MEASURES PLACED ON THE CALENDAR

The following bills were read the second time and placed on the calendar:

H.R. 908. An act to establish a Commission on structural alternatives for the Federal Courts of Appeals.

H.R. 1000. An act to require States to establish a system to prevent prisoners from being considered part of any household for purposes of determining eligibility of the household for purposes of determining eligibility of household for food stamp benefits and the amount of food stamp benefits to be provided to the household under the Food Stamp Act of 1977.

EXECUTIVE AND OTHER COMMUNICATIONS

The following communications were laid before the Senate, together with accompanying papers, reports, and documents, which were referred as indicated:

EC–2097. A communication from the Chief of the Regulations Unit, Internal Revenue Service, Department of the Treasury, transmitting, pursuant to law, a report of a rule relative to assessing and collecting tax settlements in Tax Court, received on June 2, 1997; to the Committee on Finance.

EC–2098. A communication from the Chief of the Regulations Unit, Internal Revenue Service, Department of the Treasury, transmitting, pursuant to law, a report of a rule relative to whether section 277 applies to nonexempt cooperatives, received on June 2, 1997; to the Committee on Finance.

EC–2099. A communication from the Chief of the Regulations Unit, Internal Revenue Service, Department of the Treasury, transmitting, pursuant to law, a report of a rule relative to summonses to compel taxpayers to sign consent directives, received on June 2, 1997; to the Committee on Finance.

EC–2100. A communication from the Chief of the Regulations Unit, Internal Revenue Service, Department of the Treasury, transmitting, pursuant to law, a report of a rule relative to Article 23(1)(c) of the U.S.–U.K. Income Tax Treaty, received on June 2, 1997; to the Committee on Finance.

EC–2101. A communication from the Chief of the Regulations Unit, Internal Revenue Service, Department of the Treasury, transmitting, pursuant to law, a report of a rule relative to the Application for Automatic Extension of Time to File Income Tax, received on June 2, 1997; to the Committee on Finance.

EC–2102. A communication from the Chief of the Regulations Unit, Internal Revenue Service, Department of the Treasury, transmitting, pursuant to law, a report of a rule relative to disablity benefits under the Policeman and Firefighter's Retirement Fund, received on June 2, 1997; to the Committee on Finance.

EC–2103. A communication from the Office of the Chief Counsel of the Regulations Unit of the Internal Revenue Service, Department of the Treasury, transmitting, pursuant to law, a report of a rule entitled ''Utilities Industry Coordinated Issue: Investment Credit on Transition Property,'' received on June 3, 1997; to the Committee on Finance.

EC–2104. A communication from the Chief of the Regulations Unit of the Internal Revenue Service, Department of the Treasury, transmitting, pursuant to law, a treasury notice 97–33, received on June 3, 1997; to the Committee on Finance.

EC–2105. A communication from the Chief of the Regulations Unit, Internal Revenue Service, Department of the Treasury, transmitting, pursuant to law, a treasury notice 97–34, received on June 3, 1997; to the Committee on Finance.

INTRODUCTION OF BILLS AND JOINT RESOLUTIONS

The following bills and joint resolutions were introduced, read the first and second time by unanimous consent, and referred as indicated:

By Mr. MOYNIHAN (for himself and Mr. SARBANES):

S. 863. A bill to authorize the Government of India to establish a memorial to honor Mahatma Gandhi in the District of Columbia; to the Committee on Energy and Natural Resources.

By Mr. CHAFEE (for himself, Mr. BREAUX, Mr. KERREY, and Mr. CONRAD):

S. 864. A bill to amend title XIX of the Social Security Act to improve the provision of managed care under the medicaid program; to the Committee on Finance.

By Mr. GRAHAM (for himself, Mr. MACK, and Mr. BAUCUS):

S. 865. A bill to provide for improved coordination, communications, and enforcement related to health care fraud, waste, and abuse, to create a point of order against legislation which diverts savings achieved through medicare waste, fraud, and abuse enforcement activities for purposes other than improving the solvency of the Federal Hospital Insurance Trust Fund under title XVIII of the Social Security Act, to ensure the integrity of such trust fund, and for other purposes; to the Committee on Finance.

By Mrs. HUTCHISON:

S. 866. A bill to amend title 28, United States Code, to provide that certain voluntary disclosures of violations of Federal law made as a result of a voluntary environmental audit shall not be subject to discovery or admitted into evidence during a judicial or administrative proceeding, and for other purposes; to the Committee on the Judiciary.

By Mr. DEWINE:

S. 867. A bill to assist State and local governments in establishing effective criminal records concerning serious and violent juvenile offenders and information concerning adult members of violent criminal gangs and Federal, State, and local criminal justice officials in countering the rise in serious crime, and for other purposes; to the Committee on the Judiciary.

By Mr. HARKIN (for himself, Mr. HUTCHINSON, Mr. REID, Mr. BRYAN, and Mr. ROCKEFELLER):

S. 868. A bill to amend the Social Security Act to prohibit persons from charging for services or products that the Social Security Administration and Department of Health and Human Services provide without charge; to the Committee on Finance.

By Mr. JEFFORDS (for himself, Mr. KENNEDY, Mr. LIEBERMAN, Mr. TORRICELLI, Mr. WYDEN, Mr. BINGAMAN, Mr. KERRY, Mr. WELLSTONE, Mr. HARKIN, Ms. LANDRIEU, Mr. FEINGOLD, Mrs. MURRAY, Mrs. BOXER, Mr. LEVIN, Mr. SARBANES, Mr. AKAKA, Mr. LAUTENBERG, Mr. DURBIN, Mr. CHAFEE, Mr. KOHL, Mr. INOUYE, Ms. MIKULSKI, Mr. ROBB, Mr. MOYNIHAN, Mrs. FEINSTEIN, Mr. DODD, Mr. REID, Mr. LEAHY, Mr. BRYAN, Ms. MOSELEY-BRAUN, Mr. GLENN, Mr. KERREY, Mr. REED, Mr. D'AMATO, and Mr. CLELAND):

S. 869. A bill to prohibit employment discrimination on the basis of sexual orientation; to the Committee on Labor and Human Resources.

By Mr. WELLSTONE:

S. 870. A bill to amend the Federal Food, Drug, and Cosmetic Act to facilitate the development, approval, and use of medical devices to maintain and improve the public health and quality of life of individuals, and for other purposes; to the Committee on Labor and Human Resources.

By Mr. NICKLES (for himself and Mr. INHOFE):

S. 871. A bill to establish the Oklahoma City National Memorial as a unit of the National Park System; to designate the Oklahoma City Memorial Trust, and for other purposes; to the Committee on Energy and Natural Resources.

By Mr. ROBERTS (for himself, Mr. HARKIN, Mr. HATCH, Mr. JOHNSON, Mr. BAUCUS, Mr. D'AMATO, Mr. BENNETT, and Mr. CRAIG):

S. 872. A bill to amend the Internal Revenue Code of 1986 to provide for the nonrecognition of gain for sale of stock to certain farmers' cooperatives, and for other purposes; to the Committee on Finance.

By Mr. ASHCROFT:

S. 873. A bill to amend the prohibition of title 18, United States Code, against financial transactions with state sponsors of international terrorism; to the Committee on the Judiciary.

By Mr. FAIRCLOTH (for himself and Mr. SHELBY):

S. 874. A bill to amend title 31, United States Code, to provide for an exemption to the requirement that all Federal payments be made by electronic funds transfer; to the Committee on Finance.

STATEMENTS ON INTRODUCED BILLS AND JOINT RESOLUTIONS

By Mr. MOYNIHAN (for himself and Mr. SARBAMES):

S. 863. A bill to authorize the Government of India to establish a memorial to honor Mahatma Gandhi in the District of Columbia; to the Committee on Energy and Natural Resources.

LEGISLATION TO ESTABLISH MAHATMA GANDHI MEMORIAL

Mr. MOYNIHAN. Mr. President, I rise to introduce a bill to authorize the placement of a statue of Mohandas Karamchand Gandhi —Mahatma Gandhi—on Federal land across the street from the Indian embassy in Washington DC. The Government of India has offered a statue of Gandhi as a gift to the United States. In order to place it on Federal land, an act of Congress is required. This bill will fulfill just that purpose, and I thank the Senator from Florida [Mr. MACK] and the Senator from Maryland, [Mr. SARBANES] for joining me in this endeavor.

India is currently celebrating the 50th anniversary of its independence. Authorizing the placement of a statue of Mahatma Gandhi, often called the father of the Indian nation, would serve as a fitting tribute to Indian democracy which has survived—in fact, thrived—despite enormous challenges, and a symbol of the growing strength of the bonds between our two countries.

It is particularly appropriate that a statue of Mahatma Gandhi be selected for this purpose. The effects of his non-

violent actions and the philosophy which guided them were not limited to his country, nor his time. His influence in the United States was most notably felt in the civil rights movement, but has also infused all levels of our society.

If I may invade ever so slightly the privacy of the President's luncheon table, in May 1994, Mr. Clinton had as his guest the distinguished Prime Minister of India, Mr. P.V. Narasimha Rao, who in his youth was a follower of Mahatma Gandhi. In a graceful passage, Prime Minister Rao related how it came to pass that Mahatma Gandhi, caught up in the struggle for fair treatment to the Indian community in South Africa, and in consequence in jail, read Thoreau's essay on ''Civil Disobedience'' which confirmed his view that an honest man is duty-bound to violate unjust laws. He took this view home with him, and in the end the British raj gave way to an independent Republic of India. Then Martin Luther King, Jr., repatriated the idea and so began the great civil rights movement of this century.

Dr. Martin Luther King, Jr., has written of the singular influence Gandhi's message of nonviolent resistance had on him when he first learned of it while studying at Crozier Theological Seminary in Philadelphia. He would later describe that influence in his first book, ''Stride Toward Freedom'':

> As I read I became deeply fascinated by [Gandhi's] philosophy of non-violent resistance . . . as I delved deeper into the philosophy of Gandhi, my skepticism concerning the power of love gradually diminished, and I came to see its potency in the area of social reform . . . prior to reading Gandhi, I had concluded that the love ethics of Jesus were only effective in individual relationships . . . but after reading Gandhi, I saw how utterly mistaken I was.
>
> . . . It was in this Gandhian emphasis on love and non-violence that I discovered the method for social reform that I had been seeking for so many months . . . I came to feel that this was the only morally and practically sound method open to oppressed people in their struggle for freedom . . . this principle became the guiding light of our movement. Christ furnished the spirit and motivation and Gandhi furnished the method.

Martin Luther King, Jr., believed that Gandhi's philosophy of nonviolent resistance was the guiding light of the American civil rights movement. As Dr. King wrote, ''Gandhi furnished the message.'' A statue of Gandhi, given as a gift from the Government of India, on a small plot of Federal land along Massachusetts Avenue, in front of the Indian Embassy, will stand not only as a tribute to the shared values of the two largest democracies in the world but will also pay tribute to the lasting influence of Gandhian thought on the United States. An influence that is so pervasive that when the President and the Prime Minister of India meet at the White House for lunch, a half-century after Gandhi's death, it is no surprise that he should be a topic of conversation.

By Mr. CHAFEE (for himself, Mr. BREAUX, Mr. KERREY, and Mr. CONRAD):

S. 864. A bill to amend title XIX of the Social Security Act to improve the provision of managed care under the Medicaid Program; to the Committee on Finance.

THE MEDICAID MANAGED CARE ACT OF 1997

Mr. CHAFEE. Mr. President, I am pleased today to introduce The Medicaid Managed Care Act of 1997. This legislation meets two very important objectives in the Medicaid Program. First, it gives States the additional flexibility they need to administer the Medicaid Program by allowing them to enroll Medicaid beneficiaries into managed care Programs. Second, the bill sets Federal standards for managed care to ensure that Medicaid patients receive the same quality of care as those patients who are enrolled in private managed care plans.

Under our legislation, States could require Medicaid patients to enroll in managed care plans without going through the lengthy and cumbersome process of applying to the Secretary of Health and Human Services for a waiver of current Medicaid regulations. In exchange for this important flexibility, States will have to meet a set of minimum Federal standards to ensure that Medicaid patients continue to receive quality care.

For example, States would be required to offer patients a choice of at least two health plans. Plans would be required to meet certain standards of access to care, quality, and solvency. These standards are especially important given recent problems in States that have set up Medicaid managed care programs under the waiver process. In some instances, plans have failed to contract with enough providers to serve the Medicaid population. Some have been permitted to operate under standards that are lower than commercial insurers are required to meet, and others have used fraudulent marketing practices to entice Medicaid patients to sign up with their plans. These actions have resulted in patients being denied medically necessary services, and have resulted in States and the Federal Government paying for care that was never given.

Considering these abuses, why should we allow Medicaid managed care at all? Because managed care, if implemented correctly, can vastly improve the quality of health care provided to low-income families. In today's fee-for-service program, patients face myriad problems. Some are forced to get care in hospital emergency rooms because they cannot find a private physician willing or able to accept Medicaid's low payment rates. Those who do have access to providers often must wait for hours in clinics which are overcrowded and understaffed. And, sadly, they often do not have access to primary and preventive care services which would have prevented them from becoming ill to begin with.

Medicaid managed care, if done well, provides regular prenatal care to assure that children are born healthy. These plans provide coverage for check-ups and immunizations to prevent serious illnesses. And they give patients a medical home—a provider they know they can go to if they are sick, or a number to call if they have questions.

Medicaid managed care also has the potential of benefiting our overall health care system by providing access to primary care providers rather than forcing patients to make costly and unnecessary visits to hospital emergency rooms. It gives providers the opportunity to catch and treat, or prevent, costly health problems.

Mr. President, we have worked very hard to ensure that this legislation strikes an appropriate balance between the needs of Medicaid beneficiaries and the managed care companies. I want to thank Senators BREAUX and KERREY who helped craft this legislation and are original cosponsors. I also want to thank the many advocacy organizations for their input and support. And I also want to thank some of the managed care organizations who worked with us. I am especially pleased that some of these organizations, such as the HMO Group which is an alliance of health maintenance organizations have endorsed this legislation. Their support is critical to the success of Medicaid managed care.

I ask unanimous consent that the text of the legislation be included in the RECORD.

There being no objection, the bill was ordered to be printed in the RECORD, as follows:

S. 864

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS; AMENDMENTS TO THE SOCIAL SECURITY ACT.

(a) SHORT TITLE.—This Act may be cited as the ''Medicaid Managed Care Improvement Act of 1997''.

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

Sec. 1. Short title; table of contents; amendments to the Social Security Act.
Sec. 2. Improvements in medicaid managed care program.
''PART B—PROVISIONS RELATING TO MANAGED CARE
''Sec. 1941. Beneficiary choice; enrollment.
''Sec. 1942. Beneficiary access to services generally.
''Sec. 1943. Beneficiary access to emergency care.
''Sec. 1944. Other beneficiary protections.
''Sec. 1945. Assuring quality care.
''Sec. 1946. Protections for providers.
''Sec. 1947. Assuring adequacy of payments to medicaid managed care organizations and entities.
''Sec. 1948. Fraud and abuse.
''Sec. 1949. Sanctions for noncompliance by managed care entities.
''Sec. 1950. Definitions; miscellaneous provisions.''

Sec. 3. Studies and reports.
Sec. 4. Conforming amendments.
Sec. 5. Effective date; status of waivers.

(c) AMENDMENTS TO SOCIAL SECURITY ACT.—Except as otherwise specifically provided, whenever in this Act an amendment is expressed in terms of an amendment to or repeal of a section or other provision, the reference shall be considered to be made to that section or other provision of the Social Security Act.

SEC. 2. IMPROVEMENTS IN MEDICAID MANAGED CARE PROGRAM.

Title XIX is amended—

(1) by inserting after the title heading the following:

''PART A—GENERAL PROVISIONS''; AND

(2) by adding at the end the following new part:

''PART B—PROVISIONS RELATING TO MANAGED CARE

''SEC. 1941. BENEFICIARY CHOICE; ENROLLMENT.

''(a) STATE OPTIONS FOR ENROLLMENT OF BENEFICIARIES IN MANAGED CARE ARRANGEMENTS.—

''(1) IN GENERAL.—Subject to the succeeding provisions of this part and notwithstanding paragraphs (1), (10)(B), and (23)(A) of section 1902(a), a State may require an individual who is eligible for medical assistance under the State plan under this title and who is not a special needs individual (as defined in subsection (e)) to enroll with a managed care entity (as defined in section 1950(a)(1)) as a condition of receiving such assistance (and, with respect to assistance furnished by or under arrangements with such entity, to receive such assistance through the entity), if the following provisions are met:

''(A) ENTITY MEETS REQUIREMENTS.—The entity meets the applicable requirements of this part.

''(B) CONTRACT WITH STATE.—The entity enters into a contract with the State to provide services for the benefit of individuals eligible for benefits under this title under which prepaid payments to such entity are made on an actuarially sound basis. Such contract shall specify benefits the provision (or arrangement) for which the entity is responsible.

''(C) CHOICE OF COVERAGE.—

''(i) IN GENERAL.—The State permits an individual to choose a managed care entity from managed care organizations and primary care case providers who meet the requirements of this part but not less than from—

''(I) 2 medicaid managed care organizations,

''(II) a medicaid managed care organization and a primary care case management provider, or

''(III) a primary care case management provider as long as an individual may choose between 2 primary care case managers.

''(ii) STATE OPTION.—At the option of the State, a State shall be considered to meet the requirements of clause (i) in the case of an individual residing in a rural area, if the State—

''(I) requires the individual to enroll with a medicaid managed care organization or primary care case management provider if such organization or entity permits the individual to receive such assistance through not less than 2 physicians or case managers (to the extent that at least 2 physicians or case managers are available to provide such assistance in the area), and

''(II) permits the individual to obtain such assistance from any other provider in appropriate circumstances (as established by the State under regulations of the Secretary).

''(D) CHANGES IN ENROLLMENT.—The State provides the individual with the opportunity to change enrollment among managed care entities once annually and notifies the individual of such opportunity not later than 60 days prior to the first date on which the individual may change enrollment, permits individuals to change their enrollment for cause at any time and without cause at least every 12 months, and allows individuals to disenroll without cause within 90 days of notification of enrollment.

''(E) ENROLLMENT PRIORITIES.—The State establishes a method for establishing enrollment priorities in the case of a managed care entity that does not have sufficient capacity to enroll all such individuals seeking enrollment under which individuals already enrolled with the entity are given priority in continuing enrollment with the entity.

''(F) DEFAULT ENROLLMENT PROCESS.—The State establishes a default enrollment process which meets the requirements described in paragraph (2) and under which any such individual who does not enroll with a managed care entity during the enrollment period specified by the State shall be enrolled by the State with such an entity in accordance with such process.

''(G) SANCTIONS.—The State establishes the sanctions provided for in section 1949.

''(2) DEFAULT ENROLLMENT PROCESS REQUIREMENTS.—The default enrollment process established by a State under paragraph (1)(F)—

''(A) shall provide that the State may not enroll individuals with a managed care entity which is not in compliance with the applicable requirements of this part;

''(B) shall provide (consistent with subparagraph (A)) for enrollment of such an individual with a medicaid managed care organization—

''(i) first, that maintains existing provider-individual relationships or that has entered into contracts with providers (such as Federally qualified health centers, rural health clinics, hospitals that qualify for disproportionate share hospital payments under section 1886(d)(5)(F), and hospitals described in section 1886(d)(1)(B)(iii)) that have traditionally served beneficiaries under this title, and

''(ii) lastly, if there is no provider described in clause (i), in a manner that provides for an equitable distribution of individuals among all qualified managed care entities available to enroll individuals through such default enrollment process, consistent with the enrollment capacities of such entities;

''(C) shall permit and assist an individual enrolled with an entity under such process to change such enrollment to another managed care entity during a period (of at least 90 days) after the effective date of the enrollment; and

''(D) may provide for consideration of factors such as quality, geographic proximity, continuity of providers, and capacity of the plan when conducting such process.

''(b) REENROLLMENT OF INDIVIDUALS WHO REGAIN ELIGIBILITY.—

''(1) IN GENERAL.—If an individual eligible for medical assistance under a State plan under this title and enrolled with a managed care entity with a contract under subsection (a)(1)(B) ceases to be eligible for such assistance for a period of not greater than 2 months, the State may provide for the automatic reenrollment of the individual with the entity as of the first day of the month in which the individual is again eligible for such assistance, and may consider factors such as quality, geographic proximity, continuity of providers, and capacity of the plan when conducting such reenrollment.

