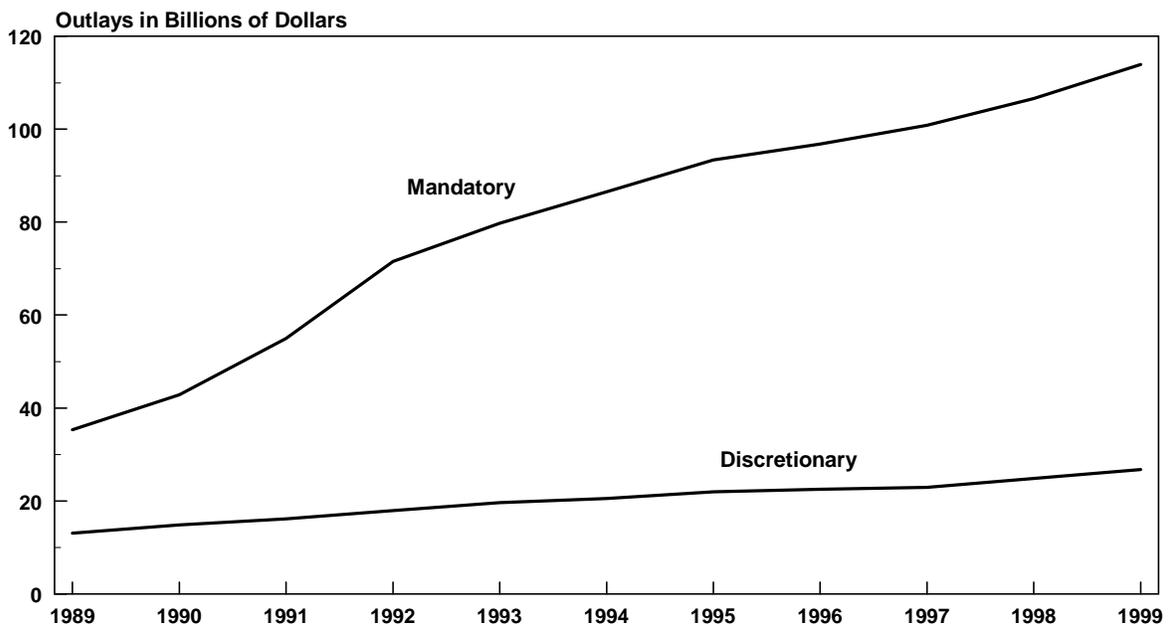


550

Health

Budget function 550 includes federal spending for health care services, disease prevention, consumer and occupational safety, health-related research, and similar activities. The largest component of spending is the federal/state Medicaid program, which pays for health services for some low-income women, children, and elderly people as well as people with disabilities. CBO estimates that in 1999, the federal government will spend \$107 billion on Medicaid and a total of \$141 billion on function 550, of which \$27 billion will be discretionary. Discretionary budget authority of over \$30 billion was provided for the function in 1999. Over the past 10 years, outlays under function 550 have increased from about 4 percent of federal spending to more than 8 percent.



550-01 REDUCE FUNDING FOR THE NATIONAL HEALTH SERVICE CORPS

	Savings (Millions of dollars)	
	Budget Authority	Outlays
Annual		
2000	29	9
2001	29	21
2002	29	26
2003	29	28
2004	29	28
2005	29	28
2006	29	28
2007	29	28
2008	29	28
2009	29	28
Cumulative		
2000-2004	144	113
2000-2009	289	254
<hr/>		
<u>SPENDING CATEGORY:</u>		
Discretionary		

The National Health Service Corps (NHSC), which is administered by the Health Resources and Services Administration, attempts to increase access to primary care services for people who live in designated Health Professional Shortage Areas. The Corps provides scholarships or loan repayment for health professionals in exchange for the recipients' agreeing to serve in a shortage area for a specified period. In recent years, over 2,200 health professionals have been serving with the NHSC—most of them in underserved rural areas but about a third in inner cities. Over half of the participants are doctors, but a substantial fraction of Corps practitioners are dentists, nurse-practitioners, or physician assistants.

This option would reduce budget authority for the NHSC by 25 percent, producing savings in outlays of \$9 million in 2000. Five-year savings would total \$113 million; savings over the 2000-2009 period would reach \$254 million.

