America's Affordable Health Choices Act of 2009
(Amendment in the Nature of a Substitute to H.R. 3200)
Introduced by Representative Waxman (D-CA) on July 15, 2009

Summary of Provisions

DIVISION A – AFFORDABLE HEALTH CARE CHOICES

TITLE I – PROTECTIONS AND STANDARDS FOR QUALIFIED HEALTH BENEFITS PLANS

Subtitle A – General Standards

New Health Insurance Market Requirements

Individuals will be required to have acceptable health care coverage beginning January 1, 2013. Acceptable coverage includes coverage by a qualified health benefits plan, a grandfathered health insurance plan or a current group health plan (individual health insurance coverage from the individual market or group health insurance coverage from the large or small group market), Medicare, Medicaid, Tricare, Veterans Administration coverage, or other health benefits coverage, such as a state health benefits risk pool. A health benefits plan will not be considered a qualified health benefits plan unless the plan complies with minimum specified standards relating to affordable coverage, essential benefits, and consumer protection. Individual health plans existing in the individual market before January 1, 2013 will be grandfathered to constitute acceptable coverage for as long as no changes are made to the terms and conditions, including benefits and cost-sharing. Employment-based health plans will have a five-year grace period, beginning January 1, 2013, to come into compliance with the qualified health benefits plan requirements. During the five-year grace period, such employment-based health plans will constitute acceptable coverage.

Individuals will be treated as being enrolled in an employment-based health plan if the individual is a participant or beneficiary in an employment-based health plan, thus meeting their individual requirement to be enrolled in acceptable health care coverage. Beginning January 1, 2013, individual health insurance coverage that is not grandfathered health insurance coverage may only be offered as an Exchange-participating health benefits plan. Thus, an individual not already enrolled or eligible for other forms of acceptable coverage will purchase a qualified health benefits plan from the Health Insurance Exchange (Exchange). Small employers will also be able to purchase qualified health benefits plans for their employees from the Exchange as specified under this Act, with limitations on the size of the small employer permitted.

Subtitle B – Standards Guaranteeing Access to Affordable Coverage

Qualified Health Benefits Plan

The Exchange will be a new marketplace for insurance. In order to participate in the Exchange, a health plan must meet the criteria set forth for a qualified health benefits plan, including the following:

Pre-Existing Conditions, Guaranteed Issue and Renewal, Community Rating

A qualified health benefits plan may not exclude individuals on the basis of pre-existing conditions. A qualified health benefits plan may not decline to offer or deny enrollment in the plan to any person requesting coverage with certain exceptions for bona fide associations. A qualified health benefits plan may not refuse to renew coverage or continue coverage, including rescission of coverage with certain exceptions for nonpayment of premiums.

Community rating is required for qualified health benefits plans. The only criteria by which the premium may vary are for age, although the variation may not be greater than a 2:1 ratio, by geographical area, and by family size and composition. The ratio of the premium for family enrollment to the premium for the individual must be proportionate as determined by state insurance regulators and the Health Choices Commissioner (Commissioner).

Nondiscrimination and Mental Health and Substance Abuse Disorder Parity

A qualified health benefits plan may not discriminate in benefits or benefit structure against an individual based on health status. If a qualified health benefits plan offers mental health benefits as well as medical and surgical benefits, it must have the same coverage limits for mental health and substance abuse disorder benefits as for other benefits.

Ensuring Adequacy of Provider Networks

A qualified health benefits plan provider network must comply with minimum network standards set forth by the Commissioner.

Fair Grievance and Appeals Mechanisms

A qualified health benefits plan offering entity must establish an internal grievance and appeals procedure which meets the standards set by the Commissioner. The Commissioner is required to establish an external grievance and appeal procedure which includes "impartial, independent and de novo review," with provisions for expedited review in urgent cases. The Commissioner also may authorize the application of external review procedures at the state level, provided that the external review procedures meets federal standards. In addition, grievance and appeal decisions under this provision may be subject to judicial review under state law.

Information Transparency
A qualified health benefits plan must operate transparently with respect to both patients and providers, and must comply with standards set by the Commissioner with respect to claims, payments, policies, practices and amounts, and with respect to rates paid to providers.

Timely Payment of Claims
Claims must be paid in the same time frame as claims made under a Medicare Advantage plan (30 days) or such shorter time as provided by the Commissioner.

Subtitle C – Standards Guaranteeing Access to Essential Benefits

Health Benefits Advisory Committee
A Health Benefits Advisory Committee will be comprised of up to 26 members chosen by the President and the Comptroller General, and chaired by the Surgeon General. This committee will recommend a minimum set of benefits for each plan level that may be offered by a qualified health benefits plan. The recommendations shall be adopted by the Secretary of Health and Human Services (Secretary) using the Federal Administrative Procedure Act regulatory procedures.

Essential Benefits Package Defined
Benefit packages for qualified health benefits plans must include, at a minimum, inpatient hospital services, outpatient hospital, clinic and emergency services, physician and other professional health care services, equipment and supplies, prescription drugs, rehabilitative and habilitative services, mental health and substance use disorder services, preventive services with a grade of A or B set by the United States Preventive Services Task Force, including maternity benefits, and well baby, childcare and oral health, vision, and hearing service equipment for persons under age 21. Although no cost sharing is permitted for preventive care services, cost sharing is authorized up to a maximum of $5,000 per year for an individual and up to $10,000 per year for a family. The cost sharing is designed to provide actuarial benefits equal to 70% of the value of an essential health benefits package if there were no cost sharing.

Levels of Cost-Sharing for Enhanced and Premium Plans
The level of cost sharing for enhanced plans and premium plans shall be designed so that such plans have benefits that are actuarially equivalent to approximately 85% and 95%, respectively, of the actuarial value of the benefits provided under the reference benefits package.

Subtitle D – Additional Consumer Protections

Consumer Protection Guidelines
The Commissioner will formulate guidelines governing the conduct of qualified health

benefits plans with respect to health consumer protection. These include: 1) fair grievance and appeals mechanisms, which shall include both an internal and an external review process; 2) standards for transparency which ensure the timely disclosure of financial and enrollment data (given in plain language, such that those with limited English proficiency can readily understand it), provide reimbursement data, and give advance warning of any changes in the plan to enrollees; 3) timely payment of claims; 4) standardized rules for coordination of benefits between multiple plans; 5) compliance with standards for electronic financial and administrative transactions; and 6) uniform marketing standards that all plan offering entities must meet.

