vested in the Social Security system and is not a means-tested program for those with low incomes. SSI, established in 1972 (PL 92–603) and begun in 1974, was intended to replace a series of state programs as well as the original program of Aid to the Old-Aged and Blind established under the original Social Security program as enacted in 1935 and the Aid to the Permanently and Totally Disabled program enacted in 1950. As envisioned at its creation, SSI was intended to "provide a positive assurance that the nation's aged, blind, and disabled people would no longer have to subsist on below

poverty-level incomes" by providing a uniform, national income support level. SSI payments are to supplement Social Security income supports, particularly for those individuals who are not fully qualified for Social Security or are qualified only for minimal payments.

In October 2007 SSI provided about $3.7 billion in payments to some 7.4 million beneficiaries. The vast majority of SSI beneficiaries are disabled or blind (about 6.2 million); just over one million are children, and just over two million are age sixty-five or over. About 45 percent of SSI beneficiaries receive supplements from states in addition to the federal payments. In 2008 the maximum SSI monthly payment was $637 for individuals and $956 for couples.

SSI, unlike other Social Security programs, is funded from general revenues, not from dedicated Social Security payroll taxes. SSI eligibility also confers automatic eligibility for MEDICAID. Most elderly individuals in nursing homes obtain Medicaid coverage for the costs of their care by qualifying for SSI after "spending down." (See SPEND-DOWN.) The 1996 welfare reform bill, the PERSONAL RESPONSIBILITY AND WORK OPPORTUNITY RECONCILIATION ACT (PL 104–193), made significant changes to the SSI program and its relationship to Medicaid. For example, it made it significantly more difficult for mentally disabled children to qualify for SSI (enrollment had been skyrocketing since the 1990 U.S. Supreme Court decision in *Sullivan v. Zebley,* leading to charges that children with minor behavioral problems were being added to the SSI and Medicaid rolls). The law also barred legal immigrants who entered the United States on or after the date of enactment (August 22, 1996) from receiving any "federal means-tested public benefit," including SSI and Medicaid, for five years from their date of entry. This affected an estimated 500,000 people. Congress, however, restored the eligibility of some two-thirds of those legal immigrants for SSI and Medicaid as part of the 1997 Balanced Budget Act (PL 105–33). Made reeligible for benefits were legal immigrants who were receiving SSI as of August 22, 1996, based on a disability; those receiving SSI on that date because they were elderly but who could requalify based on a disability; and those who were in the United States as of August 22, 1996, and subsequently became disabled. Disabled legal immigrants who entered the country after August 22, 1996, but before June 1, 1997, would also be eligible for benefits. Remaining legal immigrants who entered the United States after August 22, 1996, would still be ineligible for SSI or Medicaid for five years, and in any case until they became citizens.

Supplementary Medical Insurance (SMI)

Also known as Medicare Part B, Supplementary Medical Insurance (SMI) is an optional program that covers a set percentage of the cost of physician and other outpatient care. SMI, which cost $174 billion in fiscal 2007, is funded partially by premiums paid by the program's beneficiaries ($96.40 per month in 2008, plus an INCOME-RELATED PREMIUM from a small number of higher income beneficiaries), with the rest coming from "general revenues," which include income taxes and other fees paid to the U.S. Treasury. Originally, Part B premiums were to cover half of the program's costs. However, when Part B spending began to rise rapidly shortly after the program was launched, Congress stepped in to make sure premiums would remain affordable. In the 1997 Balanced Budget Act (PL 105–33), Congress permanently fixed the Part B premium at the amount estimated to cover 25 percent of program costs. The income-related premium was added as part of the 2003 MEDICARE MODERNIZATION ACT, which also created the MEDICARE prescription drug benefit. Part B, which is available to anyone over age sixty-five as well as to those under sixty-five who are eligible for Part A, covers physician fees and other outpatient costs, such as laboratory tests, durable medical equipment and supplies, and ambulance services. Although its overall spending per year is less than Part A, Part B is more heavily used. In 2007, 97.9 percent of the program's 43.9 million beneficiaries used services covered by Part B. (See BENEFICIARY.)

Surgeon general of the United States

The surgeon general of the United States is the chief spokesperson for PUBLIC HEALTH in the federal govern-

ment. One of the principal duties of the surgeon general is to "protect and advance the health of the nation through educating the public; advocating for effective disease prevention and health promotion programs and activities, and providing a highly recognized symbol of national commitment to protecting and improving the public's health."

The position of surgeon general has changed significantly over the years, waxing and waning in importance and prominence. The first surgeon general, John Maynard Woodworth, was appointed in 1871 to run a newly reorganized Marine Hospital Service as a national hospital system under the direction of a chief medical officer known as the supervising surgeon. Woodworth went on to found the Commissioned Corps of the Public Health Service to run the hospital system and be ready to move about the country as needed to address health needs or emergencies (see PUBLIC HEALTH SERVICE, COMMISSIONED CORPS). The surgeon general remains the titular head of the Commissioned Corps, one of seven uniformed services in the United States, and holds a rank equivalent to a four-star admiral.

Until 1966 the surgeon general remained the head of the Public Health Service, with full program, administrative, and financial management authority. But in 1966 that line authority was transferred to the new post of assistant secretary for health (ASH). The surgeon general was made a principal deputy to the ASH with responsibility for "advising and assisting on professional medical matters."

The position was the subject of controversy from 1973 to 1977, when many lawmakers wanted it abolished. From 1977 to 1981, the surgeon general and assistant secretary for health positions were held by the same person, Julius Richmond. (The situation was repeated with the confirmation of the former director of the CENTERS FOR DISEASE CONTROL AND PREVENTION [CDC] David Satcher in 1998.) In 1981 the surgeon general's office was reestablished as a separate entity.

But surgeons general in the modern era have been best known as the "nation's family doctor." In 1964 Surgeon General Luther Terry first informed the nation of the link between smoking and lung cancer. Surgeon General C. Everett Koop, an antiabortion activist and darling of the conservatives who was appointed by President Ronald Reagan in 1981, ultimately won the admiration of more liberal lawmakers who had opposed his appointment. Koop continued in the tradition of surgeons general by speaking out on tobacco issues—one of his reports detailed the scientific basis for declaring nicotine addictive—and he angered some of his conservative backers with his blunt and open handling of sexual issues associated with the emerging ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS) epidemic. President Bill Clinton's first surgeon general was Joycelyn Elders, his former health secretary from Arkansas. She ultimately proved so controversial—many felt she was in effect calling for children to be taught masturbation—that Clinton fired her.

The surgeon general's post remained vacant from Elders's departure in 1994 until Satcher's confirmation in 1998, as Congress and President Clinton sparred over whether the post should be filled and whether that person's position on ABORTION should be a litmus test. Clinton's first nominee to fill the post following Elders's departure, Tennessee obstetrician/gynecologist Henry Foster, withdrew from consideration in 1995 after the

Surgeons General of the U.S. Public Health Service

Name	*Years served*
John M. Woodworth	1871–1879
John B. Hamilton	1879–1891
Walter Wyman	1891–1911
Rupert Blue	1912–1920
Hugh S. Cumming	1920–1936
Thomas Parran	1936–1948
Leonard A. Scheele	1948–1956
Leroy E. Burney	1956–1961
Luther L. Terry	1961–1965
William H. Stewart	1965–1969
Jesse L. Steinfeld	1969–1973
S. Paul Ehrlich (acting)	1973–1977*
Julius B. Richmond	1977–1981
C. Everett Koop	1981–1989
Antonia C. Novello	1990–1993
M. Joycelyn Elders	1993–1994
David Satcher	1998–2002
Richard Carmona	2002–2006

Source: Department of Health and Human Services.
*Never confirmed.

Senate failed to break a filibuster over his nomination. Antiabortion forces objected to Foster because he had performed abortions early in his career. Abortion opponents also held up Satcher's nomination because he supported President Clinton's veto of legislation to ban so-called PARTIAL-BIRTH ABORTION. Satcher was sworn in as surgeon general on February 13, 1998, and served until his term expired in February 2002.

President George W. Bush's first nominee for the post, Arizona trauma surgeon Richard Carmona, was approved unanimously by the Senate on July 23 and sworn in on August 5, 2002. The colorful Carmona had worked variously as a paramedic and a nurse before getting his medical degree. As a member of a local specialized tactical law enforcement team that responds to hostage and other high-risk situations, Carmona once treated a man he had just shot. Like his predecessor, Carmona also assumed the position of HEALTH AND HUMAN SERVICES DEPARTMENT (HHS) assistant secretary for health. He became acting assistant secretary on February 9, 2003.

Carmona, however, kept a surprisingly low profile as surgeon general and was not reappointed when his term expired in 2007. It soon became clear why. In July 2007 Carmona told the House Government Reform Committee that he felt he was the victim of undue political interference by Bush administration political appointees. He said his reports were rewritten or watered down; he was asked to make what he deemed partisan political appearances; and he was not allowed to pursue activities he considered important to public health. In one case, he told the committee, he was asked to give a keynote address to a group affiliated with the Special Olympics. The trip was denied, he said, because the group and the Special Olympics are so strongly associated with the (Democratic) Kennedy family.

In May 2007 Bush nominated James W. Holsinger, a former undersecretary of health with the Department of Veterans Affairs, to succeed Carmona. Holsinger's nomination was held up, however, after it was reported that he authored a paper in 1991 making medical arguments against homosexuality.

T

Taft-Hartley plans

Multiemployer health and welfare plans are known as Taft-Hartley plans. These are health, pension, and welfare plans to which more than one employer is required to contribute and which are maintained pursuant to one or more collective bargaining agreements between one or more labor unions and more than one employer. Multiemployer plans must be cosponsored by a labor union and must comply with the structural requirements of the 1947 Taft-Hartley Act. Among those requirements are that the plan must be governed equally by labor and management trustees and that the plan must be established and maintained legally separate from either the union or the employers.

Taft-Hartley plans are most common in highly unionized industries in which workers typically change employers often—because they do not have to change health plans if their new employer participates. Among the industries with Taft-Hartley plans are building and construction, entertainment, and mining. "The intermittent and mobile employment patterns of most of these industries would prevent the workers from obtaining health benefit coverage absent a central pooled trust fund through which portable coverage is provided to workers as they move from employer to employer," testified James S. Ray on behalf of the National Coordinating Committee for Multiemployer Plans before a House subcommittee in May 1999. "Moreover, most employers in these industries are small and would not maintain their own employee health plans, particularly for transient workers," Ray said. (See HEALTH PLAN.)

Tax policy and health care

When people think about how much money the federal government spends on health care, they immediately think of the dollars devoted to the huge entitlement programs, MEDICARE and MEDICAID. But another major source of federal spending is almost never mentioned: the federal taxes forgone because the dollars spent on employer-provided health insurance are tax-deductible for the businesses that provide them and excluded from taxes from the employees who receive them.

According to a study published in the journal *Health Affairs,* in 2004 tax policies related to health benefits cost the federal government $188.4 billion. More than half of that amount (just over $100 billion) was due to the exclusion from employee income of employer-paid benefits. Because those benefits are not counted as income, employees do not pay taxes on them. Another third of the total comes from the fact that employers do not pay Social Security or Medicare payroll taxes on health insurance benefits, as they would if those benefits were wages. The remainder of the taxes forgone by the federal government come from health insurance premiums that are tax-deductible for those who are self-employed; various tax-preferred accounts patients can use to pay medical bills not covered by health insurance (such as HEALTH SAVINGS ACCOUNTS [HSAs]); and health expenses over 7.5 percent of income that are eligible for deductions on income taxes.

The study also found that the tax expenditures for health benefits went disproportionately to those with higher incomes. In 2004, while families with incomes over $100,000 represented 14 percent of the population, they received 26.7 percent of the tax benefits that year.

Efforts to change the tax treatment of health benefits date back several decades, although they have run into two major obstacles: the staunch opposition of union workers, who have long traded wage increases for richer health benefits, and would thus be hurt by higher taxes on their more valuable health care, and the huge price tag for changing anything to do with taxes and health.

But lawmakers from both parties also recognize that the tax treatment of health care is fundamentally unfair. Except for those who can prove they are self-employed, people who must buy their own health insurance get no tax benefit at all. Bipartisan efforts to change that have long foundered on cost considerations alone.

Republicans in particular in the early part of the 2000s hoped that changing the tax treatment of health benefits could help stem health inflation. President George W. Bush in his 2007 State of the Union address proposed a deduction for health insurance premiums of $7,500 for individuals and $15,000 for families, regardless of whether they purchased their own insurance or obtained it on the job. But if their job-based coverage was worth more than that amount, they would have to pay taxes on the excess value. Congress showed little interest in the proposal.

