HELP Committee *Affordable Health Choices Act* – Detailed Summary

September 14, 2009

Title I. QUALITY, AFFORDABLE HEALTH COVERAGE FOR ALL AMERICANS

Subtitle A. Effective Coverage for All Americans

> Synopsis: *This subtitle provides the basic structure for a reformed market for health insurance in all 50 states, the District of Columbia, and the territories. Health status underwriting and the imposition of pre-existing condition exclusions are prohibited in all individual and group employer health insurance markets. Rates within a geographic region may only vary by family composition, the value of the benefits package, tobacco use, certain health promotion and disease prevention programs, and age by a factor of not more than two to one. Guaranteed issue will be required for all insurers operating in the individual and group health insurance markets. All insurance policies must incorporate incentives for high quality and preventive health care services. Dependents will be permitted to stay on parents' policies until age 26. Lifetime and annual benefit limits will be prohibited in all individual and group policies. Existing health policies are exempt from the requirements specified in this subtitle.*

Insurance Market Reforms. Subtitle A will reform the individual and group health insurance markets in all 50 states, the District of Columbia, and the territories to promote availability of coverage for all individuals and employer groups. Under these new requirements, premium payments for insurance policies within each market will be permitted to vary only by family structure, geographic region, the actuarial value of benefits provided, tobacco use, certain health promotion and disease prevention programs, and age. Rates specifically will not be permitted to vary based on gender, class of business, or claims experience. Rating by age will be permitted to vary by no more than a factor of two to one. Insurers will be permitted to incentivize health promotion and disease prevention practices. Guaranteed issue and guaranteed renewability will be required in all states in each individual and group health insurance market. A group health plan and a health insurance issuer offering group or individual coverage will be prohibited from rescinding a policy once it has been issued, except in cases of fraud. (§ 2701, 2702, 2703, 2705)

Increasing the Transparency of Health Care Costs and Regulatory Fees. Health insurers offering group or individual policies will be required to publically report the percentage of total premium revenue that is expended on clinical services, quality and all other non-claims costs as determined by the Secretary of Health and Human Services. (§ 2704)

Prohibiting Discrimination Against Individual Participants and Beneficiaries Based on Health Status. In issuing health insurance policies, insurers will not be permitted to establish terms of coverage based on any applicant's health status, medical condition (including physical and mental illness), claims experience, prior receipt of health care, medical history, genetic information, evidence of insurability (such as being a victim of domestic violence), or disability. Employers will be permitted to reward employees for participation in certain disease prevention and health promotion programs by no more than 30 percent of the employee's premium share. (§2706)

Ensuring the Quality of Care. Health insurance policies will be required to include financial incentives to reward the provision of high quality care that include case management, care coordination, chronic disease management, wellness and health promotion activities, child health measures, activities to improve patient safety and reduce medical errors, as well as culturally and linguistically appropriate care. (§2707)

Coverage of Preventive Health Services. Health insurance policies will not be allowed to impose more than minimal cost sharing for certain preventive services endorsed by the U. S. Preventive Services Task Force as clinically and cost effective, for immunizations recommended by the CDC, and for certain child preventive services recommended by the Health Resources and Services Administration. (§2708)

Coverage of Preventive Women's Health Services. Health insurance policies will not be permitted to impose more-than-minimal cost sharing requirements for preventive care screening and services for women as defined by the U.S. Health Services and Resources Administration. (§2709)

Extension of Dependent Adults. All individual and group coverage policies will be required to continue offering dependent coverage for children until the child turns age 26, according to regulations to be established by the Secretary of Health & Human Services. (§2710)

No Lifetime or Annual Limits. No individual or group health insurance policy will be permitted to establish lifetime or annual limits on the dollar value of benefits for any enrollee or beneficiary. (§ 2711)

Notification by Plans Not Providing Minimum Qualifying Coverage. Health plans that fail to provide minimum qualifying coverage shall notify enrollees prior to enrollment or re-enrollment, according to regulations to be established by the Secretary of Health & Human Services. (§ 2712)

Non-Discrimination in Health Care. No health plan or insurer may discriminate against any health provider acting within the scope of that provider's license or certification under applicable State law. . (§ 2713)

Prohibition of Discrimination Based on Salary. Health insurers will not be permitted to limit eligibility based on the wages or salaries of employees. (§ 2720A)

No Changes to Existing Coverage. No individual must terminate his or her coverage in a plan in which the individual was enrolled prior to enactment of this Act. Family members, new employees, are permitted to enroll in health plans operating prior to enactment. This provisions in this subtitle will not apply to any individual or plan in which enrollment began prior to the effective date of the Act regardless of whether the individual renews coverage. These provisions do not apply to collective bargaining agreements ratified prior to the date of enactment or self-insured group health plans. Existing coverage plans are also excluded from the risk adjustment procedures established in section 142. The subtitle does apply if significant changes are made to the existing health insurance plan, according to regulations established by the Secretary of Health & Human Services. (§ 131, 132, 133)

Additional Market Reforms and Effective Dates. Sections 2701, 2702 and 2704 do not apply to self-insured group health plans. (§ 715) All provisions in subtitle A become effective for plan years beginning on or after one year after enactment, except Sections 2701, 2702, 2705, and 2706 which become effective in a state when such state becomes a participating or establishing state. (§ 135)

Subtitle B. Available Coverage for All Americans

> *Synopsis: This subtitle authorizes the establishment of an American Health Benefit Gateway in each state and of a Community Health Insurance Plan. Planning grants are provided to each state to support the creation of state Gateways. States may establish Gateways as quickly they wish, thus qualifying their residents for premium credits. If a state takes no action, the Secretary of Health & Human Services will establish and operate that state's Gateway. Gateways are established to help qualified individuals and qualified employers purchase affordable health insurance and related insurance products. The Gateway will establish procedures to qualify health plans to be offered through them, develop tools to enable consumers to obtain coverage, establish open enrollment periods, and assist consumers in the purchase of long term services and supports. The Secretary shall define essential health care benefits which will qualify for income-related premium credits, affordability standards, and minimum coverage standards for individuals. States may establish Navigators to assist businesses and individuals in obtaining affordable, quality coverage. The Community Health Insurance Plan will be administered by a nonprofit entity, and after receiving an initial loan for start-up expenses, will be subject to a federal solvency standards and state regulatory requirements.*

Building on the Success of the Federal Employees Health Benefit Program so All Americans have Affordable Health Benefit Choices. It is the sense of the Senate that Congress should establish a means for All Americans to have affordable choices in health benefit plans, in the same manner as Members of Congress. (§ 141)

Affordable Choices of Health Benefit Plans. Each state will have an American Health Benefit Gateway, established either by the state or by the Secretary of Health and Human Services that will be administered through a governmental agency or non-profit organization. Within 60 days of enactment, the Secretary will make planning grant awards to states to undertake activities related to establishing their own Gateway. The Gateway exists to facilitate voluntary purchase of health insurance coverage and related insurance products at an affordable price by qualified individuals and employers. States may require benefits in addition to essential health benefits and must assume additional costs. Risk pools include all enrollees in an individual plan or a group health plan. The Gateway will include a public health insurance option. The Gateway will establish procedures to qualify interested health plans to offer their health insurance policies through the Gateway. The section includes a conscience clause, under which insurance companies participating in the Gateway are prohibited from refusing to include health care providers in their networks because the providers perform abortions or refuse to perform abortions, except in emergency situations. (§ 3101)

Gateway Functioning. The Gateway will develop tools to enable consumers to make coverage choices including uniform standards for the explanation of benefits, and set up open enrollment periods to enroll in qualified health plans. After initial federal financial support, Gateways will become financially self-sustaining through establishing a surcharge on participating health plans. The Gateways will use risk adjustment mechanisms to remove incentives for plans to avoid offering coverage to those with serious health needs. Gateways will establish enrollment procedures to enable individuals to sign up for coverage, including Gateway plans with premium credits, Medicaid, CHIP, and others. The Secretary will establish a website through which individuals may connect to their state Gateway to purchase coverage. States may form regional Gateways operating in more than one state;

states may establish subsidiary regional Gateways, as long as each Gateway serves a distinct region. (§ 3101)