Although some people living in underserved areas receive greater access to health services because of the Corps, critics of the program may question whether it distributes health professionals efficiently. Concerns center on whether the services that an NHSC professional provides in an underserved area outweigh the value of the services that he or she would have provided in some other location by enough to justify the public expense of a scholarship or loan repayment. Moreover, some NHSC participants may displace other health professionals. For example, certain of the more desirable shortage areas might have been able to attract health professionals if a number of the potential patients were not already being served by Corps professionals. In addition, some observers might question whether NHSC funding represents a good return on investment. Although retention rates have increased substantially, almost half of the recruits do not remain in their underserved location beyond their obligation.

Reducing funding for the NHSC would lessen access in some underserved areas to the services provided by health professionals, although the Corps might be able to mitigate the effects of budget cuts by spending more of its resources on relatively inexpensive nonphysician providers. But even if the Corps refocused its remaining funds on nonphysician practitioners, the services of those professionals would not fully substitute for the skills and services offered by physicians. In the event of a cut in funding, community health centers, which obtain about a quarter of their physicians from the NHSC, would probably reduce their services. Moreover, lower levels of funding would probably have a disproportionate impact on people from minority groups, who constitute the majority of patients served by Corps professionals.

550-02 REDUCE THE FLOOR ON THE FEDERAL MATCHING RATE IN MEDICAID

Outlay Savings
(Millions
of dollars)

Annual

2000	3,660
2001	3,940
2002	4,260
2003	4,610
2004	5,020

2005	5,450
2006	5,940
2007	6,460
2008	7,050
2009	7,680

Cumulative

2000-2004	21,480
2000-2009	54,050

SPENDING CATEGORY:

Mandatory

RELATED OPTION:

550-03

The Medicaid program pays for medical assistance for certain low-income families, for low-income people who receive Supplemental Security Income, and for other low-income individuals—mostly children and pregnant women. The federal government and the states pay for the program jointly, with the federal government's share generally varying according to a formula that depends on a state's per capita income. High-income states pay for a larger share of benefits than low-income states, but by law, the federal share can be no less than 50 percent and no more than 83 percent. In 2000, the 50 percent floor will apply to 10 states: Colorado, Connecticut, Delaware, Illinois, Maryland, Massachusetts, Nevada, New Hampshire, New Jersey, and New York. (The floor would also apply to the District of Columbia, but the Balanced Budget Act of 1997 established a permanent special exception for that jurisdiction.)

Under this option, the 50 percent floor would be reduced to 45 percent, generating savings of about \$3.7 billion in 2000 and \$21.5 billion through 2004. (The option assumes that matching rates for other programs that are jointly funded by the federal and state governments would be unaffected, even though some programs have matching rates that are tied to the rate for Medicaid. Savings would be greater if matching rates in those programs also changed.)

Proponents of this change argue that the allocation formula does not adequately address differences in the tax base of the states and that high-income states should bear a larger share of the cost of their programs. If the floor was reduced to 45 percent, federal contributions would be more closely related to the state's per capita income, and six of the 10 jurisdictions would still be paying less than the formula alone would require.

Opponents of reducing the 50 percent floor believe that higher incomes in the affected states partly reflect higher costs of living. If the option was adopted, those states would have to compensate for the lower matching rates by either reducing Medicaid benefits, reducing expenditures for other services, or raising taxes.

550-03 REDUCE THE ENHANCED FEDERAL MATCHING RATES FOR CERTAIN ADMINISTRATIVE FUNCTIONS IN MEDICAID

Outlay Savings
(Millions
of dollars)

Annual

2000	610
2001	760
2002	980
2003	1,060
2004	1,160
2005	1,260
2006	1,370
2007	1,490
2008	1,620
2009	1,760

Cumulative

2000-2004	4,570
2000-2009	12,070

SPENDING CATEGORY:

Mandatory

RELATED OPTIONS:

550-02, 550-04-A, and 550-04-B

Under current law, the federal government pays part of the costs that states incur in administering their Medicaid programs. For most administrative activities, the federal matching rate is 50 percent, but that rate is higher for certain activities. For example, the federal government pays 75 percent of the costs of skilled medical professionals who are employed in Medicaid administration, 75 percent of the costs of utilization review, 90 percent of the development costs of systems for claims processing and management information, and 75 percent of the costs of operating such systems.

