

(c) The effective date of these amendments is October 1, 1995.

## **PART 2 - SAVINGS RELATED TO PART B**

**Section 4111. Establishment of Cumulative Expenditure Goals for Physician Services.** (a) Amends section 1848(f)(2) (relating to use of Medicare volume performance standard rates of increase) by inserting new performance standard rates of increase for fiscal years beginning with fiscal year 1994. In fiscal years 1994, 1995, and 1996, the increase shall equal the rate of increase for fiscal 1993, increased by the product of the calculation set forth at current section 1848(f)(2)(a).

(b) Amends section 1848 (d)(3)(b) to provide that beginning in fiscal 1997 updates for a particular category of physician services shall be increased or decreased by the same percentage by which the cumulative percentage increase for the category of services was less or greater than the performance standard rate of increase. The cumulative percentage increase is equal to the product of the adjusted increases beginning in 1994, up to and including the year involved, minus 1 and multiplied by 100. The term adjusted increase is equal to 1 plus the percentage increase in actual expenditures for the year.

(c) Amends section 1842(f) to repeal the volume performance standard factor.

**Section 4112. Use of Real GDP to Adjust for Volume and Intensity; Repeal of Restriction on Maximum Reduction Permitted in Default Update.** (a) Amends section 1848(f)(2)(B)(iii), as added by section 4111 to substitute average per capita growth in the real gross domestic product (increased by 1.5 percentage points for primary care services only) in place of the existing volume and intensity growth factor under current law.

(b) Amends section 1848(d)(3)(B) to eliminate the maximum reduction restriction beginning in fiscal 1995, which currently stands at 5 percentage points.

**Section 4113. Reduction in Conversion Factor for Physician Fee Schedules for 1995.** (a) Amends section 1848(d)(1) to specify for 1995 a conversion factor for primary care services equal to current law, with a three percent reduction for other types of physician services.

**Section 4114. Limitations on Payment for Physicians' Services Furnished by High-Cost Hospital Medical Staffs.** (a) Adds a new section 1849 requiring the Secretary to develop an annual, hospital-specific per-admission relative value scale and to determine whether a hospital's specific per admission relative value exceeds the allowable average per admission relative value applicable to the medical staff for the year. If the Secretary determines that the rates are excessive, the Secretary shall reduce payments for the physician services to hospital inpatients. By October 1, annually, the Secretary must notify the hospital of its specific relative value.

(b) In the case of urban hospitals, the allowable average per admission relative value equals 125 percent (or 120 percent for years after 1999) of the median 1996 hospital-specific per admission relative value for all hospital medical staffs.

In the case of rural hospitals for each year beginning with 1998 and thereafter the allowable per admission relative value equals 140 percent of the median 1996 hospital specific relative value for all hospital medical staffs.

The hospital specific projected relative value for a hospital (other than a teaching hospital) is equal to the average per admission relative value for each physician's service furnished to inpatients by the hospital's medical staff (excluding interns and residents) during 1996, and adjusted for variations in case mix and disproportionate share status

The hospital specific relative value for teaching hospitals equals (1) the average per admission relative value for each physician's service furnished to inpatients by the hospital's medical staff (excluding interns and residents) during 1996 and adjusted for variations in case mix, disproportionate share status, and teaching status; and (2) the equivalent per admission relative value of each physician service furnished to inpatients by interns and residents during 1996 adjusted for variations case mix, disproportionate share status, and teaching status.

The Secretary shall determine the equivalent relative value based on the best available data for teaching hospitals and shall adjust the relative value to take into account the additional costs of teaching and disproportionate share hospitals.

The projected excess relative value for a year means the number of percentage points (as determined by the Secretary) by which a medical staff's hospital specific per admission relative value exceeds the allowable average per admission relative value.

(c) The amount of payments otherwise due will be reduced by 15 percent for each service furnished for hospitals whose relative value per admission exceeds the allowable average per admission.

(d) Not later than October 1, beginning in 1999, the Secretary shall determine each hospital's actual average per admission relative value using claims forms submitted no later than 90 days after the last day of the previous year, adjusted by the appropriate case mix, disproportionate share factor and teaching factor.

In cases in which hospital specific actual average per admission relative value was reduced and falls below the average rate, the Secretary shall reimburse the hospital up to the average including interest at an appropriate rate. In cases where the actual average relative value is less than 15 percentage points above the national average, the Secretary shall reimburse the hospital a percent of total allowed charges representing the difference between 15 percentage points and the actual number of percentage points by which the staff exceeded the allowable average per admission relative value, including appropriate interest.

If the actual average per admission relative value exceed 15 percentage points, none of the amounts withheld shall be paid. Hospital medical executive committees shall be given as one-year advance notice of projected excessive relative values and can designate a fiduciary agent to receive and disburse amounts withheld by the carrier that are later returned. Amounts paid by the carrier may be paid directly on a pro-rata basis to treating members of the medical staff.

(e) Medical staff are defined as individuals who are subject to bylaws, rules and regulations established by the hospital and who have clinical privileges under which the individual may provide physician services independently within the scope of those privileges. Medical staff also include individuals who furnish at least one service to a Medicare beneficiary in the hospital.

Rural and urban areas have the same meaning as under section 1886(d)(2)(d). The term "teaching hospital" is a hospital with a teaching program approved under section 1861.

The effective date of this amendment is January 1, 1998.

**Section 4115. Medicare Incentives for Physicians to Provide Primary Care.** (a) Amends section 1848(c)(2) (relating to relative value payments for physicians) beginning in 1996, to increase by 10 percent the practice expenses that are allowed in calculating the relative value unit. Increases must be budget neutral, with anesthesia and primary care exempted from offsetting reductions. The Secretary is required to develop a resource based system for determining practice expenses for each physician's service.

(b) Amends section 1848(c)(2) to increase the work relative value units for office visits by 10 percent beginning in 1996.

(c) Amends section 1848 (c)(2) to reduce the work, practice expense and malpractice components of office consultations under the RBRVS system for other physicians to offset increases for primary care physicians.

(d) Amends section 1848(c)(2) to reduce the work relative value components of procedures or classes of procedures where intensity exceed thresholds established by the Secretary. The Secretary must apply the savings, from such reductions, to increase the work relative value of primary care services on a budget neutral basis.

(e) Amends section 1833(m) to increase the underserved area bonus payment to 20 percent for primary care services and remains at 10 percent for other services.

These amendments are effective on January 1, 1996.

**Section 4116. Elimination of Formula-Driven Overpayment for Certain Outpatient Hospital Services.** (a) Amends section 1833(i) (pertaining to payment for

outpatient ambulatory services) by striking 80 percent and inserting "less the amount a provider may charge under section 1866 (a)(2)(A)." (the provider's applicable charge). Also

(b) Amends radiology and diagnostic procedures under section 1833(n)(1) by striking "80 percent" and inserting "less the amount a provider may charge) under section 1866(a)(2)(A)."

The effective date of this provision is July 1, 1994.

**Section 4117. Imposition of Coinsurance on Laboratory Services.** Amends section 1833(a) to strike 100 percent and insert "80 percent of the negotiated rate."

This section is effective January 1, 1995.

**Section 4118. Application of Competitive Acquisition Process for Part B Items and Services.** (a) Adds a new section 1847 to the statute to require the Secretary to establish competitive acquisition areas for the awarding of certain items or services furnished on or after January 1, 1995. The Secretary may establish different competitive acquisition areas for different items and services.

Competitive acquisition areas must initially be within metropolitan statistical areas and must be chosen on the basis of the availability and accessibility of suppliers and on the probability of achieving savings through competitive bidding for the items and services.

The Secretary must conduct a competition among suppliers for the contracts for each class of item and service and for each acquisition area. The Secretary may not award a contract unless the supplier meets quality standards and agrees to furnish sufficient items and services to meet the needs of the area.

Each contract shall specify the quantity of items and services to be provided and such terms and conditions as the Secretary specifies.

Services subject to competitive bidding include magnetic resonance imaging tests and computerized axial tomography scans (including physician's interpretation), oxygen and oxygen equipment, and such other items and services that the Secretary determines can be cost-effectively and appropriately secured through competitive acquisition.

(b) Amends section 1862 (relating to limitations and exclusions) to exclude coverage of items and services furnished in a competitive acquisition area unless furnished through a contracting supplier.

(c) If competitive acquisition fails to achieve at least a 10 percent annual reduction in the amount of Part B payments that would otherwise have been made for items and services subject to competitive acquisition, the Secretary shall reduce payment levels by an amount necessary to achieve such savings.

These amendments are effective January 1, 1995.

**Section 4119. Application of Competitive Acquisition Procedures for Laboratory Services.** (a) Section 1847, as added by section 4117, is amended to also cover clinical

diagnostic laboratory tests.

(b) If competitive acquisition procedures do not reduce the fee schedules and negotiated rates by at least 10 percent annually, the Secretary shall reduce payments by an amount sufficient to achieve such savings.

### **PART 3 - SAVINGS RELATED TO PARTS A AND B**

**Section 4131. Medicare Secondary Payer Changes.** (a) Amends section 1862 (relating to Medicare as a secondary payer) by repealing the sunset requirement on employer data matches. Section 6103(1)(12) of the Internal Revenue Code also is amended by striking subparagraph (F).

(b) Amends section 1862(b) by repealing the sunset on disabled employees with respect to coordination with other benefits in the cases of employers of 100 or greater.

(c) Section 1862 is amended by striking the secondary payer sunset for end stage renal disease beneficiaries with respect to coordination with other benefits.

**Section 4132. Payment Limits for HMOs and CMPs with Risk Sharing Contracts.**

(a) Amends section 1876 to establish new standards for payments under Medicare to entities with Federal risk sharing contracts under section 1876.

In the case that proportion of risk payments are made from the Supplemental Medical Insurance Trust Fund, upper payment levels are limited to 95 percent of the following:

(1) In 1995, 150 percent of the weighted national average of all adjusted average per capita costs determined under paragraph (4) for that class that are attributable to payments from the trust fund, plus 80 percent of the amount by which the adjusted average per capita cost for that class exceeds 150 percent of the weighted national average.

(2) for 1996, the excess payment shall be limited to 60 percent;

(3) for 1997, the excess payment shall be limited to 40 percent;

(4) for 1998, the excess payment shall be limited to 20 percent;

(5) for 1999 and fiscal years thereafter, payment shall be at 150 percent of the weighted national average of all adjusted average per capita costs.

The limits described in this section shall not apply if the portion of the annual per capita rate of payments for each class of patients that is attributable to payments from the Hospital Insurance Trust Fund is less than 95 percent of the weighted national average of all average adjusted per capita costs.

Payments from the Supplemental Medical Insurance Trust Fund are limited as follows:

(1) For 1995, payments are limited to 170 percent of the weighted national average for all adjusted average per capita costs plus 80 percent of the amount by which, if any, the adjusted average per capita cost exceeds 170 percent of that weighted national average.

(2) In 1996, the excess amount of payment is 60 percent;

(3) In 1997, the excess amount of payment is 40 percent;

(4) In 1998, the excess amount of payment is 20 percent;

(5) In 1999 and years thereafter, payments are limited to 170 percent of the weighted national average.