''(2) CONDITIONS.—Paragraph (1) shall only apply if—

''(A) the month for which the individual is to be reenrolled occurs during the enrollment period covered by the individual's original enrollment with the managed care entity;

''(B) the managed care entity continues to have a contract with the State agency under subsection (a)(1)(B) as of the first day of such month; and

''(C) the managed care entity complies with the applicable requirements of this part.

''(3) NOTICE OF REENROLLMENT.—The State shall provide timely notice to a managed care entity of any reenrollment of an individual under this subsection.

''(c) STATE OPTION OF MINIMUM ENROLLMENT PERIOD.—

''(1) IN GENERAL.—In the case of an individual who is enrolled with a managed care entity under this part and who would (but for this subsection) lose eligibility for benefits under this title before the end of the minimum enrollment period (defined in paragraph (2)), the State plan under this title may provide, notwithstanding any other provision of this title, that the individual shall be deemed to continue to be eligible for such benefits until the end of such minimum period, but, except for benefits furnished under section 1902(a)(23)(B), only with respect to such benefits provided to the individual as an enrollee of such entity.

''(2) MINIMUM ENROLLMENT PERIOD DEFINED.—For purposes of paragraph (1), the term 'minimum enrollment period' means, with respect to an individual's enrollment with an entity under a State plan, a period, established by the State, of not more than 6 months beginning on the date the individual's enrollment with the entity becomes effective, except that a State may extend such period for up to a total of 12 months in the case of an individual's enrollment with a managed care entity (as defined in section 1950(a)(1)) so long as such extension is done uniformly for all individuals enrolled with all such entities.

''(d) OTHER ENROLLMENT-RELATED PROVISIONS.—

''(1) NONDISCRIMINATION.—A managed care entity may not discriminate on the basis of health status or anticipated need for services in the enrollment, reenrollment, or disenrollment of individuals eligible to receive medical assistance under a State plan under this title or by discouraging enrollment (except as permitted by this section) by eligible individuals.

''(2) TERMINATION OF ENROLLMENT.—

''(A) IN GENERAL.—The State, enrollment broker, and managed care entity (if any) shall permit an individual eligible for medical assistance under the State plan under this title who is enrolled with the entity to terminate such enrollment for cause at any time, and without cause during the 90-day period beginning on the date the individual receives notice of enrollment and at least every 12 months thereafter, and shall notify each such individual of the opportunity to terminate enrollment under these conditions.

''(B) FRAUDULENT INDUCEMENT OR COERCION AS GROUNDS FOR CAUSE.—For purposes of subparagraph (A), an individual terminating enrollment with a managed care entity on the grounds that the enrollment was based on fraudulent inducement or was obtained through coercion or pursuant to the imposition against the managed care entity of the sanction described in section 1949(b)(3) shall be considered to terminate such enrollment for cause.

''(C) NOTICE OF TERMINATION.—

''(i) NOTICE TO STATE.—

''(I) BY INDIVIDUALS.—Each individual terminating enrollment with a managed care entity under subparagraph (A) shall do so by

providing notice of the termination to an office of the State agency administering the State plan under this title, the State or local welfare agency, or an office of a managed care entity.

''(II) BY ORGANIZATIONS.—Any managed care entity which receives notice of an individual's termination of enrollment with such entity through receipt of such notice at an office of a managed care entity shall provide timely notice of the termination to the State agency administering the State plan under this title.

''(ii) NOTICE TO PLAN.—The State agency administering the State plan under this title or the State or local welfare agency which receives notice of an individual's termination of enrollment with a managed care entity under clause (i) shall provide timely notice of the termination to such entity.

''(3) PROVISION OF INFORMATION.—

''(A) IN GENERAL.—Each State, enrollment broker, or managed care organization shall provide all enrollment notices and informational and instructional materials in a manner and form which may be easily understood by enrollees of the entity who are eligible for medical assistance under the State plan under this title, including enrollees and potential enrollees who are blind, deaf, disabled, or cannot read or understand the English language.

''(B) INFORMATION TO HEALTH CARE PROVIDERS, ENROLLEES, AND POTENTIAL ENROLLEES.—Each medicaid managed care organization shall—

''(i) upon request, make the information described in section 1945(e)(1)(A)available to enrollees and potential enrollees in the organization's service area; and

''(ii) provide to enrollees and potential enrollees information regarding all items and services that are available to enrollees under the contract between the State and the organization that are covered either directly or through a method of referral and prior authorization.

''(e) SPECIAL NEEDS INDIVIDUALS DESCRIBED.—In this part, the term 'special needs individual' means any of the following individuals:

''(1) SPECIAL NEEDS CHILD.—An individual who is under 19 years of age who—

''(A) is eligible for supplemental security income under title XVI;

''(B) is described under section 501(a)(1)(D);

''(C) is a child described in section 1902(e)(3);

''(D) is receiving services under a program under part B or part E of title IV; or

''(E) is not described in any preceding subparagraph but is otherwise considered a child with special health care needs who is adopted, in foster care, or otherwise in an out-of-home placement.

''(2) HOMELESS INDIVIDUALS.—An individual who is homeless (without regard to whether the individual is a member of a family), including—

''(A) an individual whose primary residence during the night is a supervised public or private facility that provides temporary living accommodations; or

''(B) an individual who is a resident in transitional housing.

''(3) MIGRANT AGRICULTURAL WORKERS.—A migratory agricultural worker or a seasonal agricultural worker (as such terms are defined in section 330(g)(3) of the Public Health Service Act), or the spouse or dependent of such a worker.

''(4) INDIANS.—An Indian (as defined in section 4(c) of the Indian Health Care Improvement Act (25 U.S.C. 1603(c))).

''(5) MEDICARE BENEFICIARIES.—A qualified medicare beneficiary (as defined in section 1905(p)(1)) or an individual otherwise eligible for benefits under title XVIII.

''(6) DISABLED INDIVIDUALS.—Individuals who are disabled (as determined under section 1614(a)(3)).

''(7) PERSONS WITH AIDS OR HIV INFECTION.—An individual with acquired immune deficiency syndrome (AIDS) or who has been determined to be infected with the HIV virus.

''SEC. 1942. BENEFICIARY ACCESS TO SERVICES GENERALLY.

''(a) ACCESS TO SERVICES.—

''(1) IN GENERAL.—Each managed care entity shall provide or arrange for the provision of all medically necessary medical assistance under this title which is specified in the contract entered into between such entity and the State under section 1941(a)(1)(B) for enrollees who are eligible for medical assistance under the State plan under this title.

''(2) PRIMARY-CARE-PROVIDER-TO-ENROLLEE RATIO AND MAXIMUM TRAVEL TIME.—Each such entity shall assure adequate access to primary care services by meeting standards, established by the Secretary, relating to the maximum ratio of enrollees under this title to full-time-equivalent primary care providers available to serve such enrollees and to maximum travel time for such enrollees to access such providers. The Secretary may permit such a maximum ratio to vary depending on the area and population served. Such standards shall be based on standards commonly applied in the commercial market, commonly used in accreditation of managed care organizations, and standards used in the approval of waiver applications under section 1115, and shall be consistent with the requirements under section 1876(c)(4)(A).

''(b) OBSTETRICAL AND GYNECOLOGICAL CARE.—

''(1) IN GENERAL.—A managed care entity may not require prior authorization by the individual's primary care provider or otherwise restrict the individual's access to gynecological and obstetrical care provided by a participating provider who specializes in obstetrics and gynecology to the extent such care is otherwise covered, and may treat the ordering of other obstetrical and gynecological care by such a participating provider as the prior authorization of the primary care provider with respect to such care under the coverage.

''(2) CONSTRUCTION.—Nothing in paragraph (1)(B)(ii) shall waive any requirements of coverage relating to medical necessity or appropriateness with respect to coverage of gynecological care so ordered.

''(c) SPECIALTY CARE.—

''(1) REFERRAL TO SPECIALTY CARE FOR ENROLLEES REQUIRING TREATMENT BY SPECIALISTS.—

''(A) IN GENERAL.—In the case of an enrollee under a managed care entity and who has a condition or disease of sufficient seriousness and complexity to require treatment by a specialist, the entity shall make or provide for a referral to a specialist who is available and accessible to provide the treatment for such condition or disease.

''(B) SPECIALIST DEFINED.—For purposes of this subsection, the term 'specialist' means, with respect to a condition, a health care practitioner, facility, or center (such as a center of excellence) that has adequate expertise through appropriate training and experience (including, in the case of a child, an appropriate pediatric specialist) to provide high quality care in treating the condition.

''(C) CARE UNDER REFERRAL.—Care provided pursuant to such referral under subparagraph (A) shall be—

''(i) pursuant to a treatment plan (if any) developed by the specialist and approved by the entity, in consultation with the designated primary care provider or specialist and the enrollee (or the enrollee's designee), and

''(ii) in accordance with applicable quality assurance and utilization review standards of the entity.

Nothing in this subsection shall be construed as preventing such a treatment plan for an enrollee from requiring a specialist to provide the primary care provider with regular updates on the specialty care provided, as well as all necessary medical information.

''(D) REFERRALS TO PARTICIPATING PROVIDERS.—An entity is not required under subparagraph (A) to provide for a referral to a specialist that is not a participating provider, unless the entity does not have an appropriate specialist that is available and accessible to treat the enrollee's condition and that is a participating provider with respect to such treatment.

''(E) TREATMENT OF NONPARTICIPATING PROVIDERS.—If an entity refers an enrollee to a nonparticipating specialist, services provided pursuant to the approved treatment plan shall be provided at no additional cost to the enrollee beyond what the enrollee would otherwise pay for services received by such a specialist that is a participating provider.

''(2) SPECIALISTS AS PRIMARY CARE PROVIDERS.—

''(A) IN GENERAL.—A managed care entity shall have a procedure by which a new enrollee upon enrollment, or an enrollee upon diagnosis, with an ongoing special condition (as defined in subparagraph (C)) may receive a referral to a specialist for such condition who shall be responsible for and capable of providing and coordinating the enrollee's primary and specialty care. If such an enrollee's care would most appropriately be coordinated by such a specialist, the entity shall refer the enrollee to such specialist.

''(B) TREATMENT AS PRIMARY CARE PROVIDER.—Such specialist shall be permitted to treat the enrollee without a referral from the enrollee's primary care provider and may authorize such referrals, procedures, tests, and other medical services as the enrollee's primary care provider would otherwise be permitted to provide or authorize, subject to the terms of the treatment plan (referred to in paragraph (1)(C)(i)).

''(C) ONGOING SPECIAL CONDITION DEFINED.—In this paragraph, the term 'special condition' means a physical and mental condition or disease that—

''(i) is life-threatening, degenerative, or disabling, and

''(ii) requires specialized medical care over a prolonged period of time.

''(D) TERMS OF REFERRAL.—The provisions of subparagraphs (C) through (E) of paragraph (1) shall apply with respect to referrals under subparagraph (A) of this paragraph in the same manner as they apply to referrals under paragraph (1)(A).

''(3) STANDING REFERRALS.—

''(A) IN GENERAL.—A managed care entity shall have a procedure by which an enrollee who has a condition that requires ongoing care from a specialist may receive a standing referral to such specialist for treatment of such condition. If the issuer, or the primary care provider in consultation with the medical director of the entity and the specialist (if any), determines that such a standing referral is appropriate, the entity shall make such a referral to such a specialist.

''(B) TERMS OF REFERRAL.—The provisions of subparagraphs (C) through (E) of paragraph (1) shall apply with respect to referrals under subparagraph (A) of this paragraph in the same manner as they apply to referrals under paragraph (1)(A).

''(d) TIMELY DELIVERY OF SERVICES.—Each managed care entity shall respond to requests from enrollees for the delivery of medical assistance in a manner which—

''(1) makes such assistance—

''(A) available and accessible to each such individual, within the area served by the entity, with reasonable promptness and in a manner which assures continuity; and

''(B) when medically necessary, available and accessible 24 hours a day and 7 days a week; and

''(2) with respect to assistance provided to such an individual other than through the entity, or without prior authorization, in the case of a primary care case management provider, provides for reimbursement to the individual (if applicable under the contract between the State and the entity) if—

''(A) the services were medically necessary and immediately required because of an unforeseen illness, injury, or condition and meet the requirements of section 1943; and

''(B) it was not reasonable given the circumstances to obtain the services through the entity, or, in the case of a primary care case management provider, with prior authorization.

''(e) INTERNAL GRIEVANCE PROCEDURE.—Each medicaid managed care organization shall establish an internal grievance procedure under which an enrollee who is eligible for medical assistance under the State plan under this title, or a provider on behalf of such an enrollee, may challenge the denial of coverage of or payment for such assistance.

''(f) INFORMATION ON BENEFIT CARVE OUTS.—Each managed care entity shall inform each enrollee, in a written and prominent manner, of any benefits to which the enrollee may be entitled to medical assistance under this title but which are not made available to the enrollee through the entity. Such information shall include information on where and how such enrollees may access benefits not made available to the enrollee through the entity.

''(g) DUE PROCESS REQUIREMENTS FOR MANAGED CARE ENTITIES.—

''(1) DENIAL OF OR UNREASONABLE DELAY IN DETERMINING COVERAGE AS GROUNDS FOR HEARING.—If a managed care entity (or entity acting an agreement with a managed care entity)—

''(A) denies coverage of or payment for medical assistance with respect to an enrollee who is eligible for such assistance under the State plan under this title; or

''(B) fails to make any eligibility or coverage determination sought by an enrollee or, in the case of a medicaid managed care organization, by a participating health care provider or enrollee, in a timely manner, depending upon the urgency of the situation,

the enrollee or the health care provider furnishing such assistance to the enrollee (as applicable) may obtain a fair hearing before, and shall be provided a timely decision by, the State agency administering the State plan under this title in accordance with section 1902(a)(3). Such decisions shall be rendered as soon as possible in accordance with the medical exigencies of the cases, and in no event later than 72 hours in the case of hearings on decisions regarding urgent care and 5 days in the case of all other hearings.

''(2) COMPLETION OF INTERNAL GRIEVANCE PROCEDURE.—Nothing in this subsection shall require completion of an internal grievance procedure if the procedure does not provide for timely review of health needs considered by the enrollee's health care provider to be of an urgent nature or is not otherwise consistent with the requirements for such procedures under section 1876(c).

''(h) DEMONSTRATION OF ADEQUATE CAPACITY AND SERVICES.—

''(1) IN GENERAL.—Subject to paragraph (3), each medicaid managed care organization shall provide the State and the Secretary with adequate assurances (as determined by the Secretary) that the organization, with respect to a service area—

''(A) has the capacity to serve the expected enrollment in such service area;

''(B) offers an appropriate range of services for the population expected to be enrolled in such service area, including transportation services and translation services consisting of the principal languages spoken in the service area;

''(C) maintains a sufficient number, mix, and geographic distribution of providers of services included in the contract with the State to ensure that services are available to individuals receiving medical assistance and enrolled in the organization to the same extent that such services are available to individuals enrolled in the organization who are not recipients of medical assistance under the State plan under this title;

''(D) maintains extended hours of operation with respect to primary care services that are beyond those maintained during a normal business day;

''(E) provides preventive and primary care services in locations that are readily accessible to members of the community;

''(F) provides information concerning educational, social, health, and nutritional services offered by other programs for which enrollees may be eligible; and

''(G) complies with such other requirements relating to access to care as the Secretary or the State may impose.

''(2) PROOF OF ADEQUATE PRIMARY CARE CAPACITY AND SERVICES.—Subject to paragraph (3), a medicaid managed care organization that contracts with a reasonable number of primary care providers (as determined by the Secretary) and whose primary care membership includes a reasonable number (as so determined) of the following providers will be deemed to have satisfied the requirements of paragraph (1):

''(A) Rural health clinics, as defined in section 1905(l)(1).

''(B) Federally-qualified health centers, as defined in section 1905(l)(2)(B).

''(C) Clinics which are eligible to receive payment for services provided under title X of the Public Health Service Act.

''(3) SUFFICIENT PROVIDERS OF SPECIALIZED SERVICES.—Notwithstanding paragraphs (1) and (2), a medicaid managed care organization may not be considered to have satisfied the requirements of paragraph (1) if the organization does not have a sufficient number (as determined by the Secretary) of providers of specialized services, including perinatal and pediatric specialty care, to ensure that such services are available and accessible.

''(i) COMPLIANCE WITH CERTAIN MATERNITY AND MENTAL HEALTH REQUIREMENTS.—Each medicaid managed care organization shall comply with the requirements of subpart 2 of part A of title XXVII of the Public Health Service Act insofar as such requirements apply with respect to a health insurance issuer that offers group health insurance coverage.

''(j) TREATMENT OF CHILDREN WITH SPECIAL HEALTH CARE NEEDS.—

''(1) IN GENERAL.—In the case of an enrollee of a managed care entity who is a child described in section 1941(e)(1) or who has special health care needs (as defined in paragraph (3))—

''(A) if any medical assistance specified in the contract with the State is identified in a treatment plan prepared for the enrollee by a program described in subsection (c)(1) or paragraph (3), the managed care entity shall provide (or arrange to be provided) such assistance in accordance with the treatment plan either—

''(i) by referring the enrollee to a pediatric health care provider who is trained and experienced in the provision of such assistance and who has a contract with the managed care entity to provide such assistance; or

''(ii) if appropriate services are not available through the managed care entity, permitting such enrollee to seek appropriate specialty services from pediatric health care providers outside of or apart from the managed care entity; and

''(B) the managed care entity shall require each health care provider with whom the managed care entity has entered into an agreement to provide medical assistance to enrollees to furnish the medical assistance specified in such enrollee's treatment plan to the extent the health care provider is able to carry out such treatment plan.

''(2) PRIOR AUTHORIZATION.—An enrollee referred for treatment under paragraph (1)(A)(i), or permitted to seek treatment outside of or apart from the managed care entity under paragraph (1)(A)(ii) shall be deemed to have obtained any prior authorization required by the entity.

''(3) CHILD WITH SPECIAL HEALTH CARE NEEDS.—For purposes of paragraph (1), a child has special health care needs if the child is receiving services under—

''(A) a program administered under part B or part H of the Individuals with Disabilities Education Act; or

''(B) any other program for children with special health care needs identified by the Secretary.

''SEC. 1943. BENEFICIARY ACCESS TO EMERGENCY CARE.

''(a) PROHIBITION OF CERTAIN RESTRICTIONS ON COVERAGE OF EMERGENCY SERVICES.—

''(1) IN GENERAL.—If a managed care entity provides any benefits under a State plan with respect to emergency services (as defined in paragraph (2)(B)), the entity shall cover emergency services furnished to an enrollee—

''(A) without the need for any prior authorization determination,

''(B) subject to paragraph (3), whether or not the physician or provider furnishing such services is a participating physician or provider with respect to such services, and

''(C) subject to paragraph (3), without regard to any other term or condition of such coverage (other than an exclusion of benefits).

''(2) EMERGENCY SERVICES; EMERGENCY MEDICAL CONDITION.—For purposes of this section—

''(A) EMERGENCY MEDICAL CONDITION BASED ON PRUDENT LAYPERSON.—The term 'emergency medical condition' means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in—

''(i) placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy,

''(ii) serious impairment to bodily functions, or

''(iii) serious dysfunction of any bodily organ or part.

''(B) EMERGENCY SERVICES.—The term 'emergency services' means—

''(i) a medical screening examination (as required under section 1867) that is within the capability of the emergency department of a hospital, including ancillary services routinely available to the emergency department, to evaluate an emergency medical condition (as defined in subparagraph (A)), and

''(ii) within the capabilities of the staff and facilities available at the hospital, such further medical examination and treatment as

are required under section 1867 to stabilize the patient.

''(C) TRAUMA AND BURN CENTERS.—The provisions of clause (ii) of subparagraph (B) apply to a trauma or burn center, in a hospital, that—

''(i) is designated by the State, a regional authority of the State, or by the designee of the State, or

''(ii) is in a State that has not made such designations and meets medically recognized national standards.

''(3) APPLICATION OF NETWORK RESTRICTION PERMITTED IN CERTAIN CASES.—

''(A) IN GENERAL.—Except as provided in subparagraph (B), if a managed care entity in relation to benefits provided under this title denies, limits, or otherwise differentiates in benefits or payment for benefits other than emergency services on the basis that the physician or provider of such services is a nonparticipating physician or provider, the entity may deny, limit, or differentiate in coverage or payment for emergency services on such basis.