The purpose of enhanced matching rates is to give states incentives to develop and support particular administrative activities that the federal government considers important for the Medicaid program. But once the administrative systems are operational, there may be less reason to continue to pay higher rates. If the federal share of all Medicaid administrative costs was 50 percent, savings would be \$610 million in 2000, \$4.6 billion over the 2000-2004 period, and \$12.1 billion over the 2000-2009 period.

Opponents of the reduction might argue, however, that without high matching rates, states would be inclined to cut back on some activities, with adverse consequences for the quality of care and for program management. States might, for example, hire fewer nurses to conduct utilization review and oversee care in nursing homes, or they might undertake fewer improvements to their management information systems. If the Congress wished to protect certain administrative functions, however, it could maintain the higher matching rates for some administrative activities and reduce them for others.

550-04-A RESTRICT THE ALLOCATION OF COMMON ADMINISTRATIVE COSTS TO MEDICAID

Outlay Savings
(Millions
of dollars)

Annual

2000	300
2001	340
2002	410
2003	410
2004	410
2005	410
2006	410
2007	410
2008	410
2009	410

Cumulative

2000-2004	1,870
2000-2009	3,920

SPENDING CATEGORY:

Mandatory

RELATED OPTIONS:

550-03 and 550-04-B

Public assistance programs have certain administrative requirements that are common to the enrollment process, such as the collection of information on a family's income, assets, and other characteristics. Before the 1996 welfare reform law, the three major public assistance programs—Aid to Families with Dependent Children (AFDC), Food Stamps, and Medicaid—all reimbursed states for 50 percent of most of their administrative costs. But states usually charged the common administrative costs of those programs to AFDC.

The welfare reform law replaced AFDC and some related programs with the Temporary Assistance for Needy Families (TANF) block-grant program. The block grants that states receive are based on historical federal welfare expenditures, including administrative costs. Thus, insofar as states had previously paid for the common administrative costs of public assistance programs out of AFDC funds, those amounts are now included in their block grants. Although the welfare reform act is silent about the cost allocation process, the Department of Health and Human Services now requires states to charge part of the common administrative costs of Medicaid and TANF to Medicaid, even if those costs are already included in the states' TANF block grants.

This option would reduce federal reimbursement for Medicaid administrative costs to reflect the share of those costs that are assumed to be covered by the TANF block grant; it would also prohibit states from using TANF funds to pay for those costs. The amount of the reduction would be about one-third of the common costs of administering the Medicaid, AFDC, and Food Stamp programs that were charged to AFDC during the base period used for determining the amount of the TANF block grant. (A similar adjustment has already been made in the amount the federal government pays the states for the administrative costs of the Food Stamp program.) Savings would be \$300 million in 2000, \$1.9 billion over the 2000-2004 period, and \$3.9 billion over the 2000-2009 period. (If, however, the policy permitted the states to use TANF funds to pay for those costs, savings would be \$70 million in 2000, \$510 million over the 2000-2004 period, and \$1.3 billion over the 2000-2009 period.)

The reductions would come at a time when states are attempting to expand their outreach activities to enroll more eligible children in Medicaid and the State Children's Health Insurance Program (S-CHIP). Because the share of S-CHIP spending that can be devoted to administration is capped, states may seek to increase the share of the administrative burden that Medicaid bears. But states would be less likely to pursue that strategy if Medicaid administrative payments were reduced.

550-04-B REDUCE SPENDING FOR MEDICAID ADMINISTRATION

Outlay Savings
(Millions
of dollars)

Annual

2000	1,390
2001	1,400
2002	1,540
2003	1,720
2004	1,960
2005	2,220
2006	2,520
2007	2,860
2008	3,250
2009	3,680

Cumulative

2000-2004	8,000
2000-2009	22,540

An alternative strategy to limit federal payments for Medicaid's common administrative costs would base those payments to the states on matching payments for administrative costs in the period before the Temporary Assistance to Needy Families (TANF) block-grant program was established. Under this option, the federal government would cap the amount per enrollee that it paid the states for Medicaid administration. The per capita limit would grow at 5 percent a year from the base-year amount, which would be the administrative costs per enrollee for which the states claimed matching payments in 1996. Savings would be \$1.4 billion in 2000, \$8.0 billion over the 2000-2004 period, and \$22.5 billion over the 2000-2009 period.