Existing Markets. If individuals prefer their current coverage, they may keep it. Licensed health insurers may sell health insurance policies outside of the Gateway. Any resident will be able to purchase health insurance outside the Gateway, including policies which do not meet standards to be a qualified health plan. States will regulate health insurance sold outside the Gateway. State insurance regulators will perform their traditional obligations regarding consumer protection and market conduct. For qualified health plans sold through the Gateway, the Secretary will issue regulations regarding marketing, network adequacy, and understandability for consumers. The Secretary will establish policies to facilitate enrollment, including use of electronic enrollment tolls, and provide grants to enhance community-based enrollment and public education campaigns, and policies for the certification of qualified health plans. (§ 3101)

Financial Integrity. The Department of Health and Human Services will oversee the financial integrity of Gateways by conducting annual audits, requiring financial reporting, and other measures, and the Secretary may rescind payments from state Gateways that fail to follow federal requirements. The Secretary shall also establish procedures and protections to guard against fraud and abuse. Additionally, the Comptroller General will conduct ongoing reviews of Gateway operations and administration. (§ 3102)

Program Design. The Secretary shall establish the essential health care benefit design which shall include at least ambulatory patient services, emergency services, hospitalization, maternity and newborn care, mental health and substance abuse services, prescription drugs, rehabilitative and abilitative services and devices, laboratory services, preventive and wellness services, and pediatric services which include vision and oral care. The Secretary must submit a report to Congress certified by the Chief Actuary of the Centers for Medicare and Medicaid Services that the health benefits meet these requirements. A National Independent Commission on Essential Health Care Benefits – 17 members, one-time, temporary, and independent – will advise the Secretary in the development of the essential benefit package. (§ 3103)

Affordable Coverage. Coverage is defined to be unaffordable if the premium paid by an individual is greater than 12.5 percent of the adjusted gross income of the individual involved. (§ 3103)

Allowing State Flexibility. States have three options regarding their participation in the Gateway. An "establishing state" is one that proactively seeks such status to launch its Gateway as early as possible and which meets the requirements of the law. A "participating state" requests that the Secretary establish an initial Gateway once all necessary insurance market reforms have been enacted by the state into law, and other requirements have been met. In a state that does not act to conform to the new requirements, the Secretary shall establish and operate a Gateway in the state after a period of six years, and such state will become a "participating state." Until a state becomes either an establishing or participating state, the residents of that state will not be eligible for premium credits, an expanded Medicaid match, or small business credits. (§ 3104)

Navigators. States will receive federal support to contract with private and public entities to act as health coverage "navigators" to assist employers, workers, and self-employed individuals seeking to obtain quality and affordable coverage through Gateways. Entities eligible to become navigators may include trade, industry and professional organizations, unions and chambers of commerce, small business development centers, licensed broker and agents, and others. Navigators will conduct public education activities, distribute information about enrollment and premium credits, and provide

enrollment assistance. Health insurers or parties that receive financial support from insurers to assist with enrollment are ineligible to serve as navigators. (§ 3105)

Community Health Insurance Option. The Secretary will establish a community health insurance option through each Gateway that complies with the health plan requirements established by this title and provides only the essential health benefits established in section 3103, except in States that voluntarily finance additional benefits. No health care providers or individual may be required to participate in the plan. Premiums must be sufficient to cover plan costs. The Secretary shall negotiate rates for provider reimbursement which shall not be higher than the average of all Gateway reimbursement rates. A "Health Benefit Plan Start-up Fund" will be created to provide loans for initial operations, which the plan will be required to pay back no later than 10 years after the payment is made. After the first 90 days of operation, the community health plan will be subject to a Federal solvency standard, established by the Secretary, and will be required to have a reserve fund that is at least equal to the dollar value of incurred claims. Each state will establish a State Advisory Council to provide recommendations to the Secretary on the policies and procedures of the community health insurance plan. (§ 3106)

Application of Same Laws to Private Plans and the Community Health Insurance Option. The community health insurance plan shall be subject to the same federal and state laws as any other insurance coverage regarding guaranteed renewal, rating, pre-existing conditions, non-discrimination, quality improvement and reporting, fraud and abuse, solvency and financial requirements, market conduct, prompt payment, appeals and grievances, privacy and confidentiality, licensure, and benefit plan material and information. (§ 3107)

Health Insurance Consumer Assistance Grants. The Secretary will award grants to states to enable them to establish, expand or support offices of health insurance consumer assistance. (§ 3109)

Subtitle C. Affordable Coverage for All Americans

> Synopsis: *This subtitle establishes a new subsidy structure to support the purchase of private health insurance. For those with incomes above the maximum level for Medicaid eligibility, premium assistance and cost sharing limits will facilitate health insurance affordability. Credits to defray premium costs will be provided on a sliding scale basis up to 400 percent of the federal poverty level to enable families to purchase insurance through the Gateway. These policies will cover services recommended by the Secretary; states may cover additional benefits and services at their own expense. Enrollment and eligibility determinations will be performed by the Gateway. Individuals may allow the Gateway to use IRS information to determine eligibility. New tax credits will be available to cover a portion of employees' insurance costs.*

Support for Affordable Health Coverage. To reduce the economic burden of health care on vulnerable Americans, low- and moderate-income individuals and families who enroll in plans through the Gateways will be eligible for premium credits. Credits are provided on sliding scale, so that those with the lowest incomes receive the most help. Gateways, which will provide information on health insurance options, will administer these credits. The premium credits would be on a sliding scale up to 400% of the poverty line ($88,080 for a family of 4), with those at lower end receiving higher levels of financial support. (§ 3111)

Geographic Adjustments. To account for regional premium variations, credits will be based on a reference premium. The reference premium will be calculated on the average premiums of the three lowest cost qualified plans offered in each area. Premiums will be adjusted for variations in patient

characteristics or risk factors. Services not included in the essential benefits design package will not be paid for with premium credits. States are permitted to make payments for individuals that exceed required amounts or to defray costs of services in addition to the essential benefits package. (§ 3111)

Eligibility Determination. Gateways will conduct eligibility determinations in accordance with guidelines established by HHS. If HHS finds that Gateways are abusing the eligibility determination process, HHS may conduct such determinations itself. To enhance program integrity, the Secretary shall require income verification through the use of tax returns. Procedures are included to allow the Gateways to verify that individuals are not receiving more credits than they are entitled to receive, and to invoke fees on those who receive overpayments. The credits are funded as an entitlement, not an authorization of appropriations. (§ 3111)

Small Business Health Options Program Credit. Beginning in 2010, employers with 50 or fewer full-time workers who pay 60 percent or more of their employees' health insurance premiums will be permitted to receive program credits of up to $2,000 per employee to subsidize coverage. Credit amounts are based on the type of employee coverage, employer size, and the proportion of time the employer paid employee health insurance expenses, and are available for up to three consecutive years. Self-employed individuals who do not receive premium credits through the Gateway are eligible. (§ 3112)

Subtitle D. Shared Responsibility for Health Care

This subtitle creates a shared responsibility framework. Individuals will be required to purchase health coverage that meets minimum standards and to report such coverage annually. Exemptions will be made for individuals unable to access affordable care. Fees will be assessed on employers who do not provide qualifying coverage for full- and part-time employees. Employers with 25 or fewer employees are exempt from penalties. Standards will be established to ensure efficient use of health information technology for enrollment in qualified health plans.