Technology assessment

Research that determines if and how well a particular therapy works, technology assessment is taking on a new emphasis in the age of cost-conscious medicine. According to the INSTITUTE OF MEDICINE of the National Academy of Sciences, technology assessment evaluates medical techniques, drugs, equipment, and procedures according to their safety, effectiveness, feasibility, cost, and cost-effectiveness. Technology assessment also looks at the social, economic, and ethical consequences, both intended and unintended, of the subject. Technology assessment is a critical element of EVIDENCE-BASED MEDICINE, in which practitioners are encouraged to use the most effective therapies. But technology assessment can raise thorny issues. For example, although a new surgical technique might be more effective and cheaper than another technique, it may be so safe that it could be used in situations where surgery might not have been previously judged a good risk. Overall, that could end up costing society as a whole more, and it could risk the life or health of some patients who might otherwise have not undergone the procedure at all. (See COMPARATIVE CLINICAL EFFECTIVENESS RESEARCH.)

TennCare

One of two major statewide efforts in the 1990s to expand MEDICAID to cover all poor individuals, not just those "categorically eligible" for the program, TennCare was formally launched in Tennessee in 1994, during the national debate over health care reform. Unlike in Oregon, which sought to expand coverage by offering fewer benefits to more people, TennCare sought to expand coverage by moving its entire Medicaid population to MANAGED CARE. (See OREGON HEALTH PLAN.) The state had hoped to use the savings from managed care to cover not only the Medicaid-eligible population but also the uninsured and the "uninsurable," those who were turned down for coverage by private insurers because of their health status. Although Tennessee and Oregon could point to successes with their novel programs, both programs were buffeted by major funding crises in the early years of the twenty-first century, forcing significant changes. TennCare was effectively disbanded in 2005, when more than 200,000 adults were dropped from the program and those who remained saw their benefits curtailed.

In 1995 TennCare reached 90 percent of its target enrollment and closed down enrollment for the uninsured. Still eligible were those who would have been eligible for Medicaid under federal guidelines, as well as those who could show they could not obtain other insurance. In 1997 Tennessee opened the program to all children under age nineteen with no other access to insurance, regardless of family income. In 1998, using funds from the STATE CHILDREN'S HEALTH INSURANCE PROGRAM (SCHIP) included in the 1997 Balanced Budget Act (PL 105–33), Tennessee expanded TennCare again to cover all children in families with incomes under 200 percent of poverty, although on a modified open enrollment basis.

In 1998 TennCare contracted with twelve health maintenance organizations (HMOs), spread over twelve regions of the state, each of which received a set fee from the state. The HMOs were responsible for providing all "medically necessary" services (including inpatient and outpatient hospital care, physician services, prescription drugs, laboratory and X-ray services, medical supplies, HOME HEALTH CARE, HOSPICE care, and ambulance transportation). TennCare organizations were not required to cover LONG-TERM CARE services covered by Medicaid. That responsibility remained with the state, as under the previous Medicaid program. (See HEALTH MAINTENANCE ORGANIZATION [HMO].)

But implementation of TennCare did not go smoothly. The HMOs were responsible for contracting with individual health care providers, many of whom resisted the low payment rates offered them. That, in turn, made access difficult for many patients. Despite the low payments they paid to providers, however, many of the managed care plans lost money nonetheless. One problem was the state's closure of the program to the uninsured while leaving it open to the uninsurable, who are more expensive to serve. TennCare's failure to cover all of the state's uninsured population also caused problems. In 1997, according to the Census Bureau, 13.6 percent of Tennessee's population under sixty-five remained uninsured; twenty-two states had lower rates that year. With so many remaining uninsured, hospitals, particularly public hospitals and those that served a large proportion of low-income and uninsured patients, complained that they were losing money on TennCare, which promised lower payments, but for more patients. Instead, the hospitals said, they still had large numbers of uninsured patients and lower payments for those who were covered.

By 1999, with health care costs going up and state revenues going down, TennCare was becoming increasingly troublesome. In mid-2000 Tennessee Blue Cross-Blue Shield, which covered an estimated half of TennCare's 1.4 million enrollees, dropped out. By early 2002 the managed care portion of TennCare essentially collapsed. With several of the remaining plans insolvent, providers complained they were owed millions of dollars. The state was forced to step in to cover the shortfalls.

In June 2002 the CENTERS FOR MEDICARE AND MEDICAID SERVICES approved a near-complete overhaul of TennCare. Under the new "waiver" of Medicaid rules, good until 2007, the program would be split into four separate parts. TennCare Medicaid would operate much like Medicaid programs in other states, providing a generous benefit package for those eligible for Medicaid under federal guidelines. TennCare Standard would provide a less generous benefits package (with PREMIUMS and copayments required) for adults with no access to group insurance and incomes below the federal poverty level, for children in families with incomes up to 200 percent of poverty, and for "uninsurables." Proof of uninsurability would be based on a review of medical records, not a letter of rejection from an insurance company. A "pharmacy only" plan would be created for Medicare patients to obtain prescription drug coverage if they were already enrolled in TennCare as of December 31, 2001. The waiver also allowed a fourth option, called TennCare Assist, under which the state would pay up to 40 percent of the cost of employer-sponsored health coverage for low-income workers and those with access to employer coverage. Budget considerations, however, prevented that program from being funded by the state in 2003.

The changes, however, were still not enough to keep the program afloat, particularly since Tennessee lacked an income tax. In 2005 it was a Democratic governor, former managed care executive Phil Bredeson, who finally pulled the plug on TennCare. Declaring that the state could no longer afford the program, he cut coverage back to nearly the minimum required by federal law. That pushed more than 200,000 adults from the program and reduced benefits dramatically for those who remained. For example, the new TennCare program limited adults to no more than five prescriptions per month, only two of which could be brand-name medications. According to the Tennessee Justice Center, which fought the cuts unsuccessfully, the elimination of adult coverage represented the largest single increase in the number of uninsured Americans in the nation's history.

Tertiary care

The most advanced form of health care, tertiary care is available primarily at large ACADEMIC HEALTH CENTERS (AHCs) that do the most cutting-edge research. Tertiary care hospitals perform the most technical and advanced procedures, whereas community hospitals provide more routine services.

Tiered pricing

Most commonly associated with benefits for prescription drugs, tiered pricing schemes seek to steer consumers to a particular product or benefit using financial incentives. In a typical tiered drug benefit, consumers pay the lowest amount if they choose a generic drug, which is also usually the least expensive product available. (See GENERIC DRUGS.) Consumers pay more if they choose a brand-name drug on their health plan's FORMULARY, or approved list, on which the plan has usually negotiated a discount. Consumers pay the most if they choose a brand-name drug not on their plan's list, as a deterrent for selecting such drugs, which also cost the plan more. Some health plans in the early twenty-first century were also moving to tiered pricing for other services, such as hospitals. For example, a tiered hospital benefit might require patients to pay a higher portion of the bill if they chose a teaching hospital instead of a less expensive community hospital.

Title X Family Planning program

Title X ("title ten") of the Public Health Service Act is the nation's principal family planning program. Although Title X funds may not be used to pay for an ABORTION—the program's enactment in 1970 predated the 1973 U.S. Supreme Court's landmark ruling legalizing the procedure nationwide—Title X remains mired in the abortion debate and is one of the federal government's most contentious programs. Although it has been kept running by stop-gap funding, the program has not been formally reauthorized since 1984, largely because of unresolved fights over whether clinics funded by Title X should be allowed to refer patients for abortions and whether minors should be able to receive services without the knowledge of their parents. (See GAG RULE [IN ABORTION] and PARENTAL NOTIFICATION.)

An estimated five million women and men receive services from forty-four hundred clinics funded by Title X annually, according to the HEALTH AND HUMAN SERVICES DEPARTMENT (HHS). According to the PLANNED PARENTHOOD FEDERATION OF AMERICA (PPFA), the single largest recipient of Title X funding, each year publicly funded family planning services prevent an estimated 1.3 million pregnancies and more than 600,000 abortions that would likely have resulted from those unintended pregnancies. One study estimated that preventive exams resulted in the early detection of as many as fifty-five thousand cases of invasive cervical cancer. Title X clients are predominantly young (30 percent are teenagers) and poor (an estimated 65 percent have incomes below the federal poverty line).

Although Title X has been kept alive without formal authorization for more than two decades through the annual appropriations process, its funding has suffered. Appropriations for the program generally increased during the Clinton administration, but President George W. Bush did not seek any increases for the program. Meanwhile, the costs of contraception grew. As a result, Title X's fiscal 2008 funding level of $300 million was worth less than half as much as its fiscal 1980 appropriation of $162 million, according to the Alan Guttmacher Institute.

The first broad attacks on the program came in 1981, when the Reagan administration proposed to include it as part of a major health program block grant, thus making services optional for states. In exchange for keeping the program intact, Democrats agreed to a 25 percent funding cut, as well as creation of the companion ADOLESCENT FAMILY LIFE (AFL) PROGRAM, to provide services to pregnant teenagers and to discourage sexual activity among teenagers. That program, unlike Title X, required parental consent for most services and barred abortion counseling or referrals.

In 1983 the Reagan administration proposed a requirement that parents be notified when minors seek family planning services. The regulations, dubbed the "squeal rule" by critics, were ultimately struck down by federal courts as contrary to congressional intent for the law. In 1984 abortion opponents would unsuccessfully attempt to force votes on the regulations as part of the Title X reauthorization. The bill reauthorizing Title X and the adolescent family life program for one year would be the last time either program made it through the reauthorization process. Both programs have been kept alive only by appropriators' ignoring rules barring funding for unauthorized activities.

In 1985 backers of Title X in the House of Representatives tried to prevent parental notification amendments by seeking passage of a reauthorization bill on the "suspension" calendar, which bars amendments but requires a two-thirds vote. But opponents cried foul, and the 214-197 vote was not enough to pass the bill. In 1987 the issue was further complicated by publication of controversial rules that would bar Title X clinics from making abortion referrals and required grantees who performed abortions with nonfederal funds to physically separate the activities.

In 1989 it finally appeared that the program might get reauthorized when the Senate Labor and Human Resources Committee unanimously approved a three-year reauthorization, allowing funding for the state of Utah, which had a law requiring parental involvement for contraceptive services, through another section of the Public Health Service Act, leaving Title X's confidentiality requirement intact. But the bill was pulled from the floor in 1990 after a parental notification amendment was added.

The House passed a five-year reauthorization in 1992, which also would have overturned the counseling ban, upheld by the U.S. Supreme Court a year earlier in the case *Rust v. Sullivan.* That measure, merged with a Senate bill passed in 1991 that would have overturned the ban but not reauthorized the program, was sent to President George H. W. Bush, who vetoed it on September 25. "I have repeatedly informed the Congress that I would disapprove any legislation that would transform this program into a vehicle for the promotion of abortion," said the president in his veto statement. "Unfortunately, the Congress has seen fit to entangle this family planning program in the politics of abortion." The Senate voted 73-26 to override Bush's veto, but the House fell ten votes short on October 2 with a vote of 266-148.

In 1993 the House again passed a Title X reauthorization, which again would have codified the abortion counseling guidelines in effect from 1981 to 1988. Surprisingly, the House turned back an effort to impose a restrictive parental notification requirement for family planning clinics affiliated with abortion providers. The Senate, however, never took up the House bill.

The new Republican-led Congress in 1995 tried to kill the Title X program outright. But even the firmly antiabortion House was not ready to pull the plug on family planning. An amendment to eliminate the program's $193 million in funding offered by House Appropriations chair Robert L. Livingston, R-La., was defeated 207-221. That included fifty-three Republicans, most of them moderates.

In 1996 Livingston tried another tack—to reduce the income level of clients Title X clinics could serve. Under existing law, people with incomes up to 250 percent of poverty were eligible for reduced-price care. Livingston proposed to reduce that to 150 percent. But Livingston's own committee voted down his proposal, adopting instead a substitute offered by the Labor-HHS subcommittee chair John Edward Porter, R-Ill., restating existing law. During floor debate, the House also rejected an amendment offered by Rep. Ernest Jim Istook Jr., R-Okla. It would have required clinics funded under Title X to document parental consent before dispensing contraceptives to minors, or in the absence of parental consent, to notify the minor's custodial parent or legal guardian five business days before dispensing contraceptives. Instead, the House adopted a substitute amendment that retained existing law requiring clinics to encourage family involvement.

In 1997 Istook's amendment met the same fate as in 1996. The House did, however, vote to cut $9 million and shift it to other programs. That cut was later restored. In 1998 the parental notification amendment passed, although it was dropped in conference.

Transparency

In health policy, transparency refers to providing consumers information about the price and quality of health care services. Transparency is considered a key prerequisite for CONSUMER-DRIVEN HEALTH PLANS. The theory is that consumers cannot make smart decisions about how to spend their own money on health care without good information on both price and quality to be able to compare providers.