Subtitle E – Governance

Health Choices Administration and Commissioner

The Health Choices Administration will be established in the executive branch of the government as an independent agency. The head of the Health Choices Administration will be the Commissioner.

Duties and Authority of Health Choices Commissioner

The Administration and the Commissioner will be responsible for establishing and enforcing the standards for qualified health benefits plans, for administering the Exchange and for administering individual affordability credits. The Commissioner will also have the ability to: 1) impose sanctions for violations, including civil money penalties; 2) suspend enrollment of individuals in a non-compliant plan; and 3) suspend a plan from the Exchange.

Health Insurance Ombudsman

The Qualified Health Benefits Plan Ombudsman will assist individuals in dealing with plans.

Consultation and Coordination

The Commissioner is required to consult with the National Association of Insurance Commissioners, State Insurance Commissioners, State Attorneys General and related federal agencies in the administration of this Act.

Subtitle F – Relation to Other Requirements; Miscellaneous

Relation to Other Requirements

The Health Insurance Portability and Accountability Act's (HIPAA) market and privacy provisions continue under this Act. The Consolidated Omnibus Budget Reconciliation Act's benefits continuation provisions also remain. This Act does not abrogate state law except to the extent that state law prevents the application of provisions of the Act. No private remedies under state law or the Employee Retirement Income Security Act (ERISA) provisions are preempted by this Act.

Whistleblower Protection
Employers are prohibited from retaliating in any way (including dismissal, changing the compensation or terms of employment, or any other such discriminatory action) against employees who provide information to the employer or state or federal government that the employee reasonably believes relates to the violation of any provision of this Act.

Construction Regarding Collective Bargaining
Nothing in this Act alters or supersedes any obligation to engage in collective bargaining over the terms and conditions of employment related to health care.

Severability
If any provision of this Act, directly or in implementation, is found to be unconstitutional, it shall not affect the application of any other provision of this Act.

Subtitle G – Early Investments

Ensuring Value and Lower Premiums
Each health insurance issuer that offers health insurance coverage in the small or large group market on or after January 1, 2011 will be required to maintain a medical loss ratio (the ratio of benefits paid to administrative costs) below a level specified by the Secretary. Insurers shall provide rebates to enrollees sufficient to meet the specified loss ratio for these purposes. The methodology for calculating the acceptable loss ratio will be designed to account for variations between the size, type, and circumstances under which the plan is offered, as well as the length of time that the plan has been available. This methodology will be uniform, and apply in the same manner to plans offered in the individual market as well.

Ending Health Insurance Rescission Abuse
Insurers will only be allowed to rescind coverage upon clear and convincing evidence that the consumer has committed an act of fraud. Furthermore, the Secretary shall issue, no later than July 1, 2010, guidance in implementing this provision, which shall ensure that consumers whose coverage is being rescinded are given adequate notice and the opportunity to have a third party review the case for rescission. These provisions shall take effect October 1, 2010, and apply to all insurance coverage issued at any time, both prior to and following this date.

Administrative Simplification
The Secretary will establish standards for electronic administrative transactions that: 1) are consistent, non-redundant, and authoritative; 2) are comprehensive, efficient, and robust, requiring minimal augmentation by paper transactions or clarifications by further communications; 3) enable real-time, or near real-time, determination of an individual's financial responsibility to medical entities at the point of service and, where possible, prior to service; 4) enable real-time, or near-real time, adjudication of claims; 5) provide for timely acknowledgement and status reporting of any electronic transaction

information deemed appropriate by the Secretary; 6) describe and harmonize all data elements in unambiguous terms, and not permit optional fields; 7) enable electronic fund transfers and allow automated reconciliation with related health care payment and remittance advice; 8) require timely and transparent claim and denial management, including tracking, adjudication, and appeal processing; 9) require the use of electronic transaction management by all health care providers; and 10) provide for other requirements that facilitate administrative simplification. The specific standards set by the Secretary will apply to paper versions of medical information so that paper records can be easily transferred to electronic format. The Secretary will submit to the appropriate committees of Congress an outline for implementation and enforcement of the standards to take place over a period of no more than five years. HIPAA privacy and security standards will be maintained in implementing the standards. Use of information in any manner that would adversely affect any individual is prohibited.

Reinsurance Program for Retirees

No later than 90 days after enactment, the Secretary shall establish a temporary reinsurance program to provide reimbursement to assist eligible retirees (those above the age of 55 who are not covered under Medicare) with employment-based insurance plans in meeting premiums, co-payments, deductibles, co-insurance, or other out-of-pocket health care costs. Employment-based plans shall apply directly for participation in this plan, and must meet terms for participation. If a plan is determined to be eligible, the Secretary will reimburse 80% of the costs of claims that are between $15,000 and $90,000 (to be adjusted each year based on the Consumer Price Index). Such monies may only be used to reduce the burden of cost on the individual receiving coverage and not the employer. Funds shall be distributed out of a new Retiree Reserve Trust Fund, which will be funded out of the Treasury for an amount not to exceed ten billion dollars. The Secretary shall have the authority to cease taking applications or take other steps to reduce payments in order to maintain this upper limit on expenditures.

TITLE II – HEALTH INSURANCE EXCHANGE AND RELATED PROVISIONS

Subtitle A – Health Insurance Exchange

Exchange-Eligible Individuals and Employers

Beginning January 1, 2013, any individual who does not have "acceptable coverage" is eligible to purchase insurance through the Exchange. Acceptable coverage includes coverage by Medicare, Medicaid, Tricare, Veterans Administration, a qualified health benefits plan, a grandfathered health benefit plan, or other health benefits coverage, such as a state health benefits risk pool. In 2013, employers with fewer than ten employees may also participate in the Exchange by purchasing insurance for their employees. In 2014, employers with 20 employees may participate. In 2015 and subsequent years, the Commissioner may decide the appropriate limit beyond employers with 20 employees. Individuals who qualify for Medicaid will be given an option to participate in the Exchange so long as their state agrees to provide "wrap around" benefits such that the

benefits provided are equivalent to Medicaid coverage. An individual who is already enrolled in a qualified health benefits plan or other acceptable coverage may not participate in the Exchange.

Benefits Package Levels

The Commissioner is authorized to enter into contracts with insurers in order to offer qualified health benefits plans within the Exchange, so long as the insurer agrees to provide at least one basic benefit plan. The insurer may offer a "basic plan," an "enhanced plan," a "premium plan," or a "premium plus plan." The amount of cost sharing differentiates the plan levels. Each plan must offer the essential benefits package. Affordability credits will reduce the amount of cost sharing for eligible individuals. The Commissioner is required to set the amount of cost sharing for each plan level, but in no case may there be more than a 10% difference between levels. The premium plus plan, unlike the other three levels, offers additional benefits to the essential benefits available in the other three plan levels. An insurer may offer multiple premium plus plans with different packages. A plan within the Exchange may still be subject to state mandates for covered benefits, if the state agrees to reimburse the Exchange for any additional payments under the affordability credit which are necessary to pay for the additional benefits mandated by the state. The Commissioner will be responsible for organizing the Exchange.