Using this approach, states that before TANF allocated Medicaid's common administrative costs to AFDC would not have those costs included in their projected Medicaid administrative costs. But states that claimed those costs through the Medicaid program would have them built into their Medicaid administrative cost base. The option would generate large savings because the actual average rate of growth of administrative costs was more than 5 percent a year in the 1996-1998 period and is also projected to exceed 5 percent in 1999 and later years.

SPENDING CATEGORY:

Mandatory

RELATED OPTIONS:

550-03 and 550-04-A

550-05 CONVERT MEDICAID AND MEDICARE DSH PAYMENTS INTO A BLOCK GRANT

Outlay Savings
(Millions
of dollars)

Annual

2000	650
2001	440
2002	340
2003	510
2004	730
2005	830
2006	920
2007	1,010
2008	1,150
2009	1,310

Cumulative

2000-2004	2,660
2000-2009	7,870

SPENDING CATEGORY:

Mandatory

Under current law, states are required to adjust Medicaid payments to hospitals that treat large numbers of low-income and Medicaid patients, which are known as disproportionate share (DSH) hospitals. In the early 1990s, some states used creative financing mechanisms to generate large federal matching payments through the DSH program, and federal DSH costs soared. To curb that growth, the Congress enacted a series of restrictions on DSH payments, culminating in those of the Balanced Budget Act of 1997 (BBA). Federal outlays for Medicaid DSH payments were \$9.0 billion in 1997 and are projected to decline to \$8.4 billion by 2002, when they will start to rise with inflation.

In addition to Medicaid DSH payments, hospitals that serve a disproportionately large share of low-income patients may also receive higher payment rates under Medicare's prospective payment system (PPS). Implemented in 1986, the Medicare disproportionate share adjustment was intended to account for the presumably higher costs of treating Medicare patients in such hospitals. Recently, however, the adjustment has been seen more as a means to protect access to care for Medicare and low-income populations by providing financial support to hospitals serving large numbers of indigent patients. Outlays for Medicare DSH payments rose rapidly between 1989 and 1997, reaching \$4.5 billion in that year. Under the BBA, a temporary 5 percent reduction in Medicare DSH adjustments is being phased in over five years. As a result, payments in 2002 will be \$5.0 billion.

An alternative approach to providing federal financial support for health care institutions that serve the poor and uninsured would be to convert the current Medicaid and Medicare disproportionate share programs into block grants to the states. The grants could be constrained to grow more slowly than DSH payments would grow under current law. In exchange for slower growth, states could be given flexibility to use the funds to meet the needs of their low-income uninsured populations in the most cost-effective ways.

Under this illustrative option, which assumes a maintenance-of-effort requirement for states, the aggregate block grant in 2000 would be the sum of Medicare DSH payments and Medicaid DSH allotments for 1999, reduced by 10 percent. In subsequent years the block grant would be indexed to the increase in the consumer price index for urban consumers less 1 percentage point. Total savings would be \$650 million in 2000, \$2.7 billion for the 2000-2004 period, and \$7.9 billion for the 2000-2009 period.

Giving the states more discretion in the allocation of DSH payments could result in those funds being targeted more appropriately and equitably to facilities and providers that serve low-income populations. But allowing the states to allocate the payments could cause some large urban safety-net hospitals to receive considerably less public funding than they do now, possibly threatening their future survival. In addition, determining how to allocate the block grant funds among the states would be difficult and controversial.

550-06 REDUCE SUBSIDIES FOR HEALTH PROFESSIONS EDUCATION

Savings
(Millions of dollars)
Budget
Authority Outlays

	Annual	
2000	209	63
2001	209	152
2002	209	190
2003	209	204
2004	209	204
2005	209	204
2006	209	204
2007	209	204
2008	209	204
2009	209	204
	Cumulative	
2000-2004	1,043	814
2000-2009	2,086	1,836

SPENDING CATEGORY:

Discretionary

The Congress provided about \$209 million to the Public Health Service in 1999 to fund subsidies to institutions for educating physicians, nurses, and public health professionals. Those funds primarily furnish support through grants and contracts to schools and hospitals for designated training programs in the health professions. The programs promote primary care and community-based training for physicians and other health professionals as well as nursing education:

- o *Primary care and community-based training.* Several programs provide federal grants to medical schools, teaching hospitals, and other training centers to develop, expand, or improve graduate medical education in primary care specialties and other allied health fields and to encourage practice in rural and low-income urban areas. Funding for 1999 is \$143 million.
- o *Nursing education.* The subsidies to nursing schools are meant to promote nursing education, including graduate training for nurse administrators, educators, and nursing specialists such as nurse-midwives and nurse-practitioners. Funding for 1999 is \$66 million.