The payment limitations of this section do not apply in cases where the portion of the annual per capita rate of payment for each class of payments from the SMI trust fund is less than 95 percent of the weighted national average of all per capita costs for a particular class of patients that are attributable to payments made from the Health Insurance Trust Fund.

For 1995 and succeeding years, the portion of payments from each of the trust funds may not be less than 80 percent of 95 percent of the weighted average of all adjusted average per capita costs for any class of patients that are attributable to payments from that trust fund, unless the portion of the annual per capita rate of payment for each such class from the other trust fund is greater than 95 percent of the weighted national average of all adjusted average per capita costs for that class of patients.

For the year 2000 and succeeding years, the Secretary may revise any of the percentages otherwise applicable during a year but only if the aggregate payments made to risk sharing providers under section 1876 during the year is not greater than they would have been without the revisions (budget neutrality test). In determining the weighted average of all adjusted average per capita costs, the Secretary shall not take into account costs associated with treatment of ESRD patients.

Additional conforming amendments are made.

**Section 4133. Reduction in Routine Cost Limits for Home Health Services.** (a) Amends section 1861(v)(1) (relating to reasonable cost payment limits for home health services) by striking "112 percent" in the case of excess home health costs and inserting a limit of 100 percent of the mean for allowable visit related costs. This subsection is effective on July 1, 1996.

(b) Amends section 1861(v)(1) to strike "mean" and insert "median". This subsection is effective for cost reporting periods beginning on or after July 1, 1997.

**Section 4134. Imposition of Copayment for Certain Home Health Services.** (a) Amends section 1813(a) (relating to deductibles and coinsurance) to impose a copayment equal to 10 percent of the average of all visit costs as determined by the Secretary on a prospective basis, unless such services were furnished during the 30 days immediately following the patient's discharge as a hospital inpatient.

Amends section 1833 (a)(2) (relating to payment for benefits) to limit payment for home health benefits to the lesser of reasonable cost or customary charges less the amount of allowable copayment. Public providers and other providers are exempt from the new cost sharing requirement (other than nominal cost sharing) if they can demonstrate that a significant proportion of their patients are low income, so long as certain conditions are met. Conforming amendments are made to section 1866.

(b) The effective date of this section is July 1, 1995.

**Section 4135. Expansion of Centers of Excellence.** (a) The Secretary must contract with centers of excellence for cataract and coronary artery bypass surgery and other services determined to be appropriate. In such cases, payment under Medicare shall be made under contracts on the basis of negotiated or all-inclusive rates as follows:

- (1) the center shall cover services in an urban area;
- (2) the aggregate to the center shall be less than it would have been had the agreement not been in effect; and
- (3) the Secretary shall make payments based on the following services: facility, professional and related services related to cataract surgery; coronary artery bypass surgery and related services; such other services as the Secretary and center agree to cover.

(b) The Secretary shall give a rebate equal to 10 percent of the savings to individuals who receive care at the center.

#### **PART 4 - PART B PREMIUM**

**Section 4141. General Part B Premium.** Amends section 1839(e) (relating to amount of premiums) to continue indefinitely the increase in the part B premium to 50 percent of the monthly actuarial rate for enrollees age 65 and over. Increases in premium amounts because of this change shall be taken into account in establishing the monthly premium payment level each year.

**Section 4151. Report on Savings.** By January 30, 1999, the Secretary shall submit to Congress a report containing a determination of whether the average annual rate of growth in Medicare spending (taking into account savings under this subtitle) in the four-fiscal-year period beginning with fiscal year 2000 will exceed a rate of growth equal to the CPI plus the average annual percentage change in the size of the Medicare population plus the average annual change in the real GDP plus 1.

**SUBTITLE C - MEDICAID**  
**(H.R. 3600 and S. 1757 p. 807)**

**PART 1 - COMPREHENSIVE BENEFIT PACKAGE**

**Section 4201. Limiting Coverage Under Medicaid of Items and Services Covered Under Comprehensive Benefit Package.** Amends the Medicaid statute by adding a new section to the statute clarifying that items and services covered in the benefit package shall no longer be considered medical assistance for purposes of Federal financial participation (Federal contributions for program costs). This rule applies to all Medicaid beneficiaries who are eligible individuals under Title I of the Act but excludes Medicaid beneficiaries who also receive Medicare and persons eligible for Medicaid but covered only for emergency services because they are undocumented persons. This rule applies in any state that provides payment to regional alliances in accordance with Title VI of the Act.

This amendment applies with respect to items and services furnished in a state on or after January 1 of the first year in which the state is making payments to regional alliances.

**PART 2 - EXPANDING ELIGIBILITY FOR NURSING FACILITY SERVICES; LONG TERM CARE INTEGRATION OPTION**

**Section 4211. Spend-down Eligibility for Nursing Facility Residents.** (a) Adds as a new mandatory coverage group to Medicaid those individuals who would meet the income and resource requirements of the appropriate state plan described in subclause (I) of section 1902(a)(10)(A)(i) of the Supplemental Security Income program, if their incurred expenses for medical care were deducted from their income.

(b) Benefits for this new mandatory coverage group are limited to coverage for nursing facility services unless the state has elected the long term care benefit option described in section 4213.

(c) The effective date for this section is January 1, 1996.

**Section 4212. Increased Income and Resource Disregards for Nursing Facility Services.** (a) Amends Medicaid by increasing to \$50 per month the amount of funds that an individual who is institutionalized in a nursing facility or an intermediate care facility for the mentally retarded may retain for personal needs. The section also allows states to disregard up to the first \$12,000 in assets held by an unmarried, institutionalized individual.

(b) Separate amendments to Title XVI of the Social Security Act increase the personal needs allowance for SSI beneficiaries who are residents of nursing facilities or institutions for persons with mental retardation (section 4301).



(c) The section also provides that the Federal government shall pay 100 percent of the difference between the amount of expenditures made by the state for nursing facility services and services at intermediate care facilities for the mentally retarded (ICF/MR services) during any quarter and the amount that the state would have expended had the personal needs allowance not been increased, based on the state's personal needs allowance in effect on September 30, 1993.

(d) The amendments made by this section are effective as of the month of January, 1996.

**Section 4213. Informing Nursing Home Residents About Availability of Assistance for Home and Community Based Services.** (a) Amends the Medicaid statute to require that as a condition of participation, states inform all individuals residing in nursing facilities or ICF/MR facilities of the range of home and community based care available at the time they apply for medical assistance and periodically thereafter. Individuals must be informed about both the home and community care available under Medicaid and services available under the new block grant program established under Title II.

(b) The amendments made by this section are effective for quarters beginning on or after January 1, 1996.

### **PART 3 - OTHER BENEFITS**

**Section 4221. Treatment of Items and Services Not Covered Under the Comprehensive Benefit Package.** Amends the Medicaid statute to specify which categories of Medicaid beneficiaries continue to qualify for services that are covered by Medicaid but are not included in the comprehensive benefit package.

The section adds a new section to the statute specifying limitations on services for beneficiaries. All Medicaid enrollees, regardless of whether they are classified as mandatory coverage groups under section 1902(a)(10)(A)(i) or optional coverage groups under section 1902(a)(10)(A)(ii) or section 1902(a)(10)(C), are eligible to receive long term care services covered under their state's Medicaid plan.

Long term care services are the following items and services, but only to the extent that they are not included in the comprehensive benefit package:

- (1) nursing facility services and intermediate care facility services for the mentally retarded (and items and services that may be included as part of such services pursuant to regulations in effect as of October 26, 1993);
- (2) personal care services;
- (3) home or community based services covered under a waiver granted under section 1915;

(4) home and community care provided to functionally disabled elderly individuals under section 1929;

(5) community supported living arrangement services provided under section 1930;

(6) case management services (as described in section 1915(g)(2), for individuals eligible for Medicaid services (which now, for nearly all beneficiaries, are limited to services not covered by the Act); and

(7) home health care, clinic services, and rehabilitation services that are furnished to an individual who has a condition or disability that qualifies the individual to receive services under (1) through (6).

The section also exempts from the long term care service limitation certain Medicaid enrollees. These individuals remain entitled to receive all required and optional items and services listed in section 1905(a) that are covered under their state's Medicaid plan, as well as the mandatory items and services listed under section 1905(r) (the Medicaid Early and Periodic Screening, Diagnosis and Treatment (EPSDT) benefit package for individuals under age 21), even if the service in question is not a "long term care" service within the meaning of the statute. Services that are not long term care include both services described in sections 1905(a) or 1905(r) that are not described in this section, as well as services that would fall within the definition of long term care under this section but for the fact that the individual receiving the service does not also require a service described in categories (1) through (6) above.

The following persons are exempt from the long term care coverage limits:

(1) Aid to Families with Dependent Children (AFDC) beneficiaries (individuals receiving aid under title I, X, XIV, XVI, or part A or E of Title IV of the Social Security Act);

(2) Supplemental Security Income (SSI) beneficiaries;

(3) Individuals also receiving Medicare, and

(4) Children under 18 years of age (or, at the option of the state, under age 19, 20 or 21).

The section also amends the Medicaid secondary payer program (sections 1902(a)(25) and 1903(o)) to clarify that Medicaid is a secondary payer to a health plan. The amendments made by this section apply on or after January 1 of the first year in which a state is a participating state.

**Section 4222. Establishment of Program for Poverty Level Children with Special Needs.** The Secretary is directed to establish a federally financed program for qualified children under age 19 who are eligible for Medicaid, for those items and services described in section 1905(a) or section 1905(r) that are not long term care services and that are not covered under a child's health plan. In this section, a "qualified child" is one born after September 30, 1983, who is under age 19, and who meets the financial requirements of the section. The financial requirements are as follows:

(i) for children under age 1, family income at or below 133 percent of the Federal poverty level (or in the case of states that established an income level greater than 133 percent as of October 1, 1993, an income level greater than 133 percent but at or below 185 percent);

(ii) for children ages 1 to 6, family income at or below 133 percent of the Federal poverty level;

(iii) for children ages 6 - 19, family income at or below 100 percent of the Federal poverty level.

The Secretary shall establish procedures for the enrollment of children in the program which shall assure enrollment in both Medicaid and the new program, shall utilize essential community providers as outstationed enrollment sites, and shall utilize forms that make enrollment as simple as practicable. The Secretary is also required to develop an automatic system for enrolling qualified children in both Medicaid and the new program at the time they enroll in alliance health plans.

The Secretary is required to publish new standards for this program that specify the benefits to which the program applies, procedures for the periodic redetermination of benefits, provider qualification criteria, payment amounts for covered services, standards to ensure the quality of care, hearings and appeals procedure, and other requirements needed for the proper and efficient administration of the program.

Federal financial participation for the program is 100 percent, including administrative expenses.

Limits on expenditures for the new program are as follows: the percentage of total state and Federal expenditures on qualified children for covered services adjusted to take into account an increase or decrease in the number of qualified children and adjusted by the applicable percentage applied to the state non-cash, non-DSH baseline (under section 9003 of the Act).

The program begins in the first year in which a state is a participating state under the Act.

The section also repeals section 1902(r)(2) for states not using the coverage option for children as of October 1, 1993.