''(B) NETWORK RESTRICTIONS NOT PERMITTED IN CERTAIN EXCEPTIONAL CASES.—The denial or limitation of, or differentiation in, coverage or payment of benefits for emergency services under subparagraph (A) shall not apply in the following cases:

''(i) CIRCUMSTANCES BEYOND CONTROL OF ENROLLEE.—The enrollee is unable to go to a participating hospital for such services due to circumstances beyond the control of the enrollee (as determined consistent with guidelines and subparagraph (C)).

''(ii) LIKELIHOOD OF AN ADVERSE HEALTH CONSEQUENCE BASED ON LAYPERSON'S JUDGMENT.—A prudent layperson possessing an average knowledge of health and medicine could reasonably believe that, under the circumstances and consistent with guidelines, the time required to go to a participating hospital for such services could result in any of the adverse health consequences described in a clause of subsection (a)(2)(A).

''(iii) PHYSICIAN REFERRAL.—A participating physician or other person authorized by the plan refers the enrollee to an emergency department of a hospital and does not specify an emergency department of a hospital that is a participating hospital with respect to such services.

''(C) APPLICATION OF 'BEYOND CONTROL' STANDARDS.—For purposes of applying subparagraph (B)(i), receipt of emergency services from a nonparticipating hospital shall be treated under the guidelines as being 'due to circumstances beyond the control of the enrollee' if any of the following conditions are met:

''(i) UNCONSCIOUS.—The enrollee was unconscious or in an otherwise altered mental state at the time of initiation of the services.

''(ii) AMBULANCE DELIVERY.—The enrollee was transported by an ambulance or other emergency vehicle directed by a person other than the enrollee to the nonparticipating hospital in which the services were provided.

''(iii) NATURAL DISASTER.—A natural disaster or civil disturbance prevented the enrollee from presenting to a participating hospital for the provision of such services.

''(iv) NO GOOD FAITH EFFORT TO INFORM OF CHANGE IN PARTICIPATION DURING A CONTRACT YEAR.—The status of the hospital changed from a participating hospital to a nonparticipating hospital with respect to emergency services during a contract year and the entity failed to make a good faith effort to notify the enrollee involved of such change.

''(v) OTHER CONDITIONS.—There were other factors (such as those identified in guidelines) that prevented the enrollee from controlling selection of the hospital in which the services were provided.

''(b) ASSURING COORDINATED COVERAGE OF MAINTENANCE CARE AND POST-STABILIZATION CARE.—

''(1) IN GENERAL.—In the case of an individual who is enrolled with a managed care entity and who has received emergency services pursuant to a screening evaluation conducted (or supervised) by a treating physician at a hospital that is a nonparticipating provider with respect to emergency services, if—

''(A) pursuant to such evaluation, the physician identifies post-stabilization care (as defined in paragraph (3)(B)) that is required by the enrollee,

''(B) the coverage through the entity under this title provides benefits with respect to the care so identified and the coverage requires (but for this subsection) an affirmative prior authorization determination as a condition of coverage of such care, and

''(C) the treating physician (or another individual acting on behalf of such physician) initiates, not later than 30 minutes after the time the treating physician determines that the condition of the enrollee is stabilized, a good faith effort to contact a physician or other person authorized by the entity (by telephone or other means) to obtain an affirmative prior authorization determination with respect to the care,

then, without regard to terms and conditions specified in paragraph (2) the entity shall cover maintenance care (as defined in paragraph (3)(A)) furnished to the enrollee during the period specified in paragraph (4) and shall cover post-stabilization care furnished to the enrollee during the period beginning under paragraph (5) and ending under paragraph (6).

''(2) TERMS AND CONDITIONS WAIVED.—The terms and conditions (of coverage) described in this paragraph that are waived under paragraph (1) are as follows:

''(A) The need for any prior authorization determination.

''(B) Any limitation on coverage based on whether or not the physician or provider furnishing the care is a participating physician or provider with respect to such care.

''(C) Any other term or condition of the coverage (other than an exclusion of benefits and other than a requirement relating to medical necessity for coverage of benefits).

''(3) MAINTENANCE CARE AND POST-STABILIZATION CARE DEFINED.—In this subsection:

''(A) MAINTENANCE CARE.—The term 'maintenance care' means, with respect to an individual who is stabilized after provision of emergency services, medically necessary items and services (other than emergency services) that are required by the individual to ensure that the individual remains stabilized during the period described in paragraph (4).

''(B) POST-STABILIZATION CARE.—The term 'post-stabilization care' means, with respect to an individual who is determined to be stable pursuant to a medical screening examination or who is stabilized after provision of emergency services, medically necessary items and services (other than emergency services and other than maintenance care) that are required by the individual.

''(4) PERIOD OF REQUIRED COVERAGE OF MAINTENANCE CARE.—The period of required coverage of maintenance care of an individual under this subsection begins at the time of the request (or the initiation of the good faith effort to make the request) under paragraph (1)(C) and ends when—

''(A) the individual is discharged from the hospital;

''(B) a physician (designated by the managed care entity involved) and with privileges at the hospital involved arrives at the emergency department of the hospital and assumes responsibility with respect to the treatment of the individual; or

''(C) the treating physician and the entity agree to another arrangement with respect to the care of the individual.

''(5) WHEN POST-STABILIZATION CARE REQUIRED TO BE COVERED.—

''(A) WHEN TREATING PHYSICIAN UNABLE TO COMMUNICATE REQUEST.—If the treating physician or other individual makes the good faith effort to request authorization under paragraph (1)(C) but is unable to communicate the request directly with an authorized person referred to in such paragraph within 30 minutes after the time of initiating such effort, then post-stabilization care is required to be covered under this subsection beginning at the end of such 30-minute period.

''(B) WHEN ABLE TO COMMUNICATE REQUEST, AND NO TIMELY RESPONSE.—

''(i) IN GENERAL.—If the treating physician or other individual under paragraph (1)(C) is able to communicate the request within the 30-minute period described in subparagraph (A), the post-stabilization care requested is required to be covered under this subsection beginning 30 minutes after the time when the entity receives the request unless a person authorized by the entity involved communicates (or makes a good faith effort to communicate) a denial of the request for the prior authorization determination within 30 minutes of the time when the entity receives the request and the treating physician does not request under clause (ii) to communicate directly with an authorized physician concerning the denial.

''(ii) REQUEST FOR DIRECT PHYSICIAN-TO-PHYSICIAN COMMUNICATION CONCERNING DENIAL.—If a denial of a request is communicated under clause (i), the treating physician may request to communicate respecting the denial directly with a physician who is authorized by the entity to deny or affirm such a denial.

''(C) WHEN NO TIMELY RESPONSE TO REQUEST FOR PHYSICIAN-TO-PHYSICIAN COMMUNICATION.—If a request for physician-to-physician communication is made under subparagraph (B)(ii), the post-stabilization care requested is required to be covered under this subsection beginning 30 minutes after the time when the entity receives the request from a treating physician unless a physician, who is authorized by the entity to reverse or affirm the initial denial of the care, communicates (or makes a good faith effort to communicate) directly with the treating physician within such 30-minute period.

''(D) DISAGREEMENTS OVER POST-STABILIZATION CARE.—If, after a direct physician-to-physician communication under subparagraph (C), the denial of the request for the post-stabilization care is not reversed and the treating physician communicates to the entity involved a disagreement with such decision, the post-stabilization care requested is required to be covered under this subsection beginning as follows:

''(i) DELAY TO ALLOW FOR PROMPT ARRIVAL OF PHYSICIAN ASSUMING RESPONSIBILITY.—If the issuer communicates that a physician (designated by the entity) with privileges at the hospital involved will arrive promptly (as determined under guidelines) at the emergency department of the hospital in order to assume responsibility with respect to the treatment of the enrollee involved, the required coverage of the post-stabilization care begins after the passage of such time period as would allow the prompt arrival of such a physician.

''(ii) OTHER CASES.—If the entity does not so communicate, the required coverage of

the post-stabilization care begins immediately.

''(6) NO REQUIREMENT OF COVERAGE OF POST-STABILIZATION CARE IF ALTERNATE PLAN OF TREATMENT.—

''(A) IN GENERAL.—Coverage of post-stabilization care is not required under this subsection with respect to an individual when—

''(i) subject to subparagraph (B), a physician (designated by the entity involved) and with privileges at the hospital involved arrives at the emergency department of the hospital and assumes responsibility with respect to the treatment of the individual; or

''(ii) the treating physician and the entity agree to another arrangement with respect to the post-stabilization care (such as an appropriate transfer of the individual involved to another facility or an appointment for timely followup treatment for the individual).

''(B) SPECIAL RULE WHERE ONCE CARE INITIATED.—Required coverage of requested post-stabilization care shall not end by reason of subparagraph (A)(i) during an episode of care (as determined by guidelines) if the treating physician initiated such care (consistent with a previous paragraph) before the arrival of a physician described in such subparagraph.

''(7) CONSTRUCTION.—Nothing in this subsection shall be construed as—

''(A) preventing a managed care entity from authorizing coverage of maintenance care or post-stabilization care in advance or at any time; or

''(B) preventing a treating physician or other individual described in paragraph (1)(C) and such an entity from agreeing to modify any of the time periods specified in paragraphs (5) as it relates to cases involving such persons.

''(c) INFORMATION ON ACCESS TO EMERGENCY SERVICES.—A managed care entity, to the extent the entity offers health insurance coverage, shall provide education to enrollees on—

''(1) coverage of emergency services (as defined in subsection (a)(2)(B)) by the entity in accordance with the provisions of this section,

''(2) the appropriate use of emergency services, including use of the 911 telephone system or its local equivalent,

''(3) any cost sharing applicable to emergency services,

''(4) the process and procedures of the plan for obtaining emergency services, and

''(5) the locations of—

''(A) emergency departments, and

''(B) other settings,

in which participating physicians and hospitals provide emergency services and post-stabilization care.

''(d) GENERAL DEFINITIONS.—For purposes of this section:

''(1) COST SHARING.—The term 'cost sharing' means any deductible, coinsurance amount, copayment or other out-of-pocket payment (other than premiums or enrollment fees) that a managed care entity issuer imposes on enrollees with respect to the coverage of benefits.

''(2) GOOD FAITH EFFORT.—The term 'good faith effort' has the meaning given such term in guidelines and requires such appropriate documentation as is specified under such guidelines.

''(3) GUIDELINES.—The term 'guidelines' means guidelines established by the Secretary after consultation with an advisory panel that includes individuals representing emergency physicians, managed care entities, including at least one health maintenance organization, hospitals, employers, the States, and consumers.

''(4) PRIOR AUTHORIZATION DETERMINATION.—The term 'prior authorization determination' means, with respect to items and services for which coverage may be provided by a managed are entity, a determination (before the provision of the items and services and as a condition of coverage of the items and services under the coverage) of whether or not such items and services will be covered under the coverage.

''(5) STABILIZE.—The term 'to stabilize' means, with respect to an emergency medical condition, to provide (in complying with section 1867 of the Social Security Act) such medical treatment of the condition as may be necessary to assure, within reasonable medical probability, that no material deterioration of the condition is likely to result from or occur during the transfer of the individual from the facility.

''(6) STABILIZED.—The term 'stabilized' means, with respect to an emergency medical condition, that no material deterioration of the condition is likely, within reasonable medical probability, to result from or occur before an individual can be transferred from the facility, in compliance with the requirements of section 1867 of the Social Security Act.

''(7) TREATING PHYSICIAN.—The term 'treating physician' includes a treating health care professional who is licensed under State law to provide emergency services other than under the supervision of a physician.

"SEC. 1944. OTHER BENEFICIARY PROTECTIONS.

''(a) PROTECTING ENROLLEES AGAINST THE INSOLVENCY OF MANAGED CARE ENTITIES AND AGAINST THE FAILURE OF THE STATE TO PAY SUCH ENTITIES.—Each managed care entity shall provide that an individual eligible for medical assistance under the State plan under this title who is enrolled with the entity may not be held liable—

''(1) for the debts of the managed care entity, in the event of the medicaid managed care organization's insolvency;

''(2) for services provided to the individual—

''(A) in the event of the medicaid managed care organization failing to receive payment from the State for such services; or

''(B) in the event of a health care provider with a contractual or other arrangement with the medicaid managed care organization failing to receive payment from the State or the managed care entity for such services; or

''(3) for the debts of any health care provider with a contractual or other arrangement with the medicaid managed care organization to provide services to the individual, in the event of the insolvency of the health care provider.

''(b) PROTECTION OF BENEFICIARIES AGAINST BALANCE BILLING THROUGH SUBCONTRACTORS.—

''(1) IN GENERAL.—Any contract between a managed care entity that has an agreement with a State under this title and another entity under which the entity (or any other entity pursuant to the contract) provides directly or indirectly for the provision of services to beneficiaries under the agreement with the State shall include such provisions as the Secretary may require in order to assure that the entity complies with balance billing limitations and other requirements of this title (such as limitation on withholding of services) as they would apply to the managed care entity if such entity provided such services directly and not through a contract with another entity.

''(2) APPLICATION OF SANCTIONS FOR VIOLATIONS.—The provisions of section 1128A(b)(2)(B) and 1128B(d)(1) shall apply with respect to entities contracting directly or indirectly with a managed care entity (with a contract with a State under this title) for the provision of services to beneficiaries under such a contract in the same manner as such provisions would apply to the managed care entity if it provided such services directly and not through a contract with another entity.

"SEC. 1945. ASSURING QUALITY CARE.

''(a) EXTERNAL INDEPENDENT REVIEW OF MANAGED CARE ENTITY ACTIVITIES.—

''(1) REVIEW OF MEDICAID MANAGED CARE ORGANIZATION CONTRACT.—

''(A) IN GENERAL.—Except as provided in paragraph (2), each medicaid managed care organization shall be subject to an annual external independent review of the quality outcomes and timeliness of, and access to, the items and services specified in such organization's contract with the State under section 1941(a)(1)(B). Such review shall specifically evaluate the extent to which the medicaid managed care organization provides such services in a timely manner.

''(B) CONTENTS OF REVIEW.—An external independent review conducted under this subsection shall include—

''(i) a review of the entity's medical care, through sampling of medical records or other appropriate methods, for indications of quality of care and inappropriate utilization (including overutilization) and treatment,

''(ii) a review of enrollee inpatient and ambulatory data, through sampling of medical records or other appropriate methods, to determine trends in quality and appropriateness of care,

''(iii) notification of the entity and the State when the review under this paragraph indicates inappropriate care, treatment, or utilization of services (including overutilization), and

''(iv) other activities as prescribed by the Secretary or the State.

''(C) USE OF PROTOCOLS.—An external independent review conducted under this subsection on and after January 1, 1999, shall use protocols that have been developed, tested, and validated by the Secretary and that are at least as rigorous as those used by the National Committee on Quality Assurance as of the date of the enactment of this section.

''(D) AVAILABILITY OF RESULTS.—The results of each external independent review conducted under this paragraph shall be available to participating health care providers, enrollees, and potential enrollees of the medicaid managed care organization, except that the results may not be made available in a manner that discloses the identity of any individual patient.

''(2) DEEMED COMPLIANCE.—

''(A) MEDICARE ORGANIZATIONS.—The requirements of paragraph (1) shall not apply with respect to a medicaid managed care organization if the organization is an eligible organization with a contract in effect under section 1876.

''(B) PRIVATE ACCREDITATION.—

''(i) IN GENERAL.—The requirements of paragraph (1) shall not apply with respect to a medicaid managed care organization if —

''(I) the organization is accredited by an organization meeting the requirements described in subparagraph (C)); and

''(II) the standards and process under which the organization is accredited meet such requirements as are established under clause (ii), without regard to whether or not the time requirement of such clause is satisfied.

''(ii) STANDARDS AND PROCESS.—Not later than 180 days after the date of the enactment of this section, the Secretary shall specify requirements for the standards and process under which a medicaid managed care organization is accredited by an organization meeting the requirements of subparagraph (B).

''(C) ACCREDITING ORGANIZATION.—An accrediting organization meets the requirements of this subparagraph if the organization—

''(i) is a private, nonprofit organization;

''(ii) exists for the primary purpose of accrediting managed care organizations or health care providers; and

''(iii) is independent of health care providers or associations of health care providers.

''(3) REVIEW OF PRIMARY CARE CASE MANAGEMENT PROVIDER CONTRACT.—Each primary care case management provider shall be subject to an annual external independent review of the quality and timeliness of, and access to, the items and services specified in the contract entered into between the State and the primary care case management provider under section 1941(a)(1)(B).

''(4) USE OF VALIDATION SURVEYS.—The Secretary shall conduct surveys each year to validate external reviews of at least 5 percent of the number of managed care entities in the year. In conducting such surveys the Secretary shall use the same protocols as were used in preparing the external reviews. If an external review finds that an individual managed care entity meets applicable requirements, but the Secretary determines that the entity does not meet such requirements, the Secretary's determination as to the entity's noncompliance with such requirements is binding and supersedes that of the previous survey.

''(b) FEDERAL MONITORING RESPONSIBILITIES.—The Secretary shall review the external independent reviews conducted pursuant to subsection (a) and shall monitor the effectiveness of the State's monitoring and followup activities required under section 1942(b)(1). If the Secretary determines that a State's monitoring and followup activities are not adequate to ensure that the requirements of such section are met, the Secretary shall undertake appropriate followup activities to ensure that the State improves its monitoring and followup activities.

''(c) PROVIDING INFORMATION ON SERVICES.—

''(1) REQUIREMENTS FOR MEDICAID MANAGED CARE ORGANIZATIONS.—

''(A) INFORMATION TO THE STATE.—Each medicaid managed care organization shall provide to the State (at least at such frequency as the Secretary may require), complete and timely information concerning the following:

''(i) The services that the organization provides to (or arranges to be provided to) individuals eligible for medical assistance under the State plan under this title.

''(ii) The identity, locations, qualifications, and availability of participating health care providers.

''(iii) The rights and responsibilities of enrollees.

''(iv) The services provided by the organization which are subject to prior authorization by the organization as a condition of coverage (in accordance with subsection (d)).

''(v) The procedures available to an enrollee and a health care provider to appeal the failure of the organization to cover a service.

''(vi) The performance of the organization in serving individuals eligible for medical assistance under the State plan under this title.

Such information shall be provided in a form consistent with the reporting of similar information by eligible organizations under section 1876.

''(2) REQUIREMENTS FOR PRIMARY CARE CASE MANAGEMENT PROVIDERS.—Each primary care case management provider shall—

''(A) provide to the State (at least at such frequency as the Secretary may require), complete and timely information concerning the services that the primary care case management provider provides to (or arranges to be provided to) individuals eligible for medical assistance under the State plan under this title;

''(B) make available to enrollees and potential enrollees information concerning services available to the enrollee for which prior authorization by the primary care case management provider is required;

''(C) provide enrollees and potential enrollees information regarding all items and services that are available to enrollees under the contract between the State and the primary care case management provider that are covered either directly or through a method of referral and prior authorization; and

''(D) provide assurances that such entities and their professional personnel are licensed as required by State law and qualified to provide case management services, through methods such as ongoing monitoring of compliance with applicable requirements and providing information and technical assistance.

''(3) REQUIREMENTS FOR BOTH MEDICAID MANAGED CARE ORGANIZATIONS AND PRIMARY CARE CASE MANAGEMENT PROVIDERS.—Each managed care entity shall provide the State with aggregate encounter data for all items and services, including early and periodic screening, diagnostic, and treatment services under section 1905(r) furnished to individuals under 21 years of age. Any such data provided may be audited by the State and the Secretary.

''(d) CONDITIONS FOR PRIOR AUTHORIZATION.—Subject to section 1943, a managed care entity may require the approval of medical assistance for nonemergency services before the assistance is furnished to an enrollee only if the system providing for such approval provides that such decisions are made in a timely manner, depending upon the urgency of the situation.

''(e) PATIENT ENCOUNTER DATA.—Each medicaid managed care organization shall maintain sufficient patient encounter data to identify the health care provider who delivers services to patients and to otherwise enable the State plan to meet the requirements of section 1902(a)(27) and shall submit such data to the State or the Secretary upon request. The medicaid managed care organization shall incorporate such information in the maintenance of patient encounter data with respect to such health care provider.