Eliminating those grants and subsidies would save about \$800 million over the 2000-2004 period. Savings over the 2000-2009 period would be \$1.8 billion.

The principal justification for this option is that market forces provide strong incentives for people to seek training and jobs in the health professions. Over the past several decades, the number of physicians—the principal health profession targeted by the subsidies—has rapidly increased, rising from 142 physicians in all fields for every 100,000 people in 1960 to 274 in 1995. In the case of nurses, if a shortage indeed existed, higher wages and better working conditions would attract more people to the profession and more trained nurses to nursing jobs, and would encourage more of them to seek advanced training.

The major disadvantage of eliminating the subsidies is that the incentives supplied by market forces may not be strong enough to entirely meet the goals of the health professions programs. For example, third-party reimbursement rates for primary care may not encourage enough physicians to enter those specialties and may not include sufficient financial inducements to increase access to care in rural and inner-city areas. In addition, fewer people might choose advanced training in nursing, which could limit the opportunities for the use of relatively inexpensive physician substitutes.

550-07 COMBINE AND REDUCE PUBLIC HEALTH SERVICE BLOCK GRANTS

Savings
(Millions of dollars)
Budget
Authority Outlays

	Annual	
2000	383	138
2001	383	332
2002	383	359
2003	383	375
2004	383	376
2005	383	376
2006	383	376
2007	383	376
2008	383	376
2009	383	376
	Cumulative	
2000-2004	1,915	1,579
2000-2009	3,831	3,458

SPENDING CATEGORY:

Discretionary

In its appropriations for 1999, the Congress provided about \$3.8 billion for nine block-grant programs administered by the Health Resources and Services Administration (HRSA), the Centers for Disease Control and Prevention (CDC), and the Substance Abuse and Mental Health Services Administration (SAMHSA).

Four of the nine programs—the Maternal and Child Health Care Block Grant, HIV Care Grants to States, the Family Planning Block Grant, and the Healthy Start Initiative—are administered by HRSA. Those grants support programs that provide child health services, including immunizations, well-child examinations, and services for children with special health care needs; medical care and social support services for people who have been diagnosed with the human immunodeficiency virus; family planning services; and infant mortality efforts. CDC administers the Preventive Health and Health Services Block Grant, which is distributed to the states for programs that support Healthy People 2000, the nation's overall health objectives.

The remaining four block grants—the Substance Abuse Performance Partnership Block Grant, the Mental Health Performance Partnership Block Grant, the Projects for Assistance in Transition from Homelessness (PATH) program, and the Protection and Advocacy Program—are administered by SAMHSA. The grants fund substance abuse prevention programs, community-based mental health services for adults with serious mental illnesses and children with severe emotional disturbances, services for mentally ill people with substance abuse disorders who are also either homeless or at risk of becoming homeless, and programs that investigate allegations of abuse and neglect in facilities that provide care for people with mental illness.

This option would combine all of the block grants into two large grants and reduce funding to 90 percent of the 1999 level. The block grants currently administered by HRSA and the CDC would be combined and administered by HRSA, and the block grants currently administered by SAMHSA would be combined and administered by that agency.

The principal justification for this option is that each state would be given added flexibility to direct the grant funds toward programs that the state considers likely to have the most favorable impact. Conditions vary substantially by state, yet grant requirements often compel states to invest resources in programs that may or may not meet a given state's needs. By reducing funds for lower-priority programs, states could allocate additional resources to programs that they considered more important.

The option's major disadvantage is that improved flexibility might not entirely make up for the 10 percent cut in federal funds for state programs. The states would have to make difficult decisions to trim programs that benefited vulnerable population groups. Alternatively, if reducing resources was not feasible, they might have to raise state taxes or cut other state programs.