#### **PART 4 - DISCONTINUATION OF CERTAIN PAYMENT POLICIES**

**Section 4231. Discontinuation of Medicaid DSH Payments.** Section 1923(a)(23) (relating to payments to Disproportionate Share (DSH) hospitals), is repealed in a state at the time when it becomes a participating state. State allotments and Federal financial participation are also repealed.

**Section 4232. Discontinuation of Reimbursement Standards for Inpatient Hospital**

**Services.** The requirement for cost based reimbursement to hospital inpatient services (known as the Boren Amendment) is repealed at the time when a state becomes a participating state.

#### **PART 5 - COORDINATION WITH ADMINISTRATIVE SIMPLIFICATION AND QUALITY MANAGEMENT INITIATIVES**

**Section 4241. Requirements for Changes in Billing Procedures.** Amends the Medicaid statute to prohibit states from changing billing and claims processing procedures more frequently than once every 6 months and requires states to notify individuals and entities furnishing services at least 120 days before a change is to take effect. This amendment takes effect on January 1 of the first year that a state is a participating state.

#### **PART 6 - MEDICAID COMMISSION**

**Section 4251. Medicaid Commission.** Establishes a Medicaid Commission comprised of 15 members appointed for the life of the commission. The purpose of the commission is to study matters relating to further Medicaid reform, including the use of block grant payment systems for covered services, the integration of acute and long term care services in health plans, consolidation of institutional and community based long term care, and other matters. The Commission shall report no later than one year following enactment of the Health Security act and shall terminate as of the date of the completion of the report.

**SUBTITLE D - INCREASE IN THE SSI PERSONAL NEEDS ALLOWANCE**  
**(H.R. 3600 and S. 1757 p. 832)**

**Section 4301. Increase in the SSI Personal Needs Allowance.** Amends the SSI statute to raise the personal needs allowance to \$600 annually for an institutionalized individual and \$1200 annually for an institutionalized couple. The amendment is effective on January, 1996.

## TITLE V - QUALITY AND CONSUMER PROTECTION QUALITY

### SUBTITLE A - QUALITY MANAGEMENT AND IMPROVEMENT (H.R. 3600 and S. 1757 p. 835)

**Section 5001. National Quality Improvement Program.** Not later than 1 year after the date of enactment, the National Health Board must establish a performance-based program of quality management and improvement designed to enhance the quality, appropriateness, and effectiveness of health care services and access to such services. The Board oversees the program, to be known as the National Quality Management Program, which is administered by a National Quality Management Council.

**Section 5002. National Quality Management Council.** (a) The National Quality Management Council is authorized to carry out tasks under this subtitle.

(b) The duties of the Council are to administer the National Quality Management Program, perform any other duty specified in this subtitle, and to advise the National Health Board with respect to its duties under this subtitle.

(c) The Council is composed of 15 members appointed by the President and its members must be broadly representative of the population of the United States. Members must include individuals representing the interests of: governmental and corporate purchasers of health care; health plans; states; health care providers; academic health centers; and individuals who are distinguished in the fields of public health, health care quality, and related fields of health services research.

(d) With the exception of the first appointees (whose terms shall be staggered), Council members serve three-year terms. A member of the Council may continue to serve after the expiration of the member's term of that member until a successor is appointed.

(e) If a member of the Council does not serve the full term applicable, the individual appointed to fill the resulting vacancy must be appointed for the remainder of the predecessor's term.

(f) The President must designate an individual to serve as the chair of the Council.

(g) The Council must meet not less than once during each discrete 4-month period and must otherwise meet at the call of the President or the chair.

(h) Council members must be compensated for each day (including travel time) engaged in carrying out the duties of the Council. Compensation may not exceed the maximum rate of basic pay payable for level IV of the Executive Schedule under section 5315 of title 5, U.S.C.

(i) The National Health Board must provide to the Council such staff, information, and other assistance as may be necessary for the Council to carry out its duties.

(j) For purposes of this subtitle, "health care provider" means an individual or entity that provides, to an individual in a health plan (as defined in section 1400), an item or service that is covered under the plan.

**Section 5003. National Measures of Quality Performance.** (a) The National Quality Management Council must develop a set of national measures of quality performance, which must be used to assess the provision of health care services and access to such services.

(b) The measures of quality performance must be ones that are capable of providing information on the following subjects:

- (1) consumer access to services;
- (2) appropriateness of health care services provided to consumers;
- (3) outcomes of health care services and procedures;
- (4) health promotion;
- (5) prevention of diseases, disorders and other health conditions; and
- (6) consumer satisfaction with care.

(c) (1) In developing and selecting the national measures of quality performance, the National Quality Management Council must consult with appropriate interested parties, including:

- (A) states;
- (B) health plans;
- (C) employers and individuals purchasing health care through regional and corporate alliances;
- (D) health care providers;
- (E) the National Quality Consortium established under section 5009;
- (F) individuals distinguished in the fields of law, medicine, economics, public health, and health services research;
- (G) the Administrator for Health Care Policy and Research;
- (H) the Director of the National Institutes of Health; and
- (I) the Administrator of the Health Care Financing Administration.

(2) The following criteria must be used in developing and selecting national measures of quality performance:

(A) Measures must relate to the significance of a specific disease, disorder or other health condition in terms of its prevalence, morbidity, mortality, or the costs associated with preventing, diagnosing, treating or clinically managing the disease, disorder, or condition.

(B) The measures, taken together, must be representative of the range of services provided to health-care consumers by health care providers.

(C) The measures must be reliable and valid.

(D) The data needed to calculate the measures must be obtained without

unduly burdening the entity or individual providing the data.

(E) Performance with respect to each measure must be expected to vary widely among the individuals and providers whose performance is assessed.

(F) When a measure is a rate of a process of care the process must be linked to a health outcome based upon the best available scientific evidence.

(G) When a measure is the outcome of provision of care, the outcome must be one that is within the control of the provider. The outcome must also be one with respect to which an adequate risk adjustment can be made.

(H) The measures may incorporate standards identified by the Secretary of Health and Human Services for meeting public health objectives.

(d) The National Quality Management Council must review and update the set of national measures of quality performance each year, to reflect changing goals for quality improvement. The National Health Board must establish and maintain a priority list of performance measures that, within a five-year period, the Board intends to consider for inclusion within the set through the updating process.

**Section 5004. Consumer Surveys.** (a) The National Quality Management Council must, by periodic surveys of health care consumers, gather information concerning access to care, use of health services, health outcomes, and patient satisfaction. The surveys must monitor consumer reaction to the implementation of this Act and must be designed to assess the impact of this Act on the general population of the United States and potentially vulnerable populations.

(b) The National Council must develop and approve a standard design for the surveys, which must be administered by the Administrator for Health Care Policy and Research on a plan-by-plan and state-by-state basis. A state may add survey questions on quality measures of local interest to surveys conducted in the state.

(c) The Council must develop sampling strategies that adequately measure populations at risk of receiving inadequate care, including persons who fail to enroll in plans, resign from plans or who are members of vulnerable populations.

**Section 5005. Evaluation and Reporting of Quality Performance.** (a) In areas where there is sufficient information and consensus to develop quality standards, the National Council must recommend to the Board that it establish goals for health plan and health care provider performance.

(b) The National Council must evaluate the impact of implementation of this Act on the quality of health care services in the United States, and the access of consumers to such services.

(c)(1) Each regional and corporate alliance must publish and make available to the public each year a performance report that outlines the performance of each health



plan offered by the alliance. The report must present, in a standard format, the each plan's performance on the set of national measures of quality performance. The report must also include the results of a smaller number of such measures (of quality performance) for health care providers who are members of provider networks of such plans (as defined in section 1402(f)), if the available information is statistically meaningful. The report must also include the results of consumer surveys described in section 5004 that were conducted in the alliance during the year that is the subject of the report.

(2) The National Council must report annually to Congress and to each health alliance a report in a standard format that:

(A) outlines the performance of each alliance and each health plan;

(B) discusses state-level and national trends relating to the quality of health care; and

(C) presents data for each health alliance from consumer surveys described in section 5004 that were conducted during the year that is the subject of the report.

(d) Amends the Health Care Quality Improvement Act to require the Secretary to promulgate regulations by January 1, 1996, permitting health plan enrollees access to data bank information on physicians and other licensed practitioners. Access must also be given to point-of-service contractors under medicare.

**Section 5006. Development and Dissemination of Practice Guidelines.** (a)(1) The National Council must direct the Administrator for Health Care Policy and Research to develop and periodically review and update clinically relevant guidelines, that may be used by health care providers to assist in determining how diseases, disorders, and other health conditions can be most effectively and appropriately prevented, diagnosed, treated, and managed clinically.

(2) The practice guidelines must:

(A) be based on the best available research and professional judgment regarding the effectiveness and appropriateness of health care services and procedures;

(B) be presented in formats appropriate for use by health care providers, medical educators, medical review organizations, and consumers of health care;

(C) include treatment-specific or condition-specific practice guidelines for clinical treatments and conditions, in forms that are appropriate for use in clinical practice, in educational programs, and in reviewing quality and appropriateness of medical care.

(D) include information on risks and benefits of alternative strategies for prevention, diagnosis, treatment and management of a given disease, disorder, or other health condition;

(E) include information on the costs of alternative strategies for the prevention, diagnosis, treatment and management of a given disease, disorder,

or other health condition, where cost information is available and reliable;

(F) be developed in accordance with priorities which the Council must establish, on the basis of research priorities established under section 5007, and the five-year priority list of performance measures described in section 5003.

(3) The Council must establish standards and procedures for evaluating the clinical appropriateness of protocols used to manage health service utilization.

(4) The Secretary of Health and Human Services may use guidelines developed under this subsection in the pilot program applying practice guidelines to medical malpractice liability under section 5312.

(b)(1) The National Council must direct the Administrator for Health Care Policy and Research to develop and publish standards relating to methodologies for developing clinically relevant guidelines for health care providers.

(2) The Council must also direct the administrator to establish a procedure by which individuals and entities may submit such clinically relevant guidelines for providers to the Council, for evaluation and certification by the Council using the standards established above for such guidelines.

(3) The Secretary may use guidelines that have been certified in the practice guideline pilot program for medical malpractice liability under section 5612.

(c) The National Council must direct the Administrator for Health Care Policy and Research to establish and oversee a clearinghouse and dissemination program for the practice guidelines that are developed or certified under this section.

(d) The Council must also disseminate information documenting clinically ineffective treatments and procedures.

**Section 5007. Research on Health Care Quality.** (a) The National Council must direct the Administrator for Health Care Policy and Research to support research that is directly related to the Council's five-year priority list of performance measures under section 5003. The research related to the priority list must include research with respect to:

- (1) outcomes of health care services and procedures;
- (2) effective and efficient dissemination of information, standards, and guidelines;
- (3) quality measurement; and
- (4) design and organization of quality of care components of automated health information systems.

(b) The Council must also establish priorities for research with respect to the quality, appropriateness and effectiveness of health care, and the council must make recommendations concerning research projects. In establishing the priorities, the Council must emphasize research involving diseases, disorders, and health conditions which demonstrate:

- (1) the highest level of uncertainty concerning treatment;
- (2) the widest variation in practice patterns;

(3) significant costs associated with prevention, diagnosis, treatment, or clinical management; and

(4) high rates of incidence or prevalence for the population as a whole or for particular populations.