Individual Responsibility. All individuals will be required to obtain health insurance coverage. Exemptions will also be made for individuals for whom affordable health care coverage is not available or for those for whom purchasing coverage creates an exceptional financial hardship. The minimum penalty to accomplish the goal of enhancing participation in qualifying coverage will be no no more than $750 per year. Individuals deemed to lack availability to affordable coverage (as determined in section 3103), Indians, individuals living in states where Gateways are not yet established, and individuals without coverage for fewer than 90 days are exempt from the penalty. (§ 161, 59B)

Reporting of Health Insurance Coverage. Health plans providing qualified health insurance will file a return containing information regarding health insurance coverage. The return shall include basic information including the number of months during which an individual was covered. Health plans shall provide this information in writing to covered individuals. The IRS shall notify individuals who file income tax returns and are not enrolled in qualifying coverage and shall include information on services available through the Gateway. Employers must provide written notification informing employees about the Gateway. (§ 6055)

Shared Responsibility of Employer. Employers with more than 25 employees who do not offer qualifying coverage (as determined in section 3103) or who pay less than 60 percent of their employees' monthly premiums are subject to a $750 annual fee per uninsured full-time employees and

$375 per uninsured part-time employees. For employers subject to the assessment, the first 25 workers will be exempted. An employer that ordinarily has 25 employees or fewer is not required to pay the annual fee if it exceeds 25 employees for less than 120 days per year due to employment of seasonal workers. Beginning in 2013, the penalty amounts will be adjusted using the Consumer Price Index for urban consumers. Employers with 25 or fewer employees are exempt from penalties and are eligible for program credits in section 3112. (§ 3115)

Definitions: (§ 3116)

- Eligible Individuals are citizens or lawfully admitted permanent residents of the U.S. who are enrolled in a qualified health plan. Those eligible for other public programs are not eligible for credits, with a special rule for CHIP. Those in CHIP (or their parents) may determine whether staying in CHIP works best for them, or whether moving to the Gateway is better. Either choice is permissible, though the individual may not enroll in both the Gateway and CHIP.

- Qualified employer is an employer who chooses to make employees eligible for a qualified health plan. If enrollment takes place through a Gateway, the employer must meet State or federal criteria. The initial federal criteria are set so that only small firms are qualified. Participating employers with up to 50 employees may continue participation in the Gateway if they subsequently grow to more than 50 employees.

- Qualified health plan means a plan has certification issued by a Gateway and is offered by a licensed health insurance company. The health insurer must agree to offer at least one qualifying health plan with appropriate cost sharing levels, comply with regulation and pay any surcharge. This includes the community health insurance option.

- A qualified individual resides in a participating or establishing State, is not incarcerated, is not eligible for Medicare or Medicaid, TRICARE, FEHBP, or employer-sponsored coverage.

- Qualifying coverage means: a) a group health plan or insurance coverage an individual was enrolled in on the date of enactment; b) a plan meeting the requirements of § 3103; c) Medicare; d) Medicaid; e) Title XXI of the Social Security Act; f) Tricare; g) Veterans health coverage; h) FEHBP coverage; i) a state high risk pool; or j) coverage under a qualified health plan.

Subtitle E. Improving Access to Health Care Services

Spending for Federally Qualified Health Centers (FQHCS): FY2010 - $2.98B; FY2011 - $3.86B; FY2012 - $4.99B; FY 2013 - $6.44B; FY2014 - $7.33B; FY2015 - $8.33B. (§ 171)

Reauthorization of Wakefield Emergency Medical Services for Children Program (§ 175)

Grants for Co-Locating Primary and Specialty Care in Community-based Mental Health Settings: $50M for coordinated and integrated services through the co-location of primary and specialty care in community-based mental and behavioral health settings. (§ 176)

Subtitle F. Making Health Care More Affordable for Retirees

Reinsurance for Retirees. The Secretary will create a temporary reinsurance program to provide reimbursement to employers who provide health benefits to retirees (those older than 55 but not yet

eligible for Medicare) and their dependents who live in states that have not yet established Gateways. The reinsurance program will be funded through a Retiree Reserve Trust Fund. (§ 181)

Subtitle G. Improving the Use of Health Information Technology for Enrollment and Other Provisions

Health information technology standards. Standards and protocols shall be developed to promote the interoperability of systems for enrollment of individuals in federal and state health and human services programs. These standards shall allow for electronic data matching, and electronic documentation. The Secretary may require State or other entities to incorporate such standards as a condition of receiving federal health IT funds. Grants shall be awarded to develop and adapt systems to implement the standards described above. (§ 185, 3021)

Hawaii. Nothing in this Act shall modify or limit the application of the exemption for Hawaii's Prepaid Health Care Act under ERISA. (§ 186)

Key National Indicators. Establishes a Commission on Key National Indicators to conduct a comprehensive oversight of a newly established key national indicators system, with a required annual report to Congress. (§187)

Study and Report on Rates of Preventable Disease in New Medicare Enrollees. GAO study on rates of preventative disease. (§ 188)

Subtitle H. COMMUNITY LIVING ASSISTANCE SERVICES AND SUPPORTS (CLASS)

Establishment of National Voluntary Insurance Program for Purchasing Community Living Assistance Services and Supports

> *Synopsis: This section creates a new national insurance program to help adults who have or develop functional impairments to remain independent, employed and stay a part of their communities. Financed through voluntary payroll deductions (with opt-out enrollment similar to Medicare Part B), this program will remove barriers to independence and choice (e.g., housing modifications, assistive technologies, personal assistance services, transportation) by providing a cash benefit to individuals unable to perform two or more functional activities of daily living. The large risk pool created will make added coverage more affordable and reduce incentives for people with severe impairments to spend down to Medicaid.*

Purposes. The intent is to establish a national voluntary insurance program for purchasing community living assistance services and support in order to provide individuals with functional limitations with tools that will allow them to maintain their personal and financial independence and live in the community through a new financing strategy for community living assistance services and supports, establish an infrastructure that will help address the Nation's community living assistance services and supports needs, and alleviate burdens on family caregivers. (§ 3201)

Definitions. "Active enrollee" means an individual who has enrolled and paid premiums to maintain enrollment. "Activities of daily living" include eating, toileting, transferring, bathing, dressing, and

continence or the cognitive equivalent. An "eligible beneficiary" has paid premiums for at least 60 months and for at least 12 consecutive months. (§ 3203)

CLASS Independent Benefit Plan. The Secretary of Health & Human Services will develop two alternative benefit plans within specified limits. The monthly maximum premiums will be set by the Secretary to ensure 75 years of solvency. There is a five year vesting period for benefit eligibility. The benefit triggers when an individual is unable to perform not less than two activities of daily living for at least 90 days. The cash benefit will be not less than $50 per day. Not later than October 1, 2012, the Secretary will designate a CLASS benefit plan, taking into consideration the recommendations of the CLASS Independence Advisory Council. (§ 3203)

Enrollment and Disenrollment. The Secretary will establish procedures to allow for voluntary automatic enrollment by employers, as well as alternative enrollment processes for self-employed, employees of non-participating employers, spouses and others. Individuals may choose to waive enrollment in CLASS in a form and manner to be established by the Secretary. Premiums will be deducted from wages or self-employment income according to procedures established by the Secretary. (§ 3204)

Benefits. Eligible beneficiaries will receive appropriate cash benefits to which they are entitled, advocacy services, and advice and assistance counseling. Cash benefits will be paid into a Life Independence Account to purchase nonmedical services and supports needed to maintain a beneficiary's independence at home or in another residential setting, including home modifications, assistive technology, accessible transportation, homemaker services, respite care, personal assistance services, home care aides, and added nursing support. (§ 3206)

CLASS Independence Fund. The CLASS Independence Fund will be located in the Department of the Treasury and the Secretary of the Treasury will act as the Managing Trustee. A CLASS Independence Fund Board of Trustees will include the Commissioner of Social Security, the Secretary of the Treasury, the Secretary of Labor, the Secretary of Health & Human Services, and two members of the public. (§ 3206)