Each offering entity participating in the Exchange will have to meet the following standards:

- The offering entity must be licensed as a health insurer under applicable state law in each state in which a plan is offered.
- The offering entity must collect and report data, including risk pool data.
- The offering entity must provide for the implementation of affordability credits.
- The offering entity must accept all enrollees and notify the Commissioner if it projects reaching a capacity limitation.
- The offering entity must offer Medicaid wrap around services reimbursable by the state.
- The offering entity must participate in the risk pooling mechanism established by the Commissioner.
- The offering entity must offer appropriate cultural or linguistic services for the areas in which it operates.
- The offering entity must contract for outpatient services with eligible health care centers, clinics, and hospitals (defined as "covered entities" under Section 340B(a)(4) of the Public Health Service Act).
- The offering entity must meet other applicable requirements as specified by the Commissioner.

Additional Duties of the Commissioner

The Commissioner may establish a grievance procedure in conjunction with state insurance commissioners and must monitor and enforce compliance with the

requirements of the Exchange. The Commissioner will be responsible for assuring outreach to eligible individuals by arranging for marketing of the Exchange, assisting in enrollment, and making participation in the Exchange available to Medicaid qualified persons. The Commissioner will also be responsible for establishing a risk pooling mechanism which will adjust the distribution of premiums available to the plans to adjust for differences in the risk characteristics of employees and individuals so as to minimize the impact of adverse selection by enrollees. Furthermore, the Commissioner will review the provider networks in order to determine which plans will be used to provide services. If the network fails to meet the standards set by the Commissioner, and the individual receives a service by a provider not within the network, the individual's cost sharing would be limited to the cost sharing that it would have experienced with an in-network provider.

State-Sponsored Exchanges
A state or group of states may apply to operate an exchange in lieu of the federal Exchange. The state or group of states must apply to the Commissioner and demonstrate the local exchange will have the capacity to perform all the functions of the federal Exchange. The Commissioner will retain his or her enforcement authority over a state-sponsored exchange.

Subtitle B – Public Health Insurance Option

Establishment of Public Insurance Option
A public insurance option will be established to offer qualified health benefits plans at all four levels and is expected to operate on a level playing field with other plans in the Exchange. The public option will only be available through the Exchange.

Premiums and Financing
The public plan will charge a premium sufficient to cover both the health benefits and administrative costs without public subsidy other than start-up funding.

Payment Rates and Incentives
Initially, the public plan will pay providers at the same rate as Medicare payments, with new rates established for services, such as pediatrics, not currently covered under Medicare. Subsequently, in 2016 and after, rates will be unlinked from Medicare rates. Services for physicians who participate in Medicare and the public option will be reimbursed at Medicare plus five percent during the first three years. The public plan may also experiment with alternative payment mechanisms to provide incentives for quality improvement, cost containment, or reduction in health care disparities.

Conditions of Provider Participation
The public option will have conditions of participation comparable to those required of other providers in federal programs, including a prohibition on balance billing.

Application of Fraud and Abuse Provisions
Program integrity programs relating to fraud and abuse applicable to Medicare will apply to providers in the public option. Any providers barred from participation in other federal programs will be barred from the public option as well.

Subtitle C – Individual Affordability Credits

Affordability Credits
Credits will be provided to qualified individuals to reduce the cost of their health insurance premiums and cost sharing. Undocumented aliens will not be eligible for the credit. The Commissioner has the authority to request that state Medicaid agencies perform the eligibility determination for affordability credits and get reimbursed for the cost. To qualify, a person 1) must have a family income less than 400% of the federal poverty level; 2) must have coverage from an Exchange-participating benefits plan; and 3) may not opt to enroll in the Exchange if the individual has access to their employer's sponsored health plan. However, an exception exists if the cost to participate in an employer-sponsored plan exceeds ten percent of the employee's income. Credits will be collected by the Exchange and paid to the qualified health benefits plan on the basis of the number of eligible persons in the plan. The amount of the individual's premium credit is determined on the basis of income on a sliding scale. The Commissioner will establish six income levels for affordability credits for cost sharing and a credit will be given for each level at a percentage of the actuarial value of the plan if there were no cost sharing.

TITLE III—SHARED RESPONSIBILITY

Subtitle A – Individual Responsibility

Individual Responsibility to Obtain Acceptable Coverage
Individuals are required to acquire acceptable health care coverage meeting certain standards, enforced through the federal tax code.

Subtitle B – Employer Responsibility

Election to Satisfy Health Coverage Participation Requirements
Employers may make an election to satisfy health coverage participation requirements. An employer must: 1) offer a specified level of coverage; 2) make specified payments towards that coverage; or 3) discharge that obligation by making contributions to the Exchange. An employer's responsibility to contribute towards employee and dependent coverage will be discharged by payment towards an Exchange-participating plan. The required contribution to be paid by an employer for a full-time employee is 72.5% of the lowest cost qualified health benefits plan offered by the employer. In the case of family coverage, the employer contribution is 65% of the cost of the least expensive plan. In the case of part-time employees, the rate varies depending on the ratio of the average weekly

hours of the employee to the hours established by the Commissioner for full-time employment. Unless the employee opts out, employees will be automatically enrolled by the employer in the lowest-cost individual health benefits plan.

An alternative way for an employer (with a payroll above a certain amount) to discharge his obligation is to make a payment to the Health Insurance Exchange Trust Fund equal to eight percent of the average wages paid to the employee during the time of enrollment. Small employers pay a reduced percentage depending upon the payroll of the employer. Employers are not allowed to steer employees away from qualified health benefits plans (or current employment-based health plans) and instead to enroll in an Exchange-participating health benefits plan that may affect the Exchange's risk pool.

National Health Coverage Participation Under ERISA

Beginning in 2013, ERISA will be modified such that an employer may elect to be subject to national health coverage participation requirements and such election shall be treated under ERISA as the establishment and maintenance of a group health plan. For affiliated groups which have elected under federal tax law to be a single employer, the election to be subject to national health coverage participation shall apply to all members of the affiliated group. For such groups, the Secretary by regulation may allow separate elections to be made for separate lines of business or to distinguish between full-time employees and other employees.