**Section 5008. Regional Professional Foundations.** (a) The National Health Board must oversee the establishment of regional professional foundations.

(b)(1) The Board must also oversee the membership requirements and any other requirement for the internal operation of each such foundation.

(2) The membership of each professional foundation must include at least one academic health center (as defined in section 3101). The following types of entities may also be members of the foundation for the region in which the entity is located:

(A) schools of public health (as defined in section 799 of the Public Health Service Act);

(B) other schools and programs (as defined in the same section 799);

(C) health plans;

(D) regional alliances;

(E) corporate alliances; and

(F) health care providers.

(c) A regional professional foundation must carry out certain duties for the region in which it is located, with the boundaries of each region established by the Board, with the advice of the National Quality Consortium (established under section 5009). Each foundation must carry out the following duties:

(1) Develop programs in lifetime learning for health professionals (as defined in section 1112(c)(1), to ensure the delivery of quality health care;

(2) Foster collaboration among health plans and health care providers, to improve the quality of primary and specialized health care;

(3) Disseminate information about successful quality improvement programs, practice guidelines and research findings;

(4) Disseminate information on innovative uses of health professionals;

(5) Develop innovative patient education systems that enhance patients' involvement in decisions about their health care.

(6) Apply for and conduct the research on outcomes, quality of care and other matters described above in section 5007.

**Section 5009. National Quality Consortium.** (a) The National Health Board must establish a consortium, to be known as the National Quality Consortium.

(b) The consortium must:

(1) Establish continuing medical education programs for health professionals;

(2) Provide advice on research priorities to the National Quality Management Council and the Administrator for Health Care Policy and Research;

(3) Oversee the development of the regional professional foundations established under section 5008;

(4) Provide advice, with respect to funding proposals to establish the professional foundations, to the National Quality Management Council;

(5) Consult with the quality management council about the selection of national measures of quality performance under section 5003(c); and

(6) Provide advice, with regard to any other duty of the Board or the Council under this title, to the Board or the Council.

(c) The consortium must consist of 11 members, appointed by the Board, as follows: five individuals who represent the interests of academic health centers, and six other individuals, who represent the interests of schools of public health and other schools and programs defined in section 799 of the Public Health Service Act (including medical, nursing and allied health professional schools).

(d) The term of a member of the consortium is three years, with initial appointments on a staggered basis.

(e) The Board must also designate an individual to serve as the chair of the consortium.

**Section 5010. Eliminating CLIA Requirement for Certificate of Waiver for Simple Laboratory Examinations.** (a) Amends section 353 of the Public Health Service Act to exempt from federal rules clinical laboratories that perform only simple tests and procedures as defined by the Secretary.

(b) This section takes effect on the first day of the first month beginning after the date of the enactment of this Act.

**Section 5011. Uniform Standards for Health Care Institutions.** Not later than three years after the date of enactment the National Health Board must develop uniform standards for licensing health care institutions, that address essential performance requirements relating to patient care except in the areas of fire, safety, sanitation and patient rights. Standards must not undermine nursing home reform. The Council shall conduct and complete by January 1, 1996, demonstration projects using the standards and evaluate their impact on quality, costs, and providers. Standards once tested and revised shall replace existing standards except where changes in Federal statutes are required. The council shall also undertake efforts to develop a single consolidated annual audit and inspection.

**Section 5012. Role of Alliances in Quality Assurance.** Each alliance (regional and corporate) must:

(1) Disseminate to consumers information related to quality and access in order to aid in their selection of plans in accordance with section 1325;

(2) Disseminate information contained in reports of the National Quality

Management Council (under section 5005) on the quality of health plans and health care providers);

(3) Ensure, through negotiations with health plans, that performance and quality standards are continually improved; and

(4) In cooperation with regional professional foundations, conduct educational programs to assist consumers use quality and other information in choosing health plans.

**Section 5013. Role of Health Plans in Quality Management.** Each health plan must:

(1) Measure and disclose its performance on quality measures that are used by the following: participating states in which a plan does business; regional and corporate alliances that offer the plan; and the National Quality Management Council.

(2) Furnish the information that is required under subtitle B of this title, and provide other reports and information on the quality of care delivered by health care providers who are members of a provider network of the plan (as defined in section 1402(f)) as may be required under this Act; and

(3) Maintain quality management systems that use the national measures of quality performance developed by the National Quality Management Council under section 5003. Each plan also must measure the quality of health care that all providers who are members of a provider network of the plan furnish to enrollees under the plan.

**SUBTITLE B - INFORMATION SYSTEMS, PRIVACY, AND  
ADMINISTRATIVE SIMPLIFICATION  
(H.R. 3600 and S. 1757 p. 859)**

**PART 1 - HEALTH INFORMATION SYSTEMS**

**Section 5101. Establishment Of Health Information System.** (a) Within two years of enactment, the National Health Board must establish a system for collecting, regulating and disseminating certain health care information.

(b) The information system must be consistent with privacy security standards in the Act.

(c) The system must be consistent with reducing the costs of health care and providing health care information to state and Federal governments, health alliances and health plans.

(d) Health care information must be collected and reported in a manner that facilitates its use for the following purposes:

(1) health care planning, policy consideration and research by Federal, state and local governments and regional and corporate alliances;

(2) establishing and monitoring payments, by Federal and state governments and the alliances, for health services;

(3) assessing and improving the quality of care;

(4) measuring and improving access to health care;

(5) evaluating the cost of clinical or administrative functions;

(6) supporting public health functions and objectives;

(7) improving the capacity of health plans, providers and consumers to improve and make choices about health care; and

(8) managing and containing costs at the plan and alliance level.

(e) Health care information to be collected includes data on:

(1) enrollment and disenrollment in health plans;

(2) clinical encounters and other items and services furnished by health care providers to plan members;

(3) administrative and financial transactions of states, alliances, plans, providers, employers and individuals as are needed to determine compliances with this act or related laws;

(4) characteristics of regional alliances including the number and demographic characteristics of alliance residents;

(5) characteristics of corporate alliances including the number and demographic characteristics of enrolled individuals.

(6) terms of agreement between plans and participating providers;

(7) benefit payment information;

- (8) utilization management by health care plans and providers,
- (9) information collected and reported by the Board or disseminated through the National Quality Management Program;
- (10) grievances filed against alliances and plans and their resolution; and
- (11) information needed in order to determine compliance with health care fraud statutes.

**Section 5102. Additional Requirements For Health Information System.** (a) In developing the health information system, the Board must consult with the following agencies and entities:

- (1) Federal agencies that collect information, furnish health care, pay for health care or enforce one or more provisions of this Act;
- (2) the National Quality Management Council;
- (3) participating states;
- (4) regional and corporate health alliances;
- (5) health plans;
- (6) representatives of providers;
- (7) representatives of employers;
- (8) representatives of health care consumers;
- (9) experts in public health and health care information and technology;
- (10) representatives of organizations furnishing health care services, supplies and equipment.

(b) The National Board must establish standards for uniform collection and transmission of data. The standards must specify both the form and manner in which information is to be collected and transmitted and the frequency of transmission. To the extent practicable, standards must:

- (1) require uniform paper forms containing standard data elements in cases in which electronic transmission is not specified;
- (2) require the use of uniform data sets in the case of electronic transmission;
- (3) require uniform presentation; and
- (4) require electronic data interchange among automated systems.

(c) The Board's standards shall preempt inconsistent provisions of state law, unless the Board determines that the state law is needed to prevent fraud and abuse, or is related to controlled substances, or for other purposes.

**Section 5103. Electronic Data Network.** (a) The National Health Board, in consultation with certain entities must develop and administer an electronic data network consisting of regional centers that collect, compile and transfer information.

(b) The Board must consult with Federal agencies that collect health care information or provide or pay for health care, participating states, the National Quality Management Council, regional and corporate alliances, health plans, consumer, provider, and employer

representatives, experts in public health and health information and representatives of organizations that provide health services and supplies.

(c) The Board shall test the electronic data network prior to full implementation.

(d) Individual information may be released only in accordance with the Board's privacy standards under section 5120.

**Section 5104. Unique Identifier Numbers.** (a) The National Health Board must establish a system for assigning unique identifier numbers to the following persons:

- (1) eligible individuals;
- (2) employers;
- (3) health plans;
- (4) health-care providers;

(b) In establishing unique identifiers the Board must assure that a unique identifier number may not be used to connect individually identifiable information in the health information system with such identifiable information from any other sources, except where the Board determines that a connection is needed to carry out duties under the Act.

(c) The Board shall establish rules for the permissible use of unique identifiers.

**Section 5105. Health Security Cards.** (a) Health Security cards may be used only for obtaining benefits under:

- (1) a health plan,
- (2) a supplemental benefit policy or cost sharing policy (as defined in subtitle E of title I),
- (3) a Federal employee benefit plan supplemental policy (defined in Title VIII)
- (4) a FEHBP Medicare supplemental policy described in Title VIII, or
- (5) other program specified by the Board.

(b) The Board must issue regulations establishing standards for the use of cards and for the information to be encoded in the cards. The section requires that encoded information include

- (1) the identity of the card-holder;
- (2) the applicable health plan in which the individual is enrolled;
- (3) supplemental policies which the individual maintains; and
- (4) other information the Board determines is necessary.

(c) The unique identifier shall be encoded on the card.

(d) The Board must register the name and other features of the security card as a trademark.



(e) Misuse of the card is a criminal offense under section 5438.

**Section 5106. Technical Assistance In The Establishment Of Health Information Systems.** The Board must provide information and technical assistance on automated health information systems to participating states, alliances, health plans, and providers. Assistance must promote community-based health information systems that collect information at the place where the patient receives the care, or as a byproduct of providing care to the patient.

## **PART 2 -- PRIVACY OF INFORMATION**

**Section 5120. Health Information System Privacy Standards.** (a) Within two years of enactment, the Board shall promulgate standards for the privacy and security of individually identifiable information within the health information system. Standards must assure security. The Board must periodically revise the standards in consultation with Federal health agencies, the National Quality Management Council, participating states, regional and corporate alliances, health plans, and consumer representatives.

(b) The standards apply to individually identifiable information collected for or by, reported to or by, or the dissemination of which is regulated by, the Board.

(c) Standards shall incorporate the following principles:

(1) disclosure is prohibited unless:

(A) the enrollee discloses the information;

(B) the enrollee authorizes disclosure in writing;

(C) the disclosure is to a Federal, state or local law enforcement agency for the purpose of enforcing this act or a related act;

(D) disclosure is consistent with the Act, under rules of the Board.

(2) authorized disclosure is limited to the amount of identifiable information needed for the purpose for which it is disclosed.

(3) health plans may not transmit the identifiable information to regional or corporate alliances for purposes of setting premiums on the basis of risk-adjustment;

(4) individuals and entities that maintain, use or transmit such information must safeguard its security;

(5) individuals enrolled in health plans have the right to know what types of identifiable information is being maintained on them and why;

(6) enrollees or their representatives may see and copy information (subject to appropriate procedures) and have amendments or corrections noted;

(7) individuals must be notified in writing of the purposes for which individually identifiable information may be used or disclosed and the right of access described in paragraph (6).