CLASS Independence Advisory Council. The CLASS Independence Advisory Council, created under this Title, will include not more than 15 members, named by the President, a majority of whom will include representatives of individuals who participate or are likely to participate in the CLASS program. The Council will advise the Secretary on matters of general policy relating to CLASS. (§ 3207)

Title II. HEALTH QUALITY AND DELIVERY SYSTEM REFORM

Subtitle A. National Strategy to Improve Health Care Quality

> *Synopsis: This subtitle requires the Secretary of Health and Human services to establish a national strategy and support infrastructure necessary to improve the quality of the U.S. health care system. The strategy will target priority areas, use health information technology to incorporate quality improvements, and focus on health outcomes and population health. An interagency working group will coordinate and implement health care quality improvement initiatives. Quality measures will be identified, developed and endorsed. A streamlined and integrated quality reporting process will minimize the burden on providers.*

National Strategy for Quality Improvement in Health Care: The U.S. lacks a coherent strategy to improve the quality of the nation's health care system. The Secretary of HHS is directed to establish a national quality strategy and implement its priorities. Health outcomes, as well as quality initiatives to improve them, vary widely across the country. The National Strategy aims to reduce geographic variations in care quality and reduce health disparities while improving the delivery of health care services, patient health outcomes, and population health. The Secretary will identify priority areas to improve the delivery of health care services. Additionally, quality improvements will eliminate waste and improve efficiency in the health care system. [§ 201]

Interagency Working Group on Health Care Quality: The U.S. lacks an effective way in which to share and implement quality initiatives. The President is directed to create an inter-agency Working Group to coordinate, collaborate and streamline federal quality activities around the national quality strategy. The Working Group will also share best practices and lessons learned among all health care sectors and government agencies. The quality activities will be related to the priorities defined in the national strategy. Agencies will be required to develop individual strategic plans and then to report to both Congress and the public on the progress toward implementing the strategic plans. [§ 202]

Quality Measure Development: The U.S. lacks an effective way in which to comprehensively measure health care quality. The Director of the Agency for Health Care Research and Quality (AHRQ) is directed to provide grants to organizations, such as specialty societies, to develop measures in "gap" areas where no quality measures exist, or where existing quality measures need improvement, updating, or expansion. Measures will be developed according to priority areas related to care coordination, patient experience, health disparities, and the appropriateness of care. Quality measures developed through grants under this program will be made publicly available. [§ 203]

Quality Measure Endorsement, Public Reporting; Data Collection: The U.S. lacks a streamlined, interoperable, quality measure endorsement and reporting system. AHRQ is directed to establish a streamlined quality measure endorsement process. It is directed to contract with a consensus based organization, such as the National Quality Forum, to evaluate and endorse quality measures for use with Federal health programs. The Secretary is given the discretion about whether to adopt the measure. The data from the reporting of these quality measures will be made available in a user-friendly format to inform providers, patients, consumers, researchers, and policymakers. [§ 204]

Collection and Analysis of Quality Measure Data:

To facilitate public reporting, the Secretary will establish a process to collect, validate and aggregate data on quality measures. The Secretary will also provide grants and contracts for the collection and aggregation of quality measures as well as for analysis of health care data. [§ 205]

Subtitle B. Health System Quality Improvement

> *Synopsis: This subtitle establishes health quality initiatives to reduce medical errors, reduce hospital readmissions, improve patient safety, promote evidence-based medicine and disseminate best care practices. An integrative model of patient-centered care will be supported through the establishment of Community Health Teams. Research and informational tools will be encouraged to assist patients make informed decisions about care options available to them. In order to eliminate waste, routine administrative processes that divert scarce health resources from patients to paperwork will be streamlined.*

Health care delivery system research; Quality Improvement Technical Assistance. A Patient Safety Research Center is established in AHRQ. In addition to supporting research, technical assistance and

process implementation grants will be made to local providers to teach and implement best practices. Best practices help deliver care safely. The Patient Safety Research Center will strengthen best practice research and dissemination. Creating grants to identify and disseminate best practices to local providers will prevent medical errors and reduce their associated costs. One such practice is the Pronovost Checklist, which uses ten simple steps to properly insert a catheter and eliminate line infections. [§ 211]

Community Health Teams. The Secretary is directed to create a program to fund Community Health Teams. States or state-designated entities would be eligible for grants under this program. Community Health Teams will be established to support the development of medical homes by increasing access to comprehensive, community based, coordinated care. A patient's care is coordinated by an integrated team of providers that includes primary care providers, specialists, other clinicians and licensed integrative health professionals as well as community resources to enhance wellness and lifestyle improvements. It is patient-centered and holistic in its orientation. [§ 212]

Grants to Implement Medication Management Services in Treatment of Chronic Disease. The Secretary, through the new Patient Safety Research Center within AHRQ, will provide grants to support local health providers for medication management services. Medication management services help manage chronic disease, reduce medical errors, and improve patient adherence to therapies while reducing acute care costs and reducing hospital readmissions. This program attempts to evaluate and determine the best practices and develop quality measures specific to this service provided by pharmacists and other types of providers. [§ 213]

Regionalized Systems for Emergency Care, including Acute Trauma. This section provides funding by the Assistant Secretary for Preparedness and Response to states or local governments to help improve regional coordination of emergency services. Access to the emergency medical system will be facilitated and a mechanism to ensure that patients are directed to the most appropriate medical facility will be established. Inter-facility resources will be tracked and coordinated in real time. [§ 214]

Trauma Care Centers and Service Availability. This section reauthorizes and improves the trauma care program, providing grants by the Secretary of HHS to states and trauma centers to strengthen the nation's trauma system. Grants are targeted to assist centers in underserved areas susceptible to funding and workforce shortages. [§ 215]

Reporting and Reducing Preventable Readmissions. Hospitals will be required by the Secretary of HHS to report preventable readmission rates. Hospitals with high re-admission rates will be required to work with local patient safety organizations to improve their care transition practices including the effective use of discharge planning and counseling. [§ 216]

Program to Facilitate Shared Decision Making. The Secretary of HHS will give grants to the National Quality Form to develop, test, and disseminate educational tools to help patients and caregivers understand their treatment options. Materials will assist patients to decide with their provider what treatments are best for them based on these beliefs and preferences, options, scientific evidence, and other circumstances. Providers will be educated on the use of these tools. Quality measures related to utilization of these tools as well as patient and caregiver experiences will be developed. [§ 217]

Presentation of Drug Information. A process will be established for the FDA to evaluate and determine if the use of drug fact boxes in advertising and other forms of communication for prescription medications is warranted. A standardized, quantitative summary of the relative risks and

benefits developed by FDA is an effort to clearly communicate drug risks and benefits and support clinician and patient decision making processes. [§ 218]

Center for Health Outcomes Research and Evaluation. The Secretary of HHS shall establish a new Center within the AHRQ that will promote health outcomes research and evaluation that enables patients and providers to identify which therapies work best for most people and to effectively identify where more personalized approaches to care are necessary for others. An Advisory Commission representing diverse interests will be established by the Secretary and public input will be sought in order to ensure research conducted is meaningful to patients and providers. [§ 219]

Demonstration Program to Integrate Quality Improvement and Patient Safety training into health professionals' clinical education. Grants will be provided by AHRQ to academic institutions to develop and implement academic curricula that integrate quality improvement and patient safety into health professionals' clinical education. [§ 220]

Improving the Health of Women. This section will improve the health and the quality of care for women by making permanent women's health offices that currently exist within HHS and its agencies. Statutory authorization for federal women's health offices ensures women's health programs affecting prevention, treatment, and research will continue to receive the attention they require in the twenty-first century. [§ 221]