''(f) INCENTIVES FOR HIGH QUALITY MANAGED CARE ENTITIES.—The Secretary and the State may establish a program to reward, through public recognition, incentive payments, or enrollment of additional individuals (or combinations of such rewards), managed care entities that provide the highest quality care to individuals eligible for medical assistance under the State plan under this title who are enrolled with such entities. For purposes of section 1903(a)(7), proper expenses incurred by a State in carrying out such a program shall be considered to be expenses necessary for the proper and efficient administration of the State plan under this title.

''SEC. 1946. PROTECTIONS FOR PROVIDERS.

''(a) INFORMATION TO HEALTH CARE PROVIDERS.—Each medicaid managed care organization shall upon request, make the information described in section 1945(c)(1)(A) available to participating health care providers.

''(b) TIMELINESS OF PAYMENT.—A medicaid managed care organization shall make payment to health care providers for items and services which are subject to the contract under section 1941(a)(1)(B) and which are furnished to individuals eligible for medical assistance under the State plan under this title who are enrolled with the entity on a timely basis consistent with section 1943 and under the claims payment procedures described in section 1902(a)(37)(A), unless the health care provider and the managed care entity agree to an alternate payment schedule.

''(c) APPLICATION OF MEDICARE PROHIBITION OF RESTRICTIONS ON PHYSICIANS' ADVICE AND COUNSEL TO ENROLLEES.—A managed care entity shall comply with the same prohibitions on any restrictions relating to physicians' advice and counsel to individuals as apply to eligible organizations under section 1876.

''(d) PHYSICIAN INCENTIVE PLANS.—Each medicaid managed care organization shall require that any physician incentive plan covering physicians who are participating in the medicaid managed care organization shall meet the requirements of section 1876(i)(8).

''(e) WRITTEN PROVIDER PARTICIPATION AGREEMENTS FOR CERTAIN PROVIDERS.—Each medicaid managed care organization that enters into a written provider participation agreement with a provider described in section 1942(h)(2) shall—

''(1) include terms and conditions that are no more restrictive than the terms and conditions that the medicaid managed care organization includes in its agreements with other participating providers with respect to—

''(A) the scope of covered services for which payment is made to the provider;

''(B) the assignment of enrollees by the organization to the provider;

''(C) the limitation on financial risk or availability of financial incentives to the provider;

''(D) accessibility of care;

''(E) professional credentialing and recredentialing;

''(F) licensure;

''(G) quality and utilization management;

''(I) confidentiality of patient records;

''(J) grievance procedures; and

''(K) indemnification arrangements between the organizations and providers; and

''(2) provide for payment to the provider on a basis that is comparable to the basis on which other providers are paid.

''(f) PAYMENTS TO FEDERALLY-QUALIFIED HEALTH CENTERS.—Each medicaid managed care organization that has a contract under this title with respect to the provision of services of a federally qualified health center shall provide, at the election of such center, that the organization shall provide payments to such a center for services described in 1905(a)(2)(C) at the rates of payment specified in section 1902(a)(13)(E).

''SEC. 1947. ASSURING ADEQUACY OF PAYMENTS TO MEDICAID MANAGED CARE ORGANIZATIONS AND ENTITIES.

''(a) ADEQUATE RATES.—As a condition of approval of a State plan under this title, a State shall find, determine, and make assurances satisfactory to the Secretary that—

''(1) the rates it pays medicaid managed care organizations for individuals eligible under the State plan are reasonable and adequate to assure access to services meeting professionally recognized quality standards, taking into account—

''(A) the items and services to which the rate applies,

''(B) the eligible population, and

''(C) the rate the State pays providers for such items and services;

''(2) the methodology used to adjust the rate adequately reflects the varying risks associated with individuals actually enrolling in each medicaid managed care organization; and

''(3) it will provide for an annual review of the actuarial soundness of rates by an independent actuary selected by the Secretary and for a copy of the actuary's report on

each such review to be transmitted to the State and the Secretary and made available to the public.

''(b) ANNUAL REPORTS.—As a condition of approval of a State plan under this title, a State shall report to the Secretary, at least annually, on the rates the States pays to medicaid managed care organizations.

''SEC. 1948. FRAUD AND ABUSE.

''(a) PROVISIONS APPLICABLE TO MANAGED CARE ENTITIES.—

''(1) PROHIBITING AFFILIATIONS WITH INDIVIDUALS DEBARRED BY FEDERAL AGENCIES.—

''(A) IN GENERAL.—A managed care entity may not knowingly—

''(i) have a person described in subparagraph (C) as a director, officer, partner, or person with beneficial ownership of more than 5 percent of the organization's equity; or

''(ii) have an employment, consulting, or other agreement with a person described in such subparagraph for the provision of items and services that are significant and material to the organization's obligations under its contract with the State.

''(B) EFFECT OF NONCOMPLIANCE.—If a State finds that a managed care entity is not in compliance with clause (i) or (ii) of subparagraph (A), the State—

''(i) shall notify the Secretary of such noncompliance;

''(ii) may continue an existing agreement with the entity unless the Secretary (in consultation with the Inspector General of the Department of Health and Human Services) directs otherwise; and

''(iii) may not renew or otherwise extend the duration of an existing agreement with the entity unless the Secretary (in consultation with the Inspector General of the Department of Health and Human Services) provides to the State and to the Congress a written statement describing compelling reasons that exist for renewing or extending the agreement.

''(C) PERSONS DESCRIBED.—A person is described in this subparagraph if such person—

''(i) is debarred, suspended, or otherwise excluded from participating in procurement activities under the Federal acquisition regulation or from participating in nonprocurement activities under regulations issued pursuant to Executive Order 12549; or

''(ii) is an affiliate (within the meaning of the Federal acquisition regulation) of a person described in subparagraph (A).

''(2) RESTRICTIONS ON MARKETING.—

''(A) DISTRIBUTION OF MATERIALS.—

''(i) IN GENERAL.—A managed care entity may not distribute directly or through any agent or independent contractor marketing materials within any State—

''(I) without the prior approval of the State; and

''(II) that contain false or materially misleading information.

''(ii) CONSULTATION IN REVIEW OF MARKET MATERIALS.—In the process of reviewing and approving such materials, the State shall provide for consultation with a medical care advisory committee.

''(iii) PROHIBITION.—The State may not enter into or renew a contract with a managed care entity for the provision of services to individuals enrolled under the State plan under this title if the State determines that the entity distributed directly or through any agent or independent contractor marketing materials in violation of clause (i).

''(B) SERVICE MARKET.—A managed care entity shall distribute marketing materials to the entire service area of such entity.

''(C) PROHIBITION OF TIE-INS.—A managed care entity, or any agency of such entity, may not seek to influence an individual's enrollment with the entity in conjunction with the sale of any other insurance.

''(D) PROHIBITING MARKETING FRAUD.—Each managed care entity shall comply with such procedures and conditions as the Secretary prescribes in order to ensure that, before an individual is enrolled with the entity, the individual is provided accurate oral and written and sufficient information to make an informed decision whether or not to enroll.

''(E) PROHIBITION OF COLD CALL MARKETING.—Each managed care entity shall not, directly or indirectly, conduct door-to-door, telephonic, or other 'cold call' marketing of enrollment under this title.

''(b) PROVISIONS APPLICABLE ONLY TO MEDICAID MANAGED CARE ORGANIZATIONS.—

''(1) STATE CONFLICT-OF-INTEREST SAFEGUARDS IN MEDICAID RISK CONTRACTING.—A medicaid managed care organization may not enter into a contract with any State under section 1941(a)(1)(B) unless the State has in effect conflict-of-interest safeguards with respect to officers and employees of the State with responsibilities relating to contracts with such organizations or to the default enrollment process described in section 1941(a)(1)(F) that are at least as effective as the Federal safeguards provided under section 27 of the Office of Federal Procurement Policy Act (41 U.S.C. 423), against conflicts of interest that apply with respect to Federal procurement officials with comparable responsibilities with respect to such contracts.

''(2) REQUIRING DISCLOSURE OF FINANCIAL INFORMATION.—In addition to any requirements applicable under section 1902(a)(27) or 1902(a)(35), a medicaid managed care organization shall—

''(A) report to the State (and to the Secretary upon the Secretary's request) such financial information as the State or the Secretary may require to demonstrate that—

''(i) the organization has the ability to bear the risk of potential financial losses and otherwise has a fiscally sound operation;

''(ii) the organization uses the funds paid to it by the State and the Secretary for activities consistent with the requirements of this title and the contract between the State and organization; and

''(iii) the organization does not place an individual physician, physician group, or other health care provider at substantial risk (as determined by the Secretary) for services not provided by such physician, group, or health care provider, by providing adequate protection (as determined by the Secretary) to limit the liability of such physician, group, or health care provider, through measures such as stop loss insurance or appropriate risk corridors;

''(B) agree that the Secretary and the State (or any person or organization designated by either) shall have the right to audit and inspect any books and records of the organization (and of any subcontractor) relating to the information reported pursuant to subparagraph (A) and any information required to be furnished under section paragraphs (27) or (35) of section 1902(a);

''(C) make available to the Secretary and the State a description of each transaction described in subparagraphs (A) through (C) of section 1318(a)(3) of the Public Health Service Act between the organization and a party in interest (as defined in section 1318(b) of such Act);

''(D) agree to make available to its enrollees upon reasonable request—

''(i) the information reported pursuant to subparagraph (A); and

''(ii) the information required to be disclosed under sections 1124 and 1126;

''(E) comply with subsections (a) and (c) of section 1318 of the Public Health Service Act (relating to disclosure of certain financial information) and with the requirement of section 1301(c)(8) of such Act (relating to liability arrangements to protect members); and

''(F) notify the Secretary of loans and other special financial arrangements which are made between the organization and subcontractors, affiliates, and related parties.

Each State is required to conduct audits on the books and records of at least 1 percent of the number of medicaid managed care organizations operating in the State.

''(3) ADEQUATE PROVISION AGAINST RISK OF INSOLVENCY.—

''(A) ESTABLISHMENT OF STANDARDS.—The Secretary shall establish standards, including appropriate equity standards, under which each medicaid managed care organization shall make adequate provision against the risk of insolvency.

''(B) CONSIDERATION OF OTHER STANDARDS.—In establishing the standards described in subparagraph (A), the Secretary shall consider solvency standards applicable to eligible organizations with a risk-sharing contract under section 1876.

''(C) MODEL CONTRACT ON SOLVENCY.—At the earliest practicable time after the date of enactment of this section, the Secretary shall issue guidelines concerning solvency standards for risk contracting entities and subcontractors of such risk contracting entities. Such guidelines shall take into account characteristics that may differ among risk contracting entities including whether such an entity is at risk for inpatient hospital services.

''(4) REQUIRING REPORT ON NET EARNINGS AND ADDITIONAL BENEFITS.—Each medicaid managed care organization shall submit a report to the State and the Secretary not later than 12 months after the close of a contract year containing the most recent audited financial statement of the organization's net earnings and consistent with generally accepted accounting principles.

''(c) DISCLOSURE OF OWNERSHIP AND RELATED INFORMATION.—Each medicaid managed care organization shall provide for disclosure of information in accordance with section 1124.

''(d) DISCLOSURE OF TRANSACTION INFORMATION.—

''(1) IN GENERAL.—Each medicaid managed care organization which is not a qualified health maintenance organization (as defined in section 1310(d) of the Public Health Service Act) shall report to the State and, upon request, to the Secretary, the Inspector General of the Department of Health and Human Services, and the Comptroller General a description of transactions between the organization and a party in interest (as defined in section 1318(b) of such Act), including the following transactions:

''(A) Any sale or exchange, or leasing of any property between the organization and such a party.

''(B) Any furnishing for consideration of goods, services (including management services), or facilities between the organization and such a party, but not including salaries paid to employees for services provided in the normal course of their employment.

''(C) Any lending of money or other extension of credit between the organization and such a party.

The State or Secretary may require that information reported respecting a organization which controls, or is controlled by, or is under common control with, another entity be in the form of a consolidated financial statement for the organization and such entity.

''(2) Each such organization shall make the information reported pursuant to paragraph (1) available to its enrollees upon reasonable request.

''(e) CONTRACT OVERSIGHT.—

''(1) IN GENERAL.—The Secretary must provide prior review and approval for contracts under this part with a medicaid managed care organization providing for expenditures under this title in excess of $1,000,000.

''(2) INSPECTOR GENERAL REVIEW.—As part of such approval process, the Inspector General in the Department of Health and Human Services, effective October 1, 1997, shall make a determination (to the extent practicable) as to whether persons with an ownership interest (as defined in section 1124(a)(3)) or an officer, director, agent, or managing employee (as defined in section 1126(b)) of the organization are or have been described in subsection (a)(1)(C) based on a ground relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct or obstruction of an investigation.

''(f) LIMITATION ON AVAILABILITY OF FFP FOR USE OF ENROLLMENT BROKERS.—Amounts expended by a State for the use an enrollment broker in marketing managed care entities to eligible individuals under this title shall be considered, for purposes of section 1903(a)(7), to be necessary for the proper and efficient administration of the State plan but only if the following conditions are met with respect to the broker:

''(1) The broker is independent of any such entity and of any health care providers (whether or not any such provider participates in the State plan under this title) that provide coverage of services in the same State in which the broker is conducting enrollment activities.

''(2) No person who is an owner, employee, consultant, or has a contract with the broker either has any direct or indirect financial interest with such an entity or health care provider or has been excluded from participation in the program under this title or title XVIII or debarred by any Federal agency, or subject to a civil money penalty under this Act.

''(g) USE OF UNIQUE PHYSICIAN IDENTIFIER FOR PARTICIPATING PHYSICIANS.—Each medicaid managed care organization shall require each physician providing services to enrollees eligible for medical assistance under the State plan under this title to have a unique identifier in accordance with the system established under section 1173(b).

''(h) SECRETARIAL RECOVERY OF FFP FOR CAPITATION PAYMENTS FOR INSOLVENT MANAGED CARE ENTITIES.—The Secretary shall provide for the recovery and offset against amount owed a State under section 1903(a)(1) an amount equal to the amounts paid to the State, for medical assistance provided under such section for expenditures for capitation payments to a managed care entity that becomes insolvent, for services contracted for with, but not provided by, such organization.

''SEC. 1949. SANCTIONS FOR NONCOMPLIANCE BY MANAGED CARE ENTITIES.

''(a) USE OF INTERMEDIATE SANCTIONS BY THE STATE TO ENFORCE REQUIREMENTS.—Each State shall establish intermediate sanctions, which may include any of the types described in subsection (b) other than the termination of a contract with a managed care entity, which the State may impose against a managed care entity with a contract under section 1941(a)(1)(B) if the entity —

''(1) fails substantially to provide medically necessary items and services that are required (under law or under such entity's contract with the State) to be provided to an enrollee covered under the contract;

''(2) imposes premiums or charges on enrollees in excess of the premiums or charges permitted under this title;

''(3) acts to discriminate among enrollees on the basis of their health status or requirements for health care services, including expulsion or refusal to reenroll an individual, except as permitted by this part, or engaging in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment with the entity by eligible individuals whose medical condition or history indicates a need for substantial future medical services;

''(4) misrepresents or falsifies information that is furnished—

''(A) to the Secretary or the State under this part; or

''(B) to an enrollee, potential enrollee, or a health care provider under such sections; or

''(5) fails to comply with the requirements of section 1876(i)(8) or this part.

''(b) INTERMEDIATE SANCTIONS.—The sanctions described in this subsection are as follows:

''(1) Civil money penalties as follows:

''(A) Except as provided in subparagraph (B), (C), or (D), not more than $25,000 for each determination under subsection (a).

''(B) With respect to a determination under paragraph (3) or (4)(A) of subsection (a), not more than $100,000 for each such determination.

''(C) With respect to a determination under subsection (a)(2), double the excess amount charged in violation of such subsection (and the excess amount charged shall be deducted from the penalty and returned to the individual concerned).

''(D) Subject to subparagraph (B), with respect to a determination under subsection (a)(3), $15,000 for each individual not enrolled as a result of a practice described in such subsection.

''(2) The appointment of temporary management to oversee the operation of the medicaid-only managed care entity upon a finding by the State that there was continued egregious behavior by the plan and to assure the health of the entity's enrollees, if there is a need for temporary management while—

''(A) there is an orderly termination or reorganization of the managed care entity; or

''(B) improvements are made to remedy the violations found under subsection (a), except that temporary management under this paragraph may not be terminated until the State has determined that the managed care entity has the capability to ensure that the violations shall not recur.

''(3) Permitting individuals enrolled with the managed care entity to terminate enrollment without cause, and notifying such individuals of such right to terminate enrollment.

''(4) Suspension of default or all enrollment of individuals under this title after the date the Secretary or the State notifies the entity of a determination of a violation of any requirement of this part.

''(5) Suspension of payment to the entity under this title for individuals enrolled after the date the Secretary or State notifies the entity of such a determination and until the Secretary or State is satisfied that the basis for such determination has been corrected and is not likely to recur.

''(c) TREATMENT OF CHRONIC SUBSTANDARD ENTITIES.—In the case of a managed care entity which has repeatedly failed to meet the requirements of sections 1942 through 1946, the State shall (regardless of what other sanctions are provided) impose the sanctions described in paragraphs (2) and (3) of subsection (b).

''(d) AUTHORITY TO TERMINATE CONTRACT.—In the case of a managed care entity which has failed to meet the requirements of this part, the State shall have the authority to terminate its contract with such entity under section 1941(a)(1)(B) and to enroll such entity's enrollees with other managed care entities (or to permit such enrollees to receive medical assistance under the State plan under this title other than through a managed care entity).

''(e) AVAILABILITY OF SANCTIONS TO THE SECRETARY.—

''(1) INTERMEDIATE SANCTIONS.—In addition to the sanctions described in paragraph (2) and any other sanctions available under law, the Secretary may provide for any of the sanctions described in subsection (b) if the Secretary determines that a managed care entity with a contract under section 1941(a)(1)(B) fails to meet any of the requirements of this part.

''(2) DENIAL OF PAYMENTS TO THE STATE.—The Secretary may deny payments to the State for medical assistance furnished under the contract under section 1941(a)(1)(B) for individuals enrolled after the date the Secretary notifies a managed care entity of a determination under subsection (a) and until the Secretary is satisfied that the basis for such determination has been corrected and is not likely to recur.

''(f) DUE PROCESS FOR MANAGED CARE ENTITIES.—

''(1) AVAILABILITY OF HEARING PRIOR TO TERMINATION OF CONTRACT.—A State may not terminate a contract with a managed care entity under section 1941(a)(1)(B) unless the entity is provided with a hearing prior to the termination.

''(2) NOTICE TO ENROLLEES OF TERMINATION HEARING.—A State shall notify all individuals enrolled with a managed care entity which is the subject of a hearing to terminate the entity's contract with the State of the hearing and that the enrollees may immediately disenroll with the entity without cause.

''(3) OTHER PROTECTIONS FOR MANAGED CARE ENTITIES AGAINST SANCTIONS IMPOSED BY STATE.—Before imposing any sanction against a managed care entity other than termination of the entity's contract, the State shall provide the entity with notice and such other due process protections as the State may provide, except that a State may not provide a managed care entity with a pre-termination hearing before imposing the sanction described in subsection (b)(2).

''(4) IMPOSITION OF CIVIL MONETARY PENALTIES BY SECRETARY.—The provisions of section 1128A (other than subsections (a) and (b)) shall apply with respect to a civil money penalty imposed by the Secretary under subsection (b)(1) in the same manner as such provisions apply to a penalty or proceeding under section 1128A.

''SEC. 1950. DEFINITIONS; MISCELLANEOUS PROVISIONS.

''(a) DEFINITIONS.—For purposes of this title:

''(1) MANAGED CARE ENTITY.—The term 'managed care entity' means—

''(A) a medicaid managed care organization; or

''(B) a primary care case management provider.

''(2) MEDICAID MANAGED CARE ORGANIZATION.—The term 'medicaid managed care organization' means a health maintenance organization, an eligible organization with a contract under section 1876, a provider sponsored network or any other organization which is organized under the laws of a State, has made adequate provision (as determined under standards established for purposes of eligible organizations under section 1876 and through its capitalization or otherwise) against the risk of insolvency, and provides or arranges for the provision of one or more items and services to individuals eligible for medical assistance under the State plan under this title in accordance with a contract with the State under section 1941(a)(1)(B).