(8) transmission of individual information shall use individuals' unique identifiers.

(9) individually identifiable health care information may not be used in making employment decisions.

**Section 5121. Other Duties With Respect To Privacy.** (a) The Board may sponsor research on privacy and security of individually identifiable health information, the development of disclosure consent forms, and the development of technology to implement the standards relating to such information.

(b) The Board must establish programs for training of personnel with access to individual information about their security duties, as well as public education programs for individuals and employers about their rights and protections.

**Section 5122. Comprehensive Health Information Privacy Protection Act.** (a) Within three years of the date of enactment of this Act, the Board must submit to the President and Congress a detailed proposal for privacy protection legislation that includes an easily understood code of fair information practices regarding individually identifiable health information, as well as enforcement provisions.

**Section 5123. Definitions.** (1) the term "enrollee" means an individual enrolled in a health care plan;

(2) the term "enrollee representative" means an individual legally empowered to make health care decisions for an enrollee;

(3) the term "individually identifiable health information" means any oral or recorded information that identifies or can be connected to an individual enrolled in a health plan, and that concerns his or her mental or physical health, health care, or payment for health care.

### **PART 3 -- INTERIM REQUIREMENTS FOR ADMINISTRATIVE SIMPLIFICATION**

**Section 5130. Standard Benefit Forms.** (a) Within a year after enactment the Board must develop and publish in the Federal Register standardized forms for :

- (1) enrollment and disenrollment;
- (2) clinical encounters; and
- (3) benefit claims.

(b) Forms must include instructions for completion and standardized codes and data sets.

(c) Within 270 days of publication the forms shall take effect, and health providers furnishing items and services in the United States must use the forms to file claims for payment. Health plans are also required to use the standardized enrolment, claims payment, and clinical encounter forms.

(d)(1) Affected health plans include any public or private entity or program providing for payment for health care services, including plans that are group health

plans under the Internal Revenue Code and any other health insurance arrangement or service contract. Plans that are accident only, credit, disability, liability supplement policies, or other types designated by the Board, shall not be required to use the forms. Workers' compensation and automobile medical insurance are covered by the standardization provision. Federal and state programs providing for the direct provision of health care to patients are not covered.

(2) Affected health service providers include any person or entity furnishing health care and includes Federal and state programs that support the direct provision of health services.

(e) The Board may modify or update any standardized form.

#### **PART 4 - GENERAL PROVISIONS**

**Section 5140. National Privacy And Health Data Advisory Council.** (a) A National Privacy and Health Data Advisory Council is established to advise the National Health Board on health-care information systems, information privacy and security, and other matters. The Council is appointed by the Board and consists of a 15-member board that includes representatives of consumers, employers and other purchasers of health care, plans, providers, alliances, public health agencies, participating states and experts in data collection and protection, law, ethics, medical and health services research, and other specified matters. Members serve three-year staggered terms, and individuals appointed to fill a vacancy shall serve out the remainder of the predecessor's term. The Council shall meet three times each year.

**Section 5141. Civil Money Penalties.** Establishes civil penalties of \$10,000 per violation for non-compliance with the standards for the health care information system and for privacy and security of system information, or for using a health security card or unique personal identifier for unauthorized purposes.

These penalties are in addition to other penalties that may be imposed by law. The process for imposition of a civil money penalty under this part shall be the same process used under subtitle E of title V (all-payer fraud provisions).

**Section 5142. Relationship To Other Laws.** Stipulates that the title may not restrict or invalidate the authority of any court with jurisdiction over health care information. The section also stipulates that the title neither restricts nor invalidates laws requiring reports of disease, child abuse, birth or death.

**SUBTITLE C - REMEDIES AND ENFORCEMENT**  
**(H.R. 3600 and S. 1757 p. 887)**

**PART 1 - REVIEW OF BENEFIT DETERMINATIONS**  
**FOR ENROLLED INDIVIDUALS**

**SUBPART A - GENERAL RULES**

**Section 5201. Health Plan Claims Procedure.** (a) A claim is a claim for payment for, provision of, or authorization before receipt of, benefits under a health plan; an individual claimant is a person who submits a claim to a health plan in connection with enrollment or on whose behalf a claim is submitted; a provider claimant is a provider who submits a claim on behalf of an enrolled member.

(b)(1) Plans must notify claimants in writing, within 30 days after an individual or provider claimant submits a complete claim, whether it is approved or denied. The notice must be understandable by a typical plan member and must take into account accessibility to the information by persons whose primary language is not English. If the plan denies a claim, it must provide a notice within five days of the determination to deny the claim. The notice must state the reasons for denial, and of the claimant's right to appeal the denial. A claim for which a plan fails to meet these requirements will be considered to have been approved by the plan.

(2) Plans must review written claimant requests for reconsideration of a claim denial, if the request is made within 60 days of receipt of written notice of the denial.

(3) The plan must review the denial and provide written notice of its decision within 30 days after receiving the request for reconsideration.

(4) The review must be *de novo* and the reviewer must be a person who did not make the initial denial decision and who is authorized to approve the claim. If an issue to be reviewed requires medical expertise, review by a qualified physician must be included in the process.

(c)(1) Plans must approve or deny within 24 hours after submission an "urgent" claim for pre-authorization of items or services (other than emergency services under section 1406, which may not be subject to pre-authorization), if the claim is submitted with a statement that failure to provide the requested benefits can reasonably be expected to seriously jeopardize the health of the claimant (including an unborn child of a pregnant woman), or result in serious impairment of bodily functions or serious dysfunction of any bodily organ or part. A decision within 24 hours is also required if the claimant has made or is at risk of making an attempt to harm himself or herself or another person.

(2) In the case of an urgent claim, a health plan must approve or deny the claim within 24 hours of submission. Failure to comply within the time limits shall be treated as approval.

(3) An urgent claim which is denied must be treated as a claim for which all internal plan grievance procedures have been exhausted.

(4) Plans are prohibited from later denying a claim that has been initially approved under the 24-hour pre-authorization. For any such subsequent denial, internal plan grievance procedures will be considered to have been exhausted.

(d) For purposes of this section, a complete claim is one submitted by an individual and accepted by a provider in a health plan, or any complete individual or provider claim, unless the plan notifies a claimant in writing, within 10 days of receiving a claim, that additional information is needed in order to complete the claim. The filing of such additional material will be treated as an initial filing of the claim.

(e) A plan's denial must be accompanied by certain information as follows:

(1) the factual basis of a determination that a claimed benefit is not covered under the comprehensive benefit package, or exceeds applicable payment rates;

(2) the medical basis for, and a description of the process used in, determining that a claimed benefit is excluded as an experimental treatment or investigatory procedure;

(3) the medical basis for, the guidelines used, and a description of the process used in determining that a claimed benefit is not medically necessary or appropriate or is inconsistent with the plan's practice guidelines.

(f) A plan may not require any party to waive any right under the plan or the Act as a condition of approval of a claim under the plan, except as specified in a formal settlement agreement.

**Section 5202. Review In Regional Alliance Complaint Review Offices Of Grievances Based On Acts Or Practices By Health Plans.** (a) Each state must establish and maintain a complaint review office, under rules prescribed by the Secretary of Labor. Such offices will also serve as complaint offices for residents of the regional alliance area who are enrolled in a corporate alliance.

(2) In cases in which a state is not a participating state, the Secretary of Health and Human Services must assume these state duties, under regulations of the Secretary of Labor.

(b) A person may file a complaint in the appropriate alliance complaint review office with regard to the following actions by a health plan:

(1) actions resulting in the delay or denial of payment or provision of benefits under an alliance plan;

(2) an act or practice by any plan involving the denial of payment or benefits under a cost sharing plan.

(c) Individuals may not file complaints until all plan remedies have been exhausted.

(d) The complaint and administrative and judicial review system in section 5202, 5203 and 5204 are the exclusive means of review for the delaying or denying actions described above by a corporate alliance health plan or cost-sharing policy.

(e) Complaints must be written, be sworn under oath or affirmed, and must include information required in regulations of the Secretary of Labor.

(f) The complaint review office must notify the person(s) complained against of the alleged violation within 10 days after the complaint is filed.

(g) Complaints may not be filed later than one year after the alleged violation occurs but may be amended.

**Section 5203. Initial Proceedings In Complaint Review Offices.** (a) At the time a complaint is filed, the review office must offer the complainant the right to elect one of the following forms of relief:

- (1) to forego further proceedings in the review office and seek whatever judicial remedies may be available (except in the case of grievances involving corporate alliance plans, for which the review process is the exclusive form of relief)
- (2) to submit the complaint to an early resolution program (thereby suspending further review); or
- (3) to proceed with a hearing (with regard to the original complaint, or to matters unresolved by the early resolution process).

(b) Matters that are part of a dispute for which early resolution has been selected shall not be assigned to a hearing unless the resolution process has terminated without settlement or resolution of the dispute. Submitting a complaint for early resolution does not affect the applicability of the review process except to the extent required by terms of a settlement or other formal resolution that is reached.

**Section 5204. Hearings Before Hearing Officers In Complaint Review Offices.**

(a)(1) A complaint review office must assign a complaint to a hearing officer empowered by the state. The hearing officer must have the power to issue and serve the complaint on the health plan and to furnish notice of a hearing scheduled no earlier than 5 days after the complaint is served. Hearing officers must meet standards prescribed by the Secretary of Labor with regard to experience, conflicts of interest and other qualifications.

(2) A hearing officer may amend the complaint upon the complainant's motion or at the officer's discretion, prior to the issuance of an order.

(3) The party complained against has the right to file an answer to the complaint (and any amendments), and to appear in person or otherwise present testimony at the hearing on the complaint.

(b) The hearing officer at the officer's discretion may permit other parties to intervene

and present testimony at the hearing.

(c) Hearings shall be *de novo*. Testimony must be reduced to writing, and the officer has the discretion to hear argument or take further testimony. The officer has the right to issue subpoenas, and the appropriate Federal district court has the power to enforce the subpoena. In the case of an urgent claim for benefits, a hearing shall be scheduled within 24 hours of the receipt of the complaint by the hearing officer.

(d) A hearing officer's decision must be based on a preponderance of the evidence, include the officer's finding of fact, and must constitute the officer's final disposition of the matter. If the officer decides in favor of the complainant, the officer must order the party complained against to halt the complained-of activities, provide benefits due under the plan and applicable requirements of this Act, pay the complainant interest up to the time of judgment, on the value of the contested benefit, and to pay reasonable attorney fees and other costs. If the officer decides that the party complained against has not improperly denied benefits or engaged in other prohibited activities with regard to the complainant, the section requires the officer to dismiss the charge. The officer must also require the complainant to pay attorney's fees and other costs of the party complained against, if the officer finds that the complaint was frivolous. The review office must issue copies of the officer's decision to the parties to the proceedings.

(e) A hearing officer's decision is final and binding on all parties. However, except for "urgent" complaints receiving an expedited hearing, a party to the complaint may file an appeal of the decision to the Federal Health Plan Review Board. The appeal must be filed within 30 days after the review office has served the decision on parties.