Administrative Simplification. Enacted in 1996, the HIPAA law promised to simplify the administration of health care – yet that promise has gone largely unrealized. Since 1996, the potential of information technology to streamline commerce has increased exponentially, but the HIPAA standards have not kept pace. This section updates administrative simplification standards for the electronic age by requiring new technical standards designed to provide a common technical platform for more seamless administration of health care. This section includes a provision to ensure timely updating of standards for electronic data interchange to meet evolving requirements in health care administration. [§ 222]

Patient Navigator Program. This section reauthorizes demonstration programs to provide patient navigator services within communities to assist patients overcome barriers to health services. Program facilitates care by assisting individuals coordinate health services and provider referrals, assist community organizations in helping individuals receive better access to care , information on clinical trials, and conduct outreach to health disparity populations. [§ 223]
Authorization of Appropriations. This section provides an authorization of appropriations to carry out activities of this title. [§ 224]

Subtitle C: Safe Harbors to Anti-kickback Penalties and Criminal Penalties for the Provision of Health Information Technology and Training Services

Subtitle C provides an exception to the Stark law and anti-kickback statute to allow providers to form relationships to encourage adoption of health information technology systems to improve the quality of care they deliver. Subtitle provides a safe harbor from civil and criminal penalties to hospitals to provide physicians with resources to support installation, maintenance and training for health information technology. Safe harbors from civil and criminal penalties would not apply in cases where health information technology support was conditioned on limiting services to beneficiaries, referral of patients to the entity providing this IT support, or limitations on the use of health IT to interact with other providers. [§ 231, 232, 233]

Title III: IMPROVING THE HEALTH OF THE AMERICAN PEOPLE

Synopsis: This title seeks to make preventive health and wellness services available and accessible to all Americans, regardless of age, gender, ethnicity, or physical or cognitive ability. The activities proposed by the title are designed to reduce or eliminate barriers for all Americans in achieving and maintaining optimal health.

Subtitle A: Modernizing Our Disease Prevention and Public Health Systems

Synopsis: This subtitle provides for an enhanced national strategy to prevent disease, promote health, and build our public health system. Health promotion activities will be supported and coordinated on the federal level. In addition, the most effective disease prevention strategies will be identified and promoted in a nationwide campaign.

National Prevention, Health Promotion and Public Health Council**:** Creates an interagency council dedicated to promoting healthy policies at the federal level. The Council shall consist of representatives of federal agencies that interact with federal health and safety policy, including the departments of HHS, Agriculture, Education, Labor, Transportation, and others. The Council will establish a national prevention and health promotion strategy and develop interagency working relationships to implement the strategy. The Council will report annually to Congress on the health promotion activities of the Council and progress in meeting goals of the national strategy. [S 301]

Prevention and Public Health Investment Fund**:** Establishes a Prevention and Public Health Investment Fund. The goal of the Investment Fund is to provide an expanded and sustained national investment in prevention and public health programs to improve health and help restrain the rate of growth in private and public sector health care costs. This will involve a dedicated, stable funding stream for prevention, wellness and public health activities authorized by the Public Health Service Act. [S 302]

Clinical and Community Preventive Services**:** Expands the efforts of, and improves the coordination between, two task forces which provide recommendations for preventive interventions. The U.S. Preventive Services Task Force is an independent panel of experts in primary care and prevention that systematically reviews the evidence of effectiveness of clinical preventive services such as colorectal cancer screening or aspirin to prevent heart disease, and develops recommendations for their use. The Community Preventive Services Task Force uses a public health perspective to review the evidence of effectiveness of population-based preventive services such as tobacco cessation, increasing physical activity and preventing skin cancer, and develops recommendations for their use. [§ 303]

Education and Outreach Campaign Regarding Preventive Benefits**:** Directs the Secretary to convene a national public/private partnership for the purposes of conducting a national prevention and health promotion outreach and education campaign. The goal of the campaign is to raise awareness of activities to promote health and prevent disease across the lifespan. [§ 304]

Subtitle B: Increasing Access to Clinical Preventive Services

> *Synopsis: This subtitle enhances access to comprehensive primary medical, dental, and behavioral health care services that are key to prevention and wellness, especially for vulnerable populations and underserved communities.*

Right Choices Program**:** Establishes a temporary program giving uninsured adults access to preventive services. The Right Choices Program would provide chronic disease health risk assessment, a care plan, and referrals to community-based resources for low-income, uninsured adults until universal insurance coverage is made available through the Gateway. The program could significantly improve the health of working age adults as they enter the healthcare system, offering significant long-term cost savings. [§ 311]

School-based Health Clinics**:** Authorizes a grant program for the operation and development of School-based Health Clinics, which provide comprehensive and accessible preventive and primary health care services to medically underserved children and families. The goal of establishing such clinics is to improve the physical health, emotional well-being and academic performance of the populations they serve. The clinics will work in collaboration with schools to integrate health into the overall school environment. [§ 312]

Oral Healthcare Prevention Activities: Establishes an oral healthcare prevention education campaign at CDC focusing on preventive measures and targeted towards key populations including children and pregnant women. Creates demonstration programs on oral health delivery and strengthens surveillance capacity. [§ 313]

Subtitle C: Creating Healthier Communities

> *Synopsis: This subtitle enables health improvement to occur in communities as well as in medical settings. Most chronic diseases can be prevented through lifestyle and environmental changes. Community prevention programs encourage physical activity, good nutrition, and the reduction of tobacco use, making it easier for individuals to make healthy choices.*

Community Transformation Grants**:** This section authorizes the Secretary to award competitive grants to eligible entities for programs that promote individual and community health and prevent the incidence of chronic disease. Communities can carry out programs to prevent and reduce the incidence of chronic diseases associated with overweight and obesity, tobacco use, or mental illness; or other activities that are consistent with the goals of promoting healthy communities. [§ 321]

Healthy Aging, Living Well**:** The goal of this program is to improve the health status of the pre-Medicare-eligible population to help control chronic disease and reduce Medicare costs. The CDC would provide grants to states or large local health departments to conduct pilot programs in the 55-to-64 year old population. Pilot programs would evaluate chronic disease risk factors, conduct evidence-

based public health interventions, and ensure that individuals identified with chronic disease or at-risk for chronic disease receive clinical treatment to reduce risk. Pilot programs would be evaluated for success in controlling Medicare costs in the community.
[§ 322]

Wellness for Individuals with Disabilities**:** Amends the Americans with Disabilities Act to establish standards for accessibility of medical diagnostic equipment to individuals with disabilities. [§ 323]

Immunizations**:** Authorizes states to purchase adult vaccines under CDC contracts. Currently, 23 states purchase vaccines under CDC contracts. These contracts for adult vaccines provide savings that range from 23-69 percent compared to the private sector cost. Authorizes a demonstration program to improve immunization coverage. Under this program, CDC will provide grants to states to improve immunization coverage of children, adolescents, and adults through the use of evidence-based interventions. States may use funds to implement interventions that are recommended by the Community Preventive Services Task Force, such as reminders or recalls for patients or providers, or home visits. Reauthorizes the Immunization Program in Section 317 of the Public Health Service Act.
[§ 324]

Menu Labeling: This initiative represents a compromise between the Menu Education and Labeling (MEAL) Act, sponsored by Senator Harkin, and the Labeling Education and Nutrition (LEAN) Act, sponsored by Senators Carper and Murkowski. Under the terms of the compromise, a restaurant that is part of a chain with 20 or more locations doing business under the same name (other restaurants are exempt) would be required to disclose calories on the menu board and in a written form, available to customers upon request, additional nutrition information pertaining to total calories and calories from fat, as well as amounts of fat, saturated fat, cholesterol, sodium, total carbohydrates, complex carbohydrates, sugars, dietary fiber, and protein. [§ 325]

Encouraging a Healthy Start: This initiative would amend the Fair Labor Standard Act to require employers to provide break time and a place for breastfeeding mothers to express milk. This would not apply to an employer with fewer than 50 employees, and there are no monetary damages.