550-08 ADOPT A VOUCHER PLAN FOR THE FEHB PROGRAM

	Savings ^a (Millions of dollars)	
	Discretionary ^b	Mandatory
Annual		
2000	0	0
2001	150	150
2002	370	370
2003	610	610
2004	860	880
2005	1,140	1,180
2006	1,450	1,520
2007	1,780	1,880
2008	2,130	2,280
2009	2,520	2,710
Cumulative		
2000-2004	1,990	2,010
2000-2009	11,010	11,580

a. Estimates do not include any savings realized by the U.S. Postal Service.

b. Savings measured from the 1999 funding level adjusted for premium increases and changes in employment.

SPENDING CATEGORIES:

Discretionary and mandatory

RELATED OPTION:

550-09

RELATED CBO PUBLICATION:

Comparing Federal Employee Benefits with Those in the Private Sector (Memorandum), August 1998.

The Federal Employees Health Benefits (FEHB) program provides health insurance coverage for over 4 million active federal employees and annuitants, as well as for their 4.6 million dependents and survivors, at a cost to the government of about \$12 billion in 1999. The cost-sharing structure of the FEHB program encourages federal employees to switch from high-cost to lower-cost plans to blunt the effects of rising premiums; cost sharing also intensifies competitive pressures on all participating plans to hold down premiums. The Balanced Budget Act of 1997 set the federal government's share of premiums for employees and annuitants (including family coverage) at 72 percent of the average weighted premium of all plans beginning January 1, 1999. (The employer's costs are higher under the U.S. Postal Service's collective bargaining agreement.) The act, which made largely technical changes to the FEHB formula for determining the government's contribution, did not significantly change the government's average share of those premiums. Moreover, the government still requires policyholders to pay at least 25 percent of the premium of any particular plan.

To reduce expenditures, the government could offer a flat voucher for health insurance premiums. It could pay the first \$1,900 of premiums for employees and retirees (\$4,350 for family coverage). Those amounts are based on the government's average expected contribution for nonpostal employees in 2000 and would increase annually by the rate of inflation rather than by the average weighted rate of change for premiums in the FEHB program. Budgetary savings would come from indexing the premiums to inflation rather than to the growth of premiums, which the Congressional Budget Office expects will rise at a rate more than twice that of inflation. Savings in discretionary spending from lower payments for current employees and their dependents would be zero in 2000, \$2 billion over five years, and \$11 billion over 10 years. Savings in mandatory spending from reduced payments for retirees would be zero in 2000, \$2.0 billion over five years, and \$11.6 billion over 10 years.

The option would strengthen price competition among health plans in the FEHB program because almost all current enrollees would be faced with paying all of the incremental premiums above the voucher amount. In addition, removing the requirement that enrollees pay at least 25 percent of the premiums should increase price competition among low-cost plans to attract participants.

On the downside, participants would pay an ever-increasing share of their premiums—possibly just under 40 percent by 2004—if premiums rose as expected. The added cost to enrollees could exceed \$600 per worker in 2004 and more in later years. Currently, large private-sector plans provide better health benefits for their employees—although not for their retirees—which might make it harder for the government to attract and retain high-quality workers. In addition, for current retirees and long-time federal workers, the option would cut benefits that have already been earned.

550-09 BASE RETIREE HEALTH BENEFITS ON LENGTH OF SERVICE

	Savings ^a (Millions of dollars)	
	Budget	Outlays
Annual		
2000	50	50
2001	100	100
2002	150	150
2003	200	200
2004	250	250
2005	300	300
2006	400	400
2007	500	500
2008	600	600
2009	700	700
Cumulative		
2000-2004	750	750
2000-2009	3,250	3,250

a. Estimates do not include any savings realized by the U.S. Postal Service.

SPENDING CATEGORY:

Mandatory

RELATED OPTION:

550-08

RELATED CBO PUBLICATION:

Comparing Federal Employee Benefits with Those in the Private Sector (Memorandum), August 1998.