The obstacle is that doctors and hospitals have been reluctant to divulge such information. The nation's largest single payer for health care, the federal MEDICARE program, made its first tentative effort at providing transparency in 1986, when it issued its first public report on hospital mortality rates. Hospitals complained that these data painted an unfair picture, because they did not account for facilities that had sicker patients, so they made some hospitals look like they were delivering poorer quality care when, in fact, they were not.

To some extent, transparency has a chicken-and-egg relationship with ELECTRONIC MEDICAL RECORDS. If more doctors and hospitals were able to keep and share patient information electronically, insurers and researchers would have more data to use in producing comparable quality data.

Meanwhile, Medicare continued its transparency efforts. In 2001 the George W. Bush administration launched "Medicare Health Plan Compare," "Nursing Home Compare," and "Dialysis Facility Compare," which were Web sites to help provide limited quality information to beneficiaries to help them choose between health or insurance providers. Later, Medicare added quality information to its Web site about home health agencies and hospitals.

In August 2006 President Bush issued an executive order directing every federal agency that administered or sponsored a federal health insurance program to increase transparency in pricing and quality. That included not only Medicare and MEDICAID, but also the Department of Defense, the Department of Veterans Affairs, and the Office of Personnel Management, which ran the FEDERAL EMPLOYEE HEALTH BENEFITS PLAN (FEHBP).

TRICARE

Formerly CHAMPUS (Civilian Health and Medical Program of the Uniformed Services), TRICARE is the program that provides health care services to active-duty members of the military, military dependents, and retirees outside of facilities operated directly by the Department of Defense (DoD). Under federal law, active-duty personnel and their dependents are entitled to receive services from DoD-run medical facilities. Retirees and their dependents may receive care there under certain circumstances. For all except active-duty personnel, however, care is provided by military medical facilities only on a space-available basis. That led Congress in 1966 to expand a 1956 law providing care for military dependents. The new CHAMPUS provided for care delivered by private or public providers under contract to the DoD. TRICARE, which gradually replaced CHAMPUS during the 1990s, pays for care that is not available from the military or for those who live too far from military medical care. Some 9.1 million Americans are eligible for TRICARE, which offers three options: TRICARE Prime, a type of HEALTH MAINTENANCE ORGANIZATION (HMO) plan; TRICARE Extra, a type of PREFERRED PROVIDER ORGANIZATION (PPO) plan; and TRICARE Standard, a traditional type of FEE-FOR-SERVICE plan. As with most private insurance, out-of-pocket cost-sharing requirements are lowest in the HMO and highest in the fee-for-service plan. In 2001 the DoD introduced TRICARE for Life, a plan to supplement MEDICARE coverage for those aged sixty-five and over. The program, available to Medicare-eligible uniformed service retirees and their Medicare-eligible family members, pays for care covered by TRICARE but not by Medicare (such as care delivered outside the United States), as well as for Medicare-required cost-sharing. TRICARE coverage becomes secondary to Medicare, meaning Medicare pays its share before TRICARE is charged.

Tuskegee experiments

The exposure to syphilis in a notorious study undertaken by the U.S. PUBLIC HEALTH SERVICE (PHS) at the Tuskegee Institute helped revolutionize rules regarding the use of human research participants in scientific research. The study had its origins in 1928, when a private foundation joined with U.S. public health workers in an effort to improve the health of African Americans in the South. Earlier studies had shown a high prevalence of syphilis among black men. But funding for the project ran out before treatment programs could be fully implemented, and, instead, the Public Health Service decided to study the effects of untreated syphilis.

Federal researchers enlisted the aid of the Tuskegee Institute, founded by Booker T. Washington, which was highly regarded in the African American community. Study participants were offered free physicals and other medical care, but those with syphilis were not told they had the disease. Later, researchers prevented the men with syphilis from being treated by draft boards during World War II, and the men were kept out of treatments using penicillin when it was first found to be effective in curing the disease. The men were kept in the dark about their condition until the study was made public in 1972 by the Associated Press.

News of the study triggered 1973 hearings by the Senate Committee on Labor and Public Health and led to a major rewrite of federal regulations on research protocols using human research participants. In December 1974 the federal government paid $10 million in an out-of-court settlement to the research participants and their families. But it was not until 1997 that the federal government formally apologized. In a ceremony in the White House's East Room, President Bill Clinton addressed eight of the survivors or members of their immediate families. "The United States government did something that was wrong—deeply, profoundly, morally wrong," Clinton said. "It was an outrage to our commitment to integrity and equality for all our citizens."

A government study originally intended to improve the health of African Americans in the South, the Tuskegee experiments prevented men with syphilis from receiving penicillin that would have cured the disease. Here, a government doctor draws blood from a participant in the experiments. Source: *Centers for Disease Control and Prevention*

Although the study ended more than three decades ago, its effects have still not disappeared. A significant portion of the African American community remains suspicious of government health officials, which has made public health efforts to control the spread of ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS) and HIV (human immunodeficiency virus) within this community problematic, and the rate of African American organ donors remains lower than among other ethnic communities.

U

Unborn Victims of Violence Act

ABORTION rights backers said the Unborn Victims of Violence Act, which President George W. Bush signed into law (PL 108–212) on April 1, 2004, represented a new tactic in the abortion debate: a desire by abortion opponents to establish legal rights for fetuses as a predicate to outlawing the practice.

The law makes it an additional federal crime to injure or kill a fetus during the commission of a federal violent crime on a woman. In practice, relatively few violent crimes are federal—largely limited to those committed against federal workers while carrying out their duties or on Indian reservations, military bases, national parks, or other federal facilities. Backers of the bill noted that more than thirty states already had laws making the "involuntary termination" of a pregnancy a criminal offense and said the measure was needed to bring the federal code into line. "If a woman who is pregnant is assaulted, for example, on a military base and her finger is broken, and another woman is assaulted and her unborn child is killed, these two offenses are regarded as the same," said Douglas Johnson of the NATIONAL RIGHT TO LIFE COMMITTEE (NLRC).

But abortion rights backers said the bill had nothing to do with protecting women. In early debates on the measure, the House turned back substitute amendments that would have increased penalties for violent crimes against pregnant women. Instead, they said the goal of the measure was to give fetuses a legal status separate from the pregnant woman. "There is the real threat that this bill will spur the anti-choice movement to use this bill as a building block to undermine a woman's right to choose," wrote eleven members of the House Judiciary Committee in their 2001 dissent to the panel's report.

Ironically, the 2002 murder of Laci Peterson, a pregnant California woman, gave the bill major impetus. Peterson's husband, Scott, was later charged and convicted with murdering Laci and the couple's unborn son, whom the family named Connor. The murder was not, however, a federal crime, and California law already allowed Scott Peterson to be prosecuted for both crimes. Still, the massive publicity surrounding the case—Laci Peterson was missing for nearly four months before she and the fetus washed up separately a day apart on the shore of San Francisco Bay—led backers of the federal measure to rename their bill "Laci and Connor's Law."

The bill passed the House in both 1999 and 2001 but not the Senate. It passed the House a third and final time on February 26, 2004, and the Senate for the first time March 25, clearing it for the president. By 49-50 the Senate defeated an amendment by Dianne Feinstein, D-Calif., that would have allowed prosecutors to pursue multiple charges against defendants who harmed pregnant women and adversely affected their pregnancies but would not have established separate legal status for fetuses.

Uncompensated care

Uncompensated care refers to medical care provided free, although not necessarily intentionally so. The term is often defined to include both charity care and "bad debt," care for which bills are rendered but not paid. In the past, health care providers often made up the cost of their uncompensated care by passing it along to other

payers (see COST SHIFTING). But MANAGED CARE, with its strict payment limits, has strained the ability of some hospitals to shift costs to other payers, leaving analysts to worry that care will be more difficult for uninsured individuals to obtain.

Underinsured

Different from having no insurance, being at risk for financial catastrophe despite coverage is known as being underinsured. Policy analysts describe *underinsurance* as having insurance all year long but still lacking adequate financial protection, defined as medical expenses totaling 10 percent of income or higher; medical expenses totaling 5 percent of income for those earning less than twice the federal poverty level; or health plan deductibles at or above 5 percent of income. In 2003, according to a study published in the journal *Health Affairs,* 12 percent of insured adults—nearly sixteen million people—met the criteria for being underinsured. Those underinsured adults were disproportionately low income (73 percent had incomes below 200 percent of poverty) and suffered from health problems (43 percent of sicker adults were either uninsured or underinsured, compared with 31 percent of healthier adults). Like their counterparts with no insurance, the underinsured are more likely than those with adequate coverage to go without needed medical care due to cost.

Underwriting

Underwriting is the process by which an insurer investigates an individual's medical history and health status to determine whether or not it will issue insurance and at what cost. The underwriting process may result in insurers' placing temporary or permanent limitations on a PREEXISTING CONDITION.

UNFPA

See UNITED NATIONS POPULATION FUND (UNFPA).

Uninsured

The uninsured is health policy's version of the weather: everyone talks about it, but no one seems to do anything about it. In 2006, according to the Census Bureau, forty-seven million Americans under age sixty-five lacked coverage for the entire year, which represented 15.8 percent of the nonelderly population. (Virtually everyone over sixty-five has access to coverage through MEDICARE.) That marked increases in both the number and percentage of the uninsured from the year before. The number alone was up by 2.2 million. Since 2001 the number of uninsured had risen by more than six million. The major reason for the increase was a decline in the number of Americans getting insurance at work. In 2006, according to the Kaiser Family Foundation, 60 percent of employers offered health benefits to at least some of their workers, down from 69 percent as recently as the year 2000. Despite the success of the STATE CHILDREN'S HEALTH INSURANCE PROGRAM (SCHIP), which covered an estimated six million children in households with low or moderate income, the number of uninsured children rose for the second straight year in 2006, by roughly 600,000.

Contrary to popular perception, most of the uninsured are not poor, and they are not unemployed. Many of the poorest Americans, along with those who cannot work because of disability, are covered by MEDICAID (or, in the case of disabled individuals who have been in the workforce, Medicare). In 2006, 22.9 percent of uninsured individuals had incomes higher than $50,000, 21.1 percent had incomes between $25,000 and $50,000, and 24.9 percent had income under $25,000. The South and West had the highest rates of uninsurance (at 19 and 17.9 percent, respectively), and younger people were more likely than older people to lack coverage. In 2006, 29.3 percent of those ages 18–24 lacked coverage for the full year, compared with 14.2 percent of those between 45 and 64.

Nearly three-quarters of those without insurance were workers, or lived in a family with someone who worked, in 2006. Yet nearly 18 percent of full-time workers and nearly 23 percent of part-time workers still lacked health insurance. Many of those workers were in

Selected Sources of Health Insurance Coverage of Nonelderly Americans, 1994–2006

	1994	*1995*	*1996*	*1997*	*1998*	*1999*	*2000*	*2001*	*2002*	*2003*	*2004*	*2005*	*2006*
Number (millions)													
Total	229.9	231.9	234.1	236.2	238.6	242.6	244.8	247.5	250.8	252.7	255.1	257.4	260.0
Employment-based coverage	148.1	149.7	151.7	156.9	160.4	164.7	167.5	166.1	164.9	162.9	161.0	161.3	161.7
Own name	76.3	76.9	78.0	78.5	80.2	82.2	84.6	84.1	82.5	81.5	81.6	82.3	82.9
Dependent coverage	71.9	72.8	73.7	78.4	80.2	82.4	82.9	82.0	82.4	81.5	79.4	79.0	78.8
Individually purchased	17.3	16.8	16.8	17.1	16.5	16.4	16.0	16.0	16.6	16.7	18.0	17.9	17.7
Public	39.4	38.8	37.8	35.3	34.6	34.8	35.8	37.9	40.0	42.5	45.1	45.5	45.5
Medicare	3.7	4.1	4.6	4.7	4.8	4.9	5.4	5.6	5.8	6.2	6.3	6.4	6.5
Medicaid	29.1	29.4	28.6	26.4	25.2	25.5	26.2	28.3	29.9	32.4	34.6	34.7	34.9
TRICARE/CHAMPVA[a]	8.7	7.5	6.9	6.6	6.9	6.6	6.8	6.6	6.9	6.9	7.4	7.7	7.1
No health insurance	36.5	37.3	38.3	39.9	39.4	38.5	38.2	39.5	41.8	43.1	43.0	44.4	46.5
Percentage													
Total	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
Employment-based coverage	64.4	64.6	64.8	66.4	67.2	67.9	68.4	67.1	65.7	64.5	63.1	62.7	62.2
Own name	33.2	33.2	33.3	33.2	33.6	33.9	34.6	34.0	32.9	32.2	32.0	32.0	31.9
Dependent coverage	31.3	31.4	31.5	33.2	33.6	34.0	33.8	31.1	32.8	32.2	31.1	30.7	30.3
Individually purchased	7.5	7.2	7.2	7.2	6.9	6.8	6.5	6.5	6.6	6.6	7.1	7.0	6.8
Public	17.1	16.7	16.2	15.0	14.5	14.3	14.6	15.3	15.9	16.8	17.7	17.7	17.5
Medicare	1.6	1.8	2.0	2.0	2.0	2.0	2.2	2.3	2.3	2.5	2.5	2.5	2.5
Medicaid	12.7	12.7	12.2	11.2	10.6	10.5	10.7	11.4	11.9	12.8	13.6	13.5	13.4
TRICARE/CHAMPVA[a]	3.8	3.2	2.9	2.8	2.9	2.7	2.8	2.7	2.8	2.7	2.9	3.0	2.7
No health insurance	15.9	16.1	16.4	16.5	16.5	15.9	15.6	16.0	16.6	17.1	16.9	17.2	17.9

Source: Employee Benefit Research Institute estimates of the Current Population Survey, March 1995–2007 Supplements.