Encouraging Employer-Sponsored Wellness Programs: This provision provides more flexibility under HIPAA and expands the amount that is allowed for employers to reward employees for participating in wellness programs from 20 percent (current law) to 30 percent premium discount. It also allows the Secretaries of Health and Human Services, Department of Labor and Department of Treasury to increase this reward to 50 percent if deemed appropriate. Lastly it also includes important provisions to ensure discriminatory practices do not occur.

Subtitle D: Support for Prevention and Public Health Innovation

Synopsis: This subtitle provides support for prevention and public health research. We must develop tools and interventions to address new public health challenges and build the evidence base for public health interventions that improve the health and safety of the nation.

Research on Optimizing the Delivery of Public Health Services**:** The Secretary, acting through the Director of CDC, shall provide funding for research in the area of public health services and systems. This research shall include examining best practices relating to prevention, analyzing the translation of interventions from academic institutions to clinics and communities, and identifying effective strategies for delivering public health services in real world settings. CDC shall annually report research findings to Congress. [§331]
Data Collection, Analysis, and Quality**:** Ensures that any ongoing or new federal health program achieve the collection and reporting of data by race, ethnicity, geographic location, socioeconomic status, health literacy, primary language and any other indicator of disparity. The Secretary shall analyze data collected to detect and monitor trends in health disparities and disseminate this information to the relevant federal agencies. The Secretary shall also award grants to develop appropriate methods to detect and assess health disparities. [§ 332]

Health Impact Assessments**:** Establishes a program at the Centers for Disease Control and Prevention to support the development of health impact assessments and dissemination of best practices related to health impact assessments. The Centers for Disease Control shall award grants to State or local governments working in coalitions with community-based organizations, public health agencies, health care providers or academic institutions to implement, further support or conduct research on health impact assessments. [§333]

CDC and Employer-based Wellness Programs**:** The Centers for Disease Control and Prevention will study and evaluate best employer-based wellness practices and provide an educational campaign and technical assistance to promote the benefits of worksite health promotion to employers. [§ 334]

Environmental Health Tracking: Establishes a Coordinated Environmental Public Health Network. This network will build upon and coordinate among existing environmental and health data collection systems and create state environmental public health networks. State networks will track the incidence, prevalence, and trends of priority chronic conditions and potentially related environmental exposures, paying particular attention to low income and minority communities.

Title IV. HEALTH CARE WORKFORCE

Synopsis: This title seeks to improve access to and the delivery of health care services for all individuals, particularly low income, underserved, uninsured, minority, health disparity, and rural populations by: gathering and assessing comprehensive data in order for the health care workforce to meet the health care needs of individuals, increasing the supply of a qualified health care workforce, enhancing health care workforce education and training, and providing support to the existing health care workforce to improve access to and the delivery of health care services for all individuals.

Subtitle A. Purpose and Definitions

Subtitle B. Innovations in the Health Care Workforce

National Health Care Workforce Commission: Establishes a national commission tasked with reviewing health care workforce and projected workforce needs. The overall goal of the Commission is to provide comprehensive, unbiased information to Congress and the Administration about how to align federal health care workforce resources with national needs. Congress will use this information when providing appropriations to discretionary programs or in restructuring other federal funding sources. The Commission leverages existing federal resources and programs including the expertise and work of: the U.S. Department of Health and Human Service, including the Health Resources and Services Administration, the U.S. Department of Education, the U.S. Department of Labor, and other appropriate federal agencies. (§ 411)

State health care workforce development grants: Competitive grants are created for the purpose of enabling state partnerships to complete comprehensive planning and to carry out activities leading to coherent and comprehensive health care workforce development strategies at the state and local levels. Grants will support innovative approaches to increase the number of skilled health care workers such as health care career pathways for young people and adults. (§ 412)

Health care workforce program assessment: Establishes one national and multiple regional centers for health workforce analysis to collect, analyze and report data related to Title VII. The centers will coordinate with state and local agencies collecting labor and workforce statistical information and coordinate and provide analyses and reports on Title VII programs to the Commission. (§ 413)

Subtitle C. Increasing the Supply of the Health Care Workforce

Federally supported student loan funds: Current law is amended to ease criteria for schools and students to qualify for loans, shorten payback periods, and ease the non-compliance provision. (§ 421)

Nursing student loan program: Increases the grant amounts and updates the years for nursing schools to establish and maintain student loan funds. (§ 422)

Health care workforce loan repayment programs: Establishes a loan repayment program for pediatric subspecialists and providers of mental and behavioral health services to children and adolescents who are or will be working in a Health Professional Shortage Area, Medically Underserved Area, or with a Medically Underserved Population. (§423)

Public health recruitment and retention program: Offers loan repayment to public health workers employed at federal, state, local or tribal public health agencies in exchange for working at least 3 years. (§ 424)

Allied health recruitment and retention program: Offers loan repayment to allied health professionals employed at federal, state, local or tribal public health agencies or in settings providing health care to patients, including acute care facilities, ambulatory care facilities, residences, and other settings located in Health Professional Shortage Areas, Medically Underserved Areas, or with Medically Underserved Populations. (§ 425)

Grants for states and local programs: Mid-career professional programs: Awards scholarships to mid-career public and allied health professionals employed in public and allied health positions at the federal, state, tribal, or local level to receive additional training in public or allied health fields. (§ 426)

National Health Service Corps: Increases and extends the authorization of appropriations for the National Health Service Corps scholarship and loan repayment program for FY10-15. (§ 427)

Nurse-managed health clinics: Strengthens the health care safety-net by creating a $50 million grant program to support nurse-managed health clinics to be administered by the Health Resources and Services Administration's Bureau of Primary Health Care. (§ 428)

Elimination of cap on Commissioned Corps: Eliminates the artificial cap on the number of Commissioned Corps members, allowing the Corps to expand to meet national public health needs. (§ 429)

Establishing a Ready Reserve Corps: Establishes a Ready Reserve Corps within the Commissioned Corps for service in time of national emergency. Ready Reserve Corps members may be called to active duty to respond to national emergencies and public health crises and to fill critical public health positions left vacant by members of the Regular Corps who have been called to duty elsewhere. (§ 430)

Subtitle D. Enhancing Health Care Workforce Education and Training

Training in family medicine, general internal medicine, general pediatrics, and physician assistantship: Provides grants to: develop and operate training programs, provide financial assistance to trainees and faculty, and enhance faculty development in primary care and physician assistant programs. This section provides grants to establish, maintain and improve academic units in primary care. Priority is given to programs that educate students in team-based approaches to care, including the patient-centered medical home. Authorization is $125 million. (§ 431)

Training opportunities for direct care workers: Authorizes $10 million over three years to establish new training opportunities for direct care workers (CNAs, home health aides and personal/home care aides) already employed in long-term care facilities. (§ 432)

Training in general, pediatric, and public health dentistry: This provision reinstates dental funding under its own Title. This section allows dental schools and education programs to use grants for pre-doctoral training, faculty development, dental faculty loan repayment, and academic administrative units. Educating dental students to provide oral health care to patients with special medical, physical, psychological, cognitive or social needs is included as a priority. Authorization is $30 million. (§433)

Alternative dental health care provider demonstration project: Authorizes the Secretary to award grants to establish training programs for alternative dental health care providers to increase access to dental health care services in rural, tribal, and underserved communities. (§ 434)

Geriatric education and training: Authorizes $12 million to geriatric education centers to support training in geriatrics, chronic care management, and long-term care for faculty in health professions schools and family caregivers; develops curricula and best practices in geriatrics; expands the geriatric career awards to advanced practice nurses, clinical social workers, pharmacists, and psychologists; and

establish traineeships for individuals who are preparing for advanced education nursing degrees in geriatric nursing. (§ 435)

Mental and behavioral health education and training grants: Awards grants to schools for the development, expansion, or enhancement of training programs in social work, graduate psychology, professional training in child and adolescent mental health, and pre-service or in-service training to paraprofessionals in child and adolescent mental health. (§ 436)