Noncompliance with Health Coverage Participation Requirements

If an employer is in substantial noncompliance with the health coverage participation requirements, the Secretary in coordination with the Health Choices Commissioner may terminate the health coverage participation election of the employer and must refer the determination to the Secretary of the Treasury. A civil penalty of $100 per day may be assessed for the failure to satisfy health coverage participation requirements. Defenses to this penalty include: 1) a good faith lack of knowledge by an employer exercising reasonable diligence to know that the failure existed; and 2) the failure was due to reasonable cause, not intentional neglect and was corrected within 30 days after knowledge or constructive knowledge that the failure had occurred. There is a cap on the amount which may be assessed against an employer in any one year when the failures are due to reasonable cause and not willful neglect, and any fines are to be coordinated with excise taxes to avoid duplication of penalties.

The Secretaries of Labor, Treasury, and HHS are required to execute an inter agency memorandum of authority to coordinate interpretations among ERISA, the Internal Revenue Code and the Public Health Service Act, and to not engage in duplication of enforcement efforts.

TITLE IV – AMENDMENTS TO INTERNAL REVENUE CODE OF 1986

Subtitle A – Shared Responsibility

Tax on Individuals without Acceptable Health Care Coverage
A tax will be imposed on any individual who does not meet the requirements of acceptable health care coverage (such as a qualified health benefits plan, grandfathered health insurance, Medicare, Medicaid, etc.) at any time during the taxable year. Such a tax shall not apply to: 1) any individual if a deduction is allowable under Section 151 of the Internal Revenue Code (dependents); 2) non-resident aliens; 3) individuals residing outside the United States; 4) individuals residing in possessions of the United States; or 5) individuals who had in effect an exemption which certifies that individual is a member of a recognized religious sect or division. In addition, the Secretary of Treasury may prescribe regulations or other necessary guidance which provide: 1) exemption from the tax on individuals without acceptable health care coverage in cases of de minimis lapses of acceptable coverage; and 2) a process for applying for a waiver of the tax in cases of hardship. This tax shall apply to taxable years beginning after December 31, 2012.

Election to Satisfy Health Coverage Participation Requirements
An excise tax will be imposed on any employer who fails to meet the health coverage participation requirements but that has made an election prescribed by the Secretary that is in effect. If the Secretary, in conjunction with the Commissioner, determines that an employer is in substantial noncompliance with the health coverage participation requirements, he or she may terminate the election of that employer. No tax shall be imposed for any employer whose failure to satisfy health coverage participation requirements if: 1) such failure was due to reasonable cause and not willful neglect, and 2) such failure is corrected within 30 days.

Responsibilities of Nonelecting Employers
An excise tax equal to eight percent of wages paid will be imposed on every nonelecting employer, with special provisions for small employers that fall under this category. In the case of an employer who makes a separate election with respect to health coverage participation requirements, the excise tax shall apply only by taking into account the wages paid to employees who are not subject to the separate election. Similar rules are set forth for railroads.

Subtitle B – Credit for Small Business Employee Health Coverage Expenses

Credit for Small Business Employee Health Coverage Expenses
In the case of qualified small employers, a small business employee health coverage credit will be available, with an applicable percentage of 50%. A qualified small employer is defined as any employer whose number of qualified employees for the taxable year does not exceed 25.

Subtitle C – Disclosures to Carry Out Health Insurance Exchange Subsidies

Disclosures to Carry Out Health Insurance Exchange Subsidies
Taxpayer return information that may be disclosed by the Secretary of Treasury is limited to: 1) taxpayer identity information with respect to such taxpayer; 2) the filing status of such taxpayer; 3) the modified adjusted gross income of such taxpayer; 4) the number of dependents of the taxpayers; 5) such other information as is prescribed by the Secretary of Treasury in regulation as might indicate whether the taxpayer is eligible for such affordability credits (and the amount thereof); and 6) the taxable year with respect to which the information gathered relates to, or if applicable, the fact that this information is not available. Any return information disclosed is limited to use by officers and employees of the Health Choices Administration, or such state-based Exchanges for purposes of establishing and verifying the amount of affordability credits.

Subtitle D – Other Revenue Provisions

Surcharge on High Income Individuals
A surcharge will be imposed on high income individuals who have income that exceeds $350,000, with incremental increases based on income up to $1,000,000. Adjustments to such surcharge shall be made depending on the amount of excess federal health reform savings. The Director of the Office of Management and Budget shall determine the aggregate reductions in federal expenditures as a result of health reform and conduct a study of the reductions in expenditures during fiscal years 2010 through 2019.

Limitation on Treaty Benefits for Certain Deductible Payments
In the case of any deductible related-party payment, any withholding tax imposed under Chapter 3 (withholding of tax on nonresident aliens and foreign corporations) of the Internal Revenue Code with respect to such payment may not be reduced under any treaty of the United States unless any such withholding tax would be reduced under a treaty of the United States if such payment were made directly to the foreign parent corporation. The Secretary may prescribe regulations or other necessary guidance providing for: 1) the treatment of two or more persons as members of a foreign controlled group of entities if such persons would be the common parent of such group, if treated as one corporation; and 2) the treatment of any member of a foreign controlled group of entities as the common parent of such group if such treatment is appropriate taking into account the economic relationships among such entities.

Codification of Economic Substance Doctrine
The Economic Substance Doctrine is defined as the common law doctrine under which tax benefits under income taxes with respect to a transaction are not allowable if the transaction does not have economic substance or lacks a business purpose. It provides that a transaction shall be treated as having economic substance only if: 1) the transaction changes in a meaningful way (apart from federal income tax effects) the taxpayer's

economic position; and 2) the taxpayer has a substantial purpose (apart from federal income tax effects) for entering into such transaction. Fees and other transaction expenses and foreign taxes shall be taken into account as expenses in determining pre-tax profit. Any state or local income tax effect which is related to a federal income tax effect shall be treated in the same manner as a federal income tax effect.

Penalties for Underpayments
Penalties will be imposed for underpayments of taxes attributable to transactions lacking economic substance.

DIVISION B – MEDICARE AND MEDICAID IMPROVEMENTS

TITLE I – IMPROVING HEALTH CARE VALUE

Subtitle A – Provisions Related to Medicare Part A

Productivity Adjustments
Productivity improvements for skilled nursing facilities, long term care hospitals, inpatient rehabilitation facilities, psychiatric hospitals, hospice care, and outpatient hospital services will be included in the market basket effective in fiscal year (FY) 2010.