Note: Details may not add to totals because individuals may receive coverage from more than one source.

a. TRICARE (formerly known as CHAMPUS, for the Civilian Health and Medical Program of the Uniformed Services) is a program administered by the Department of Defense for military retirees as well as families of active-duty, retired, and deceased service members. CHAMPVA, the Civilian Health and Medical Program for the Department of Veterans Affairs, is a health care benefits program for disabled dependents of veterans and certain survivors of veterans.

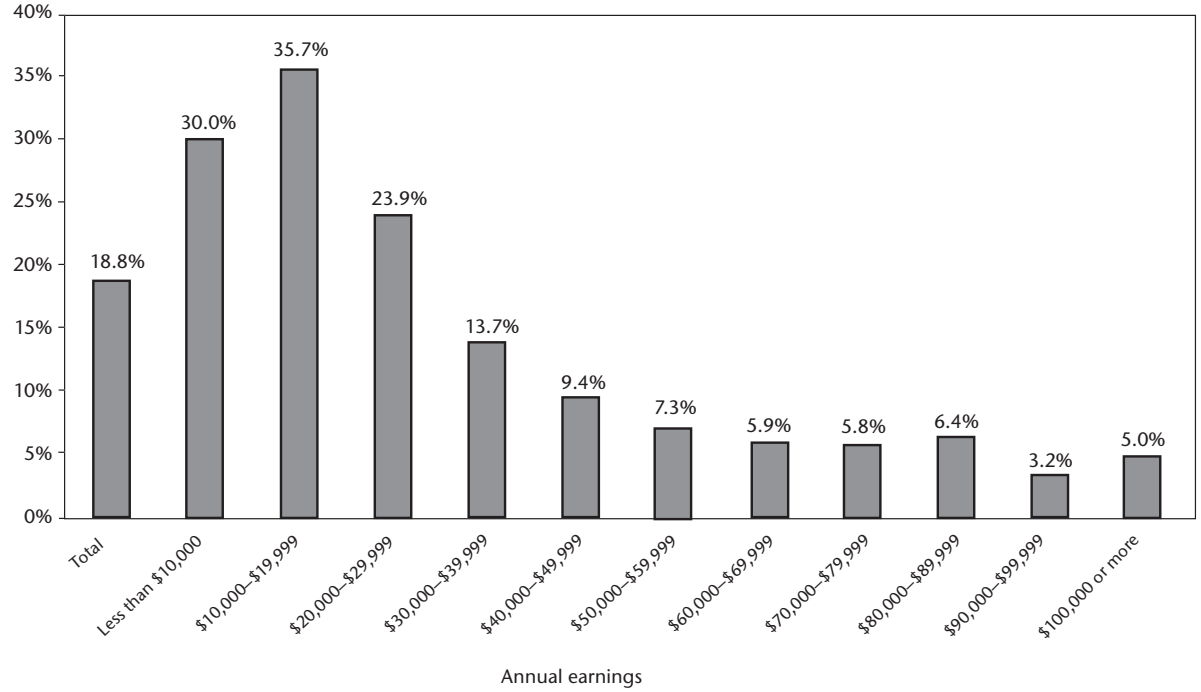
jobs in the service sector that paid low wages. Or they worked for smaller firms, which are less likely to offer insurance or, if they do, were more likely to require workers to pay the full cost of the premiums.

Medicaid expansions between 1984 and 1990 helped mask the rise of uninsured individuals. During that time Congress extended eligibility to a half-million pregnant women, four million to five million children, and more than four million elderly and disabled individuals. Between 1988 and 1993, however, private coverage declined, and in 1996 about 64 percent of nonelderly Americans had employer-provided coverage, down from 69.2 percent in 1987. The trend has not so much been for employers to drop coverage altogether as it has been for them to raise costs for workers who participate, putting coverage out of reach for low-income workers.

Although every American theoretically has access to needed health care through public facilities, having insurance does make a difference in health status. Study after study has shown that the uninsured are more likely to go without needed care, less likely to get preventive care, and more likely to be hospitalized for avoidable health problems. When they are hospitalized, they receive fewer diagnostic tests than people with coverage, and they are more likely to die in the hospital.

A series of studies by the INSTITUTE OF MEDICINE (IoM) between 2001 and 2003 concluded that eighteen thousand people die prematurely every year as a result of the lack of insurance and that the problem of the uninsured cost the economy between $65 billion and $130 billion annually. The IoM studies also found that the problems of the uninsured affect those beyond the individuals

Percentage Uninsured among Workers Ages 18–64, by Total Earnings, 2006



Source: Employee Benefit Research Institute estimates from the Current Population Survey, March 2007 Supplement.

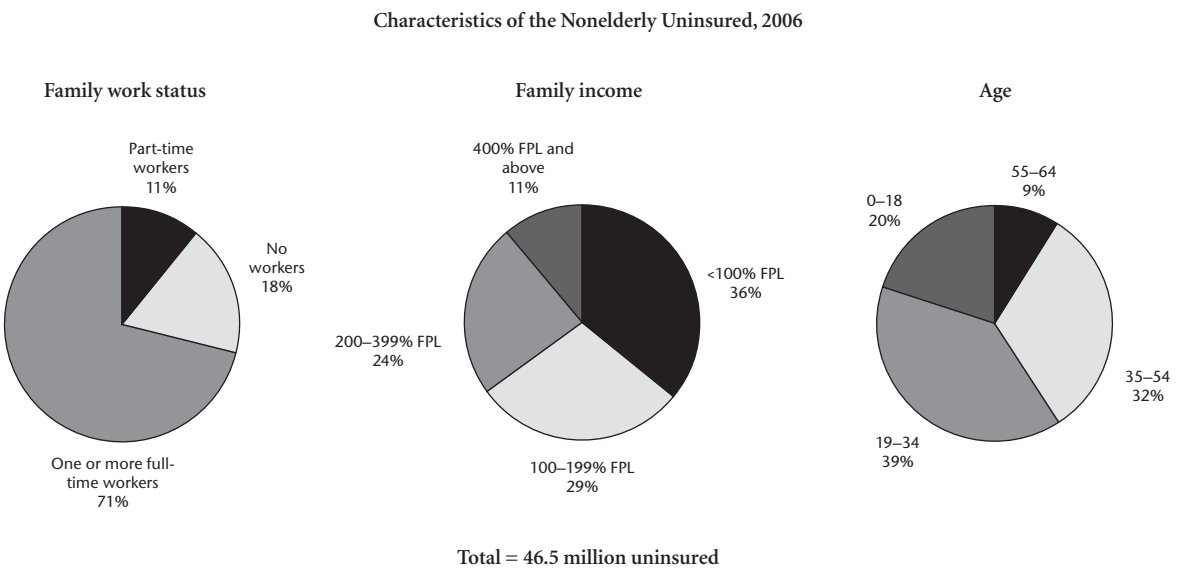
who lack insurance. Communities with large proportions of uninsured individuals suffer from a more fragile health care infrastructure, and they may not be able to provide high-need, but often money-losing, services such as trauma or burn care or neonatal intensive care.

Lawmakers have not completely ignored the plight of people without insurance. In 1996 Congress addressed the issue in a modest way in the HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA) (PL 104–191), which was aimed primarily at helping those who already had insurance to keep it. The measure's "portability" provisions made it more difficult for insurers to cancel or deny coverage to those with preexisting health conditions and required insurers to sell individual policies to those previously covered as part of a group who had not had a break in coverage.

As part of the 1997 Balanced Budget Act (PL 105–33), Congress addressed the issue of the uninsured more directly, approving SCHIP, which was estimated to cover up to half of the ten million Americans under age eighteen who lacked coverage.

President Bill Clinton continued to try to expand coverage incrementally, proposing first a plan to help temporarily unemployed individuals pay for extended coverage under the CONSOLIDATED OMNIBUS BUDGET RECONCILIATION ACT OF 1985 (COBRA) and later a scheme to allow those under age sixty-five to "buy in" to Medicare coverage. Neither proposal, however, was given much attention in Congress in 1997 or 1998.

President George W. Bush proposed a three-prong effort to help those without insurance. Part of his proposal, which won broad bipartisan support, consisted of doubling the number of COMMUNITY HEALTH CENTERS that serve many uninsured patients. His other proposals, however, proved more controversial. One would provide tax credits to help those without coverage purchase their own in the individual market. Opponents were concerned that the tax credits were too small to enable peo-



Source: Kaiser Commission on Medicaid and the Uninsured/Urban Institute analysis of March 2007 Current Population Survey. Reproduced from Henry J. Kaiser Family Foundation, "Health Care Affordab lity and the Uninsured," no. 7767, April 2008.

Note: The federal poverty level (FPL) was $20,614 for a family of four in 2006.

ple to buy adequate plans and that the individual market was a particularly bad buy—with many people with a PREEXISTING CONDITION unable to purchase coverage at any price. President Bush also endorsed existing GOP proposals in Congress to create ASSOCIATION HEALTH PLANS (AHPs) that would let small businesses band together to offer coverage without having to obey state benefits mandates or other insurance laws. That proposal was opposed both by consumer groups, worried that plans would not have to abide by state consumer protection laws, and insurers, who worried that plans would undercut their coverage of small businesses. President Bush's 2007 proposal to dramatically overhaul the tax code to encourage more individuals to purchase their own coverage was also ignored by the then Democratic-led Congress.

Unions, doctor

By the mid-1990s, with antipathy growing toward MANAGED CARE, an increasing number of doctors sought to strengthen their bargaining power by joining unions. By 1999 an estimated thirty-eight thousand physicians belonged to a union. Over the objections of its board, the AMERICAN MEDICAL ASSOCIATION's (AMA) House of Delegates in June 1999 voted to form a bargaining unit for doctors, which is named Physicians for Responsible Negotiations (PRN).

But most doctors were unable to join unions even if they wanted to. That is because federal antitrust laws blocked any joint action by doctors who were not salaried employees. As of 1999, that restriction left only an estimated 15 percent of the nation's four hundred thousand practicing physicians eligible to participate in the bargaining unit the AMA voted to form.

Some doctors in private practice did try to argue that managed care plans that dictated not only the terms of contracts but also the way doctors practiced medicine in effect made those doctors de facto employees, entitled to collective bargaining rights under federal law. But in May 1999, the National Labor Relations Board (NLRB) ruled that even if plans did control some elements of doctors' practices, that control was not enough to establish an employer-employee relationship.

The AMA turned to Capitol Hill to support antitrust relief in the form of legislation introduced in the 106th Congress by Rep. Tom Campbell, R-Calif. The Quality Health Care Coalition Act of 1999 would "correct the dangerous imbalance in the health care marketplace by returning professional medical decision making to physicians," testified AMA executive vice president E. Ratcliffe Anderson Jr. before the House Judiciary Committee in June 1999.

> In many markets physicians have virtually no bargaining power with dominant health plans that refuse to negotiate any terms of their contracts—including terms with important patient care implications. As a result, plans present physicians with nonnegotiable contract terms that no businessperson with any bargaining power would agree to. Consequently, the power of health plans alone to determine the kind of health care that patients receive is virtually unchecked.

The bill would have created a limited antitrust exemption for physicians, dentists, pharmacists, and other health care professionals who are not otherwise employees. It would allow them to negotiate collectively over fees and to refuse to deal with a plan that did not meet their demands.

The Clinton administration opposed the measure. "This bill would allow nonemployee, health care professionals collectively to raise their fees to health insurers without fear of antitrust liability and without regard to competitive market forces fostered by the antitrust laws," assistant attorney general for antitrust Joel Klein said in the same Judiciary Committee hearing. Klein added that the cost would likely be passed on to consumers. "There is no justification to accord special status to health care professionals under the antitrust laws, differentiating them from other professionals and independent contractors such as architects, engineers, or lawyers."