Cultural competency, prevention and public health and individuals with disabilities training: Creates a program to support the development, evaluation, and dissemination of model curricula for cultural competency, prevention, and public health proficiency and aptitude for working with individuals with disabilities training for use in health professions schools and continuing education programs. (§ 437)

Advanced nursing education grants: Strengthens language for accredited Nurse Midwifery programs to receive advanced nurse education grants in Title VIII. (§ 438)

Nurse education, practice, and retention grants: Awards grants to nursing schools to strengthen nurse education and training programs and to improve nurse retention. (§ 439)

Loan repayment and scholarship program: Adds faculty at nursing schools as eligible individuals for loan repayment and scholarship programs. (§ 440)

Nurse faculty loan program: Establishes a federally-funded student loan repayment program for nurses with outstanding debt who pursue careers in nurse education. Nurses agree to teach at an accredited school of nursing for at least 4 years within a 6-year period. (§ 441)

Grants to promote the community health workforce: Authorizes the Secretary to award grants to states, public health departments, federally qualified health centers, and other nonprofits to promote positive health behaviors for populations in medically underserved areas through the use of community health workers. (§ 443)

Youth public health program: Establishes a youth public health program to expose and recruit high school students into public health careers. (§ 444)

Fellowship training in public health: Authorizes the Secretary to address workforce shortages in state and local health departments in applied public health epidemiology and public health laboratory science and informatics. (§ 445)

U.S. Public Health Sciences Track: Directs the Surgeon General to establish a U.S. Public Health Sciences Track to train physicians, dentists, nurses, physician assistants, mental and behavior health specialists, and public health professionals emphasizing team-based service, public health, epidemiology, and emergency preparedness and response in affiliated institutions. Students receive tuition remission and a stipend and are accepted as Commission Corps officers in the U.S. Public Health Service with a 2 year service commitment for each year of school covered.
Substantial training occurs in Health Professions Shortage Areas in preparation for practice in these sites. (§ 446)

Subtitle E. Supporting the Existing Health Care Workforce

Centers of Excellence: The Centers of Excellence program, focusing on development of a minority applicant pool to enhance recruitment, training, academic performance and other supports for minorities, is reauthorized at 150% of 2005 appropriations, $50 million. (§ 451)

Health professions training for diversity: Provides scholarships for disadvantaged students who commit to work in medically underserved areas as primary care providers. Funding is increased from $37 to $51 million for 2009 through 2013. This section increases loan repayments for individuals who will serve as members of faculties of eligible institutions from $20,000 to $30,000. (§ 452)

Interdisciplinary, community-based linkages: This section establishes community-based training and education grants for Area Health Education Centers (AHECs) and Programs. Two programs are supported—Infrastructure Development Awards and Points of Service Enhancement and Maintenance Awards targeting individuals seeking careers in the health professions from urban and rural medically underserved communities. Authorization is $125 million. (§ 453)

Workforce diversity grants: Expands the allowable uses of diversity grants to include completion of associate degrees, bridge or degree completion program, or advanced degrees in nursing, as well as pre-entry preparation, advanced education preparation, and retention activities. (§ 454)

Primary Care Extension Program: Creates a Primary Care Extension Program to educate and provide technical assistance to primary care providers about evidence-based therapies, preventive medicine, health promotion, chronic disease management, and mental health. The Center for Primary Care, Prevention, and Clinical Partnerships at the Agency for Healthcare Research and Quality (AHRQ) will award planning and program grants to state hubs including, at a minimum, the state health department, state-level entities administering Medicare and Medicaid, and at least one health professions school. These state hubs may also include Quality Improvement Organizations, Area Health Education Centers, and other quality and training organizations. (§ 455)

Title V. FIGHTING HEALTH CARE FRAUD AND ABUSE

Synopsis: The National Health Care Anti-Fraud Association (NHCAA) estimates that three percent of all health care spending – or $72 billion – is lost to health care fraud perpetrated against public and private health plans. Other government and law enforcement agencies estimate losses from fraud as high as ten percent. Fraud committed against both public and private plans, increases the cost of medical care and health insurance for employers, families, and taxpayers, and undermines public trust in our health care system.

Subtitle A. Establishment of New Health and Human Services (HHS) and Department of Justice (DOJ) Health Care Fraud Positions

Synopsis: The HHS Secretary will appoint a new Senior Advisor for Health Care Fraud. The Attorney General will appoint a Senior Counsel for Health Care Fraud Enforcement.

This section creates senior positions within HHS and DOJ with primary oversight and coordination responsibility for each Department's overall health care fraud efforts, and oversight of implementation of the Program Integrity Coordinating Council's (PICC) responsibilities. Persons serving in these positions will serve as "point persons" for purposes of inter-agency coordination, coordination of program integrity efforts with respect to private plans, and coordination with State entities such as insurance regulators and State Medicaid Fraud Control Units. A Commission on Fraud, Waste, and Abuse is also established to review federal health care programs and private health insurance to align public and private sector efforts to combat fraud, waste and abuse. (§ 501, 502, 503)

Subtitle B. Health Care Program Integrity Coordinating Council (PICC)

> *Synopsis: A coordinating council is established to coordinate strategic planning among federal agencies involved in health care integrity and oversight.*

HIPAA established a national Health Care Fraud and Abuse Control Program (HCFAC), under the joint direction of the Secretary of Health and Human Services (HHS), acting through the Department's Inspector General (HHS-OIG), and the Attorney General to facilitate collaboration among federal, state, and local law enforcement activities with respect to health care fraud and abuse. The proposed Health Care Program Integrity Coordinating Council (PICC) would retain the current HCFAC Program structure, and establish additional formal coordination and strategic planning roles for the federal agencies involved in health care integrity and oversight.

The PICC will develop a strategic plan to improve the efficacy of the HCFAC Program to ensure coordination of fraud prevention efforts. The PICC will develop and issue guidelines to federal agencies to carry out the HCFAC Program. The PICC will recommend measures to estimate the amount of fraud, waste and abuse in connection with public and private plans, and the annual savings resulting from specific program integrity measures. (§ 511)

Subtitle C. False Statements and Representations

> *Synopsis: Employees and agents of Multiple Employer Welfare Arrangements (MEWAs) will be subject to criminal penalties if they provide false statements in marketing materials regarding a plan's financial solvency, benefits provided, or regulatory status.*

This section amends criminal penalties provisions in ERISA, 29 U.S.C. § 1131, to add a prohibition against false statements used by corrupt operators and marketers of MEWAs without requiring that false statements be contained in ERISA-required documents. Examples of such false statements include misrepresentations regarding financial solvency or regulatory status of a plan or other arrangements undertaken to generate business and evade state regulation.

Currently, 18 U.S.C. § 1027 criminalizes the making of false statements and omissions in connection with the operation of ERISA plans, and is limited to false statements or concealments contained in documents that must be kept, published, or certified under title I of ERISA. Section 1027 does not reach misrepresentations of fact in marketing materials used by corrupt operators and marketers to induce employers or employee organizations to purchase particular health care claims coverage for their respective employees or members. (§ 521)

Subtitle D. Federal Health Care Offense

> *Synopsis: The Department of Justice will be permitted to prosecute crimes involving MEWAs. This change will enable the agency to seize the proceeds of health care offenses, employ administrative subpoenas, and enjoin ongoing criminal activities.*

Revised section 24(a)(2) of Title 18 adds three crimes relating to MEWAs to the list of federal health care offenses. The proceeds of these federal health care offenses will become subject to criminal forfeiture under 18 U.S.C. § 982(a)(7), and the offenses themselves will also be included as specified unlawful activity for money laundering offenses at 18 U.S.C. § 1956(c)(7)(F). Designation of these crimes as federal health care offenses will permit employment of an administrative subpoena provision at 18 U.S.C. § 3486, to facilitate government investigation of fraud and abuse involving such offenses.