Payments to Skilled Nursing Facilities
The Secretary shall adjust the case mix indexes by the recalibration factor as proposed in the FY 2010 Notice of Proposed Rulemaking for the Medicare skilled nursing facility prospective payment system. Also, there will be a budget neutral adjustment within the payment system to improve payment accuracy for nontherapy ancillary services and therapy services by introducing separate payment components for such services. This change would take into account nontherapy services such as drugs, IV medications, and respiratory services in overall patient care. These payment components would be calculated using appropriate physical indicators, potentially using hospital diagnosis as criteria, and would be made to reflect outliers.

Subtitle B – Provisions Related to Part B

Sustainable Growth Rate Reform
A new formula will be introduced for reimbursement rates for physician services in Medicare. This would allow primary care services to grow at a higher rate than other services without reducing physician pay rates. Certain items that are currently not paid directly to physicians—such as Part B drugs and clinical lab services—would be removed from the calculation of the formula, making it easier for doctors to avoid exceeding the spending targets. As an additional incentive to reduce fee schedule rates, this policy would encourage physicians to form Accountable Care Organizations (ACOs), multi-service groups sharing responsibility for the quality and cost of care as a result of their own target and update factors.

Misvalued Codes
The Secretary will regularly review fee schedule rates for physician services paid by Medicare in order to identify misvalued codes and update them accordingly. Those services experiencing high growth rates will be reviewed particularly.

Efficient Areas
Incentive payments will be provided through Medicare to physicians practicing in geographic areas that are identified as the most cost-efficient areas of the country. Efficient areas are defined as those counties in the lowest fifth percentile of spending per capita.

Integration of Physician Quality Reporting and EHR Reporting
For payments under Medicare Part B, the Secretary will integrate the Physician Quality Reporting Incentive (PQRI) program and the "meaningful use" of electronic health records (as determined by the Secretary) incentive program.

Cost Data Reports for Ambulatory Surgical Centers
The Secretary will develop a cost report on ambulatory surgical centers (ASCs) within two years, and after such report is released, will require the reporting of quality cost data by ASCs. Currently, ASCs are paid under a system that aligns ASC payment rates with the rates paid for similar services in hospital outpatient departments. The purpose of the reports is to assess the costs associated with procedures performed in ASCs independent from those done in hospitals.

Payment for Imaging Services
The presumed utilization rate will be raised from 50% to 75% for imaging and computer-assisted imaging services, excluding mammography. Operating under the assumption that individual imaging machines are being used more frequently and more efficiently as a diagnostic tool, payments to service providers utilizing such tools will be reduced. Similarly, the reduction in expenditures attributable to single-session imaging involving consecutive body parts will be raised from 25% to 50%.

Subtitle C – Provisions Related to Medicare Parts A and B

Preventable Hospital Readmissions
Beginning in 2011, Medicare payments to hospitals with higher than expected readmissions will have those payments reduced for every Medicare discharge. The reduction in payments will be based on the hospital's performance related to three Diagnostic Related Groupings (DRGs) that are endorsed by the National Quality Forum. The performance measure is that of risk adjusted readmission rates for Medicare readmissions for those DRGs identified as potentially preventable. The applicable DRGs endorsed will most likely be heart attack, heart failure and pneumonia. Beginning in 2013, the applicable conditions will be expanded by an additional four conditions

identified by the Medicare Payment Advisory Commission. Beginning in 2015, the applicable conditions will be expanded to include "all-cause" readmissions. The performance ranking would be based on that of a national ranking hierarchy for all readmissions. Hospitals with readmissions greater than the Medicare expected (calculated) readmission rate will have their Medicare payments adjusted.

The plan requires the monitoring of admission practices and hospital policies to determine whether practices put patients at risk for readmissions. Sanctions may be imposed against hospitals engaging in such practices. Assistance will be provided to hospitals that develop programs to address factors impacting the potential for readmissions. Such programs include providing care coordination services to transition from hospital to an alternative care setting, hiring translators, increasing use of discharge planners, providing summaries of care and medication orders upon discharge, and developing and implementing quality improvement plans to identify and reduce readmissions for targeted patient populations. The plan calls for the reduction of payments to post acute providers whose patients are readmitted within 30 days of discharge, beginning in 2011. By FY 2013, risk adjusted readmission rates and payment systems must be established for post acute providers. A focused study will be conducted to determine the best process for this task. A report is required to be presented to Congress within one year of the enactment of the Act detailing how physicians will be incorporated into the readmission payment reduction plan.

Bundling of Post-Acute Services

Post acute services are defined by the Act as "services for which payment may be made under the Medicare program that are furnished by skilled nursing facilities, inpatient rehab facilities, long term care hospitals, hospital based outpatient rehab facilities, and home health agencies to an individual after discharge of such individual from a hospital, and such other services determined appropriate by the Secretary. The Act requires a bundled payment for post acute care services to be submitted to Congress within three years after the law is enacted. The plan must include discussion of the following issues: 1) nature of payments included in the Post Acute Bundle; 2) type, entity, scope of services, physician services, and persons covered by bundle; 3) inclusion of inpatient services for payment in bundle; 4) inclusion of all categories of providers; 5) payment rates inclusive of efficiencies achieved with bundling; 6) national or geographical basis; 7) protection requirements for beneficiaries to ensure quality of services and choice of provider; 8) nature of relationship between hospital and providers to avoid anti-kickback, antitrust, gainsharing, and anti-referral laws; 9) quality metrics for reporting outcomes; 10) cost sharing rules and programmatic issues relating to providers, transfers, three-day stay rule, and coordination of payments under Medicaid and Medicare programs. The existing Acute Care Episode demonstration project is to be expanded to include post-acute care services within six months of enactment of the Act. Expansion may include additional geographical sites or conditions.

Home Health Payments
There will be a freeze in the market basket update for Home Health agencies for 2010. Adjustments of the case mix scheduled for FY 2011 will be applied in FY 2010. The Home Health Prospective Payment System (PPS) will be adjusted based on multiple factors including changes in the average number and type of visits in an episode, changes in intensity of visits in an episode, and growth in cost per episode. The productivity adjustment incorporated into the market basket update for the Home Health agency in FY 2010 cannot cause the market basket update to go below zero, based on the combination of the product adjustment and any goal reporting adjustments.

Limitations on Physician Referrals to Hospitals
The Stark law, governing self referrals by physicians to hospitals in which they have a direct financial interest, will be modified by further limiting referrals to physician-owned hospitals as of January 1, 2009. While the plan grandfathers existing ownership agreements of physician owned hospitals prior to January 1, 2009, it limits any further percentage of ownership growth by the physician in those hospitals.