''(3) PRIMARY CARE CASE MANAGEMENT PROVIDER.—

''(A) IN GENERAL.—The term 'primary care case management provider' means a health care provider that—

''(i) is a physician, group of physicians, a Federally-qualified health center, a rural health clinic, or an entity employing or having other arrangements with physicians that provides or arranges for the provision of one or more items and services to individuals eligible for medical assistance under the State plan under this title in accordance with a contract with the State under section 1941(a)(1)(B);

''(ii) receives payment on a fee-for-service basis (or, in the case of a Federally-qualified health center or a rural health clinic, on a reasonable cost per encounter basis) for the provision of health care items and services specified in such contract to enrolled individuals;

''(iii) receives an additional fixed fee per enrollee for a period specified in such contract for providing case management services (including approving and arranging for the provision of health care items and services specified in such contract on a referral basis) to enrolled individuals; and

''(iv) is not an entity that is at risk.

''(B) AT RISK.—In subparagraph (A)(iv), the term 'at risk' means an entity that—

''(i) has a contract with the State under which such entity is paid a fixed amount for providing or arranging for the provision of health care items or services specified in such contract to an individual eligible for medical assistance under the State plan and enrolled with such entity, regardless of whether such items or services are furnished to such individual; and

''(ii) is liable for all or part of the cost of furnishing such items or services, regardless of whether such cost exceeds such fixed payment.''.

SEC. 3. STUDIES AND REPORTS.

(a) REPORT ON PUBLIC HEALTH SERVICES.—

(1) IN GENERAL.—Not later than January 1, 1998, the Secretary of Health and Human Services (in this section referred to as the ''Secretary'') shall report to the Committee on Finance of the Senate and the Committee on Commerce of the House of Representatives on the effect of managed care entities (as defined in section 1950(a)(1) of the Social Security Act) on the delivery of and payment for the services traditionally provided through providers described in section 1941(a)(2)(B)(i) of such Act.

(2) CONTENTS OF REPORT.—The report referred to in subsection (a) shall include—

(A) information on the extent to which enrollees with eligible managed care entities seek services at local health departments, public hospitals, and other facilities that provide care without regard to a patient's ability to pay;

(B) information on the extent to which the facilities described in such subsection provide services to enrollees with eligible managed care entities without receiving payment;

(C) information on the effectiveness of systems implemented by facilities described in such subsection for educating such enrollees on services that are available through eligible managed care entities with which such enrollees are enrolled;

(D) to the extent possible, identification of the types of services most frequently sought by such enrollees at such facilities; and

(E) recommendations about how to ensure the timely delivery of the services traditionally provided through providers described in section 1941(a)(2)(B)(i) of the Social Security Act to enrollees of managed care entities and how to ensure that local health departments, public hospitals, and other facilities are adequately compensated for the provision of such services to such enrollees.

(b) REPORT ON PAYMENTS TO HOSPITALS.—

(1) IN GENERAL.—Not later than October 1 of each year, beginning with October 1, 1998, the Secretary and the Comptroller General shall analyze and submit a report to the Committee on Finance of the Senate and the Committee on Commerce of the House of Representatives on rates paid for hospital services under managed care entities under contracts under section 1941(a)(1)(B) of the Social Security Act.

(2) CONTENTS OF REPORT.—The information in the report described in paragraph (1) shall—

(A) be organized by State, type of hospital, type of service, and

(B) include a comparison of rates paid for hospital services under managed care entities with rates paid for hospital services furnished to individuals who are entitled to benefits under a State plan under title XIX of the Social Security Act and are not enrolled with such entities.

(c) REPORTS BY STATES.—Each State shall transmit to the Secretary, at such time and in such manner as the Secretary determines appropriate, the information on hospital rates submitted to such State under section 1947(b)(2) of such Act.

(d) INDEPENDENT STUDY AND REPORT ON QUALITY ASSURANCE AND ACCREDITATION STANDARDS.—The Institute of Medicine of the National Academy of Sciences shall conduct a study and analysis of the quality assurance programs and accreditation standards applicable to managed care entities operating in the private sector or to such entities that operate under contracts under the medicare program under title XVIII of the Social Security Act to determine if such programs and standards include consideration of the accessibility and quality of the health care items and services delivered under such contracts to low-income individuals.

SEC. 4. CONFORMING AMENDMENTS.

(a) REPEAL OF CURRENT REQUIREMENTS.—

(1) IN GENERAL.—Except as provided in paragraph (2), section 1903(m) (42 U.S.C. 1396b(m)) is repealed on the date of the enactment of this Act.

(2) EXISTING CONTRACTS.—In the case of any contract under section 1903(m) of such Act which is in effect on the day before the date of the enactment of this Act, the provisions of such section shall apply to such contract until the earlier of—

(A) the day after the date of the expiration of the contract; or

(B) the date which is 1 year after the date of the enactment of this Act.

(b) FEDERAL FINANCIAL PARTICIPATION.—

(1) CLARIFICATION OF APPLICATION OF FFP DENIAL RULES TO PAYMENTS MADE PURSUANT TO MANAGED CARE ENTITIES.—Section 1903(i) (42 U.S.C. 1396b(i)) is amended by adding at the end the following sentence: ''Paragraphs (1)(A), (1)(B), (2), (5), and (12) shall apply with respect to items or services furnished and amounts expended by or through a managed care entity (as defined in section 1950(a)(1)) in the same manner as such paragraphs apply to items or services furnished and amounts expended directly by the State.''.

(2) FFP FOR EXTERNAL QUALITY REVIEW ORGANIZATIONS.—Section 1903(a)(3)(C) (42 U.S.C. 1396b(a)(3)(C)) is amended—

(A) by inserting ''(i)'' after ''(C)'', and

(B) by adding at the end the following new clause:

''(ii) 75 percent of the sums expended with respect to costs incurred during such quarter (as found necessary by the Secretary for the proper and efficient administration of the State plan) as are attributable to the performance of independent external reviews of managed care entities (as defined in section 1950(a)(1)) by external quality review organizations, but only if such organizations conduct such reviews under protocols approved by the Secretary and only in the case of such organizations that meet standards established by the Secretary relating to the independence of such organizations from agencies responsible for the administration of this title or eligible managed care entities; and''.

(c) EXCLUSION OF CERTAIN INDIVIDUALS AND ENTITIES FROM PARTICIPATION IN PROGRAM.—Section 1128(b)(6)(C) (42 U.S.C. 1320a-7(b)(6)(C)) is amended—

(1) in clause (i), by striking ''a health maintenance organization (as defined in section 1903(m))'' and inserting ''a managed care entity, as defined in section 1950(a)(1),''; and

(2) in clause (ii), by inserting ''section 1115 or'' after ''approved under''.

(d) STATE PLAN REQUIREMENTS.—Section 1902 (42 U.S.C. 1396a) is amended—

(1) in subsection (a)(30)(C), by striking ''section 1903(m)'' and inserting ''section 1941(a)(1)(B)''; and

(2) in subsection (a)(57), by striking ''hospice program, or health maintenance organization (as defined in section 1903(m)(1)(A))'' and inserting ''or hospice program'';

(3) in subsection (e)(2)(A), by striking ''or with an entity described in paragraph (2)(B)(iii), (2)(E), (2)(G), or (6) of section 1903(m) under a contract described in section 1903(m)(2)(A)'' and inserting ''or with a managed care entity, as defined in section 1950(a)(1);

(4) in subsection (p)(2)—

(A) by striking ''a health maintenance organization (as defined in section 1903(m))'' and inserting ''a managed care entity, as defined in section 1950(a)(1),'';

(B) by striking ''an organization'' and inserting ''an entity''; and

(C) by striking ''any organization'' and inserting ''any entity''; and

(5) in subsection (w)(1), by striking ''sections 1903(m)(1)(A) and'' and inserting ''section''.

(e) PAYMENT TO STATES.—Section 1903(w)(7)(A)(viii) (42 U.S.C. 1396b(w)(7)(A)(viii)) is amended to read as follows:

''(viii) Services of a managed care entity with a contract under section 1941(a)(1)(B).''.

(f) USE OF ENROLLMENT FEES AND OTHER CHARGES.—Section 1916 (42 U.S.C. 1396o) is amended in subsections (a)(2)(D) and (b)(2)(D) by striking ''a health maintenance organization (as defined in section 1903(m))'' and inserting ''a managed care entity, as defined in section 1950(a)(1),'' each place it appears.

(g) EXTENSION OF ELIGIBILITY FOR MEDICAL ASSISTANCE.—Section 1925(b)(4)(D)(iv) (42 U.S.C. 1396r-6(b)(4)(D)(iv)) is amended to read as follows:

''(iv) ENROLLMENT WITH MANAGED CARE ENTITY.—Enrollment of the caretaker relative and dependent children with a managed care entity, as defined in section 1950(a)(1), less than 50 percent of the membership (enrolled on a prepaid basis) of which consists of individuals who are eligible to receive benefits under this title (other than because of the option offered under this clause). The option of enrollment under this clause is in addition to, and not in lieu of, any enrollment option that the State might offer under subparagraph (A)(i) with respect to receiving services through a managed care entity in accordance with part B.''.

(h) PAYMENT FOR COVERED OUTPATIENT DRUGS.—Section 1927(j)(1) (42 U.S.C. 1396r-8(j)(1)) is amended by striking ''***Health Maintenance Organizations, including those organizations that contract under section 1903(m),'' and inserting ''health maintenance organizations and medicaid managed care organizations, as defined in section 1950(a)(2),''.

(i) APPLICATION OF SANCTIONS FOR BALANCED BILLING THROUGH SUBCONTRACTORS.—

(1) Section 1128A(b)(2)(B) (42 U.S.C. 1320a–7a(b)) is amended by inserting '', including section 1944(b)'' after ''title XIX''.

(2) Section 1128B(d)(1) (42 U.S.C. 1320a–7b(d)(1)) is amended by inserting ''or, in the case of an individual enrolled with a managed care entity under part B of title XIX, the applicable rates established by the entity under the agreement with the State agency under such part'' after ''established by the State''.

(j) REPEAL OF CERTAIN RESTRICTIONS ON OBSTETRICAL AND PEDIATRIC PROVIDERS.—Section 1903(i) (42 U.S.C. 1396b(i)) is amended by striking paragraph (12).

(k) DEMONSTRATION PROJECTS TO STUDY EFFECT OF ALLOWING STATES TO EXTEND MEDICAID COVERAGE FOR CERTAIN FAMILIES.—Section 4745(a)(5)(A) of the Omnibus Budget Reconciliation Act of 1990 (42 U.S.C. 1396a note) is amended by striking ''(except section 1903(m)'' and inserting ''(except part B)''.

(l) CONFORMING AMENDMENT FOR DISCLOSURE REQUIREMENTS FOR MANAGED CARE ENTITIES.—Section 1124(a)(2)(A) (42 U.S.C. 1320a–3(a)(2)(A)) is amended by inserting ''managed care entity under title XIX,'' after ''renal dialysis facility,''.

(m) ELIMINATION OF REGULATORY PAYMENT CAP.—The Secretary of Health and Human Services may not, under the authority of section 1902(a)(30)(A) of the Social Security Act or any other provision of title XIX of such Act, impose a limit by regulation on the amount of the capitation payments that a State may make to qualified entities under such title, and section 447.361 of title 42, Code of Federal Regulations (relating to upper limits of payment: risk contracts), is hereby nullified.

(n) CONTINUATION OF ELIGIBILITY.—Section 1902(e) (42 U.S.C. 1396a(e)) is amended by striking paragraph (2) and inserting the following:

''(2) For provision providing for extended liability in the case of certain beneficiaries enrolled with managed care entities, see section 1941(c).''.

(o) CONFORMING AMENDMENTS TO FREEDOM-OF-CHOICE PROVISIONS.—Section 1902(a)(23) (42 U.S.C. 1396a(a)(23)) is amended—

(1) in the matter preceding subparagraph (A), by striking ''subsection (g) and in section 1915'' and inserting ''subsection (g), section 1915, and section 1941,''; and

(2) in subparagraph (B), by striking ''a health maintenance organization, or a'' and inserting ''or with a managed care entity, as defined in section 1950(a)(1), or''.

SEC. 5. EFFECTIVE DATE; STATUS OF WAIVERS.

(a) EFFECTIVE DATE.—Except as provided in subsection (b), the amendments made by this Act shall apply to medical assistance furnished—

(1) during quarters beginning on or after October 1, 1997; or

(2) in the case of assistance furnished under a contract described in section 4(a)(2), during quarters beginning after the earlier of—

(A) the date of the expiration of the contract; or

(B) the expiration of the 1-year period which begins on the date of the enactment of this Act.

(b) APPLICATION TO WAIVERS.—

(1) EXISTING WAIVERS.—If any waiver granted to a State under section 1115 or 1915 of the Social Security Act (42 U.S.C. 1315, 1396n) or otherwise which relates to the provision of medical assistance under a State plan under title XIX of the such Act (42 U.S.C. 1396 et seq.), is in effect or approved by the Secretary of Health and Human Services as of the applicable effective date described in subsection (a), the amendments made by this Act shall not apply with respect to the State before the expiration (determined without regard to any extensions) of the waiver to the extent such amendments are inconsistent with the terms of the waiver.

(2) SECRETARIAL EVALUATION AND REPORT FOR EXISTING WAIVERS AND EXTENSIONS.—

(A) PRIOR TO APPROVAL.—On and after the applicable effective date described in subsection (a), the Secretary, prior to extending any waiver granted under section 1115 or 1915 of the Social Security Act (42 U.S.C. 1315, 1396n) or otherwise which relates to the provision of medical assistance under a State plan under title XIX of the such Act (42 U.S.C. 1396 et seq.), shall—

(i) conduct an evaluation of—

(I) the waivers existing under such sections or other provision of law as of the date of the enactment of this Act; and

(II) any applications pending, as of the date of the enactment of this Act, for extensions of waivers under such sections or other provision of law; and

(ii) submit a report to the Congress recommending whether the extension of a waiver under such sections or provision of law should be conditioned on the State submitting the request for an extension complying with the provisions of part B of title XIX of the Social Security Act (as added by this Act).

(B) DEEMED APPROVAL.—If the Congress has not enacted legislation based on a report submitted under subparagraph (A)(ii) within 120 days after the date such report is submitted to the Congress, the recommendations contained in such report shall be deemed to be approved by the Congress.

By Mr. GRAHAM (for himself, Mr. MACK, and Mr. BAUCUS):

S. 865. A bill to provide for improved coordination, communications, and enforcement related to health care fraud, waste, and abuse, to create a point of order against legislation which diverts savings achieved through medicare waste, fraud, and abuse enforcement activities for purposes other than improving the solvency of the Federal hospital insurance trust fund under title XVIII of the Social Security Act, to ensure the integrity of such trust fund, and for other purposes; to the Committee on Finance.

THE MEDICARE ANTI-FRAUD ACT OF 1997

Mr. GRAHAM. Mr. President, I rise today, and join my colleagues, Senator MACK and Senator BAUCUS, to introduce timely legislation that addresses a problem that continues to plague the Medicare Program—fraud and abuse. The premise of this bill is quite simple: if Congress is to look for cuts in the Medicare Program, it should begin with eradicating fraud—for several reasons:

First, we cannot fix Medicare while letting fraud erode the system. The General Accounting Office estimates that the Medicare waste, fraud, and abuse ripoff rate is about 10 percent. With fraud pilfering the health system's resources losses to Medicare and the Federal share of Medicaid could be $30 billion annually. Using the most conservative of estimates, we could cover an additional 2 million seniors a year with funds lost just to Medicare waste, fraud, and abuse.

Mr. President, over the next few weeks, Congress will be ironing out the details of a historic budget agreement—one which will finally balance the budget. And both Congress and the President deserve credit for doing so. However, a balanced budget does not come without some pain—some consequences. For instance, the Medicare Program will realize cuts of approximately $115 billion over the next 5 years. We will be asking our Nation's seniors to share in the sacrifice along with the rest of the country.

Congress cannot, in good conscience, ask the Medicare Program and its beneficiaries to accept cuts unless we also work hard to eradicate fraud and abuse. Passage of the Kennedy-Kassebaum legislation last year was a step in the right direction. But the cheats and swindlers are clever at gaming the system. It is a sad fact that there will always be greedy people looking to take advantage of our Nation's seniors. So it is imperative that Congress be equally vigilant by cracking down on fraud wherever possible. Passage of my bill will continue the process and send this signal to the con artists and thieves: ''Your days are numbered.''

My legislation is crafted to build on State successes. For instance, one of the most crucial provisions in my bill, modeled after an extremely successful Florida Medicaid antifraud program, requires providers of durable medical equipment, home health, and transportation services to post a $50,000 surety bond to participate in the Medicare Program.

While a $50,000 bond is relatively inexpensive to post for scrupulous contractors, at the cost of between $500 and $1,500, the requirement has achieved tremendous results in my State. Since implementation of the surety bond requirement, the fly-by-night providers have scattered like so many roaches when the lights are turned on.

Durable medical equipment suppliers have dropped by 62 percent, from 4,146 to 1,565; home health agencies have decreased by 41 percent, from 738 to 441; providers of transportation services have disenrolled from the State's Medicaid Programs in droves—from 1,759 to 742, a drop of 58 percent. Fewer providers bilking the State's Medicaid Program is projected to save over $192 million over the next 2 years in Florida.

Two years ago I spent a day working in the U.S. attorney's Office in south Florida. I realized then that it was easier to get a provider number under Medicare than a personal VISA; easier to get a blank check paid for by the Treasury than a VISA or MasterCard.

This bill requires individuals to provide their social security number [SSN] and employer identification number [EIN] to get a Medicare provider number. This will make it more difficult for swindlers to enter the program. This bill has several other provisions which are critical to stemming rampant fraud in the Medicare Program:

My bill would enable State fraud control units, often the first line in the

fight against health care fraud, to investigate and prosecute fraud in Federal health care programs.

It would also prevent providers from discharging Medicare debt by declaring bankruptcy. The bill would also preclude Medicare swindlers from transferring their business to a family member in order to circumvent exclusion from the Medicare Program.

This legislation enacts a broad-based Federal statute aimed at suppressing Medicare fraud. It enhances the arsenal of weapons to combat fraud and prescribes stiff penalties against those convicted of fraud.

At the signing of the Medicare bill in Missouri 30 years ago, President Johnson said that Medicare had been planted with ''the seed of compassion and duty which have today flowered into care for the sick and serenity for the fearful.'' Medicare has lived up to its promise. But fraud is threatening to compromise the integrity of the system. We have the prescriptions to combat fraud. Now is the time to employ them if we want to save the integrity of Medicare.

By Mrs. HUTCHISON:

S. 866. A bill to amend title 29, United States Code, to provide that certain voluntary disclosures of violations of Federal law made as a result of a voluntary environmental audit shall not be subject to discovery or admitted into evidence during a judicial or administrative proceeding, and for other purposes; to the Committee on the Judiciary.

THE ENVIRONMENTAL PROTECTION PARTNERSHIP ACT

Mrs. HUTCHISON. Mr. President, the title of the bill I send to the desk is the Environmental Protection Partnership Act of 1997. By introducing this bill, I am suggesting that the Federal Government take a cue from the States regarding environmental protection. Many State governments have passed laws that allow for voluntary audits of environmental compliance. These laws encourage a company to conduct an audit of its compliance with environmental laws. By conducting the audit, the company determines whether it is in compliance with all environmental laws. If it is not, these state laws allow the company, without penalty, to correct any violations it finds so it will come into compliance.

What my bill does is let the Federal Government do the same thing. It lets the Federal Government say to companies all over America, if you want to do a voluntary audit for environmental compliance, we are going to let you do that. We will encourage you but not force you to do it. And we are not going to come in and threaten you with the hammer of the EPA if you, in fact, move swiftly to come into compliance when you find that you are not in compliance.

We think this is the most effective way to clean up the air and water. Our air and water are invaluable natural resources. They are cleaner than they have been in 25 years, and we want to keep improving our efforts to guarantee their protection. This bill will ensure that, in the same fashion as many States have done. It does not preempt State law. If State laws are on the books, then the State laws prevail. But this offers companies all over our country the ability to comply with Federal standards in a voluntary way, to critically assess their compliance and not be penalized if they then take action to immediately come into compliance.

So I am asking that we take up this bill very quickly in committee. I think through this bill we can do a lot of good for America.

Mr. President, today I introduce legislation that will ensure that we continue to increase the protection of our environment in the United States. My bill, the Environmental Protection Partnership Act of 1997, provides incentives for companies to assess their own environmental compliance. Rather than playing a waiting game for EPA to find environmental violations, companies will find—and stop—violations. Many more violations will be corrected, and many others will be prevented.