Despite the opposition, House leaders promised Campbell, who was running for the Senate in 2000, a vote on his bill. That vote, originally scheduled for May 2000, was put off after the CONGRESSIONAL BUDGET OFFICE (CBO) estimated that the measure could cost the federal government more than $6 billion over the next ten years and could raise the cost of private health insurance by 2.6 percentage points.

Campbell ultimately got his vote a month later—with the House taking up the bill shortly after 11 P.M. on June 29. Shortly before 2 A.M., the House passed the bill 276-136. But the Senate would fail to take it up, and Campbell, who lost his Senate race, did not return to the House.

Meanwhile, the AMA suffered a setback with its in-house organizing efforts. In June 2001 the U.S. Supreme Court in *Kentucky River Community Care v. National Labor Relations Board* struck down an NLRB ruling on determining when nurses were "supervisors" and therefore not eligible to unionize. PRN stopped trying to organize doctors at private health care facilities following the ruling, pending a decision by the NLRB on whether or not doctors who are employees are considered supervisors. In August 2002 the AMA gave the PRN, which then represented only about 275 physicians, a $600,000 loan to keep the organization afloat pending determination of its fate.

In 2004 the twenty thousand members of the PRN affiliated with the Service Employees International Union, which already represented two other groups of physicians: the Committee of Interns and Residents, and the Doctors Council, whose members were doctors employed on salary.

United Nations Population Fund (UNFPA)

U.S. funding for the United Nations Population Fund, formally the United Nations Fund for Population Activities (UNFPA), a United Nations (UN) agency the United States helped found in 1969, has been a bone of contention almost ever since. ABORTION opponents have since the mid-1980s sought to end U.S. contributions because of the UNFPA's continuing support of activities in China, whose government has practiced coercive sterilization and abortion policies in support of its "one child per family" population control efforts.

According to the organization, the UNFPA provides assistance to developing countries "to improve reproductive health and family planning services on the basis of individual choice, and to formulate population policies in support of efforts towards sustainable develop-

ment." Among UNFPA's mandates, as set out by the UN Economic and Social Council, is "to assist developing countries, at their request, in dealing with their population problems in the forms and means best suited to the individual countries' needs." In 1997 the agency provided support to 168 countries. UNFPA funding provided more than two-thirds of all population assistance in a quarter of the countries it funded that year.

The organization does not provide any support for abortion or abortion-related activities. Instead, it says "UNFPA seeks to prevent abortion by increasing access to family planning services, and to reduce maternal deaths through better management of complications of unsafe abortions."

In 1986 Congress defunded UNFPA by barring aid to any group that "participates in the management of a program of coercive abortion or involuntary sterilization." That ban lasted until 1993, when, under President Bill Clinton, Congress appropriated $50 million for the agency, which insisted its activities in China were intended to eliminate involuntary population control policies and that it only operated in areas where quotas had been removed. But when Republicans took over Congress in 1995, the issue of UNFPA funding was back on the table.

In 1998 funding, which was only $20 million the previous year, was again eliminated. In 1999 funding was restored, but the U.S. contribution was reduced by the same amount the UNFPA spent in China.

In 2002 UNFPA funding became entangled with that of the United States' own population programs, funded through the Agency for International Development. As part of a year-end compromise in 2001 on fiscal 2002 spending for foreign aid programs, Democrats in the Senate agreed to drop language to strike down President George W. Bush's reimplementation of the MEXICO CITY POLICY that barred U.S. aid from international family planning groups that supported abortion rights in exchange for an increase in the United States' contribution to UNFPA to $34 million.

Abortion opponents, however, prevailed on the president not to provide the money to UNFPA after an antiabortion group reported that UNFPA officials in China were complicit in coercive family planning policies. They said that funding UNFPA under those circumstances would violate the 1985 Kemp-Kasten law, which prohibited U.S. funding for "any organization or program which, as determined by the President of the United States, supports or participates in the management of a program of coercive abortion or involuntary sterilization."

A State Department fact-finding mission in May 2002 failed to substantiate the accusations made against the group, finding no evidence that it knowingly participated in coercive abortion or sterilization programs. But in July the president invoked the 1985 law and redistributed the funds to other Agency for International Development population programs instead. UNFPA officials said the U.S. funds would have allowed the agency to prevent two million unwanted pregnancies and more than seventy-seven thousand infant and child deaths.

President Bush continued to withhold congressionally appropriated funds for UNFPA through fiscal 2007. The fiscal 2008 omnibus spending bill (PL 110–161), however, not only boosted the U.S. UNFPA contribution from $34 million to $40 million, but it also required the president to explain his rationale for withholding the funding. Within six months the president was required to provide Congress "a comprehensive analysis as well as the complete evidence and criteria used to make the determination" that the UNFPA was violating the Kemp-Kasten law.

United Network for Organ Sharing (UNOS)

The United Network for Organ Sharing (UNOS) is a private nonprofit organization that operates the nation's organ distribution system, under contract to the HEALTH AND HUMAN SERVICES DEPARTMENT (HHS). In 1998 UNOS and HHS got into a heated dispute over proposed new HHS rules that would have required that organs be distributed nationally, not regionally. Under the previous system, organs for transplant were first offered locally, because transportation time cut down on their viability. But advances in medicine made it more feasible to fly organs even across the country without increasing the chances of an unsuccessful transplant.

Thus, HHS proposed that organs be distributed to the patient with the most serious need and with the best chance of benefiting from the organ, regardless of where that patient was located. UNOS charged that such a plan could put smaller transplant centers out of business, because most of the organs would end up going to the largest transplant centers with the most patients. After a lengthy battle in Congress (see ORGAN DONATIONS AND TRANSPLANTS) UNOS ultimately agreed to most of the changes HHS proposed when it signed a new contract in September 2000.

Universal coverage

Universal coverage is a term referring to a health system that guarantees insurance to all citizens. Universal coverage can be provided by a state government, but it is generally a national responsibility. There are various ways to guarantee universal coverage. One is a government-run system, such as the ones in Canada or Great Britain, where the government pays directly for health care services provided to its citizens, either by private doctors and hospitals (as in Canada) or by those on government salary (as in Britain). But combination systems can also provide coverage for all. During the 1993–1994 health reform debate, President Bill Clinton wanted to guarantee universal coverage by requiring employers to provide insurance to their workers, with the government providing subsidies for everyone else. A large subset of Democrats wanted a SINGLE PAYER system similar to Canada's, in which the government would pay private health care providers (the way MEDICARE works). Some Republicans wanted to guarantee universal coverage through a third mechanism, an individual mandate, which would require every person to purchase insurance coverage (just as drivers are required to carry car insurance), with subsidies for those with low incomes. Universal coverage is not the same as *universal access,* which simply requires that insurance companies sell coverage to all comers, regardless of their health status. As of 2008, the United States did not have universal access, either, although the 1996 HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA) (PL 104–191) did eliminate some restrictions on individuals' ability to get and keep coverage.

UNOS

See UNITED NETWORK FOR ORGAN SHARING (UNOS).

UPL

See UPPER PAYMENT LIMIT (UPL).

Upper Payment Limit (UPL)

Upper Payment Limit, known by its initials, UPL, is technically the highest amount states may pay health care providers under the MEDICAID program. States have aggregate upper payment limits for groups of providers—for example, public hospitals or nursing homes. The payment limits are generally tied to the maximum amount payable under the MEDICARE program, which generally pays providers higher rates than Medicaid.

UPL became controversial in 2000, when dozens of states realized they could exploit a loophole in the law to, in effect, get the federal government to underwrite more of their Medicaid programs than was intended. The tactic worked like this: A state would increase its Medicaid payment to a group of public health facilities, for example, from $80 to $100 per day for nursing homes. The state would then collect federal "matching payments" based on the $100 level but would subsequently require the nursing homes to return some or all of the additional $20 to state coffers.

Some states, notably California and New York, were clearly using the additional money for health-related purposes. But in practice, the additional money was impossible to track, and a long list of analysts, including the General Accounting Office, said the practice "violates the integrity of Medicaid's federal/state partnership."

The Clinton administration moved to close down the loophole in late 2000, after it was estimated that the

mechanism boosted federal Medicaid spending by $2.3 billion in just a single quarter. Many lawmakers backed the move. Senate Finance Committee chair William V. Roth Jr., R-Del., said the practice "fundamentally undermines the fiscal integrity of the Medicaid program." But lawmakers from other states just as adamantly vowed to allow the practice to continue. HOUSE ENERGY AND COMMERCE COMMITTEE chair W. J. "Billy" Tauzin, R-La., said cutting off the practice "will undermine the health care programs in our states."

In a budget move that left many observers scratching their heads, Congress as part of a MEDICARE and Medicaid funding bill (PL 106–554) at the end of the 106th Congress ultimately softened the administration's proposal to stop the practice, making it save less money than the administration had wanted. But lawmakers then used the savings even the slower shutdown would produce—some $75 billion over ten years—to finance other Medicare and Medicaid changes.

By late 2001, however, the Clinton administration's efforts clearly still left, in the words of Bush administration Medicare and Medicaid chief Tom Scully, "a hole you can drive a truck through." In November 2001 the Bush administration issued a regulation to further limit how much states could pay public hospitals. Associations representing public hospitals sued in federal court, charging that the administration used faulty data and that the change threatened patient care. A federal district court judge dismissed the case in May 2002. Despite lawmakers' vows to stop the change through legislation, the issue remained at an impasse through mid-2008.

UR

See UTILIZATION REVIEW (UR).

U.S. Department of Health and Human Services

See HEALTH AND HUMAN SERVICES DEPARTMENT (HHS).

U.S. Public Health Service

See PUBLIC HEALTH SERVICE (PHS).

Utilization review (UR)

Utilization review (UR) refers to an insurance company practice that decides if care recommended or provided to a patient is appropriate and of high quality. "Retrospective" utilization review examines patient records after the fact to determine whether the care provided was the best and most cost-effective. "Prospective" utilization review occurs after care is prescribed but before it is delivered. Critics of UR note that it may be undertaken by health professionals who are not doctors (typically, first-line reviewers are nurses) and that a HEALTH PLAN may deny coverage for purely economic reasons—that is, because it is too expensive. Defenders of the practice, however, say that it can help standardize and raise the quality of care for all patients.

V

Vaccine Injury Compensation Program

Congress created the Vaccine Injury Compensation Program (VICP) in 1986 (PL 99–660) in an effort to address intermittent shortages of vaccines to protect against childhood diseases, particularly the diphtheria-pertussis-tetanus (DPT) vaccine. The problem was that the pertussis portion of the vaccine in particular on rare occasions produced severe adverse reactions, including brain damage and death. Parents sued, and the resulting liability was driving drugmakers out of the vaccine business, which was not as profitable as other lines of drugmaking in any case. The DPT shortage was so acute by late 1984 that the CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC) asked doctors to delay "booster" shots for older children to ensure that adequate supplies would be available for infants.

At the same time manufacturers were clamoring for Congress to relieve them of liability concerns, groups representing parents of children injured by vaccine side effects were insisting on an easier, faster way to get compensation than the legal system.

The result was creation of a no-fault system under which families of children (or, largely in the case of the influenza vaccine, added in 2005, adults) who could show injuries or deaths were caused by reactions to vaccines required by state law would qualify for compensation under a noncourt, fast-track system. The VICP program maintains a "table" of known adverse reactions that occur within set time periods after vaccines are administered. Children who can show they suffered one of those effects within the set time period are presumed to have suffered it due to the vaccine. Children who suffered "non-table" injuries must present medical evidence to prove the vaccine was the source of their problem. Court-appointed "special masters" were to preside over hearings to determine whether a particular injury or death qualified for compensation and how much the award should be.

Families were allowed to reject the award and go to court, but those who accepted the award would give up their right to sue. Awards for deaths are limited by statute to $250,000 plus attorney fees. According to the HEALTH AND HUMAN SERVICES DEPARTMENT (HHS), total awards, including medical costs, to those who have proved an injury was vaccine-caused have averaged just over $1 million.

The new program was funded for injuries incurred after 1988 by a seventy-five cents per dose excise tax on vaccines, which Congress passed the next year (largely because lawmakers ran out of time in 1986). Compensation for pre-1988 injuries was funded by an appropriation.

From fiscal 1989 through fiscal 2008, 2,865 petitions were filed under the VICP program, and the program paid out just under $800 million in claims, not including $32 million in attorney fees.