The Federal Employees Health Benefits (FEHB) program provides health insurance to federal retirees and active employees through participating fee-for-service plans and managed care plans. Participants and the government share the cost of premiums. The government's share for annuitants and employees is 72 percent of the weighted average premium of all participating plans (up to a cap of 75 percent of the total premium). Retirees are generally eligible to continue receiving benefits from the FEHB program if they have been participants during their last five years of service and are eligible to receive an immediate annuity. About 80 percent of eligible new retirees elect to receive retiree health benefits. After age 65, FEHB program benefits are coordinated with Medicare; the program pays amounts not covered by Medicare (but no more than the amount it would have paid in the absence of Medicare). Consequently, many retirees receive benefits superior to those they received while employed. In 1998, the government paid \$4.3 billion in premiums for 1.9 million annuitants and their dependents and survivors.

In contrast to federal pensions, retiree health benefits are not based on length of service. Moreover, federal retiree health benefits are significantly more generous than those offered by most large private firms, which have been aggressively paring and, in some cases, eliminating retiree health benefits in recent years. A survey of all U.S. employers found that fewer than half provide medical benefits to retirees.

Federal retiree health benefits could be reduced for those with relatively short federal careers while preserving the right of retirees to participate in the FEHB program. For new retirees only, the government's share of the premium could be cut by 2 percentage points for every year of service under 30. For example, the government's contribution would fall to 52 percent of the average premium for a retiree with 20 years of service. In 1998, about 55 percent of the roughly 60,000 new retirees who continued in the FEHB program had less than 30 years of service. The average new nonpostal retiree affected by the proposal would pay 47 percent of the premium rather than 28 percent, an annual increase of \$750 in 2000. The estimated savings to the government in mandatory spending would total \$50 million in 2000 and \$750 million over five years. Ten-year savings would rise to \$3.3 billion.

The option might make the government's compensation mix fairer and more efficient by improving the link between service and deferred compensation. And even with this change, federal retiree health benefits would remain comparable with those offered by firms that continued to provide retiree benefits.

A negative aspect of the option is that it would mean a substantial cut in benefits whose effects would be felt most strongly by the roughly 20 percent of new retirees with less than 20 years of service. The option could also encourage some employees with short service careers to delay retirement, whereas others might accelerate retirement plans to avoid the new rules.

550-10 ESTABLISH NEW USER FEES FOR MEDICAL DEVICES REGULATED BY THE FDA

	Savings (Millions of dollars)	
	Budget Authority	Outlays
Annual		
2000	12	9
2001	28	23
2002	32	30
2003	31	31
2004	31	31
2005	31	31
2006	31	31
2007	31	31
2008	31	31
2009	31	30
Cumulative		
2000-2004	134	124
2000-2009	289	277

SPENDING CATEGORY:

Discretionary

The Prescription Drug User Fee Act of 1992 (PDUFA) authorized the Food and Drug Administration (FDA) to collect fees from pharmaceutical manufacturers to help speed up the review of applications for marketing and approval of new drugs. The Food and Drug Administration Modernization Act of 1997 (FDAMA) reauthorized the PDUFA user fee program but did not address user fees for medical devices. The Congress considered but did not pass legislation authorizing user fees for medical devices in 1994. The Administration's 2000 budget includes a proposal to impose user fees on medical devices as well as on other products regulated by the FDA.

Manufacturers must notify the FDA before they market any new medical device, and for certain products, they must obtain approval before marketing them. Imposing fees of \$7,000 for each new medical device requiring pre-market notification, \$3,500 for those devices qualifying for abbreviated or special notification processes, and \$60,000 for each new medical device needing premarket approval would raise \$9 million in 2000 and \$277 million during the 2000-2009 period. Taken together, those fees would ultimately constitute about 21 percent of the cost of regulating medical devices. The estimates assume that only a few exemptions would be granted for small businesses or devices with very small markets.

Establishing new user fees for medical devices would require new authorizing legislation. To generate budgetary savings, that legislation would have to permit user fee collections to offset other FDA appropriations for salaries and expenses. PDUFA does not permit that offset for prescription drug user fees.

Proponents of user fees for medical devices argue that regulatory activities benefit both consumers and industry. The FDA's primary function is to ensure public safety by monitoring the quality of pharmaceutical products, medical devices, and food. Firms benefit from the public confidence that results from the FDA's regulation, those proponents maintain, and should therefore bear a share of the costs of those activities.

People who oppose levying new user fees on medical devices might argue that the agency's current oversight of medical devices is excessive and unnecessary. Rather than adding user fees, those opponents might contend that the FDA could cut costs by scaling back its regulatory requirements.