Under my bill, if a company voluntarily completes an environmental audit—a thorough review of its compliance with environmental laws—the audit report may not be used against the company in court. The report can be used in court, however, if the company found violations and did not promptly make efforts to comply. By extending this privilege, a company that looks for, finds, and remedies problems will continue this good conduct, and protect the environment.

In addition, if a company does an audit, and promptly corrects any violations, the company may choose to disclose the violation to EPA. If the company does disclose the violation, the company will not be penalized for the violations. By ensuring companies that they will not be dragged into court for being honest, the bill encourages companies to find and fix violations and report them to EPA.

This does not mean that companies that pollute go scot-free. Under this bill, there is no protection for: willful and intentional violators; companies that do not promptly cure violations; companies asserting the law fraudulently; or companies trying to evade an imminent or ongoing investigation. Further, the bill does not protect companies that have policies that permit ongoing patterns of violations of environmental laws. And where a violation results in a continuing adverse public health or environmental effect, a company may not use the protections of this law.

Nor does this bill mean that EPA loses any authority to find violations and punish companies for polluting. EPA retains all its present authority.

At the same time that EPA retains full authority to enforce environmental laws, I propose to engage every company voluntarily in environmental protection by creating the incentive for those companies to find and cure their own violations. This frees EPA to target its enforcement dollars on the bad actors—the companies that intentionally pollute our water and air.

Twenty-one States have already passed audit laws. These States understand that to truly protect the environment, everyone must participate. These States have made it possible for companies to want to be good actors and play an active role in environmental protection. Texas has an audit law. Hundreds of companies have carried out a voluntary environmental audit, and after only 18 months, companies had already reported and corrected 50 violations. Other States report similar success.

My bill does not mandate that States adopt these policies. It does not mandate that States amend their laws. Quite the opposite. My bill specifically does not preempt State law. Therefore, a State may choose not to enact an audit law, but a company in that State can still conduct a voluntary audit with respect to Federal environmental law. Further, in a State with an audit law, a company will be able to thoroughly review its entire State and Federal compliance, and remedy any violations it may find. Therefore, my bill supports—but does not supplant—State efforts by encouraging companies to audit their compliance with Federal environmental laws as well.

We have made great strides in cleaning up our environment over the past 30 years. To continue this trend, we need to be preventing pollution, rather than always reacting to environmental problems after they occur. Even EPA agrees that to achieve this, companies need to play an active role in environmental protection. In a recent policy Statement, EPA pointed out that because Government resources are limited, maximum compliance cannot be achieved without active efforts by the regulated community to police themselves. The Environmental Protection Partnership Act will make companies active partners with EPA in assuring compliance with environmental laws.

I am very pleased to be working with the majority leader on this legislation and I hope Members on both sides of the aisle will join me in this effort to increase environmental protection.

By Mr. HARKIN (for himself, Mr. HUTCHINSON, Mr. REID, Mr. BRYAN and Mr. ROCKEFELLER):

S. 868. A bill to amend the Social Security Act to prohibit persons from charging for services or products that the Social Security Administration and Department of Health and Human Services provide without charge; to the Committee on Finance.

THE SOCIAL SECURITY CONSUMER PROTECTIONS ACT

Mr. HARKIN. Mr. President. Today, I am introducing, on behalf of myself,

Senators HUTCHINSON, REID, BRYAN, and ROCKEFELLER, the Social Security Consumer Protection Act. This is a simple, commonsense legislation that will arm consumers with the information they need to protect themselves from a growing type of consumer scam.

Several years ago Congress took an important step toward stamping out frauds against older Americans. We passed a law making it illegal for companies to prey upon senior citizens and others by misrepresenting an affiliation with Social Security or Medicare. After some delay, the Social Security inspector general has begun to enforce this important new consumer protection law. However, we are finding that many scam artists are squirming through a loophole in the law that allows them to charge unwitting consumers for services that are available free of charge from Social Security or Medicare.

A recent investigation by my staff found that unsuspecting consumers—from new parents to senior citizens—are falling prey to con artists charging them for services that are available free of charge from the Social Security Administration. Many of the schemes involve use of materials and names which mislead consumers into believing that the scam artists are affiliated with the federal government.

Companies operating under official sounding names like Federal Document Services, Federal Record Service Corp., National Records Service, and U.S. Document Services are mailing information to thousands of unsuspecting Americans, including many Iowans. These companies are scaring people into remitting a fee to receive basic Social Security benefits and eligibility information such as a new Social Security number and card for a baby and changing names upon marriage or divorce.

We began to look into this problem based on a number of complaints from Iowans who had received these deceptive mailings. One example was sent to me by Deb Conlee of Fort Dodge. She received a mailing from a company called Document Service. The official looking letter starts: ''Read Carefully: Important Facts about your Social Security Card. The response envelope is stamped ''SSA–7701'' giving the impression that it is connected with the Social Security Administration. The solicitation goes on to say that she is required to provide Social Security with any name change associated with her recent marriage and get a new Social Security card. It then urges her to send them $14.75 to do this. It says, ''We urge you to do this immediately to help avoid possible problems where your Social Security benefits or joint income taxes might be questioned.''

Ms. Conlee paid $60 to this company and was furious when she learned that she could have gotten the same services free of charge from Social Security.

Last year I asked Social Security Commissioner Shirley Chater to investigate the complaints of Iowans and those of consumers like her. She responded that the services provided by Document Service ''are completely unnecessary. Not only do they fail to produce any savings of time or effort for the customer, they also tend to delay issuance of the new Social Security card.'' While it is now illegal for a company to imply any direct connection with Social Security or Medicare in mailings, it is not illegal to charge for the very same services that are available at no cost from the government.

So while Congress has acted to try and stop scam artists from trying to fool people into thinking their business is somehow affiliated with Social Security, Medicare, or some other government agency, many are skirting around the edges of this law and are conning consumers into paying for services that they can get free of charge. Nowhere in any of the mailings from these outfits that I have reviewed is there any mention that the services they offer are in fact available to consumers at no cost from the government.

The Social Security Consumer Protection Act would require that any such solicitation prominently display the following consumer alert: ''IMPORTANT PUBLIC DISCLOSURE: The product or service described here and assistance to obtain the product or service is available free of charge from the Social Security Administration or the Department of Health and Human Services.'' Armed with this information, consumers would be able to make informed decisions about where to obtain the service they need or want. Companies found to be in violation of this simple requirement would face fines.

Our legislation would not stop the provision of services by private companies. Rather, it would simply make sure that consumers are fully informed, so that they can make an informed choice about where and how they prefer to receive certain services.

These scams must be put to an end. A simple change in the law would go a long way toward stopping them. The bill we are introducing today would make such a change without imposing an undue burden on legitimate businesses or restricting consumer freedom of choice.

Mr. President, this legislation has been endorsed by the National Committee to Preserve Social Security and Medicare. The National Committee is an effective and aggressive advocate of the rights of older Americans. I am pleased to have their endorsement and ask unanimous consent to include a copy of their letter of support be printed in the RECORD.

I urge my colleagues to review this bill and to work with us to ensure its prompt approval.

There being no objection, the letter was ordered to be printed in the RECORD, as follows:

NATIONAL COMMITTEE TO PRESERVE SOCIAL SECURITY AND MEDICARE,
Washington, DC, May 8, 1997.

Hon. TOM HARKIN,
U.S. Senate,
Washington, DC.

DEAR SENATOR HARKIN: On behalf of the 5.5 million members and supporters of the National Committee to Preserve Social Security and Medicare, I am pleased to offer our endorsement of your legislation, the Social Security Consumer Protection Act.

Your legislation would require that any business which solicits direct payment for services which the Social Security Administration provides free of charge must include a clear and prominent written disclaimer. Your bill would also impose new civil and criminal penalties for failure to comply with its provisions. A growing number of businesses have emerged across the country which, for a direct fee, assist individuals who seek to change their names, social security numbers, or obtain other information relative to their work record. Unfortunately, some of these enterprises do not adequately inform would be consumers that they are not affiliated with the federal government, or that such services are provided free of charge by the government. As a consequence, some individuals may be led to believe that they must pay the fee to obtain these services.

We appreciate your leadership on this important matter. People should not be coerced to pay twice for services which are already provided with their hard earned tax dollars.

Sincerely,

MARTHA A MCSTEEN, *President.*

By Mr. JEFFORDS (for himself, Mr. KENNEDY, Mr. LIEBERMAN, Mr. TORRICELLI, Mr. WYDEN, Mr. BINGAMAN, Mr. KERRY, Mr. WELLSTONE, Mr. HARKIN, Ms. LANDRIEU, Mr. FEINGOLD, Mrs. MURRAY, Mrs. BOXER, Mr. LEVIN, Mr. SARBANES, Mr. AKAKA, Mr. LAUTENBERG, Mr. DURBIN, Mr. CHAFEE, Mr. KOHL, Mr. INOUYE, Ms. MIKULSKI, Mr. ROBB, Mr. MOYNIHAN, Mrs. FEINSTEIN, Mr. DODD, Mr. REID, Mr. LEAHY, Mr. BRYAN, Ms. MOSELEY-BRAUN, Mr. GLENN, Mr. KERREY, Mr. REED, Mr. D'AMATO, and Mr. CLELAND):

S. 869. A bill to prohibit employment discrimination on the basis of sexual orientation; to the Committee on Labor and Human Resources.

THE EMPLOYMENT NON-DISCRIMINATION ACT OF 1997

Mr. JEFFORDS. Mr. President, I am pleased to be here today to introduce the Employment Non-Discrimination Act of 1997 [ENDA]. As many of you recall, my colleagues and I introduced similar legislation in the last Congress. While we were unable to pass ENDA in the last Congress, I was encouraged that ENDA was only narrowly defeated, by a vote of 50 to 49. It is my hope that in the 105th Congress, we can bridge that narrow gap and pass this legislation. By extending to sexual orientation the same Federal employment discrimination protections established for race, religion, gender, national origin, age, and disability, this legislation will further ensure that principals of equality and opportunity apply to all Americans.

I believe that all Americans deserve to be judged at work based on their ability to do their jobs and not their sexual orientation. People who work hard and perform well should not be kept from leading productive and responsible lives because of an irrational, non-work-related prejudice. Unfortunately, many responsible and productive members of our society face discrimination in their workplaces based on nothing more than their sexual orientation. Because this insidious discrimination persists, there is a need for Congress to pass the Employment Non-Discrimination Act.

Mr. President, the Senate's vote last Congress is no doubt reflective of the American people's support of the concept behind ENDA. In a recent poll, 83 percent of the respondents support the passage of a law extending civil rights and preventing job discrimination against gays and lesbians. While ENDA will achieve this goal of equal rights for job opportunities, it does so by not creating any special rights for gays and lesbians. Specifically, this legislation prohibits preferential treatment based on sexual orientation. In addition, ENDA does not require an employer to justify a neutral practice that may have a statistically disparate impact based on sexual orientation, nor provide benefits for the same-sex partner of an employee. Rather, it simply protects a right that should belong to every American, the right to be free from discrimination at work because of personal characteristics unrelated to successful performance on the job.

Since ENDA's narrow defeat last September, we have taken a fresh look at this important legislation in an attempt to allay some of the concerns raised by ENDA's detractors in the last Congress. I am pleased to announce that we have made several significant improvements in the bill.

Our first change is intended to address the concern raised that employees' privacy rights would be violated if the Equal Employment Opportunity Commission [EEOC] required employers to provide the Government with data on the sexual orientation of their employees. As a result, the bill now prohibits the EEOC from collecting such statistics and from compelling employers to do so. Opponents of the previous legislation were also concerned that the EEOC would require employers who have violated ENDA to hire gay and lesbian employees as part of its enforcement scheme. To alleviate that possibility, the new legislation precludes the EEOC from entering into a consent decree that includes quotas, or gives preferential treatment based on sexual orientation. In addition, we have narrowed the language of the previous bill so that only actual paid employees are protected and we have attempted to ensure that exempted religious organizations from coverage.

In today's global economy, our Nation must take full advantage of every resource that is at our disposal if we want U.S. companies to maintain their competitive advantage over their international competitors. The fact that a majority of Fortune 500 companies have incorporated many of ENDA's policies, clearly indicates the acceptance of these changes within the workplace. In fact, it can be stated that without these American companies, on their own, undertaking these actions to insure adequate working protections for all of their employees they would be less competitive and may even be unable to maintain their existence within this fiercely competitive international environment.

Mr. President, some concern has been raised by my colleagues that passing ENDA will create a new wave of litigation. I am proud to say that my home State of Vermont is one of several States and localities that have enacted a sexual orientation anti-discrimination law, and it is no surprise, to me, that the sky has not fallen. Since the enactment of Vermont's law in 1991 the Vermont Attorney General has initiated only 17 investigations of alleged sexual orientation discrimination. Seven are pending at this time. Five have been closed with determinations that unlawful discrimination cannot be proven to have occurred. Four have been closed for miscellaneous administrative reasons, unrelated to the merits of the charge, and one resulted in a settlement. In addition, I am not aware of a single complaint from Vermont employers about the enforcement of the State law. However, I do know that thousands of Vermonters no longer need to live and work in the shadows. The facts bear out my belief that the effect experienced in Vermont on litigation has been experienced in other States and the District of Columbia that have implemented policies similar to the one of my home State of Vermont.

As I have stated before, success at work should be directly related to one's ability to do the job, period. The passage of ENDA would be a significant step toward ensuring the ability of all people, be they gay, lesbian, or heterosexual, to be fairly judged on their work product, not on an unrelated personal characteristic. I urge all my colleagues to join me in supporting this bill.

I ask unanimous consent that a copy of this bill be printed in the RECORD.

There being no objection, the bill was ordered to be printed in the RECORD, as follows:

S. 869

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Employment Non-Discrimination Act of 1997''.

SEC. 2. PURPOSES.

The purposes of this Act are—

(1) to provide a comprehensive Federal prohibition of employment discrimination on the basis of sexual orientation;

(2) to provide meaningful and effective remedies for employment discrimination on the basis of sexual orientation; and

(3) to invoke congressional powers, including the powers to enforce the 14th amendment to the Constitution and to regulate interstate commerce, in order to prohibit employment discrimination on the basis of sexual orientation.

SEC. 3. DEFINITIONS.

In this Act:

(1) COMMISSION.—The term ''Commission'' means the Equal Employment Opportunity Commission.

(2) COVERED ENTITY.—The term ''covered entity'' means an employer, employment agency, labor organization, joint labor-management committee, an entity to which section 717(a) of the Civil Rights Act of 1964 (42 U.S.C. 2000e–16(a)) applies, an employing authority to which section 302(a)(1) of the Government Employee Rights Act of 1991 (2 U.S.C. 1202(a)(1)) applies, or an employing office, as defined in section 101 of the Congressional Accountability Act of 1995 (2 U.S.C. 1301). The term ''covered entity'' includes an employing office, as defined in section 401 of title 3, United States Code.

(3) EMPLOYER.—The term ''employer'' means a person engaged in an industry affecting commerce (as defined in section 701(h) of the Civil Rights Act of 1964 (42 U.S.C. 2000e(h))) who has 15 or more employees (as defined in section 701(f) of such Act (42 U.S.C. 2000e(f)) for each working day in each of 20 or more calendar weeks in the current or preceding calendar year, and any agent of such a person, but such term does not include a bona fide private membership club (other than a labor organization) that is exempt from taxation under section 501(c) of the Internal Revenue Code of 1986.

(4) EMPLOYMENT AGENCY.—The term ''employment agency'' has the meaning given the term in section 701(c) of the Civil Rights Act of 1964 (42 U.S.C. 2000e(c)).

(5) EMPLOYMENT OR AN EMPLOYMENT OPPORTUNITY.—Except as provided in section 10(a)(1), the term ''employment or an employment opportunity'' includes job application procedures, hiring, advancement, discharge, compensation, job training, or any other term, condition, or privilege of employment, but does not include the service of a volunteer for which the volunteer receives no compensation.

(6) LABOR ORGANIZATION.—The term ''labor organization'' has the meaning given the term in section 701(d) of the Civil Rights Act of 1964 (42 U.S.C. 2000e(d)).

(7) PERSON.—The term ''person'' has the meaning given the term in section 701(a) of the Civil Rights Act of 1964 (42 U.S.C. 2000e(a)).

(8) RELIGIOUS ORGANIZATION.—The term ''religious organization'' means—

(A) a religious corporation, association, or society; or

(B) a school, college, university, or other educational institution or institution of learning, if—

(i) the institution is in whole or substantial part controlled, managed, owned, or supported by a religion, religious corporation, association, or society; or

(ii) the curriculum of the institution is directed toward the propagation of a religion.

(9) SEXUAL ORIENTATION.—The term ''sexual orientation'' means homosexuality, bisexuality, or heterosexuality, whether the orientation is real or perceived.

(10) STATE.—The term ''State'' has the meaning given the term in section 701(i) of the Civil Rights Act of 1964 (42 U.S.C. 2000e(i)).

SEC. 4. DISCRIMINATION PROHIBITED.

A covered entity shall not, with respect to the employment or an employment opportunity of an individual—

(1) subject the individual to a different standard or different treatment, or otherwise

discriminate against the individual, on the basis of sexual orientation; or

(2) discriminate against the individual based on the sexual orientation of a person with whom the individual is believed to associate or to have associated.

SEC. 5. RETALIATION AND COERCION PROHIBITED.

(a) RETALIATION.—A covered entity shall not discriminate against an individual because the individual opposed any act or practice prohibited by this Act or because the individual made a charge, assisted, testified, or participated in any manner in an investigation, proceeding, or hearing under this Act.

(b) COERCION.—A person shall not coerce, intimidate, threaten, or interfere with any individual in the exercise or enjoyment of, or on account of the individual's having exercised, enjoyed, assisted in, or encouraged the exercise or enjoyment of, any right granted or protected by this Act.

SEC. 6. BENEFITS.

This Act does not apply to the provision of employee benefits to an individual for the benefit of the partner of the individual.

SEC. 7. NO DISPARATE IMPACT; COLLECTION OF STATISTICS.

(a) DISPARATE IMPACT.—The fact that an employment practice has a disparate impact, as the term ''disparate impact'' is used in section 703(k) of the Civil Rights Act of 1964 (42 U.S.C. 2000e–2(k)), on the basis of sexual orientation does not establish a prima facie violation of this Act.

(b) COLLECTION OF STATISTICS.—The Commission shall not collect statistics on sexual orientation from covered entities, or compel the collection of such statistics by covered entities.

SEC. 8. QUOTAS AND PREFERENTIAL TREATMENT PROHIBITED.

(a) QUOTAS.—A covered entity shall not adopt or implement a quota on the basis of sexual orientation.

(b) PREFERENTIAL TREATMENT.—A covered entity shall not give preferential treatment to an individual on the basis of sexual orientation.

(c) CONSENT DECREES.—The Commission may not enter into a consent decree that includes a quota, or preferential treatment to an individual, based on sexual orientation.

SEC. 9. RELIGIOUS EXEMPTION.

(a) IN GENERAL.—Except as provided in subsection (b), this Act shall not apply to a religious organization.

(b) UNRELATED BUSINESS TAXABLE INCOME.—This Act shall apply to employment or an employment opportunity for an employment position of a covered entity that is a religious organization, if the duties of the position pertain solely to activities of the organization that generate unrelated business taxable income subject to taxation under section 511(a) of the Internal Revenue Code of 1986.

SEC. 10. NONAPPLICATION TO MEMBERS OF THE ARMED FORCES; VETERANS' PREFERENCES.

(a) ARMED FORCES.—

(1) EMPLOYMENT OR AN EMPLOYMENT OPPORTUNITY.—In this Act, the term ''employment or an employment opportunity'' does not apply to the relationship between the United States and members of the Armed Forces.

(2) ARMED FORCES.—In paragraph (1), the term ''Armed Forces'' means the Army, Navy, Air Force, Marine Corps, and Coast Guard.

(b) VETERANS' PREFERENCES.—This Act does not repeal or modify any Federal, State, territorial, or local law creating a special right or preference concerning employment or an employment opportunity for a veteran.

SEC. 11. CONSTRUCTION.

Nothing in this Act shall be construed to prohibit a covered entity from enforcing rules regarding nonprivate sexual conduct, if the rules of conduct are designed for, and uniformly applied to, all individuals regardless of sexual orientation.

SEC. 12. ENFORCEMENT.