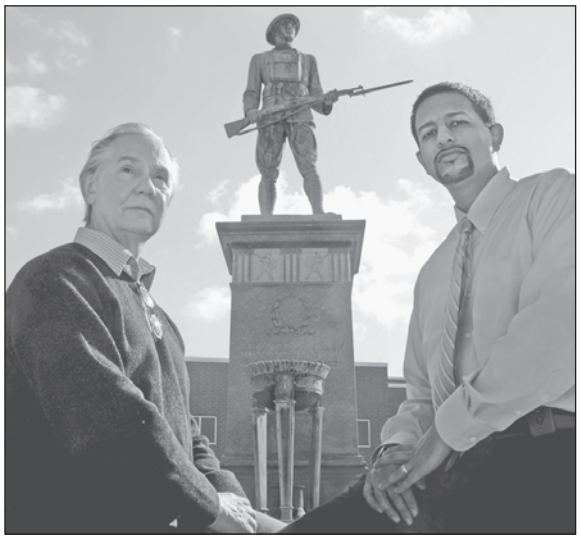
The program was threatened in the early 2000s, however, by the filing of more than five thousand claims by parents who said that their children's autism was caused in whole or part by thimerosal, a mercury-based additive that was used as a preservative in many childhood vaccines until 2001. Although several scientific studies have shown no demonstrable link between thimerosal and autism, the vaccine program in 2007 launched a series of test cases to adjudicate the autism claims. Any compensation for autism under the vaccine program would likely swamp the program's financing mechanism.

Veterans health care

Among the groups that are guaranteed health care by federal law are the nation's veterans. Whereas MEDICARE and MEDICAID pay for care provided by private health care entities or those run by state or local governments, the federal government itself runs the Department of Veterans Affairs (VA) health care program, which in 2006 provided care to an estimated 5.5 million veterans and their dependents at 155 hospitals (at least one in each state, as well as the District of Columbia and Puerto Rico); 872 outpatient, community, and outreach clinics; 135 nursing homes; 45 residential rehabilitation treatment programs; 209 Veterans Centers, which provide psychological counseling for war-related trauma and other support services for veterans and their families; and 108 home care programs. In fiscal 2008 the department received an appropriation of $37.2 billion for its health care programs.

The VA also trains doctors and conducts medical research. The VA manages the nation's largest medical education and training program, through affiliations with 107 medical schools, 55 dental schools, and 1,200 other medical education programs. Each year more than ninety thousand health professionals train in VA facilities. About half of the nation's practicing physicians had some of their training in the VA system. The VA's research programs, which received $480 million in fiscal 2008, have also contributed to the nation's medical knowledge base. In addition to pioneering treatments for such battle-related conditions as post-traumatic stress disorder, exposure to Agent Orange (a defoliant used in the Vietnam War and later found to cause health problems), and artificial limbs, VA researchers helped develop such medical advances as cardiac pacemakers and CT (computed tomography) scanners. The first kidney transplant in the United States was performed in a VA medical facility.

Not every veteran is eligible for health care services provided by the VA. Originally, only those with service-related ailments or those who could not otherwise afford care were guaranteed care in VA facilities. In 1996 Congress overhauled eligibility rules in legislation (PL 104–262) designed to deemphasize inpatient care and move more patients into less expensive outpatient clinics. Previously, the system guaranteed outpatient care only to severely disabled veterans with injuries connected to their military services and a few other categories of veterans. Other groups eligible for VA care, such as less disabled or low-income veterans, often had to have been in a VA hospital already or meet other complex legal requirements to receive outpatient treatment.



One significant challenge facing veterans health care providers today is post-traumatic stress disorder (PTSD) suffered by those returning from the wars in Iraq and Afghanistan. Responding to that need Rob Smith (left), a clinical social worker, and Chirag Raval, a psychiatrist, work with veterans with PTSD at the VA hospital in Hines, Ill. Source: AP Images/ *M. Spencer Green*

The 1996 legislation eliminated statutory restrictions governing which categories of veterans were eligible for the full range of VA health care, including treatment in outpatient clinics, home care, and other services as well as hospitalization. It gave the VA authority to treat all veterans as it saw fit as long as it stayed within its budget (which the bill also capped). The bill required the VA to set up a priority system to decide which categories of veterans would receive care and in what order.

In 1999 Congress passed legislation expanding the availability of LONG-TERM CARE services to veterans. The

bill (PL 106–117), signed by President Bill Clinton on November 30, created a four-year program during which the department would be required to provide long-term care services to any veteran with service-connected disabilities and any veteran at least 70 percent disabled by a service-related injury. Such care had been permitted but was not required. Some lawmakers were concerned that the long-term care program could end up squeezing other areas of the budget if it got too expensive.

The VA health system was stressed in the early years of the twenty-first century by the wars in Afghanistan and Iraq. Ironically, advances in medical care resulted in the survival, albeit with serious injuries or lingering disabilities or both, of many servicemen and servicewomen who would have died in earlier conflicts. As a result, the number of patients treated by the VA health system increased from 4.2 million in 2001 to nearly 5.5 million in 2006—an increase of nearly 30 percent. The scandalous conditions in which servicemembers were being kept at Walter Reed Medical Center in 2007, detailed in a series in the *Washington Post,* were not associated with the VA. Walter Reed is part of the Department of Defense military medical system. It treats active-duty servicepeople, not veterans.

VHAs

See VOLUNTARY HEALTH AGENCIES (VHAs).

Voluntary health agencies (VHAs)

Voluntary health agencies (VHAs) are private nonprofit groups that work "to improve health by providing patient and family services, community services, public and professional education, medical research support and health related advocacy," according to the National Health Council, the umbrella organization for 115 health-related groups, 51 of them VHAs. Major VHAs include the American Red Cross, American Cancer Society, the March of Dimes Birth Defects Foundation, and Easter Seals.

W

Webster v. Reproductive Health Services

Webster v. Reproductive Health Services was a pivotal ABORTION case decided by the U.S. Supreme Court on July 3, 1989. The Court upheld a series of restrictions on the procedure, including banning the use of public employees or facilities for abortion and requiring physicians to perform tests to determine viability on fetuses of more than twenty weeks gestation. In upholding the restrictions on a 5-4 vote, the Court signaled—but did not expressly say—that it no longer considered abortion a fundamental right. Thus, both sides agreed, it essentially invited states to pass their own laws limiting abortion.

The *Webster* decision, handed down on the final day of the term, produced seven separate opinions, with no single opinion joined by more than three justices. But the plurality opinion, written by Chief Justice William H. Rehnquist, pointedly declined to overturn *ROE V. WADE,* although the justices noted that they "would modify and narrow *Roe* and succeeding cases."

In some ways the *Webster* decision had the opposite effect than the justices intended. Instead of spurring states to pass new abortion restrictions, the threat to *Roe* and the real possibility that the right to abortion could be eliminated with the vote of one more justice mobilized abortion rights forces. In the subsequent months, both the House of Representatives and the Senate voted to roll back various restrictions imposed over the previous decade, including the ban on federal funding of abortion in cases of rape or incest and barring the District of Columbia from using its own tax dollars to pay for abortions. Four vetoes from President George H. W. Bush, however, prevented any of the restrictions from being eliminated. The Court clarified the *Webster* decision three years later, in *PLANNED PARENTHOOD OF SOUTHEASTERN PENNSYLVANIA V. CASEY.*

WIC (Special Supplemental Nutrition Program for Women, Infants, and Children)

Technically the Special Supplemental Nutrition Program for Women, Infants, and Children, WIC provides food, nutritional counseling, and access to health services for an estimated eight million Americans monthly, including nearly one of every two infants in the United States. Permanently authorized in 1974, WIC is available to pregnant or postpartum women, infants, and children up to age five in families with incomes up to 185 percent of the federal poverty level and who are determined by a health professional to be at "nutritional risk." Risk factors can include medical conditions (such as anemia, underweight, or a history of complications with pregnancy) or failure to consume an adequate diet. WIC, which is administered by the U.S. Agriculture Department Food and Nutrition Service, received a $6 billion appropriation in fiscal 2008. Of the total WIC population in fiscal 2004, approximately four million were children, two million were infants, and 1.9 million were pregnant or postpartum women.

WIC participants receive food vouchers they can use to purchase foods high in protein, calcium, iron, and vitamins A and C, such as milk, cheese, iron-fortified cereals, fruit or vegetable juice, and peanut butter. Although WIC mothers are encouraged to breast-feed their babies, those who do not can receive formula from WIC programs that states obtain through special discount

agreements with manufacturers. The WIC Farmers' Market Nutrition Program, established in 1992, gives WIC participants additional vouchers they can use to purchase fresh produce at participating farmers' markets. Ten million dollars of WIC's total appropriation is set aside for the farmers' market program.

Women's Health, Office of Research on

Established in statute in the 1993 National Institutes of Health Revitalization Act (PL 103–43), the office, located within the office of the director of the NATIONAL INSTITUTES OF HEALTH (NIH), is charged with ensuring that issues relating to women's health are adequately identified and addressed in research activities. The office is also charged with recruiting women to participate in CLINICAL TRIALS. The 1993 bill required that women and members of minority groups be included as subjects in research projects in most cases. Women and minorities could be excluded only if scientific reasons existed to assume that the variables being studied did not affect women or minorities differently from men.

The 1993 requirements grew out of a 1990 study by the General Accounting Office (known now as the GOVERNMENT ACCOUNTABILITY OFFICE) that found that the NIH had not been enforcing its own 1986 policy requiring inclusion of women in research trials. In many cases, researchers worried that women could become pregnant and endanger themselves and their babies, or, more commonly, they worried that women's different chemical make-up would confound the study results. As a result of the near-systematic exclusion, however, many landmark studies told nothing about the effect of certain treatments on women.

Z

Zidovudine

The formal name of the drug AZT, zidovudine was the first effective medication to fight the virus that causes ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS). Zidovudine, which was originally developed by federal researchers, has been shown to delay the onset of AIDS when taken before patients become symptomatic. The drug, sold under the brand name Retrovir, has been particularly effective when taken by pregnant women, having been shown to prevent mother-to-infant transmission of the AIDS virus. Retrovir's patent expired in 2005. The FOOD AND DRUG ADMINISTRATION (FDA) has since approved several generic versions. (See GENERIC DRUGS.)

Reference Material

Health Policy Time Line

1796 British physician Edward Jenner successfully demonstrates use of a vaccine to prevent smallpox

1798 Founding of first marine hospital under the Department of Treasury marks creation of the U.S. Public Health Service

1842 Ether used as anesthesia in surgery for first time

1847 American Medical Association, the national trade association for physicians, is founded

1869 First surgery performed using antiseptic techniques to prevent infection, developed by Joseph Lister

1871 John Maynard Woodworth becomes the first surgeon general of the United States

1887 Bacteriological laboratory established in Staten Island, which would lead to creation of the National Institutes of Health

1895 German physicist Wilhelm Roentgen discovers that radiation can render images of the human anatomy; wins Nobel Prize for physics in 1901 for his discovery and research on x-rays

1902 Congress passes the Biologics Control Act giving the federal government regulatory power over biomedical product manufacturing (July 1; 32 Stat. 728)

1906 Congress passes the Pure Food and Drug Act, making it illegal to market misbranded or adulterated drugs (June 30; PL 59–384, 34 Stat. 768)

1916 Margaret Sanger founds what would become Planned Parenthood, which campaigns for women's right to plan their pregnancies

1918–1919 A global influenza pandemic kills tens of millions of people

1930 Congress passes the Ransdell Act, formally establishing the National Institutes of Health (May 26; PL 71–251, 46 Stat. 379)

1932 U.S. Public Health Service begins its "Tuskegee Study of Untreated Syphilis in the Negro Male," which lasts until 1972

1938 Congress passes the Food, Drug, and Cosmetic Act, requiring that drugs be proven safe before they can be marketed (June 25; PL 717, 52 Stat. 1040–1059)

1944 Congress passes the Public Health Service Act, which, among other things, codifies the U.S. Public Health Service (July 1; PL 410, 57 Stat. 587–589)

1945 Congress passes the McCarran-Ferguson Act, specifically leaving the "business of insurance" to be regulated by the states (March 9; PL 15, 59 Stat. 33–34)

1946 Congress passes the Hill-Burton Hospital Survey and Construction Act, to build and rehabilitate the nation's hospitals (August 13; PL 725, 60 Stat. 1040–1049)

Communicable Disease Center is established in Atlanta, which later becomes the Centers for Disease Control and Prevention

1948 World Health Organization is founded as an agency of the United Nations

1953 Department of Health, Education, and Welfare is established (April 11; PL 13, 67 Stat. 631–632)

James Watson and Francis Crick discover DNA (deoxyribonucleic acid), the building block of cells