The Act also outlines requirements relating to the mandatory disclosure of physician investments in a hospital on any public website and any public advertising for that hospital. Failure to report or disclose investments may result in civil monetary fines for both the hospital and the physicians. Ownership and investment by a physician in a hospital must be a bona fide investment and referrals to the hospital must not benefit the physician. All investment and financial terms are subject to a market based analysis. Parameters will also be established for increased growth based on an increase in population, annual inpatient admissions, statewide bed capacity and statewide average bed occupancy rates. The expansion is limited to the main campus of a hospital. Administration or judicial review of the final capacity decision is prohibited. A patient safety requirement related to physician availability is provided. The requirement states that if a hospital admits patients and does not have physicians on-site and available twenty four hours a day seven days a week, the hospital must disclose that fact to the patient and obtain a signed acknowledgement that the patient understands before admitting the patient. The Secretary may engage in the use of unannounced site reviews to verify compliance with this rule.

Subtitle D – Medicare Advantage Reforms

Payment and Administration
Beginning in 2011, Medicare Advantage (MA) plans identified as high quality will have their blended benchmark amount increased by 1% in 2011, 2% in 2012, and 3% for a subsequent year. MA plans that are identified as improved quality will have their blended benchmark amount increased by 0.33% in 2011, 0.66% in 2012, and 1% for a subsequent year. The Secretary will provide for the computation of the quality performance score beginning in 2010; the score will include the plan's performance on effectiveness of care quality measures, quality measures, and other measures of clinical

quality specified by the Secretary. The Secretary will implement quality reporting for outcome-based measures for MA plans by 2013. The measures reported may include rates of admission and readmission to a hospital, prevention quality, patient mortality and morbidity following surgery, health functioning, and patient safety. In choosing the quality measures, the Secretary shall take into consideration the recommendations of the Medicare Payment Advisory Commission. Prior to the measures being selected, the Secretary will publish them in the Federal Register and provide a period of public comment. Beginning in 2016, the measures will be used to decide payments for outcomes measures. Payment in 2011 will be based on quality performance data for the plan from 2009; payments beginning in 2012 will be based on quality performance data for the plans for the second preceding year. Each MA organization will provide the quality performance data to the Secretary in a time and manner decided by the Secretary. Using this information, the Secretary will rank the plans from highest to lowest based on both absolute scores and percentage improvement from the previous year. If a plan does not report quality performance data, they will be counted as having the lowest performance.

High quality plans will include the highest score that are projected to include in the aggregate 20% of the total projected enrollment for that year. Improved quality plans will include the plans with the greatest percentage improvement score that are projected to include in the aggregate 20% of the total projected enrollment for the year. The Secretary can determine not to identify a MA plan if the Secretary identifies deficiencies in the plan's compliance with rules. The Secretary will notify the MA organization that is offering the high quality or improved quality plans and the payment adjustment for the year and this information will also be published on the Medicare website.

Risk Adjustments

Within a year of enactment, the Secretary will submit to Congress a report evaluating the adequacy of the risk adjustment system in predicting costs for: 1) beneficiaries with chronic or co-morbid conditions; 2) beneficiaries eligible for both Medicare and Medicaid; and 3) non-Medicaid eligible low-income beneficiaries. The Secretary will implement improvements to the risk adjustment system by January 1, 2012.

Medicare Advantage Regional Plan Stabilization Fund

The Medicare Advantage Regional Plan Stabilization Fund will be eliminated and any money remaining will be transferred to the Federal Supplementary Medical Insurance Trust Fund.

Limitation on Cost-Sharing for Individual Health Services

MA Plans can use flat co-payment or per diem rate in lieu of cost-sharing as long as the amount of cost-sharing does not exceed the amount that would be imposed if the individual were not enrolled in a plan. MA plans may not impose cost-sharing for dual eligible individuals or qualified Medicare beneficiaries enrolled in MA plans that exceed

the amount of cost-sharing that would be permitted under Medicaid if the individual were not enrolled in the plan.

Medicare Advantage Plan Administrative Costs
The Secretary will publish the medical loss ratio of each MA plan from the previous year beginning November 1, 2011. Each MA plan will submit the necessary information to the Secretary. The Secretary will develop and implement standardized data elements and definitions for reporting. In developing these elements, the Secretary will consult with the Commissioner, representatives of the MA organizations, experts, and representatives of the National Association of Insurance Commissioners. If the Secretary determines that an MA plan has failed to meet a medical loss ratio of at least 85%, the MA plan will give its beneficiaries a rebate of premiums and will not be allowed to enroll new beneficiaries for three years. If the MA plan fails to have a medical loss ratio for five consecutive years, the Secretary will terminate the plan.

Enforcement of Audits and Deficiencies
The Secretary is authorized to take actions necessary to address deficiencies in MA organizations identified by audits or similar activities beginning on January 1, 2011.

Limitation on Enrollment Outside of Open Enrollment Period
MA plans will not enroll individuals on or after January 1, 2011 except during the annual open enrollment period or when a diagnosis is made that qualifies the individual.

Subtitle E – Improvements to Medicare Part D

Elimination of Coverage Gap
Beginning in 2011, the initial coverage limit will be increased and the annual out-of-pocket threshold will be decreased until there is a continuation of coverage from the initial coverage limit for expenditures for Medicare Part D.

Drug Rebates
Drug manufacturers will be required to supply a rebate to the Secretary for any drugs dispensed to any full-benefit dual eligible individual paid for by prescription drug plan (PDP) sponsor under Part D or MA plan. The PDP sponsor shall report to each manufacturer as well as to the Secretary the information on the drugs dispensed to full-benefit dual eligible Medicare drug plan enrollees, respecting the applicable confidentiality. The penalties for PDP sponsors who fail to provide this information timely or provide false information is a civil monetary fine of $10,000 for each day the information has not been provided or $100,000 for each false information provided. The rebate money shall be used to pay for the elimination of the coverage gap.