(a) ENFORCEMENT POWERS.—With respect to the administration and enforcement of this Act in the case of a claim alleged by an individual for a violation of this Act—

(1) the Commission shall have the same powers as the Commission has to administer and enforce—

(A) title VII of the Civil Rights Act of 1964 (42 U.S.C. 2000e et seq.); or

(B) sections 302 and 304 of the Government Employee Rights Act of 1991 (2 U.S.C. 1202 and 1220);

in the case of a claim alleged by the individual for a violation of such title or of section 302(a)(1) of such Act (2 U.S.C. 1202(a)(1)), respectively;

(2) the Librarian of Congress shall have the same powers as the Librarian of Congress has to administer and enforce title VII of the Civil Rights Act of 1964 (42 U.S.C. 2000e et seq.) in the case of a claim alleged by the individual for a violation of such title;

(3) the Board (as defined in section 101 of the Congressional Accountability Act of 1995 (2 U.S.C. 1301)) shall have the same powers as the Board has to administer and enforce the Congressional Accountability Act of 1995 (2 U.S.C. 1301 et seq.) in the case of a claim alleged by the individual for a violation of section 201(a)(1) of such Act (2 U.S.C. 1311(a)(1));

(4) the Attorney General shall have the same powers as the Attorney General has to administer and enforce—

(A) title VII of the Civil Rights Act of 1964 (42 U.S.C. 2000e et seq.); or

(B) sections 302 and 304 of the Government Employee Rights Act of 1991 (2 U.S.C. 1202 and 1220);

in the case of a claim alleged by the individual for a violation of such title or of section 302(a)(1) of such Act (2 U.S.C. 1202(a)(1)), respectively;

(5) the President, the Commission, and the Merit Systems Protection Board shall have the same powers as the President, the Commission, and the Board, respectively, have to administer and enforce chapter 5 of title 3, United States Code, in the case of a claim alleged by the individual for a violation of section 411 of such title;

(6) a court of the United States shall have the same jurisdiction and powers as the court has to enforce—

(A) title VII of the Civil Rights Act of 1964 (42 U.S.C. 2000e et seq.) in the case of a claim alleged by the individual for a violation of such title;

(B) sections 302 and 304 of the Government Employee Rights Act of 1991 (2 U.S.C. 1202 and 1220) in the case of a claim alleged by the individual for a violation of section 302(a)(1) of such Act (2 U.S.C. 1202(a)(1));

(C) the Congressional Accountability Act of 1995 (2 U.S.C. 1301 et seq.) in the case of a claim alleged by the individual for a violation of section 201(a)(1) of such Act (2 U.S.C. 1311(a)(1)); and

(D) chapter 5 of title 3, United States Code, in the case of a claim alleged by the individual for a violation of section 411 of such title.

(b) PROCEDURES AND REMEDIES.—The procedures and remedies applicable to a claim alleged by an individual for a violation of this Act are—

(1) the procedures and remedies applicable for a violation of title VII of the Civil Rights Act of 1964 (42 U.S.C. 2000e et seq.) in the case of a claim alleged by the individual for a violation of such title;

(2) the procedures and remedies applicable for a violation of section 302(a)(1) of the Government Employee Rights Act of 1991 (2 U.S.C. 1202(a)(1)) in the case of a claim alleged by the individual for a violation of such section;

(3) the procedures and remedies applicable for a violation of section 201(a)(1) of the Congressional Accountability Act of 1995 (2 U.S.C. 1311(a)(1)) in the case of a claim alleged by the individual for a violation of such section; and

(4) the procedures and remedies applicable for a violation of section 411 of title 3, United States Code, in the case of a claim alleged by the individual for a violation of such section.

(c) OTHER APPLICABLE PROVISIONS.—With respect to a claim alleged by a covered employee (as defined in section 101 of the Congressional Accountability Act of 1995 (2 U.S.C. 1301)) for a violation of this Act, title III of the Congressional Accountability Act of 1995 (2 U.S.C. 1381 et seq.) shall apply in the same manner as such title applies with respect to a claim alleged by such a covered employee for a violation of section 201(a)(1) of such Act (2 U.S.C. 1311(a)(1)).

SEC. 13. STATE AND FEDERAL IMMUNITY.

(a) STATE IMMUNITY.—A State shall not be immune under the 11th amendment to the Constitution from an action in a Federal court of competent jurisdiction for a violation of this Act.

(b) REMEDIES AGAINST THE UNITED STATES AND THE STATES.—Notwithstanding any other provision of this Act, in an action or administrative proceeding against the United States or a State for a violation of this Act, remedies (including remedies at law and in equity, and interest) are available for the violation to the same extent as the remedies are available for a violation of title VII of the Civil Rights Act of 1964 (42 U.S.C. 2000e et seq.) by a private entity, except that—

(1) punitive damages are not available; and

(2) compensatory damages are available to the extent specified in section 1977A(b) of the Revised Statutes (42 U.S.C. 1981a(b)).

SEC. 14. ATTORNEYS' FEES.

Notwithstanding any other provision of this Act, in an action or administrative proceeding for a violation of this Act, an entity described in section 12(a) (other than paragraph (4) of such section), in the discretion of the entity, may allow the prevailing party, other than the United States, a reasonable attorney's fee (including expert fees) as part of the costs.The United States shall be liable for the costs to the same extent as a private person.

SEC. 15. POSTING NOTICES.

A covered entity shall post notices for employees, applicants for employment, and members, to whom the provisions specified in section 12(b) apply, that describe the applicable provisions of this Act in the manner prescribed by, and subject to the penalty provided under, section 711 of the Civil Rights Act of 1964 (42 U.S.C. 2000e–10).

SEC. 16. REGULATIONS.

(a) IN GENERAL.—Except as provided in subsections (b), (c), and (d), the Commission shall have authority to issue regulations to carry out this Act.

(b) LIBRARIAN OF CONGRESS.—The Librarian of Congress shall have authority to issue regulations to carry out this Act with respect to employees of the Library of Congress.

(c) BOARD.—The Board referred to in section 12(a)(3) shall have authority to issue regulations to carry out this Act, in accordance with section 304 of the Congressional Accountability Act of 1995 (2 U.S.C. 1384), with respect to covered employees, as defined in section 101 of such Act (2 U.S.C. 1301).

(d) PRESIDENT.—The President shall have authority to issue regulations to carry out this Act with respect to covered employees, as defined in section 401 of title 3, United States Code.

SEC. 17. RELATIONSHIP TO OTHER LAWS.

This Act shall not invalidate or limit the rights, remedies, or procedures available to an individual claiming discrimination prohibited under any other Federal law or any law of a State or political subdivision of a State.

SEC. 18. SEVERABILITY.

If any provision of this Act, or the application of the provision to any person or circumstance, is held to be invalid, the remainder of this Act and the application of the provision to any other person or circumstance shall not be affected by the invalidity.

SEC. 19. EFFECTIVE DATE.

(a) IN GENERAL.—Except as provided in subsection (b), this Act shall take effect 60 days after the date of enactment of this Act and shall not apply to conduct occurring before the effective date.

(b) PRESIDENTIAL OFFICES.—The second sentence of section 3(2), and sections 12(a)(5), 12(a)(6)(D), 12(b)(4), and 16(d), shall take effect on, and shall not apply to conduct occurring before, the later of—

(1) October 1, 1997; and

(2) the effective date described in subsection (a).

Mr. LIEBERMAN. Mr. President, I am delighted to join with Senators JEFFORDS, KENNEDY, and over 30 of our colleagues as an original cosponsor of this important legislation, the Employment Non-Discrimination Act of 1997. By guaranteeing that American workers cannot lose their jobs simply because of their actual or perceived sexual orientation, this bill would extend the bedrock American values of fairness and equality to a group of our citizens who too often have been denied the benefit of those most basic values.

Our Nation's foundational document, the Declaration of Independence, expressed a vision of our country as one premised upon the essential equality of all people and upon the recognition that our Creator endowed all of us with the inalienable rights to life, liberty, and the pursuit of happiness. Two hundred and twenty years ago, when that document was drafted, our laws fell far short of implementing the declaration's ideal. But since that time, we have come ever closer, extending by law to more and more of our citizens—to African-Americans, to women, to disabled Americans, to religious minorities, and to others—a legally enforceable guarantee that, with respect to their ability to earn a living at least, they will be treated on their merits and not on characteristics unrelated to their ability to do their jobs.

It is time to extend that guarantee to gay men and lesbians, who too often have been subject to incidents of discrimination and denied the most basic of rights: the right to obtain and maintain a job. A collection of nearly two dozen studies shows that as many as 46 percent of gay and lesbian workers have experienced significant discrimination in the workplace. The fear in which these workers live was clear from a survey of 1,400 gay men and lesbians in Philadelphia. Seventy-six percent of the men and 81 percent of the women told those conducting the survey that they hide their orientation at work out of concern for their job security. This result, although unfortunate, is not surprising in light of a University of Maryland study that found gay men's income to be 11 to 27 percent lower than that of heterosexual men, thanks to the effects of discrimination.

The toll this discrimination takes extends far beyond its effect on those individuals who must live in fear and without full employment opportunities. It also takes an unacceptable toll on America's definition of itself as a land of equality and opportunity, as a place where we judge each other on our merits, and as a country that teaches its children that anyone can succeed here as long as they are willing to do their job and work hard.

This bill provides for equality and fairness—that and no more. It says only what we already have said for women, for people of color, and for others: that you are entitled to have your ability to earn a living depend only on your ability to do the job and nothing else. In fact, the bill would even do somewhat less than it does for women and people of color, because it would not give gay men and women all of the protections we currently provide to other groups protected under our civil rights laws.

Mr. President, this bill would bring our Nation one large step closer to realizing the vision that Thomas Jefferson so eloquently expressed 220 years ago when he wrote that all of us have a right to life, liberty, and the pursuit of happiness. I urge my colleagues to join me in supporting this important legislation.

By Mr. WELLSTONE:

S. 870. A bill to amend the Federal Food, Drug, and Cosmetic Act to facilitate the development, approval, and use of medical devices to maintain and improve the public health and quality of life of individuals, and for other purposes; to the Committee on Labor and Human Resources.

THE MEDICAL TECHNOLOGY, PUBLIC HEALTH, AND INNOVATION ACT OF 1997

Mr. WELLSTONE. Mr. President, the legislation that I am introducing today, the Medical Technology, Public Health and Innovation Act of 1997, takes a significant step toward improving the effectiveness, timeliness, and predictability of the FDA review process for medical devices.

It is important that we improve the system for device approval in order to provide access to optimal technology to American consumers. We need to do this in order to promote the public health. We must also maintain protections for consumers, which are provided by the FDA's oversight of device manufacturing, development, and marketing. This legislation maintains those protections, while allowing for new efficiencies within the FDA.

Over the past 2 years, I have met with numerous representatives of Minnesota's medical device industry, patient advocates, clinicians, and officials from the FDA, and have concluded that there are indeed steps that Congress should take to make the regulatory process for medical devices more efficient. Minnesotans want the FDA not only to protect public health, but also to promote public health. They want to know not only that new technologies will be safe, but that they will be available to them in a timely manner. Many of Minnesota's medical device manufacturers, researchers, clinicians, and patients in need of new and improved health care technology have become increasingly concerned about the regulatory environment at the FDA. While there have been some improvements in the device review process, there is still a need to increase communication between the FDA and industry; to decrease review times; and to have consistency in the review process.

These needs are highlighted by the following example. A plant operated by a Minnesota-based device company was developing a new treatment for aortic aneurysms, which would require less invasive measures than are currently used. The company developed a protocol for testing its product, submitted the protocol to the FDA and was told by the reviewer that the protocol was invalid. The reviewer suggested a different protocol and the company followed it. Upon completion of the clinical trial, the company submitted the required data to the FDA. The original reviewer was on an extended leave of absence, so the data went to a different reviewer. The new reviewer deemed the protocol that was used to be invalid, and requested a new clinical trial, which basically followed the protocol that had been rejected by the first reviewer. The company was forced to do a new trial, which resulted in significant delays in getting this important product to market for patient use. I am certain that this is but one of many examples of inconsistently applied processes that delay the release of life-saving technology to the consumer.

The technologies that the FDA regulates are changing rapidly. We cannot afford a regulatory system that is ill-equipped to speed these advances. As a result, both Congress and the Administration are reexamining the paradigms that have governed the FDA. Our challenge will be to define FDA's mission and scope of responsibility, as well as to give guidance on an appropriate balance between the risks and rewards of streamlining all aspects of how FDA does its job—including the approval process for breakthrough products.

The legislation that I am introducing would begin to address these issues in three important ways:

First, it would enable the FDA to adopt nationally and internationally recognized performance standards to improve the transparency and effectiveness of the device review process.

Resource constraints and the time-consuming rulemaking process have precluded FDA promulgation of performance standards in the past. This legislation would allow the FDA, when appropriate, to simply adopt consensus standards that are already being used by most of the world and use those standards to assist in determining the safety and effectiveness of class III medical devices. The FDA could require additional data from a manufacturer relevant to an aspect of a device covered by an adopted performance standard if necessary to protect patient safety. Currently, the lack of clear performance standards for class III medical devices is a barrier to the improvement of the quality and timeliness of the premarket approval process.

Second, it would improve communication between the industry and the FDA and the predictability of the review process. I believe that these two factors are extremely important. The bill includes provisions for meetings between the applicant and the FDA to ensure that applicants are promptly informed of any deficiencies in their application, that questions that can be answered easily would be addressed right away, and that applicants would be well informed about the status of their application. I believe that improving communication between the FDA and industry would result in greater compliance with regulations and that this will ultimately benefit consumers and patients.

Third, the legislation would help the FDA focus its resources more appropriately. PMA supplements or 510(k)'s that relate only to changes that can be shown to not adversely affect the safety or effectiveness of the device would not require premarket approval or notification. Manufacturers would instead make information and data supporting the change part of the master record at the FDA. In addition the FDA would be able to exempt from premarket notification requirements those class II devices for which such requirements are unnecessary to ensure the public health without first having to go through the time consuming and bureaucratic process of reclassifying them to class I. The FDA would also have the option of relying on postmarket controls classifying devices. Enabling the FDA to focus its attention where the real risks are will not only streamline the approval process but also benefit consumers.

I look forward to working with Senator JEFFORDS, the chairman of the Labor and Human Resources Committee, and my other colleagues on the Committee on the concepts included in my proposal. I will work vigorously to ensure that they are included in FDA legislation considered by the Senate this year. I look forward to continuing to work on these issues with Minnesotans. Clearly, there are actions that Congress can take to improve the FDA without sacrificing the assurance of safety that all Americans depend on.

I ask unanimous consent that the text of the bill be printed in the RECORD.

There being no objection, the bill was ordered to be printed in the RECORD, as follows:

S. 870

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE AND REFERENCE.

(a) SHORT TITLE.—This Act may be cited as the ''Medical Technology, Public Health, and Innovation Act of 1997''.

(b) REFERENCE.—Whenever in this Act an amendment or repeal is expressed in terms of an amendment to, or a repeal of, a section or other provision, the reference shall be considered to be made to a section or other provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.)

SEC. 2. FINDINGS; MISSIONS STATEMENT.

(a) FINDINGS.—The Congress finds the following:

(1) While the United States appropriately puts a top priority on the regulation of medical technologies to ensure the safety and efficacy of medical technologies that are introduced into the marketplace, the administration of such regulatory effort is causing the United States to lose its leadership role in producing innovative, top-quality medical devices.

(2) One of the key components of the medical device regulatory process that contributes to the United States losing its leadership role in medical device development is the inordinate amount of time it takes for medical technologies to be reviewed by the Food and Drug Administration.

(3) The most important result of the United States losing its leadership role is that patients in the United States do not have access to new medical technology in a timely manner.

(4) Delayed patient access to new medical technology results in lost opportunities to save lives, to reduce hospitalization and recovery time, and to improve the quality of life of patients.

(5) The economic benefits of the United States medical device industry, which is composed principally of smaller companies, has provided through growth in jobs and global trade are threatened by the slow and unpredictable regulatory process at the Food and Drug Administration.

(6) The pace and predictability of the medical device regulatory process are in part responsible for the increasing tendency of United States medical device companies to shift research, product development, and manufacturing offshore, at the expense of American jobs, patients, and leading edge clinical research.

(b) MISSION STATEMENT.—This legislation seeks to improve the timeliness, effectiveness, and predictability of the medical device approval process for the benefit of United States patients and the United States economy by—

(1) providing for the use of nationally and internationally recognized performance standards to assist the Food and Drug Administration in determining the safety and effectiveness of medical devices;

(2) facilitating communication between medical device companies and the Food and Drug Administration;

(3) targeting the use of Food and Drug Administration resources on medical devices that are likely to have serious adverse health consequences; and

(4) requiring the Food and Drug Administration to determine the least costly, most efficient approach to reasonably assuring the safety and effectiveness of devices.

SEC. 3. DEVICE PERFORMANCE STANDARDS.

(A) ALTERNATIVE PROCEDURE.—Section 514 (21 U.S.C. 360d) is amended by adding at the end the following:

''RECOGNITION OF A PERFORMANCE STANDARD

''(c)(1)(A) The Secretary, through publication in the Federal Register, issue notices identifying and listing nationally and internationally recognized performance standards for which persons may provide a certification of a device's conformity under paragraph (3) in order to meet the premarket submission requirements or other requirements under the Act to which the standards are applicable.

''(B) Any person may elect to utilize data other than data required by the standards described in subparagraph (A) to meet any requirement under the Act to which the standards are applicable.

''(2) The Secretary may remove from the list of standards described in paragraph (1) a standard that the Secretary determines is no longer appropriate for making determinations with respect to the regulation of devices.

''(3)(A) A person may provide a certification that a device conforms to an applicable standard listed under paragraph (1) to meet the requirements described in paragraph (1) and the Secretary shall accept such certification.

''(B) The Secretary may, at any time, request a person who submits a certification described in subparagraph (A) to submit the data or information that the person relied on in making the certification.

''(C) A person who submits a certification described in subparagraph (A) shall maintain the data and information upon which the certification was made for a period of 2 years after the submission of the certification or a time equal to the expected design life of a device, whichever is longer.''.

(b) SECTION 301.—Section 301 (21 U.S.C. 331) is amended by adding at the end the following:

''(x) The falsification of a certification submitted under section 514(c)(3) or the failure or refusal to provide data or information requested by the Secretary under such section.''.

(c) SECTION 501.—Section 501(e) (21 U.S.C. 351(e)) is amended by striking ''established'' and inserting ''established or listed''.

SEC. 4. PREMARKET APPROVAL.

(a) APPLICATION.—Section 515(c) (21 U.S.C. 360e(c)) is amended—

(1) in paragraph (1)—

(B) in subparagraph (F), by striking ''; and'' and inserting a semicolon;

(C) in subparagraph (G), by striking ''require.'' and inserting ''require; and''; and

(D) by adding at the end the following:

''(H) an identifying reference to any performance standard listed under section 514(c) that is applicable to such device.

(2) by adding at the end the following:

''(3) The Secretary shall accept historical clinical data as a control for use in determining whether there is a reasonable assurance of safety and effectiveness of a device in a case in which the effects of the progression of a disease are clearly defined and well understood.

''(4) The Secretary may not require the sponsor of an application to conduct clinical trials for a device using randomized controls unless the controls—

''(A) are necessary;

''(B) are scientifically and ethically feasible; and

''(C) other less burdensome controls, such as historical controls, are not available to permit a determination of a reasonable assurance of safety and effectiveness.''.

(b) ACTION ON APPLICATION.—Section 515(d) (21 U.S.C. 30e(d)) is amended—

(1) in paragraph (1)(A)—

(A) by striking ''paragraph (2) of this subsection'' each place it appears and inserting ''paragraph (8)''; and

(B) by adding at the end the following flush paragraph:

''In making a determination to approve or deny an application, the Secretary shall rely on the conditions of use proposed in the labeling of device as the basis for determining whether or not there is a reasonable assurance of safety and effectiveness. If, based on a fair evaluation of all material facts, the proposed labeling of the device is neither false nor misleading in any particular, the Secretary shall not consider conditions of use not included in such labeling in making the determination.'';

(3) by redesignating paragraphs (2) and (3) as paragraphs (8) and (9), respectively; and

(3) by inserting after paragraph (1) the following:

''(2) Each application received under subsection (c) shall be reviewed in a manner to achieve final action within the 180-day period described in subparagraph (A), and the 180-day period may not be altered for any reason without the written consent of an applicant.