1954 A kidney transplant between identical twins marks the first successful organ transplant in the United States

1955 Food and Drug Administration approves vaccine developed by Jonas Salk to prevent polio (April 12)

1959 Congress passes the Federal Employee Health Benefits Act of 1959 to provide health insurance coverage to federal workers and their families (September 28; PL 86–382, 73 Stat. 703–717)

1960 Congress passes the Kerr-Mills bill as part of the Social Security Amendments of 1960, creating Medical Assistance for the Aged, a predecessor of the Medicaid program (September 13; PL 86–778, 74 Stat. 924–997)

Food and Drug Administration approves the first version of the "pill" to prevent pregnancy

1962 Congress passes the Kefauver-Harris Amendments to the Food and Drug Amendments of 1962, requiring that drugs be proven not only safe but also effective, before marketing (October 10; PL 87–781, 76 Stat. 780–796)

1964 U.S. surgeon general Luther Terry releases landmark report on the health risks of smoking

1965 President Lyndon B. Johnson signs into law the Social Security Amendments of 1965, creating Medicare and Medicaid, in Independence, Missouri (July 30; PL 89–97, 79 Stat. 286–353)

1968 First heart transplant is performed in South Africa by Christiaan Barnard

1970 National health care spending totals $73.2 billion

Congress creates the National Health Service Corps to provide scholarships to medical students who agree to serve for a period of time following their medical training in areas with shortages of medical personnel (December 31; PL 91–623, 84 Stat. 1868–1869)

1972 Medicare is expanded to cover those with permanent disabilities and those with end-stage renal (kidney) disease

1973 U.S. Supreme Court legalizes abortion nationwide in *Roe v. Wade* (January 22; 410 U.S. 1313)

Congress passes the HMO Act, to encourage the growth of pre-paid, managed care, health maintenance organization plans (December 29; PL 93–222, 87 Stat. 914)

1974 Congress passes the Employee Retirement Income Security Act (ERISA), a pension law that would also come to govern health benefits provided by employers (September 2; PL 93–406, 88 Stat. 829–1035)

Congress places first moratorium on research involving the "living human fetus, before or after abortion" (July 12; PL 93–348, 88 Stat. 342–354)

1976 Congress adopts the Hyde amendment, barring federal funding for abortion "except where the life of the mother would be endangered if the fetus were carried to term" (September 30; PL 94–439, 90 Stat. 1418)

1977 Health Care Financing Administration is created within the Department of Health, Educa-

tion, and Welfare to run the Medicare and Medicaid programs

Hyde amendment takes effect, after the Supreme Court holds that states are not required to use public funds for abortion

1978 Louise Brown, the first "test-tube baby," is born in England

1979 After a global effort by the World Health Organization to rid the world of smallpox, the disease is officially declared eradicated

1980 National health care spending totals $247.3 billion

Department of Health and Human Services is established, after the Department of Education Organization Act of 1979 created a freestanding Department of Education (October 17, 1979; PL 96–88, 93 Stat. 668)

1981 Food and Drug Administration approves cyclosporine, the first drug to prevent rejection in organ transplant patients, greatly expanding the potential for such procedures

Centers for Disease Control documents the first cases of what would come to be called Acquired Immune Deficiency Syndrome, or AIDS (June 5)

1984 Congress passes the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman), creating an abbreviated approval process for generic copies of brand-name drugs and extending brand-name patents to make up for approval delays by the Food and Drug Administration (September 24; PL 98–417, 98 Stat. 1585–1605)

President Ronald Reagan imposes the Mexico City policy, barring U.S. aid to international family planning organizations that use non-U.S. funds to "perform or promote" abortion

Congress passes the National Organ Transplant Act, creating a nationwide system to collect and distribute organs for transplant (October 19; PL 98–507, 98 Stat. 2339–2348)

1987 Food and Drug Administration approves AZT (zidovudine), the first drug to treat AIDS (March 19)

1988 President Reagan signs into law the Medicare Catastrophic Coverage Act, adding a prescription drug benefit and "stop-loss" coverage to the program, but requiring that the new benefits be financed by the program's beneficiaries themselves through new premiums that are higher for those with higher incomes (July 1; PL 100–360, 102 Stat. 684–817)

Congress passes the Clinical Laboratory Improvement Amendments, regulating laboratories that test "specimens derived from humans" for diagnosis, prevention, or treatment of disease (October 31; PL 100–578, 102 Stat. 2903)

Abortion pill RU486 is approved for use in France

1989 Supreme Court, in *Webster v. Reproductive Health Services,* upholds a series of state restrictions on abortions, including bans on the use of public employees or facilities to perform abortions (July 3; 492 U.S. 490)

Congress repeals Medicare Catastrophic Coverage Act after beneficiaries complain about the law's "income-related" financing structure (November 22; PL 101–234, 103 Stat. 1979–1986)

Congress creates Agency for Health Care Policy and Research, later renamed Agency for Healthcare Research and Quality (December 19; PL 101–239, 103 Stat. 2106)

1990 National health care spending totals $699.5 billion

President George H. W. Bush signs the Americans with Disabilities Act of 1990, creating civil rights for the disabled and those regarded as having disabilities (July 26; PL 101–336, 104 Stat. 327–378)

Congress passes the Nutrition Labeling and Education Act, requiring most food products to provide nutrition information for consumers (November 8; PL 101–535, 104 Stat. 2353–2367)

1992 Supreme Court upholds right to abortion in *Planned Parenthood of Southeastern Pa. v. Casey* (June 29; 505 U.S. 833)

1993 Congress relaxes Hyde amendment abortion restrictions to allow abortions in cases of rape and incest

President Bill Clinton unveils his Health Security Act to overhaul the nation's health insurance structure

1994 Congress fails to pass health reform legislation; Republicans win majority in both houses of Congress in November elections

1996 President Clinton signs Health Insurance Portability and Accountability Act into law, making it easier for those with job-based insurance to keep coverage and ordering new rules on privacy of medical information (August 22; PL 104–193, 110 Stat. 2105–2355)

1997 Dolly the sheep is cloned

Congress passes the Balanced Budget Act, creating a series of new private plan options for Medicare as well as the State Children's Health Insurance Program (August 5; PL 105–33, 111 Stat. 251–787)

2000 Abortion pill RU486 is approved for use in the United States

2001 Health Care Financing Administration changes its name to the Centers for Medicare and Medicaid Services

President George W. Bush allows limited federal funding for research using stem cells from human embryos

2002 Congress passes the Public Health Security and Bioterrorism Preparedness and Response Act, aimed at protecting the nation's food and water supply from biological attack, as well as increasing readiness for the possibility of diseases being used as weapons (June 12; PL 107–188, 116 Stat. 594, 42 U.S.C. 201 note)

2003 Congress passes the Partial-Birth Abortion Ban Act, the first-ever federal ban on a specific abortion procedure (November 5; PL 108–105)

Congress passes the Medicare Modernization Act, adding the first outpatient prescription drug benefit to the Medicare program, expanding federal subsidies to private insurers that serve Medicare beneficiaries, and establishing tax-preferred Health Savings Accounts for all Americans (December 8; PL 108–173)

2004 President Bush signs into law the Project BioShield Act of 2004, providing funding for the development of medical countermeasures to biological acts of terrorism and other weapons of mass destruction (July 21; PL 108–276)

2005 Tennessee removes more than 200,000 adults from the rolls of its TennCare health insurance program, in an effort to close the state's budget gap; those remaining in the program see their benefits cut

2006 Medicare prescription drug benefit takes effect, amidst considerable confusion, as many pharmacies and insurance plans prove unready to fill the millions of prescriptions presented in the first few weeks

Supreme Court upholds Oregon's controversial Death with Dignity Act, which allows individuals certified by two doctors as having a prognosis of less than six months to live to take drugs that would end their lives (January 17)

Massachusetts GOP governor Mitt Romney signs a law that requires, by the end of 2007,

nearly every state resident to have health insurance; the measure includes substantial subsidies for those with low incomes and provides for creation of a "connector" to help match insurance plans with those who need coverage

Food and Drug Administration approves sale to women age eighteen and over, without prescription, of the "morning after" emergency contraception pill, which can prevent most pregnancies if taken within seventy-two hours of unprotected intercourse

2007 Supreme Court upholds the Partial-Birth Abortion Ban Act in *Gonzales v. Carhart* (April 18)

Health Care Policy Acronyms

ACGME Accreditation Council on Graduate Medical Education
ACOG American College of Obstetricians and Gynecologists
ACR adjusted community rate
ADA Americans with Disabilities Act
ADL activity of daily living
AFDC Aid to Families with Dependent Children, later replaced by the Temporary Aid for Needy Families program
AFL adolescent family life program
AFLA Adolescent Family Life Act
AHC academic health center (*same as* academic medical center)
AHCPR Agency for Health Care Policy and Research (later renamed Agency for Healthcare Research and Quality)
AHIP America's Health Insurance Plans
AHPs association health plans
AHRQ Agency for Healthcare Research and Quality
AIDS Acquired Immune Deficiency Syndrome
AMA American Medical Association
AMC academic medical center (*same as* academic health center)
ATSDR Agency for Toxic Substances and Disease Registry, U.S.
BCBSA Blue Cross/Blue Shield Association
CalPERS California Public Employee Retirement System
CARE Act Ryan White Comprehensive AIDS Resources Emergency Act
CBO Congressional Budget Office
CDC Centers for Disease Control and Prevention, U.S.
CHAMPUS Civilian Health and Medical Program of the Uniformed Services (later replaced by TRICARE)
CHCs community health centers
CHDR Center for Health Dispute Resolution (Medicare)
CHIP Children's Health Insurance Program (officially the State Children's Health Insurance Program, or SCHIP)
CLIA Clinical Laboratory Improvement Act
CMS Centers for Medicare and Medicaid Services
CNS clinical nurse specialist
COBRA Consolidated Omnibus Budget Reconciliation Act (PL 99–272), fiscal 1986 budget reconciliation legislation
COGME Council on Graduate Medical Education
CPT current procedural terminology, a coding mechanism for health care services
CRNA certified registered nurse anesthetist
DEA Drug Enforcement Administration
DEFRA Deficit Reduction Act (PL 98–369), fiscal 1984 budget reconciliation legislation
DME durable medical equipment; *also* direct medical education (payments, Medicare)
DNR "do not resuscitate," an order pertaining to terminal patients in hospitals or nursing homes
DSH disproportionate share hospital payments
EMTALA Emergency Medical Treatment and Active Labor Act
EPSDT Early and Periodic Screening, Diagnostic, and Treatment program (Medicaid)
ERISA Employee Retirement Income Security Act
ESRD end-stage renal disease program (Medicare)
FACE Act Freedom of Access to Clinic Entrances Act
FDA Food and Drug Administration, U.S.
FEHBP Federal Employee Health Benefits Program
FFDCA Federal Food, Drug, and Cosmetic Act
FMAP federal medical assistance percentage (Medicaid)
FMG foreign medical graduate (*same as* international medical graduate)
FOCA Freedom of Choice Act
FQHC federally qualified health center
GAO Government Accountability Office (formerly the General Accounting Office)
GME graduate medical education
HCFA Health Care Financing Administration, U.S. (later renamed Centers for Medicare and Medicaid Services)
HEDIS Health Plan Employer Data and Information Set
HELP Health, Education, Labor, and Pensions Committee (Senate)