Drug Discounts
Drug manufacturers involved in a prescription drug plan with PDP or MA plans shall give a discount to each enrollee for qualifying drugs if the enrollee is in the original gap

coverage after December 31, 2010. The qualifying drugs are any drugs produced under or originally marketed under a new drug application approved by the Food and Drug Administration (FDA) that is covered under the formulary of the plan and is dispensed to an individual who is in the original gap in coverage. The terms and conditions will be set by the Secretary and the discounts will be applied to the MA plans instead of State plans under Medicaid. The discount is equal to 50% of the amount of the drug-component negotiated price for qualifying drugs. The discounted amount paid by an enrollee who is in the actual gap of coverage will be counted as out-of-pocket costs. The actual gap in coverage is the gap in prescription drug coverage between the initial coverage limit and the annual out-of-pocket threshold. The discount will be provided at the time the enrollee pays for the drug. If the enrollee is in the original gap in coverage that is not the actual gap in coverage, then the discount will not be applied against the negotiated price. The original gap in coverage that would occur between the initial coverage limit and the out-of-pocket threshold will not apply.

Subtitle F – Medicare Rural Access Protections

Telehealth Expansion and Enhancements

A Telehealth Advisory Committee will be established. The committee will have nine members appointed by the Secretary to advise the Secretary on policies for the Centers for Medicare and Medicaid Services (CMS) regarding telehealth services, adding or deleting them and the payment for them. The nine members will include five physicians, two non-physician health care practitioners and two telehealth administrators all appointed for a term decided by the Secretary. If the Secretary does not follow the recommendations of the Committee, the Secretary must publish the reasons explaining why the recommendations were not followed.

TITLE II – MEDICARE BENEFICIARY IMPROVEMENTS

Subtitle A – Improving and Simplifying Financial Assistance for Low Income Medicare Beneficiaries

Eliminating Barriers to Enrollment

Allows Medicare beneficiaries to self-certify their income and automatically reenroll for their Part D low-income subsidy. Within one year of enactment, the Secretary of Treasury and the Commissioner of Social Security are instructed to develop the criteria by which the eligibility of a low-income individual is determined. Two years from their first report they are to submit a report to Congress describing the effectiveness of removing enrollment barriers.

Automatic Enrollment Process

Authorizes HHS to automatically enroll subsidy-eligible beneficiaries into plans using a process that accounts for the quality, cost, and/or formulary of plans, while also giving beneficiaries the option of choosing another plan.

Subtitle B – Reducing Health Disparities

Language Services
Within one year of enactment, the Secretary will conduct a study examining the extent that Medicare providers utilize, offer, or make available language services for beneficiaries who have limited English proficiency. The report will include an analysis of the feasibility of various payment systems for such language services. If it is determined that an MA organization fails to provide limited English proficient beneficiaries with language services, the Secretary may impose appropriate remedies, including fines, and/or suspension of payment. In addition, the Secretary, with CMS, is required to carry out a demonstration program to reimburse Medicare providers for the inclusion of language services, and to make an evaluation of such demonstration programs. Finally, the Secretary, with the Institute of Medicine, will conduct a study examining the impact of language access services on the quality of care, access to care, and reduction in medical errors and costs.

Subtitle C – Miscellaneous Improvements

Advance Care Planning Consultation
Consultation between enrollees and practitioners to discuss orders for life-sustaining treatment will be a Medicare covered benefit. CMS will modify the "Medicare & You" handbook to include information on end-of-life planning resources, and to incorporate measures on advance care planning into the Physician's Quality Reporting Initiative.

Patient Decision Aids Demonstration Program
A demonstration program will allow a group of 30 eligible providers to use decision aids and other technologies to help patients and consumers improve their understanding of the risks and benefits of their treatment options and make informed decisions about their medical care. The participating provider will be responsible for all costs associated with the use of decision aids.

TITLE III – PROMOTING PRIMARY CARE, MENTAL HEALTH SERVICES, AND COORDINATED CARE

Medicare Accountable Care Organization Pilot Program
Authorizes a pilot program to test payment incentive models using Accountable Care Organizations (ACOs). The pilot program should be designed to: 1) promote accountability for a patient population and coordinate items and services under Medicare Parts A and B; 2) encourage investment in infrastructure and redesigned care processes with the goal of improving quality and efficiencies; and 3) provide a reward system for physician practice models that deliver quality and efficiencies in the delivery of health care services.

Criteria for a Qualifying ACO

A qualifying ACO is defined as a group of physicians organized to provide physician services that meet the following criteria: 1) a legal structure providing for the receipt and distribution of incentive payments; 2) a sufficient number of primary care physicians to care for its beneficiaries; 3) all members of the group must be participating physicians; 4) the group must provide routine quality reports as outlined by the Secretary to monitor and evaluate outcomes of the pilot program; 5) the group must notify beneficiaries of its involvement in the pilot program; and 6) the group must participate in the Secretary's "Best Practice" network for the purpose of sharing information regarding quality improvement, care coordination and efficiency tactics.

ACO Payment Incentive Models

Payment incentive models for an ACO may be a performance target model, a partial capitation model, or other payment model developed by the Secretary. The performance target model consists of the ACO receiving an incentive payment for maintaining expenses below the target spending level or rate of growth for items and services covered under Medicare Parts A and B. The partial capitation model is a model in which a qualifying ACO would be at risk for some portion of the items and services covered under Medicare Parts A and B. Generally, this model is limited to only ACOs that are highly integrated systems and capable of bearing risk.

The pilot program is to be operational by January 1, 2012, with multi-year agreements for a qualifying ACO to span a period of three to five years. Monitoring elements of the payment incentive model for each ACO will be conducted by the Secretary and will include the impact on the beneficiaries, providers, suppliers and the program itself with public disclosure. The Inspector General of HHS will monitor the ACOs for potential violations of the Stark Law. Congress will receive a report on the pilot program with emphasis on the expenditures, access, and quality outcomes within two years of enactment of the first ACO, and biennially thereafter.

Medicare Medical Home Pilot Program

A pilot program will be established to determine the feasibility of reimbursing qualified patient centered medical homes for the provision of services to high-need beneficiaries. The pilot will consist of both an individual patient-centered medical home model and a community-based medical home model. The individual patient-centered medical home service model will provide direct and on-going access to a primary care physician or nurse practitioner who will provide first contact, continuous and comprehensive care to the beneficiary as the leader of a care team. The team will implement evidenced based guidelines. The patient-centered medical home model will be a physician or nurse practitioner directed practice certified to provide patient centered home services to high need beneficiaries requiring regular monitoring, advising or treatment for chronic illness. Payment will be based on the clinical work and practice required, access needs, care coordination services, disease management, teaching needs of the beneficiary, and capability of the medical home, and risk adjusted criteria.

Evaluation of the pilot program will be based on improvement in the quality and coordination of healthcare services, health outcomes, patient satisfaction, efficiency of the care provided, the reduction of health disparities, reduction of preventable hospitalizations and emergency room visits, and the reduction of duplicated diagnostic tests and total healthcare expenditures. Funding for the pilot program will be provided by the Federal Supplementary Medical Insurance Trust Fund.