(f) If the decision in favor of a complainant is not appealed, a party to the proceeding may file for enforcement of the decision with any court with jurisdiction. In such an enforcement action, the court may not review the decision of the hearing officer and may award reasonable attorney's fees and costs.

**Section 5205. Review By Federal Health Plan Review Board.** (a) The Secretary of Labor must establish a five-member Federal Health Plan Review Board, which must operate under rules established by the Secretary. Board transactions must be recorded, and Board hearings and records must be open to the public.

(b) The Board must provide for reasonable notice of each appeal and for consideration of arguments by any party to the hearing on which the appealed decision is based. The section authorizes the Board, at its discretion, to permit any other person to intervene and present written argument. The National Health Board also may intervene in such proceedings.

(c) The Board's review shall be only for the purpose of determining:

(1) whether substantial evidence in the record, considered as a whole, supports the hearing officer's determination;

(2) whether the officer's determination is supported by a preponderance of the evidence if the hearing issue was interpretation of contract terms (regardless of the extent to which the officer considered extrinsic evidence);

(3) whether the officer's determination exceeds statutory jurisdiction, authority, limitations or violates a statutory right; or

(4) whether the determination was made without following proper legal procedures.

(d) The decision of a hearing officer, as approved, modified or reversed by the Board, is the final, binding order of the Board, subject to judicial review. The Board must serve parties with copies of its decision no later than five days after it is reached.

(e) A person who is aggrieved by a Board's final order may seek review of the order in a Federal court of appeals for the circuit in which the violation is alleged to have occurred or in which the complainant lives. Such appeal must be filed within 60 days after the Board's final order is entered, and the amount in controversy must be more than \$10,000. The court's jurisdiction over the appeal is exclusive once the record is filed, and its judgment is final, except as reviewed by the United States Supreme Court. The court may enforce the order by decree if it does not reverse the Board.

(f) The Board and the reviewing court may award a prevailing complainant reasonable costs and attorney's fees.

**Section 5206. Rules Governing Benefit Claims Determinations.** Determinations made under this part or by any state court in connection with a complaint under section 5202(b) shall be in accordance with the provisions of this Act, the comprehensive benefit package under the Act, and rules, regulations, and decisions of the National Health Board. Subject to this section, the rights and remedies available in state court against a health plan based on complaints under section 5202(b) shall be governed by state law.

**Section 5207. Civil Money Penalties.** The Secretary of Labor may assess civil penalties against persons for actions involving corporate alliance health plans, or any other plan in connection with a cost-sharing policy, for unreasonably denying or delaying payment or provision of benefits. The section authorizes penalties of up to \$25,000 per violation; but up to \$75,000 per violation if bad faith on the part of the plan is found; or up to \$1,000,000, in addition to the total amount of the foregoing penalties, if a pattern or practice of such violations is found. Each violation with regard to a single individual is a separate violation for purposes of assessing penalties. The section authorizes the Secretary to enforce the civil penalties in any court of competent jurisdiction.



## SUBPART B -- EARLY RESOLUTION PROGRAMS

**Section 5211. Establishment Of Early Resolution Programs In Complaint Review Offices.** (a) Each state must establish and maintain an Early Resolution Program in each of the state's complaint review offices. Each resolution program must establish and maintain forums for dispute mediation as described in this subpart, and any forums for other forms of alternative dispute resolution (including binding arbitration) that the Secretary of Labor may require by regulation. A state must ensure that the same requirements with regard to qualifications of personnel and confidentiality are observed in dispute mediation as are required by the Secretary of Labor for other types of dispute resolution.

(b) A complaint review office must administer its early resolution program and recruit and train attorneys to be resolution facilitators according to regulations of the Secretary of Labor. The office must provide sites, records, staff and attorney referral panels for resolution proceedings. The office must also inform a complainant of the complainant's options upon the filing of a complaint and monitor and evaluate the resolution program on an ongoing basis.

**Section 5212. Initiation Of Participation In Mediation Proceedings.** (a) A dispute may be submitted to an early resolution program only if the dispute involves an individual health plan enrollee's claim against a plan or a cost-sharing policy for the denial of payment or provision of benefits alleged to be covered by the plan or policy. A claim may be either a claim for payment or benefits, or a request for information or documentation that is required by the Act to be disclosed.

(b) An eligible complainant may choose to submit the dispute to mediation under the early resolution program no later than 15 days after filing the complaint with the review office. Submission of a dispute to mediation must be by written agreement (including complainant's agreement to comply with program rules, and consent for the complaint review office to contact the health plan); a complainant must also release plan records to the program, for exclusive use of the facilitator assigned to the dispute. The section requires each party designated by the complainant to participate in mediation to fully participate in the mediation; a party must provide to the claims review office a copy of a plan's written record of its claims procedure, and all relevant plan documents, with regard to the dispute.

**Section 5213. Mediation Proceedings.** (a) The facilitator assigned to a dispute in an early resolution program must prepare parties for a dispute conference and serve as a neutral mediator to settle the dispute.

(b) Before the conference the facilitator must determine if the case needs to be further developed or if additional information and documents are needed.

(c) During the conference the facilitator must help parties identify issues not in dispute, explore settlements, and help prepare a written agreement reflecting any settlement

reached. If there is no settlement, the facilitator must assess the parties' positions and the likely outcome of additional administrative action or litigation and suggest how to narrow the issues in dispute.

(d) The facilitator must ensure that mediation of a dispute conclude within 120 days after a complainant chooses mediation. Parties to mediation may agree to one extension of the mediation, of up to 30 days, if the mediation is suspended in order to obtain an agency ruling, or to reconvene the mediation for another session.

(e) Formal rules of evidence do not apply under an early resolution program, and all statements and evidence may be admitted. The facilitator acts as the sole judge of the proper weight to be given to each submission. The facilitator may not require parties to a proceeding to make their statements or present evidence under oath.

(f) Parties may proceed *pro se* or be represented by an attorney.

(g) Mediation proceedings under an early resolution program are subject to the Federal confidentiality rules that apply to dispute resolution proceedings (section 574 of title V, U.S.C), and the Secretary of Labor may assess a civil penalty of three times the amount of the claim involved against a person who discloses information in violation of appropriate regulations. The Secretary may enforce the penalty in any court with jurisdiction.

**Section 5214. Legal Effect Of Participation In Mediation Proceedings.** (a) The findings and conclusions of mediation proceedings of Early Resolution Programs shall be treated as advisory and nonbinding and, except to the extent foreclosed by a settlement reached in the proceedings, without effect on the rights of parties to the proceedings.

(b) A facilitator must assist parties write an agreement reflecting a settlement. Such an agreement, if signed by the parties, constitutes a binding and enforceable contract between them.

(c) A settlement agreement does not have the effect of waiving or otherwise affecting the rights to review under subpart A of this Part with respect to any person who is not a party to the settlement agreement.

**Section 5215. Enforcement Of Settlement Agreements.** (a) A party to a settlement agreement resulting from mediation proceedings may enforce the agreement through a court with jurisdiction. The order of the hearing officer is not subject to review in an enforcement proceeding.

(b) The court in which enforcement is sought has a duty to expedite a party's petition for enforcement.

(c) The prevailing party in an enforcement action is entitled to attorney's fees and

costs.

## **PART 2 -- ADDITIONAL REMEDIES AND ENFORCEMENT PROVISIONS**

**Section 5231. Judicial Review Of Federal Action On State Systems.** (a) A state or alliance aggrieved by a determination of the National Health Board with regard to the Board's review and approval of the state's system (subpart B of part 1 of subtitle F of title I) may seek judicial review of the determination.

(b)(1) The courts of appeals of the United States have jurisdiction to review the determination and to affirm the decision or to set it aside in whole or in part. A judgement under this section is subject to review by the United States Supreme Court upon certiorari or petition.

(2) A state or alliance that desires judicial review must file a petition for review in the court of appeals for the circuit in which the state or alliance is located, within 30 days after the state or alliance has been notified of the disputed National Board determination. The Board must file with the court a record of the proceedings on which its determination or action was based, as provided under section 2112 of Title 28 of the U.S. Code.

(3) The findings of fact by the National Board shall be considered conclusive if supported by substantial evidence, but the Court may remand a case to the Board for further evidence and the Board may make new or modified findings of fact and certify the record of further proceedings. New or modified findings shall be considered conclusive if supported by substantial evidence.

**Section 5232. Administrative And Judicial Review Relating To Cost Containment.** There is no administrative or judicial review of any National Health Board determination on any matter under subtitle A of title VI.

**Section 5233. Civil Enforcement.** Except as provide otherwise in the Act, Federal district courts have jurisdiction over civil actions by the Secretaries of Labor and Health and Human Services to enforce final orders of or civil money penalties assessed by the secretaries.

**Section 5234. Priority Of Certain Bankruptcy Claims.** Certain claims for monies owed to regional and corporate alliances or to the Secretary of Labor are given priority in bankruptcy proceedings.

**Section 5235. Private Right To Enforce State Responsibilities.** The failure by a participating state to carry out its responsibility under the act constitutes a deprivation of rights secured by this Act under section 1977 of the Revised Statutes of the United States (42 U.S.C. section 1983). A court must exercise jurisdiction over the claim regardless of whether the person bringing the action has exhausted any administrative or other remedies

provided by law.

**Section 5236. Private Right To Enforce Federal Responsibilities In Operating a System In a State.** (a) The failure of the Secretary of Health and Human Services to carry out the Secretary's responsibility to operate an alliance system in a non-participating state under section 1522 of the Act confers an enforceable right of action on any person aggrieved by the failure.

(b) Action may be brought in an appropriate state court or Federal district court regardless of whether the person bringing the action has exhausted his or her administrative or other remedies provided by law.

(c) A court may award compensatory and punitive damages and, at the discretion of the court, other appropriate relief if the court finds a failure in the Secretary.

(d) The court may also award reasonable attorney fees to a prevailing party but not to the United States as a party, and the United States is liable for costs as a private person would be.

**Section 5237. Private Right To Enforce Responsibilities Of Alliances.**

(a) Individuals aggrieved by the failure of a regional or corporate alliance to carry out its responsibility under the Act have an enforceable right of action and may commence action in an appropriate state or Federal district court.

(b) An action may be brought in an appropriate state court or Federal district court only if, with certain exceptions, the person bringing the action has exhausted his or her administrative or other remedies provided by law. Exceptions to the exhaustion rule include actions relating to determinations of a person's eligibility under the Act for health benefits (section 1001(c)), a premium discount (subpart A of Part 1 of subtitle B of title VI), or a reduction in cost sharing (subpart D of part 3 of subtitle D of title I. A court must also exercise jurisdiction regardless of exhaustion of remedies in actions relating to enrollment or disenrollment in a health plan.

(c) If the court finds a failure, it is authorized to award compensatory and punitive damages and any other appropriate relief.

(d) The court may allow the prevailing party reasonable attorney's fees, and the United States shall be liable for costs as a private person.