''(3)(A) Not later than 100 days after the receipt of an application that has been filed by the Secretary because the application satisfies the content requirements of subsection (c)(1), the Secretary shall meet with the applicant and disclose each deficiency relating to the application that would preclude approval of the application under paragraph (1).

''(B) The applicant shall have the right to be informed in writing with respect to the information communicated to the applicant during the meeting.

''(4) To permit better treatment or better diagnoses of life-threatening or irreversibly debilitating diseases or conditions, the Secretary shall expedite the review for devices—

''(A) representing breakthrough technologies;

''(B) offering significant advantages over existing approved alternatives; or

''(C) for which accelerated availability is in the best interest of the public health.

''(5) The Secretary shall complete the review of all supplemental applicants to an application approved under paragraph (1) that do not contain clinical data within 90 days after the receipt of a supplement that has been accepted for filing.

''(6)(A) A supplemental application shall be required for any change to a device subject to an approved application under this subsection if the change affects safety or effectiveness, unless the change is a modification in a manufacturing procedure or method of manufacturing and the holder of an approved application submits a notice to the Secretary that describes the change and informs the Secretary that the change has been made under the requirements of section 520(f).

''(B)(i) In reviewing a supplement to an approved application for an incremental change to the design of a device that affects safety or effectiveness, the Secretary shall approve the supplement if—

''(I) nonclinical data demonstrate that a design modification creates the intended additional capacity, function, or performance of the device; and

''(II) clinical data from the approved application and any supplements to the approved application provide a reasonable assurance of safety and effectiveness.

''(ii) The Secretary may require, when necessary, additional clinical data to evaluate the design modification to provide a reasonable assurance of safety and effectiveness.

''(7) Any representation in promotional materials for a device subject to an approved application under this subsection shall not be subject to premarket approval under this section, unless such representations establish new conditions of use. Any representations made in promotional materials for devices subject to an approved application shall be supported by appropriate data or information that can substantiate the representations at the time such representations are made.''.

(c) WITHDRAWAL OR TEMPORARY SUSPENSION OF APPROVAL OF APPLICATION.—Section 515(e)(1) (21 U.S.C. 360e(1)) is amended in subparagraph (G) by inserting after the word ''effect'' the words ''or listed.''

SEC. 5. PREMARKET NOTIFICATION.

(a) EXEMPTION OF CERTAIN DEVICES.—Section 510 (21 U.S.C. 360) is amended—

(1) in subsection (k), by striking ''intended for human use'' and inserting ''intended for human use (except a device that is classified into class I under section 513 or 520 or a device that is classified into class II under section 513 or 520, and is exempt from the requirements of this subsection under subsection (1))'';

(2) by adding at the end of subsection (k) (as amended by paragraph (1)) the following flush sentence:

''The Secretary shall review the notification required by this subsection and make a determination under section 513(f)(1)(A) within 90 days after receiving the notification.''; and

(3) by adding at the end of the following:

''(1)(A) Within 30 days after the date of enactment of this subsection, the Secretary shall develop and publish in the Federal Register a list of each type of class II device that does not require a report under subsection (k) to provide reasonable assurance of safety and effectiveness. Each type of class II device identified by the Secretary not to require the report shall be exempt from the requirement to file a report under subsection (k) as of the date of the publication of the list in the Federal Register.

''(B) Beginning on the date that is 1 day after the date of the publication of a list under this subsection, any person may petition the Secretary to exempt a type of class II device from the requirement of subsection (k). The Secretary shall respond to the petition within 120 days after the receipt of the petition and determine whether or not to grant the petition in whole or in part.''.

(b) SPECIAL RULE RELATING TO EXEMPTION OF CLASS I DEVICES FROM 510K NOTIFICATIONS.—The exemption of a class I device from the notification requirement of section 510(k) shall not apply to a class I device that is life sustaining or life saving or that is intended to be implanted into the human body.

SEC. 6. INVESTIGATIONAL DEVICE EXEMPTION.

(a) REGULATIONS.—Section 520(g) (21 U.S.C. 360j(g)) is amended—

(1) by redesignating paragraphs (4) and (5) as paragraphs (5) and (6), respectively; and

(2) by inserting after paragraph (3) the following:

''(4) The Secretary shall, within 120 days after the date of enactment of this paragraph, by regulation, amending the content of part 812 of title 21 of the Code of Federal Regulations, amend the procedures with respect to the approval of clinical studies under this subsection as follows:

''(A) The Secretary shall permit the sponsor of an investigation to meet with the Secretary prior to the submission of an application to develop a protocol for a clinical study subject to the regulation and require that the protocol be agreed upon in writing by the sponsor and the Secretary.

''(B)(i) The Secretary shall permit developmental changes to devices in response to information gathered during the course of an investigation without requiring an additional approval of an application for an investigational device exemption, or the approval of a supplement to the application, if the changes meet the following requirements:

''(I) The changes do not constitute a significant change in the design of the product or a significant change in basic principles of operation.

''(II) The changes do not adversely affect patient safety.

''(ii) The Secretary shall require that each such change shall be documented with information describing the change and the basis of the sponsor of application for concluding that the change does not constitute a significant change in design or operating principles, and that the change does not adversely affect patient safety.

''(b) CONFORMING AMENDMENTS.—Section 517(a)(7) (21 U.S.C. 360g(a)(7)) is amended—

(1) by striking ''section 520(g)(4)'' and inserting ''section 520(g)(5)''; and

(2) by striking ''section 520(g)(5)'' and inserting ''section 520(g)(6)''.

SEC. 7. PRODUCT REVIEW.

Section 513 (21 U.S.C. 360c) is amended by—

(1) in subsection (a)(3)(A)—

(A) by striking ''including clinical investigations where appropriate'' and inserting ''including 1 or more clinical investigations where appropriate'';

(B) by adding at the end the following: ''When evaluating the type and amount of data necessary to find a reasonable assurance of device effectiveness for an approval under section 515, the Secretary shall consider the extent to which reliance on postmarket controls may contribute to such assurance and expedite effectiveness determinations without increasing regulatory burdens on persons who submit applications under section 515(c).'';

(2) in subsection (a)(3), by adding at the end the following:

''(C)(i) The Secretary upon the request of any person intending to submit an application under section 515 shall meet with the person to determine the type of valid scientific evidence within the meaning of subparagraphs (A) and (B) that will be necessary to demonstrate the effectiveness of a device for the conditions of use proposed by such person to support an approval of an application.

''(ii) Within 30 days after such meeting, the Secretary shall specify in writing the type of valid scientific evidence that will provide a reasonable assurance that a device is effective under the conditions of use proposed by the person.

''(iii) Any clinical data, including 1 or more well-controlled investigations, specified by the Secretary for demonstrating a reasonable assurance of device effectiveness shall reflect the Secretary's determination that such data are necessary to establish device effectiveness and that no other less burdensome means of evaluating device effectiveness are available which would have a reasonable likelihood of resulting in an approval.

''(2) The determination of the Secretary with respect to the specification of the valid scientific evidence under clause (ii) shall be binding upon the Secretary, unless such determination by the Secretary would be contrary to the public health''; and

(3) in subsection (i), by adding at the end the following:

''(C) to facilitate reviews of reports submitted to the Secretary under section 510(k), the Secretary shall consider the extent to which reliance on postmarket controls may expedite the classification of devices under subsection (f)(1).

''(D) Whenever the Secretary requests information to demonstrate that devices with differing technological characteristics are substantially equivalent, the Secretary shall only request information that is necessary to making substantial equivalence determinations. In making such requests, the Secretary shall consider the least burdensome means of demonstrating substantial equivalence and request information accordingly.

''(E) Any determinations of substantial equivalence by the Secretary shall be based upon the intended uses proposed in labeling submitted in a report under section 510(k).

''(F) Any representations made in promotional materials for devices shall not require a report under section 510(k), unless such representations establish new intended uses for a legally marketed device.''.

By Mr. NICKLES (for himself, and Mr. INHOFE):

S. 871. A bill to establish the Oklahoma City National Memorial as a unit of the National Park System; to designate the Oklahoma City Memorial Trust, and for other purposes; to the Committee on Energy and Natural Resources.

OKLAHOMA CITY NATIONAL MEMORIAL ACT OF 1997

Mr. NICKLES. Mr. President, I rise today to introduce legislation with Senator INHOFE to establish the Oklahoma City National Memorial and create the Oklahoma City Memorial Trust. The memorial will commemorate the national tragedy ingrained in all of our minds that occurred in downtown Oklahoma City at 9:02 a.m. on April 19, 1995, in which 168 Americans lost their lives and countless thousands more lost family members and friends.

The Oklahoma City National Memorial, to be established as a unit of the National Park Service, will serve as a monument to those whose lives were taken and others will bear the physical and mental scars for the rest of their days. It will stand as a testament to the hope, generosity, and courage shown by Oklahomans and fellow Americans across the country following the Oklahoma City bombing. This will be a place of remembrance, peace, spirituality, comfort, and learning. The memorial complex will include a special place for children, 19 of whom were killed in the blast, to assure them that the world holds far more good than bad.

The memorial site will encompass the footprint of the Alfred P. Murrah Federal Building, Fifth Street between Robinson and Harvey, the site of the Water Resources Building, and the Journal Record Building. Both Park Service and non-Park Service personnel will staff the memorial grounds and interpretive center on the site. The Memorial Trust, comprised of nine unpaid trustees, will administer the operation, maintenance, management, and interpretation of the memorial.

While the thousands of family members and friends of those killed in the bombing will forever bear scars of having their loved ones taken away, the Oklahoma City National Memorial will revere the memory of those lost and venerate the bonds that drew us all closer together as a result.

I welcome all Members to cosponsor this important piece of legislation.

By Mr. ASHCROFT:

S. 873. A bill to amend the prohibition of title 18, United States Code, against financial transactions with state sponsors of international terrorism; to the Committee on the Judiciary.

THE PROHIBITION ON FINANCIAL TRANSACTIONS WITH COUNTRIES SUPPORTING TERRORISM ACT OF 1997

Mr. ASHCROFT. Mr. President, I would like to introduce The Prohibition on Financial Transactions with Countries Supporting Terrorism Act of 1997. This legislation will further isolate state sponsors of international terrorism from the community of responsible nations. By prohibiting financial transactions between U.S. persons and such criminal regimes, this bill will also reduce the financial resources available to terrorist states.

Unfortunately, this is the second time the Senate has had to consider legislation to prohibit financial transactions with state sponsors of terrorism. The Anti-terrorism and Effective Death Penalty Act, passed by Congress and signed into law by the President on April 24, 1996, contained a similar provision—section 321—which prohibited financial transactions with state sponsors of terrorism. Unfortunately, the manner in which the State Department implemented section 321 effectively exempted at least two terrorist States, Sudan and Syria, from the ban on financial transactions with United States citizens.

The Clinton administration seemingly misinterpreted the clear language of section 321 which states that:

> . . . whoever, being a United States person, knowing or having reasonable cause to know that a country is designated . . . as a country supporting international terrorism, engages in a financial transaction with the government of that country, shall be fined under this title, imprisoned for not more than 10 years, or both.

Somehow, our Government read such plain language to permit—not prohibit—almost all financial transactions with terrorist states. The only transactions the lawyers down at Foggy Bottom saw fit to prohibit were financial transactions which might further terrorism within the United States. The bureaucrats at the State Department evidently feel that transactions which further terrorism against citizens of foreign countries or Americans abroad—such as Pan Am flight 103—should not be targeted by this law.

Mr. President, the Congress of the United States has worked extensively in a bipartisan manner to provide the legislative tools needed to defend America and our allies against the rising threat of international terrorism, and I am sorry that the Senate must now revisit this antiterrorism legislation to correct the misguided efforts of this administration to confront and isolate terrorist-supporting nations in an effective manner.

We no longer live in a cold war world where the threats to our national security are easily identifiable. The fluid and complex international environment we face today demands the highest national security vigilance, the kind of vigilance that appears to be lacking in the Clinton administration. The administration's abysmal performance in enforcing United States laws against the proliferation of weapons of mass destruction by China is now mirrored by the administration's evisceration of Congress' antiterrorism sanctions. This administration finds no inconsistency between President Clinton's claim in an August 1996 speech at George Washington University that America ''cannot do business with * * * terrorists who kill * * * innocent civilians,'' and the State Department issuing regulations for the Anti-terrorism Act that same month that permit most business transactions with terrorist states to continue.

Mr. President, terrorism is no longer a far away phenomenon that American only risk when traveling abroad. Terrorist violence that primarily targeted U.S. citizens overseas is now finding its way to American shores, and the most stringent U.S. antiterrorism policy will be essential to protect our citizens. State sponsors of terrorism possess a hatred of global dimensions, and America is one of their primary targets. Our policies must reflect this understanding.

Mr. President, in the Africa Subcommittee, I have followed closely the global efforts of one particular country on the list of terrorist nations. Since democracy was overthrown by a radical Islamic military coup in 1989, Sudan has quickly joined Iran as the worst of the world's state sponsors of terrorism. Sudan's Government harbors elements of the most violent terrorist organizations in the world: Jihad, the Armed Islamic Group, Hamas, Abu Nidal, Palestinian Islamic Jihad, Hezbollah, and the Islamic Group all run terrorist training camps in Sudan.

Those groups are responsible for hundreds of terrorist attacks around the world that have killed thousands of innocent people. Abu Nidal alone has been responsible for 90 terrorist attacks in 20 countries which have killed or injured almost 900 people. Jihad is responsible for the assassination of Egyptian President Anwar Sadat and Jihad's leader, Sheikh Omar abdel Rahman, is the ideological ringleader of the terrorists that attacked the World Trade Center and plotted to bomb the United Nations in New York. Another terrorist organization, the Islamic Group, regularly targets westerners in Egypt for attack and claims responsibility for the failed assassination attempt on Egyptian President Hosni Mubarak during his visit to Ethiopia in 1995. In addition to harboring such terrorist organizations, Sudan has also given refuge to some of the

most notorious individual terrorists in the world, including Imad Moughniyeh who is believed to be responsible for the 1983 bombing of the United States Marine barracks in Beirut which killed 241 American soldiers.

Sudan is not simply a favorite training camp for terrorists, Mr. President. The Sudanese Government actively supports this terrorist activity. For instance, Sudan reportedly provided the weapons and travel documentation for the assassins who attacked President Mubarak during his Ethiopia visit. Two Sudanese diplomats at the United Nations in New York conspired to help Jihad terrorists gain access to the U.N. complex in order to bomb the building.

The conspiracy to bomb the United Nations was just one in a series of terrorist plots to bomb numerous locations around New York, including the Lincoln and Holland Tunnels, the George Washington Bridge, and various U.S. military installations. Five of the twelve defendants convicted in this series of terrorist plots were Sudanese nationals. Thankfully, law enforcement authorities thwarted most of these tragedies before they occurred, but the earlier terrorist attack against the World Trade Center was carried out by the same broader terrorism network in New York and killed six people. Those who bombed the World Trade Center only expressed regret that the twin towers were not toppled as they had planned, a catastrophe that in an instant could have resulted in more American casualties than the entire Vietnam war.

Sudan's involvement in the conspiracy to wage an urban war of terrorism in New York makes it patently clear why our Government has justifiably designated some nations as state sponsors of terrorism and has imposed upon them the most severe penalties and sanctions provided by United States law. I am grateful that America has been relatively isolated from most of the world's terrorist violence, but just as terrorists have targeted Americans abroad in the past, they are now targeting Americans here at home. International terrorism is one of the great threats to our national security, but unfortunately yet another example of a national security threat this administration is failing to forcefully address. By cutting off the flow of financial resources to these rogue regimes, it will become more difficult for them to seed the globe with their acts of violent cowardice.

Mr. President, the legislation I am introducing today will effectively prohibit financial transactions with state sponsors of terrorism—regardless of whether the terrorist attack occurs within the United States or abroad. This prohibition is one step in the fight against international terrorism the administration is evidently unwilling to take.

An analysis of Sudan's involvement in international terrorism gives us an idea of the global designs of terrorist states. Business as usual should not proceed with such regimes, and President Clinton should not have to be coaxed into aggressively enforcing U.S. antiterrorism law to isolate these countries. This legislation will diminish the financial resources available to terrorist states for their campaign of violence and hatred, and I urge the Senate's prompt consideration and passage of this bill.

By Mr. FAIRCLOTH (for himself and Mr. SHELBY):

S. 874. A bill to amend title 31, United States Code, to provide for an exemption to the requirement that all Federal payments be made by electronic funds transfer; to the Committee on Finance.

ELECTRONIC BENEFITS TRANSFER LEGISLATION

Mr. FAIRCLOTH. Mr. President, I am pleased to introduce legislation today that would modify the mandatory EBT legislation that was passed in 1996.

Mr. President, in 1996, the Congress amended the Federal Financial Management Act of 1994—as part of the Omnibus Appropriations Act of 1996, Public Law 104–134—to require that all Federal payments after January 1, 1999, be made by electronic funds transfer.

The legislation I am introducing today would provide an exemption from that requirement for Social Security and veterans benefits, except that a recipient may send written notification to the agency head authorizing that such payments be made electronically. Thus, the legislation makes it optional for the vast majority of Federal beneficiaries, particularly retirees.

This would affect nearly 20 million Social Security recipients who still receive their check through the mail. Also, nearly 40 percent of veterans benefits are still by mail.

Mr. President, I have found that many retirees are unaware of this requirement, and do not desire to have their checks electronically deposited.

Mr. President, these are not welfare checks. The Government should not force retirees to accept this mandate.

In fact, AARP testified before the House Government Reform and Oversight Committee last year, stating that ''AARP believes that direct deposit of federal payments should remain optional for current payment recipients.'' Further, AARP has found that Social Security recipients receiving checks by mail were clustered in a handful of States, including my home State of North Carolina.

Mr. President, many people worked all of their lives for these benefits. They have the right to receive them. Many people served their country for these benefits. The very notion that they will be told where their benefits are being sent is abhorrent. Further, it has even been suggested that benefits could be withheld if persons do not choose a bank to receive a check.

Mr. President, this is wrong. I am not opposed to direct deposit, but I am opposed to it being forced on people. I would urge the Senate to act soon on this legislation.

ADDITIONAL COSPONSORS

S. 121

At the request of Mr. MOYNIHAN, the names of the Senator from Florida [Mr. GRAHAM], the Senator from Texas [Mr. GRAMM], and the Senator from Utah [Mr. HATCH] were added as cosponsors of S. 121, a bill to amend the Internal Revenue Code of 1986 to provide for 501(c)(3) bonds a tax treatment similar to governmental bonds, and for other purposes.

S. 127

At the request of Mr. MOYNIHAN, the names of the Senator from Florida [Mr. GRAHAM] and the Senator from Texas [Mr. GRAMM] were added as cosponsors of S. 127, a bill to amend the Internal Revenue Code of 1986 to make permanent the exclusion for employer-provided educational assistance programs, and for other purposes.

S. 278

At the request of Mr. GRAMM, the name of the Senator from Oklahoma [Mr. INHOFE] was added as a cosponsor of S. 278, a bill to guarantee the right of all active duty military personnel, merchant mariners, and their dependents to vote in Federal, State, and local elections.

S. 356

At the request of Mr. GRAHAM, the name of the Senator from California [Mrs. FEINSTEIN] was added as a cosponsor of S. 356, a bill to amend the Internal Revenue Code of 1986, the Public Health Service Act, the Employee Retirement Income Security Act of 1974, the title XVIII and XIX of the Social Security Act to assure access to emergency medical services under group health plans, health insurance coverage, and the medicare and medicaid programs.

S. 387

At the request of Mr. HATCH, the name of the Senator from Texas [Mrs. HUTCHISON] was added as a cosponsor of S. 387, a bill to amend the Internal Revenue Code of 1986 to provide equity to exports of software.

S. 389

At the request of Mr. ABRAHAM, the names of the Senator from North Dakota [Mr. DORGAN] and the Senator from New York [Mr. D'AMATO] were added as cosponsors of S. 389, a bill to improve congressional deliberation on proposed Federal private sector mandates, and for other purposes.

S. 394

At the request of Mr. HATCH, the names of the Senator from California [Mrs. BOXER] and the Senator from Florida [Mr. GRAHAM] were added as cosponsors of S. 394, a bill to partially restore compensation levels to their past equivalent in terms of real income and establish the procedure for adjusting future compensation of justices and judges of the United States.