HEW Health, Education, and Welfare Department, U.S.(later divides into the Department of Health and Human Services and the Department of Education)
HHS Health and Human Services Department
HI Hospital Insurance program (Medicare)
HIAA Health Insurance Association of America
HIPAA Health Insurance Portability and Accountability Act of 1996
HIV human immunodeficiency virus
HMO health maintenance organization (managed care)
HPSA health professional shortage area
HRSA Health Resources and Services Administration, U.S.
HSA Health Savings Account
IADL instrumental activity of daily living
ICF-MR intermediate care facility for the mentally retarded (Medicaid)
IME indirect medical education (payments, Medicare)
IMG international medical graduate (*same as* foreign medical graduate)
IoM Institute of Medicine (National Academy of Sciences)
IRBs institutional review boards
JCAHO Joint Commission on Accreditation of Healthcare Organizations
MedPAC Medicare Payment Advisory Commission
MSA medical savings account
MVPS Medicare Volume Performance Standard
NAIC National Association of Insurance Commissioners
NCCAM National Center for Complementary and Alternative Medicine
NCQA National Committee for Quality Assurance
NFIB National Federation of Independent Business
NIH National Institutes of Health, U.S.
NLEA Nutrition Labeling and Education Act (PL 101–535)
NRLC National Right to Life Committee
OBRA Omnibus Budget Reconciliation Act: fiscal 1987 (PL 99–509), fiscal 1988–1989 (PL 100–203), fiscal 1990 (PL 101–239), fiscal 1991 (PL 101–508), and fiscal 1994 (PL 103–66)
PA physician assistant
PACE Program of All-inclusive Care for the Elderly
PboR Patients' Bill of Rights
PCPs primary care physicians
PDUFA Prescription Drug User Fee Act (PL 102–571)
PEPFAR President's Emergency Plan for AIDS Relief
PHS Public Health Service; *also known as* the U.S. Public Health Service, or USPHS
POS point of service plan (managed care)
PPFA Planned Parenthood Federation of America
PPO preferred provider organization (managed care)
PPRC Physician Payment Review Commission; with Prospective Payment Assessment Commission (ProPAC) later folded into Medicare Payment Advisory Commission (MedPAC)
PPS prospective payment system
ProPAC Prospective Payment Assessment Commission; with Physician Payment Review Commission (PPRC) later folded into Medicare Payment Advisory Commission (MedPAC)
PROs peer review organizations
PSO provider-sponsored organization
PSRO professional standards review organization (Medicare)
QIOs quality improvement organizations
QMB qualified Medicare beneficiary
RBRVS resource-based relative value scale (Medicare)
RN registered nurse
RRC residency review committee
SAMHSA Substance Abuse and Mental Health Services Administration, U.S.
SARS severe acute respiratory syndrome
SCHIP State Children's Health Insurance Program
SLMB Specified Low-Income Medicare Beneficiary
SMI Supplementary Medical Insurance (Medicare)
SSDI Social Security Disability Insurance
SSI Supplemental Security Income program
TANF Temporary Aid for Needy Families program, replaced Aid to Families with Dependent Children
TEFRA Tax Equity and Fiscal Responsibility Act (PL 97–248), fiscal 1983 budget reconciliation legislation
UNFPA United Nations Fund for Population Activities; popularly known as the UN Population Fund
UPL Upper Payment Limit
UR utilization review
VHAs voluntary health agencies
WIC Special Supplemental Nutrition Program for Women, Infants, and Children

Congressional Committees Responsible for Health Care Policy

House Committees

Appropriations Committee

Address: H-218 Capitol Building, Washington, D.C. 20510
Phone: (202) 225–2771
Web site: appropriations.house.gov

Subcommittee on Labor, Health and Human Services, and Education

Address: 2358 Rayburn Building, Washington, D.C. 20515
Phone: (202) 225–3508

Education and Labor Committee

Address: 2181 Rayburn Building, Washington, D.C. 20515
Phone: (202) 225–3725
Web site: edlabor.house.gov

Subcommittee on Health, Employment, Labor, and Pensions

Address: 2181 Rayburn Building, Washington, D.C. 20515
Phone: (202) 225–3725

Energy and Commerce Committee

Address: 2125 Rayburn Building, Washington, D.C. 20515
Phone: (202) 225–2927
Web site: energycommerce.house.gov

Subcommittee on Health

Address: 2125 Rayburn Building, Washington, D.C. 20515
Phone: (202) 225–2927

Ways and Means Committee

Address: 1102 Longworth Building, Washington, D.C. 20515
Phone: (202) 225–3625
Web site: waysandmeans.house.gov

Subcommittee on Health

Address: 1136 Longworth Building, Washington, D.C. 20515
Phone: (202) 225–4021

Senate Committees

Appropriations Committee

Address: S-131 Capitol, Washington, D.C. 20510
Phone: (202) 224–7363
Web site: appropriations.senate.gov

Subcommittee on Labor, Health and Human Services, and Education

Address: 131 Dirksen Building, Washington, D.C. 20510
Phone: (202) 224–9145

Finance Committee

Address: 219 Dirksen Building, Washington, D.C. 20510
Phone: (202) 224–4515
Web site: senate.gov/~finance

Subcommittee on Health Care

Address: 219 Dirksen Building, Washington, D.C. 20510
Phone: (202) 224–4515

Health, Education, Labor, and Pensions Committee

Address: 428 Dirksen Building, Washington, D.C. 20510
Phone: (202) 224–5375
Web site: help.senate.gov

Special Committee on Aging

Address: G31 Dirksen Building, Washington, D.C. 20510
Phone: (202) 224–5364
Web site: aging.senate.gov

Suggested Readings

General

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Abortion and Bioethics

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Acquired Immune Deficiency Syndrome (AIDS)

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Sources of Further Information

The following organizations can provide extensive information on the topics covered in this book. All maintain highly useful Web sites. This is not intended to be an exhaustive list of health policy sources. Instead, it provides a starting point for those wishing to delve more deeply into the subject.

For organizations that maintain a Washington, D.C., office in addition to a main headquarters in another city, the address of the Washington office is provided, because that office generally provides policy information.

Government

Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244–1850
Phone: (410) 786–3000
Web site: www.cms.hhs.gov

The Centers for Medicare and Medicaid Services (CMS) oversees the operations of Medicare, Medicaid, and the State Children's Health Insurance Program (SCHIP). CMS is also responsible for implementing the Clinical Laboratory Improvement Amendments (CLIA) and various provisions of the Health Insurance Portability and Accountability Act (HIPAA).

Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Ave. S.W.
Washington, D.C. 20201
Phone: (202) 690–7000
Web site: www.hhs.gov

The Department of Health and Human Services (HHS) oversees federal health agencies and programs, including the National Institutes of Health, Centers for Disease Control and Prevention, Medicare, and Medicaid.

THOMAS—Legislative Information on the Internet
Web site: http://thomas.loc.gov/

Maintained by the Library of Congress, THOMAS is the official site for online information related to Congress. The site also includes links to House and Senate committees and individual member offices.

Foundations and Think Tanks

Alliance for Health Reform
1444 Eye St. N.W.
Suite 910
Washington, D.C. 20005
Phone: (202) 789–2300
Web site: www.allhealth.org

The Alliance for Health Reform is a nonpartisan group that produces publications and holds briefings on a variety of health policy issues currently before Congress and the nation.

American Enterprise Institute for Public Policy Research
1150 17th St. N.W., Suite 1100
Washington, D.C. 20036
Phone: (202) 862–5800
Web site: www.aei.org

The American Enterprise Institute for Public Policy Research (AEI) is one of the few major think tanks in Washington that is home to both liberal and conservative scholars, although most of its scholars have a decidedly free-market bent.

The Brookings Institution
1775 Massachusetts Ave. N.W.
Washington, D.C. 20036
Phone: (202) 797–6000
Web site: www.brookings.edu

Brookings is Washington's leading liberal think tank.

The Cato Institute
1000 Massachusetts Ave. N.W.
Washington, D.C. 20001
Phone: (202) 842–0200
Web site: www.cato.org

The Cato Institute is a think tank representing the libertarian point of view.

Center on Budget and Policy Priorities
820 1st St. N.E., Suite 510
Washington, D.C. 20002
Phone: (202) 408–1080
Web site: www.cbpp.org

The liberal-leaning Center on Budget and Policy Priorities (CBPP) conducts research on health, welfare, and tax issues.

Center for Studying Health System Change
600 Maryland Ave. S.W.
Suite 500
Washington, D.C. 20024
Phone: (202) 484–5261
Web site: www.hschange.org

Funded by the Robert Wood Johnson Foundation, the Center for Studying Health System Change conducts research on the changes in financing, insurance, and delivery of health care.

The Commonwealth Fund
One East 75th St.
New York, N.Y. 10021–2692
Phone: (212) 606–3800
Website: www.commonwealthfund.org

The Commonwealth Fund makes grants related to health policy, with a special emphasis on women's health.

Employee Benefit Research Institute
1100 13th St. N.W.
Washington, D.C. 20005
Phone: (202) 659–0670
Web site: www.ebri.org

Funded by employers, unions, and employee benefits firms, the Employee Benefit Research Institute (EBRI) is known for producing reliable information on health insurance and pensions topics.

The Henry J. Kaiser Family Foundation
2400 Sand Hill Road
Menlo Park, CA 94025
Phone: (650) 854–9400
Web site: www.kff.org

Not associated with the managed care company Kaiser Permanente, the Kaiser Family Foundation is a philanthropy that makes grants on health policy, Acquired Immune Deficiency Syndrome (AIDS), and reproductive health issues.

The Heritage Foundation
214 Massachusetts Ave. N.E.
Washington, D.C. 20002
Phone: (202) 546–4400
Web site: www.heritage.org

The Heritage Foundation is Washington's leading conservative think tank.

National Center for Policy Analysis
601 Pennsylvania Ave. N.W.
Suite 900, South Building
Washington, D.C. 20004
Phone: (202) 220–3082
Web site: www.ncpa.org

The National Center for Policy Analysis (NCPA) is a conservative think tank based in Dallas, Texas.

National Committee for Quality Assurance
1100 13th St. N.W.
Suite 1000
Washington, D.C. 20005
Phone: (202) 955–3500
Web site: www.ncqa.org

The National Committee for Quality Assurance (NCQA) develops standards for and accredits managed care organizations.

The Robert Wood Johnson Foundation
College Road East
P.O. Box 2316
Princeton, N.J. 08543–2316
Phone: (877) 843–7953
Web site: http://rwjf.org

The largest of the health policy philanthropies, the Robert Wood Johnson Foundation (RWJF) funds a wide variety of projects related to health and health care.

The Urban Institute
2100 M St. N.W.
Washington, D.C. 20037
Phone: (202) 833–7200
Web site: www.urban.org

Originally founded as a think tank to research problems of cities, the Urban Institute today is a major source of research on health and welfare issues.

Interest Groups

AARP
601 E St. N.W.
Washington, D.C. 20049
Phone: (202) 434–2277
Web site: www.aarp.org

AARP represents the interests of people over age fifty, with a particular emphasis on Medicare and Social Security.

America's Health Insurance Plans
601 Pennsylvania Ave. N.W.
South Building, Suite 500
Washington, D.C. 20004
Phone: (202) 778–3200
Web site: www.ahip.org

America's Health Insurance Plans (AHIP), the product of a merger between the American Association of Health Plans and the Health Insurance Association of America, represents almost the entire health insurance industry.

American Health Care Association
1201 L St. N.W.
Washington, D.C. 20005–4014
Phone: (202) 842–4444
Web site: www.ahcancal.org

Despite its name, the American Health Care Association (AHCA) represents only the long-term care community: nursing homes, assisted living facilities, and "subacute" care providers.

American Hospital Association
Liberty Place, Suite 700
325 7th St. N.W.
Washington, D.C. 20004–2802
Phone: (202) 638–1100
Web site: www.AHA.org

The American Hospital Association (AHA) represents the nation's estimated five thousand community hospitals and health networks.

American Medical Association
1101 Vermont Ave. N.W.
Washington, D.C. 20005
Phone: (202) 789–7400
Web site: www.ama-assn.org

The American Medical Assocation (AMA) represents physicians of all specialties.

American Nurses Association
8515 Georgia Ave.
Silver Spring, MD 20910
Phone: 1–800-274–4ANA
Web site: http://nursingworld.org

The American Nurses Association (ANA) represents the nation's nurses.

Blue Cross/Blue Shield Association
1310 G St. N.W.
Washington, D.C. 20005
Phone: (202) 626–4780
Web site: www.BCBS.com

The Blue Cross/Blue Shield Association (BCBSA) is the federation of the nation's independent Blue Cross and Blue Shield plans.

Families USA
1201 New York Ave. N.W.
Washington, D.C. 20005
Phone: (202) 628–3030
Web site: www.famliesusa.org

Families USA is a consumer advocacy group for affordable health and long-term care.

Medicare Rights Center
520 Eighth Ave.
North Wing, 3rd Floor
New York, N.Y. 10018
Phone: (212) 869–3850
Web site: www.Medicarerights.org

The Medicare Rights Center (MRC) is a national not-for-profit organization that helps consumers navigate Medicare's complex rules and procedures through counseling, public education, and advocacy.

NARAL Pro-Choice America
1156 15th St. N.W.
Suite 700
Washington, D.C. 20005
Phone: (202) 973–3000
Web site: www.prochoiceamerica.org

NARAL Pro-Choice America is an advocacy organization for reproductive and abortion rights.

National Right to Life Committee
512 10th St. N.W.
Washington, D.C. 20004
Phone: (202) 626–8800
Web site: www.nrlc.org

The National Right to Life Committee (NRLC) is Washington's leading antiabortion organization. The group also works against euthanasia and health care rationing.

Pharmaceutical Research and Manufacturers' Association
950 F St. N.W.
Suite 300
Washington, D.C. 20004
Phone: (202) 835–3400
Web site: www.phrma.org

The Pharmaceutical Research and Manufacturers' Association (PhRMA) represents makers of brand-name prescription drugs.

Physicians for a National Health Program
29 East Madison
Suite 602
Chicago, IL 60602
Phone: (312) 782–6006
Web site: www.pnhp.org

The Physicians for a National Health Program (PNHP) represents doctors who support creation of a national single-payer health system.

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