**Section 5238. Discrimination Claims.** (a) Individuals aggrieved by the failure of a health plan to comply with section 1402(c) may commence a civil action against the plan in an appropriate state or Federal court. The standards to be used to determine whether discrimination on the basis of age or disability has occurred shall be the standards that are applied under the Age Discrimination Act of 1975 (42 U.S.C. 6101 et seq.) and the

Americans with Disabilities Act of 1990 (42 U.S.C. 12101 et seq.) If a court finds that the plan has failed to comply with the Act, it may award compensatory and punitive damages and order other appropriate relief. The court may also award reasonable attorney fees to a prevailing party (but not to the United States as a party), and the United States is liable for costs as a private person would be.

(b) If the Secretary of Health and Human Services finds that a health plan has failed to comply with the anti-discrimination provisions or applicable regulations under section 1402, the Secretary must notify the plan of its failure. The Secretary is authorized to refer the matter to the Attorney General with a recommendation to commence an appropriate civil action, to terminate a plan's participation in an alliance or to take other action as provided by law, if the health plan fails or refuses to comply with the anti-discrimination provisions or regulations within a reasonable time after the notification.

(c) The Attorney General may bring a civil action in a district court on matters referred by the Secretary with recommendation for such action. The action may be for appropriate relief, including injunctive relief. A court may grant equitable relief as appropriate and other appropriate relief, including compensatory and punitive damages. The court may also assess a civil money penalty against the plan of \$50,000 for a first violation and \$100,000 for each subsequent violation.

**Section 5239. Nondiscrimination In Federally Assisted Programs.** Federal payments to regional alliances (under part 2 of subtitle C of title VI of the Act) constitute Federal financial assistance for purposes of section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794), section 303 of the Age Discrimination Act of 1975 (42 U.S.C. 6102), and section 601 of the Civil Rights Act of 1964 (42 U.S.C. 2000d).

**Section 5240. Civil Action By Essential Community Provider.** (a) An electing essential community provider (as defined by section 1431(d)) that is aggrieved by the failure of a health plan to comply with section 1431 requirements for the community provider's participation in the health plan may commence a civil action against the plan in state or Federal court.

(b) The court may award compensatory damages to the provider and order any other appropriate relief if it finds the health plan failed to comply with a duty imposed by section 1431. At its discretion the court may award reasonable attorney's fees to a prevailing party (but not to the United States as a party), and the United States is liable for costs as a private person would be.

**Section 5241. Facial Constitutional Challenges.** The United States District Court for the District of Columbia has original and exclusive jurisdiction over constitutional challenges brought against the Act or any provision of it, on its face and for every purpose. The court is prohibited from issuing a temporary order or preliminary injunction restraining enforcement, operation or execution of the Act or any provision of it, in connection with

such a constitutional challenge. A constitutional challenge must be initiated no later than a year after the enactment of the Act.

Facial constitutional challenges must be heard and determined by a district court of three judges (under section 2284 of title 28, U.S.C.). The court must consolidate any such constitutional challenges that are pending before the court and that involve a common question or law or fact. Appeal is authorized directly to the U.S. Supreme Court of any final judgment, decree or order in which the district court invalidates the Act or a provision thereof and determines that the holding will materially undermine application of the Act as a whole.

This section should not be read to limit the right of a person to bring litigation regarding the Act or a part of the Act, or to petition the Supreme Court for review of a district court holding at any time before judgment is rendered in a court of appeals, nor does the section limit the authority of the Supreme Court to grant review of such a petition.

**Section 5242. Treatment Of Plans As Parties In Civil Actions.** A health plan may sue or be sued as an entity. Summons may be served on a plan and other legal process of a court in connection with such a suit. Any money judgement against a plan shall be enforceable only against a plan as an entity and shall not be enforceable against any individual person.

**Section 5243. General Nonpreemption Of Existing Rights And Remedies.** Nothing in this title shall be construed to deny, impair or otherwise adversely affect a right or remedy available under law to any person on the date the Act is enacted, except to the extent that the right or remedy is inconsistent with the title.

**SUBTITLE D -- MEDICAL MALPRACTICE**  
**(H.R. 3600 and S. 1757 p. 933)**

**PART 1 - LIABILITY REFORM**

**Section 5301. Federal Tort Reform.**

(a)(1) The provisions in this part apply in any malpractice liability action brought in any state or Federal court, with the exception of cases involving claims or actions for damages arising from a vaccine-related injury or death, to the extent that title XXI of the Public Health Service Act applies to such a claim or action.

(2) This subtitle preempts any state law to the extent that such a law is inconsistent with the limitations contained in such provisions, except state laws providing for additional defenses, limiting liability, placing greater limitations on attorneys' fees, or otherwise imposing more restrictions than those contained in this part.

(3) The preemption in this part shall not be construed as a waiver of any defense of sovereign immunity asserted by any state under any provision of law, or by the United States. The preemption may not be construed to affect the applicability of any provision of the Foreign Sovereign Immunities Act of 1976. It shall not be construed to preempt state choice-of-law rules with respect to claims brought by a foreign nation or citizen of a foreign nation, nor to affect the right of any court to transfer venue or apply the law of a foreign nation, or to dismiss a claim of a foreign nation or a citizen thereof on the ground of inconvenient forum.

(4) This part shall not be construed to establish jurisdiction over medical malpractice liability actions in the district courts of the United States on the basis of section 1331 or 1337 of title 28, United States Code.

(b) For purposes of this subtitle:

(1) "Alternative dispute resolution system" (ADR) means a system for resolving medical malpractice claims in a manner other than by medical malpractice liability actions.

(2) "Claimant" means any person who alleges a medical malpractice claim and any person on whose behalf such a claim is alleged, including the deceased individual when such an action is brought through or on behalf of the individual's estate.

(3) "Health care professional" means any individual who provides health care services in a state and who is required by the state's laws or regulations to be licensed or certified by the state to provide the services in the state.

(4) "Injury" means any illness, disease, or other harm that is the subject of a medical malpractice liability action or a medical malpractice claim.

(5) "Medical malpractice liability action" means a civil action brought

in a state or Federal court against a health care provider or health care professional in which the plaintiff alleges a medical malpractice claim. This definition applies to any such civil action, regardless of the theory of liability on which the claim is based.

(6) "Medical malpractice claim," with two exceptions, means a claim in a civil action brought against a health care provider or health care professional in which a claimant alleges that injury was caused by the provision of (or the failure to provide) health care services. The term "medical malpractice claim" does not apply to any claim alleging an intentional tort, or to any claim based on an allegation that a product is defective and that is brought against an individual or entity that is not a health care professional or health care provider.

**Section 5302. Plan-based Alternative Dispute Resolution Mechanisms.** (a) No medical malpractice liability action may be brought by an individual enrolled in an alliance health plan (regional or corporate) for services covered until a final resolution of the claim under the plan's alternative dispute resolution system.

(b) Each regional or corporate alliance plan:

(1) must adopt at least one of the alternative specified dispute resolution methods for resolving medical malpractice claims arising from the provision of health care services to individuals enrolled in the plan.

(2) must disclose to enrollees and potential enrollees the availability of, and procedures for, consumer grievances under the plan, including the alternative dispute resolution method or methods adopted under this part.

(c)(1) The National Health Board must develop alternative dispute resolution methods for use by alliance plans (regional and corporate in resolving the medical malpractice claims. The methods are to be developed by regulation and must include at least the following: arbitration; required mediation; and a process requiring parties to make early offers of settlement.

(2) In developing the required alternative dispute resolution methods, the Board must assure that the methods promote resolution of medical malpractice claims in a manner that:

(A) is affordable for the parties involved;

(B) provides for timely resolution of claims;

(C) provides for the consistent and fair resolution of claims;

(D) provides for reasonably convenient access to dispute resolution for individuals enrolled in plans.

(d) After final resolution of an enrollee's claim under an alternative dispute resolution method applied under this section, an enrollee dissatisfied with the resolution may bring a cause of action to seek damages or other redress with respect to that claim, to the extent permitted under state law.



**Section 5303. Requirement for Certificate of Merit.** (a) Any medical malpractice liability complaint must be accompanied by an affidavit declaring that the individual (or the individual's attorney) has consulted and reviewed the facts of the action with a qualified medical specialist. The affidavit must also include a written report by the specialist that clearly identifies the individual and that states that the specialist, after reviewing the medical record and other material, has determined that there is a reasonable and meritorious cause for filing the action against the defendant. The affidavit must also state that the individual or the individual's attorney has concluded, on the basis of the qualified medical specialist's review and consultation, that there is a reasonable and meritorious cause for filing the action.

(b)(1) The requirement of subsection (a) does not apply if the individual bringing the medical malpractice liability action cannot obtain the affidavit before the applicable statute of limitations expires. The requirement also does not apply if at the time the individual brings the action, the individual has not been able to obtain medical records or other information necessary to prepare the affidavit pursuant to any applicable law.

(2) The action of an individual that is brought without the required affidavit must be dismissed unless the individual submits the required affidavit within 90 days after the action is brought or 90 days after medical records or other necessary information has been obtained.

(c) For purposes of the affidavit, a "qualified medical specialist" means a health care professional who is knowledgeable of, and has expertise in the same specialty area of, medical practice that is subject to the action. The medical specialist must also be one whom the individual reasonably believes to be knowledgeable in the relevant issues in the action, to practice or teach in the same area of health care or medicine at issue in the action within the preceding 6 years, and to be qualified by experience or demonstrated competence in the subject of the case.

(d) On a motion by any party or on its own initiative, the court in a medical malpractice liability action may impose a sanction on a party, the party's attorney, or both, if any information in the affidavit is submitted without reasonable cause and is found to be untrue. The sanction may include an order requiring that the sanctioned party reimburse the other party to the action for costs and reasonable attorney's fees.

**Section 5304. Limitation on Amount of Attorney's Contingency Fees.** (a) An attorney who represents on a contingency fee basis a plaintiff in a medical malpractice liability action may not charge, demand, receive or collect more than 33 and 1/3 percent of the total amount recovered by judgment or settlement in the action. This limitation applies also to resolution of the claim that is the subject of the action under any alternative dispute resolution.

(b) In the event that a judgement involves periodic payment, the amount recovered for purposes of computing the limit on the fee shall be based on the cost of the immunity or trust

established to make such payments or on the present value of the payments in cases in which there is no annuity or trust.

(c) For purposes of this section, "contingency fee" means any fee for professional legal services that is partly or completely contingent on recovering any amount of damages, whether through judgment or settlement.

**Section 5305. Reduction of Awards for Recovery from Collateral Sources.** The total amount of damages that an individual recovers in a medical malpractice liability action must be reduced by the amount of past or future payment that the individual has received, or is eligible to receive from other sources for the injury that is the subject of the claim. These sources include:

- (1) Federal or state disability or sickness programs;
- (2) Federal, state or private health insurance programs;
- (3) private disability insurance programs;
- (4) employer wage continuation programs; and
- (5) any other program, if the payment is intended to compensate the claimant for the same injury for which damages are awarded.

**Section 5306. Periodic Payment of Awards.** At the request of any party to a medical malpractice liability action, the defendant shall be permitted to make such payments periodically, based on a schedule that the court considers appropriate, taking into account the periods for which the injured party will need medical and other services.