The designation authorizes the Attorney General to commence a civil action under 18 U.S.C. § 1345 to enjoin an ongoing violation of these criminal statutes. An action by the United States to promptly enjoin and prevent the future sale or marketing of a health care benefit program's health insurance product is needed where corrupt insurers are sponsoring, marketing, and selling health care insurance and claims products in multiple states. (§ 531)

Subtitle E. Uniformity in Fraud and Abuse Reporting

> *Synopsis: To facilitate consistent reporting by private health plans of suspected cases of fraud and abuse, a model uniform reporting form will be developed by the National Association of Insurance Commissioners, under the direction of the HHS Secretary.*

This section encourages the development of a model uniform reporting form for private health plans seeking to refer suspected cases of fraud and abuse to State Insurance Departments for investigation. The current lack of uniformity is an impediment to consistent reporting that can be compared and analyzed across state lines, and a hindrance to effective anti-fraud activities. The Secretary of Health and Human services will request the National Association of Insurance Commissioners to develop recommendations for uniform reporting standards. (§ 541)

Subtitle F. Applicability of State Law to Combat Fraud and Abuse

> *Synopsis: The Department of Labor will adopt regulatory standards and/or issue orders to prevent fraudulent MEWAs from escaping liability for their actions under state law by claiming that state law enforcement is preempted by federal law.*

Fraudulent insurance plans often escape accountability under state insurance laws and regulations by claiming that federal law preempts the application of state law to their actions. When cases are brought against fraudulent plans in state courts, plans allege that state courts do not have jurisdiction. Two laws are often abused: ERISA and the Liability Risk Reduction Act. Many fraudulent plans claim they are employer-sponsored plans subject to ERISA and not "in the business of insurance," as defined in ERISA. If the plans were "in the business of insurance" they would, under ERISA, be subject to state insurance laws and could be held responsible for their fraudulent activities.

The preemption provisions in ERISA and the Liability Risk Reduction Act are complex. Fraudulent plans take advantage of this complexity to evade justice. To circumvent fraudulent plans' efforts, the Department of Labor will be authorized to adopt regulations establishing, and issue orders relating to, when an entity engaging in the business of the insurance is subject to state law. These standards and orders will make clear when a plan is subject to state law. (§ 551)

Subtitle G. Enabling the Department of Labor to Issue Administrative Summary Cease and Desist Orders and Summary Seizures Orders against Plans in Financially Hazardous Condition.

> Synopsis: *The Department of Labor will be authorized to issue "cease and desist" orders to temporarily shut down operations of plans conducting fraudulent activities or posing a serious threat to the public, until hearings can be completed. If it appears that a plan is in a financially hazardous condition, the agency may seize the plan's assets.*

The section authorizes the Department of Labor to issue cease and desist orders if it appears to the Secretary that a plan's alleged conduct is fraudulent, or creates an immediate danger to public safety or welfare, or is causing significant, imminent, and irreparable public injury. A person adversely affected by the issuance of a cease and desist order may request a hearing regarding such order. The burden of proof in this hearing will be on the party requesting the hearing to show cause why the cease and desist order should be set aside. Based on evidence, the cease and desist order may be affirmed, modified, or set aside in whole or in part. DOL may issue a summary seizure order if it appears an entity is in financially hazardous condition. States will be empowered to act quickly through administrative orders to shut down illegal and financially hazardous insurance schemes. (§521)

Subtitle H. Requiring Multiple Employer Welfare Arrangement (MEWA) plans to file a registration form with the Department of Labor prior to enrolling anyone in the plan.

> Synopsis: *Multiple Employer Welfare Arrangements (MEWAs) are a type of employer-sponsored plan involving two or more employers, rather than a single employer. Employers join together to negotiate cheaper premiums. MEWAs have been prone to fraud. To protect the public, MEWAs will be required to file their federal registration forms, and thereby be subject to government verification of their legitimacy, before enrolling anyone.*

MEWAs are required to file a Form M-1 with the Department of Labor each year. The annual reporting of the Form M-1 is helpful to states. In certain situations, plans are able to operate for more than a year before filing the M-1. It is helpful to states to have basic information about entities operating in their state without a time delay that works to the advantage of those who seek to operate illegally. The registration would provide basic information about the entity, where the entity will operate, and what exclusion from state authority they may claim. (§ 571)

<u>Subtitle I. Permitting Evidentiary Privilege and Confidential Communications.</u>

> <u>Synopsis</u>*: This section permits the Department of Labor to allow confidential communication among public officials relating to investigation of fraud and abuse.*

The section creates an optional federal privilege that would include all confidential communications among state regulators (and the NAIC) and federal regulators to conduct regulatory oversight of an entity subject to regulation. This will enable federal and state regulators to communicate on a confidential basis. Currently, such confidential communication requires adoption by both entities of a Memorandum of Understanding - a time-consuming process. People perpetrating fraudulent and abusive schemes seek victims and don't care whether the mechanism to do so is health, property, life, annuity or other insurance product or some other financial product. The same operators or even schemes often show up in multiple ways.

<u>Title VI: Improving Access to Innovative Medical Therapies</u>

<u>Subtitle A—Biologics Price Competition and Innovation</u>

> <u>Synopsis</u>*: This section establishes a pathway for licensure of a biological product based on its similarity to a previously licensed biological product (reference product).*

The Biologics Price Competition and Innovation Act of 2009 requires HHS to license a biological product that is shown to be biosimilar to or interchangeable with a licensed biological product, commonly referred to as a reference product.

The Act prohibits the approval of an application as either biosimilar or interchangeable until 12 years from the date on which the reference product is first approved.

If FDA approves a biological product on the grounds that it is interchangeable to a reference product, HHS is prohibited from making a determination that a second or subsequent biological product is interchangeable to that same reference product until 1 year after the first commercial marketing of the first interchangeable product.

The Act authorizes HHS to issue guidance with respect to the licensure of biological products under this new pathway, and it includes provisions governing patent infringement concerns such as the exchange of information, good faith negotiations, and initiation infringement actions.

The Act also requires HHS to develop recommendations for Congress with respect to the goals for the process for the review of biosimilar biological product applications for the first five fiscal years after FY 2012.

<u>Subtitle B—More Affordable Medicines for Children and Underserved Communities</u>

<u>Expanded Participation in 340B Program</u>: Section 340B of the Public Health Service Act enables safety-net hospitals and other providers serving a large volume of low-income and uninsured patients

to access significant discounts on pharmaceuticals. These discounts now are mandated only in outpatient settings. While the MMA of 2003 permits pharmaceutical companies to offer these discounts on the inpatient setting, there have been few instances of such discounts being offered. This section amends the 340B Program in these ways: 1) Expanding the drug discount program to allow participation as a covered entity by free-standing children's hospitals, free-standing cancer hospitals, rural referral centers, sole community hospitals which have a disproportionate share hospital percentage greater than eight percent, and all critical access hospitals; 2) Expanding the program to include a drug used in connection with an inpatient service by enrolled hospitals; 3) Allowing enrolled hospitals to obtain inpatient drugs through a group purchasing agreement or the 340B Prime Vendor Program; and 4) Requiring hospitals enrolled in the 340B program to provide a credit to each state on the estimated annual costs of covered drugs provided to Medicaid recipients for inpatient use. (§ 611) A study evaluating the expanded 340B Program will be conducted by the GAO. (§ 613)

Improvements to 340B Program Integrity: Improves the integrity of the 340B Program by: 1) Requiring the Secretary to carry out activities to increase compliance by manufacturers and covered entities with the requirements of the drug discount program; 2) Establishing an administrative process to resolve claims by covered entities and manufacturers of violations of such requirements; and 3) Providing clarifications about the ceiling price used to sell to 340B participants. (§ 612)