## **PART 2 - OTHER PROVISIONS RELATING TO MEDICAL MALPRACTICE LIABILITY**

**Section 5311. Enterprise Liability Demonstration Project.** (a) Not later than January 1, 1996, the Secretary of Health and Human Services shall establish and fund a demonstration project in one or more states to demonstrate whether making the plan in which a physician participates, rather than the physician, liable for the physician's medical malpractice will improve the quality of health care provided under the plan, reduce defensive medical practices, and improve risk management. The funds for such demonstrations will be in the amount that the Secretary considers appropriate.

(b) A state is eligible to participate in the above-referenced demonstration project if the state submits an application to the Secretary that contains the following assurances:

- (1) the state has entered into an agreement with a health plan other than a fee for service plan under which the plan assumes legal liability for malpractice claims arising from the provision or failure to provide services under the plan by any participation physician;
- (2) the state provides that participating physicians in such plans may not be liable for damages and may not be required to indemnify the plan;
- (3) the state will provide periodic reports as required.

(c) Such sums as are necessary to carry out the demonstration are authorized to be appropriated.

**Section 5312. Pilot Program Applying Practice Guidelines to Medical Malpractice Liability Actions.** (a) No later than one year after determining that appropriate practice guidelines are available, the Secretary must establish and fund state demonstration projects to determine the effect of applying practice guidelines in the resolution of medical malpractice liability cases.

(b) A state is eligible to participate in the pilot program if the state submits an application to the Secretary containing:

(1) Assurances that under the law of the state, in a medical malpractice action alleging that the defendant was negligent in providing (or failing to provide) services, it is a complete defense that the defendant followed the appropriate practice guideline with regard to providing (or failing to provide) the services that are the subject of the action. The "appropriate practice guideline" is the guideline (for the services at issue) established by the National Quality Management Program under subtitle A.

(2) Other information and assurances as required by the Secretary.

(c) The Secretary must submit annual reports to Congress on the pilot program. Such reports must be submitted no later than 3 months after each year in which the pilot program is in effect. The reports must describe the operation of the program during the previous year and make such recommendations as the Secretary considers appropriate, including recommendations on revising the laws governing medical malpractice liability.

**SUBTITLE E - FRAUD AND ABUSE**  
**(H.R. 3600 and S. 1757 p. 948)**

**PART 1 -- ESTABLISHMENT OF ALL-PAYER HEALTH CARE  
FRAUD AND ABUSE CONTROL PROGRAM**

**Section 5401. All-Payer Health Care Fraud and Abuse Control Program.**

Requires the Secretary of the Department of Health and Human Services, through the Office of the Inspector General of the Department of Health and Human Services, and the Attorney General to establish a program to coordinate their programs and facilitate the enforcement of laws with respect to fraud and abuse; and to conduct investigations, audits, evaluations and inspections relating to the delivery of and payment for health care. Requires the Secretary and Attorney General to consult and share data and resources with law enforcement and other relevant public agencies, and to consult with and arrange for sharing data with health alliances and plans. Authorizes the Attorney General, the Secretary, and the Inspector General to carry out their duties under the program and to have access (including on-line access where available) to all records of health plans and health alliances to carry out their duties. Provides for qualified immunity for persons providing information to the Secretary or Attorney General. In addition to any other amounts authorized to be appropriated for health care anti-fraud and abuse activities in a year, authorizes the appropriation of such additional amounts as necessary to carry out the program. Authorizes the Inspector General to exercise all powers under the Inspector General Act of 1978 in carrying out this part.

**Section 5402. Establishment of All-Payer Health Care Fraud and Abuse Control Account.** Establishes an all-payer health care fraud and abuse control account in the Treasury, to contain gifts and bequests, criminal fines imposed for health care offenses, penalties paid to the government under the False Claims Act, administrative penalties and assessments imposed under the Social Security act, civil monetary penalties imposed under Section 5412, and amounts resulting from forfeiture of property by reason of a health care offense. Provides that amounts in the account shall be available without appropriation and may be used to cover the costs of carrying out the program established under section 5401 as determined by the Secretary and the Attorney General. States that such funds are intended to be supplementary to appropriated operating budgets of the agencies. Requires the Secretary and Attorney General to submit an annual report to Congress on the revenue generated and disbursed by the account. Defines a "health care offense" as a violation of specified sections of title 18 of the United States Code, of the Social Security Act, of ERISA, and of the Food Drug and Cosmetic Act, including certain sections as amended in the Health Security Act.

**Section 5403. Use of Funds by Inspector General.** Authorizes the Inspector General to retain and use any funds paid to reimburse for the costs of conducting investigations. Establishes in the Treasury the "HHS Office of Inspector General Asset Forfeiture Proceeds Fund," to be administered and continually available to the Inspector General for investigations. Requires that funds transferred from the Department of Justice

from forfeitures be deposited in the fund.

## **PART 2 -- APPLICATION OF FRAUD AND ABUSE AUTHORITIES UNDER THE SOCIAL SECURITY ACT TO ALL PAYERS**

**Section 5411. Exclusion from Participation.** Requires the Secretary to exclude from participation in an applicable health plan for not less than five years an individual or entity convicted of health care crimes or patient abuse (described in section 1128(a) of the Social Security Act, as amended under section 4044, supra). Permits the Secretary to exclude from participation in an applicable health plan for periods of different duration an individual or entity convicted of health care crimes (described in specified subsections of section 1128(b) of the Social Security Act, as amended under section 4044, supra). Requires the Secretary to provide notice of exclusions to sponsors of health plans, entities administering state health care programs, and state licensing agencies. Provides for notice, hearings, and judicial review of exclusions, with prior hearings except where the health or safety of individuals warrants exclusion prior to such a hearing. Provides terms for termination of the exclusion by the Secretary and for requests for exclusion by a health plan. Prohibits payments for items and services (other than emergency care) furnished by, or under the direction of, an excluded person (in situations in which persons working under the direction of an excluded person knew or had reason to know, of the exclusions.

**Section 5412. Civil Monetary Penalties.** Provides for the imposition by the Secretary for the following actions: actions with respect to health plans that are similar to those that would subject a person to a penalty under paragraphs (1) through (12) of section 1128A of the Social Security Act; terminating enrollment of a person in violation of subtitle E of title I or state law; discriminating on the basis of perceived need for medical services; inducing enrollment in a health plan under false pretenses; or providing financial incentives to enroll in a particular health plan. The provisions of section 1128A shall apply to imposition of penalties. Civil monetary penalties for actions similar to those that would subject a person to a penalty under the Social Security Act are as provided in that Act, and for other offenses are up to \$50,000. In addition to the civil monetary penalties, the Secretary may exclude persons committing such offenses from participation in all applicable health plans. Generally requires the Secretary to follow procedures and provide for appeals as would be required for similar proceedings under section 1128A of the Social Security Act, except that the Attorney General must take action within 60 days. If no proceeding to impose a civil monetary penalty has been initiated within 120 after the Secretary has presented a case to the Attorney General, the state in which the regional alliance is located may initiate such a proceeding. Amounts recovered are repaid to a health plan that has made such payments, with the remainder paid into the All-Payer Health Care Fraud and Abuse Account under section 5402, supra. Provides for notification by the Secretary to appropriate licensing agencies or organizations of the imposition of sanctions under this section. Authorizes the Secretary of Labor or state to take civil monetary penalty action against corporate or regional alliance plans if authorized by the Attorney General and the Secretary

of HHS. Provides the Attorney General and Secretary of HHS 120 days from date of notification by the Secretary of Labor to reach a determination.

**Section 5413. Limitations on Physician Self-Referral.** Provides for the application of the prohibitions, safe harbors, and penalties under section 1877 of the Social Security Act (dealing with physician self-referral) to similar actions taken with respect to health plans, and provides the Secretary of Labor and the states the authorities provided under that section to the Secretary of the Department of Health and Human Services.

**Section 5414. Construction of Social Security Act References.** Provides that the references to provisions under the Social Security Act are to that Act as amended by title IV of the Health Security Act but otherwise as that Act is in effect on the date of enactment of the Health Security Act.

### **PART 3 -- AMENDMENTS TO ANTI-FRAUD AND ABUSE PROVISIONS UNDER THE SOCIAL SECURITY ACT**

**Section 5421. Reference to Amendments.** Notes that amendments to anti-fraud and abuse provisions under the Social Security Act are found in part 5 of subtitle A of title IV.

### **PART 4 -- AMENDMENTS TO CRIMINAL LAW**

**Section 5431. Health Care Fraud.** Amends Chapter 63 of title 18, U.S.C., by adding a provision providing imprisonment of up to 10 years, or fines, or both, for anyone who knowingly attempts to or actually does defraud (or wrongfully obtain the property of) an alliance, plan or any other person. Provides for imprisonment for life or any term of years if the violation results in serious bodily injury.

**Section 5432. Forfeitures for Violations of Fraud Statutes.** Amends section 982(a) of title 18, U.S.C., to provide for forfeiture of property used in or derived from commission of a health care offense that poses a serious threat to the health of a person or has a significant detrimental impact on the health care delivery system, in proportionate value to the seriousness of the offense, from an individual convicted of the offense. Proceeds from such forfeitures are to be paid into the all-payer health care fraud and abuse control account in the Treasury.

**Section 5433. False Statements.** Adds a new section 1033 to Chapter 47 of title 18, U.S.C., providing for fines and imprisonment for up to five years for knowingly and willfully falsifying or covering up material facts, making false statements or representations, or making or using documents with false entries, and similar acts of misrepresentation.

**Section 5434. Bribery and Graft.** Adds a new section 226 to Chapter 11 of title 18, U.S.C., making unlawful the giving or promising to give anything of value to officials of

health plans, health alliances, provider organizations, state agencies, or related entities, for the purpose of influencing decisions by such officials or inducing them to engage in unlawful activities, and the soliciting and acceptance by such officials of such things of value. Authorizes fines, imprisonment for up to 15 years, or both. Bribes relating to health care officials' actions involving plans and alliances are also subject to fines and imprisonment.

**Section 5435. Injunctive Relief Relating to Health Care Offenses.** Amends section 1345(a)(1) of title 18, U.S.C., to include injunctive relief with respect to the anticipated commission of a health care offense.

**Section 5436. Grand Jury Disclosure.** Amends section 3322 of title 18, U.S.C., to authorize persons privy to grand jury information concerning a health law violation to disclose that information to the Government for use in civil proceedings or civil forfeitures.

**Section 5437. Theft or Embezzlement.** Adds a new section 668 to Chapter 31 of title 18, U.S.C., providing for fines and imprisonment for up to 10 years for theft or embezzlement of assets or funds of health plans or alliances.

**Section 5438. Misuse of Health Security Card or Unique Identifier.** Adds a new section 716 to Chapter 33 of title 18, U.S.C., providing for fines and imprisonment for up to 2 years for the use of a health security care or disclosure of a unique identifier for purposes other than those authorized under the Act.

## **PART 5 -- AMENDMENTS TO CIVIL FALSE CLAIMS ACT**

**Section 5441. Amendments to Civil False Claims Act.** Amends section 3729 of title 31, U.S.C., to provide that false claims for payments by health plans shall be considered false claims subject to the provisions of the False Claims Act.