Rate Increase for Primary Home Services
Beginning January 1, 2011, an increase of five percent will be paid to providers of primary care services. An increase of 10% will be paid for primary care provider services provided in an area designated as a health professional shortage area. A primary care provider is defined as one who specializes in family medicine, internal medicine, pediatric medicine, or geriatric medicine and has allowed charges for primary care services for at least 50% of their total allowed charges.

Reimbursement Increase for Certified Nurse-Midwives
Reimbursement of covered services performed by a Certified Nurse Mid-Wife will be increased from 65% to 100% of physician reimbursement rates for those services.

Coverage and Waiver of Cost-Sharing for Preventive Services
Payment for preventive services will be increased to 100% of the actual charges of the services. Cost sharing in the form of co-insurance or deductibles will be waived for: 1) prostate cancer screening; 2) colorectal screening diabetes outpatient self-management training; 3) glaucoma screening; 4) medical nutritional therapy for certain individuals; 5) initial preventive physical exams; 6) cardiovascular blood test screening; 7) diabetes screening; 8) ultrasound for abdominal aortic aneurysm for certain individuals; 9) pneumococcal and influenza vaccines and administration; 10) screening mammography; 11) screening pap smear and pelvic exam; 12) bone mass measurement; 13) kidney disease education; and 14) additional preventive services as determined by the Secretary.

Waiver of Deductible for Colorectal Screening
A waiver of deductibles for colorectal screening will be implemented regardless of the coding of the exam, the subsequent diagnosis based on the result of the test, or the result of the tissue biopsy.

Clinical Social Worker Services
Effective July 1, 2010, clinical social workers may bill separately for their services in a skilled nursing facility setting. Social worker services will no longer be included under the skilled nursing facility prospective payment system.

Marriage, Family Therapist and Mental Health Counselor Services
Effective January 1, 2011, a marriage and family therapist who meets state licensure and certification requirements will be included as a Medicare provider. Payment for those

services will be 80% of the actual charge or 75% of the rate of payment for a psychologist, whichever is less.

Extension of Physician Fee Schedule for Mental Health Add-On
The termination date for a five percent rate increase for mental health services is extended from the original expiration date of December 31, 2009 to December 31, 2011.

Expanding Access for Vaccines
Effective January 1, 2011, all Medicare covered vaccines and their administration (including Hepatitis B) will be paid for under Medicare Part B coverage.

Elimination of 190 Day Lifetime Limit for Psychiatric Hospitalization
Effective January 1, 2010, the 190 day lifetime limit for psychiatric hospitalizations under Medicare will be eliminated.

TITLE IV – QUALITY

Subtitle A – Comparative Effectiveness Research

Comparative Effectiveness Research
A Comparative Effectiveness Research Center will be established within the Agency for Healthcare Research and Quality (AHRQ). The Center will have responsibility and oversight to conduct, support and coordinate research activities related to the effectiveness of that research on items, services and systems utilized in the delivery of healthcare. Oversight for activities of the Center will be provided by a newly formed Commission. The Commission will have stakeholder involvement and membership from community groups including those of consumers, clinicians, third-party payers, providers, researchers, and advisors. The Commission will determine priorities for the research, identify standards for that research, ensure stakeholder feedback on the research, appoint advisory panels on specific issues/priorities, and recommend methods for the dissemination of findings to the public. The source of funding for the Center and the Commission will be from the Comparative Research Effectiveness Trust Fund (CERTF). The CERTF will receive contributions from both Medicare and private health insurance plans.

Subtitle B – Nursing Home Transparency

Required Disclosure of Ownership and Additional Disclosable Party Information
New measures for transparency of information available regarding nursing care provided in both Skilled Nursing Facilities (SNFs) and Nursing Facilities (NFs) will include required disclosure of ownership and the organizational structure of the facility. SNFs and NFs will establish compliance programs along with a plan to comply with the quality assurance and improvement program developed by the Secretary.

Nursing Home Compare Medicare Website
SNFs and NFs will be required to submit information to the Nursing Home Compare Medicare Website detailing staffing data and expenses for both direct and indirect costs. The website also will contain information related to complaints filed against the facilities.

Standardized Complaint Form
Additional quality measures will also include a standardized form for reporting complaints and a standardized format for the reporting of staffing data allowing for comparison of nursing facilities listed on the Nursing Home Compare site. The Secretary will be authorized to enforce sanctions for violations of healthcare regulations.

Ensuring Staffing Accountability
Improvements in the training of staff and supervisors providing care to nursing home patients/residents and the establishment of national quality performance measurements for SNFs and NFs also will be implemented.

Subtitle C – Quality Measurements

National Priorities for Quality Improvement Measures
National priorities for quality improvement measures for healthcare services will be implemented. The priorities will reflect areas that incorporate populations suffering from chronic disease, have the potential to decrease morbidity and mortality, have the potential to improve affordability of healthcare, address health disparities, and have the potential to produce rapid improvements in healthcare. The priorities will be based on recommendations from multiple healthcare stakeholders and endorsed by a consensus based entity. These measures will be made public and may be considered for usage in federal payment systems.

Subtitle D – Physician Payments Sunshine Provision

Physician Payments Sunshine Provision
Manufacturers and distributors that provide payment or other transfer of value to a covered recipient, or to an entity or individual at the request of or designated on behalf of a covered recipient, will be required to submit to the Secretary, annually starting in 2011, a report containing the recipient's information, a description of the device or drug exchanged, and the nature of the payment. Hospitals and other healthcare entities will also be required to report on the ownership shares of each physician, including the physician's family members, who own an interest in the entity. Each of the aforementioned reports are to be made public, and failure to report by either party shall result in a civil money penalty between $1,000 and $10,000 for each payment, transfer of value, or investment interest not reported, not exceeding a sum of $150,000 for that year. Furthermore, knowing failure to report shall result in a civil money penalty between $10,000 and $100,000 for each condition, not exceeding a sum of $1,000,000 per year.

Subtitle E – Public Reporting on Health Care-Associated Infections

Requirement to Report Health Care Associated Infections

In order to participate in the Medicare or Medicaid programs, hospitals and ambulatory surgical centers will be required to report health care associated infections that develop in the hospital or center and demographic information associated with the infection, as the Secretary specifies in coordination with the Centers for Disease Control and Prevention (CDC) and its National Healthcare Safety Network.

TITLE V – MEDICARE GRADUATE MEDICAL EDUCATION

Criteria for Secretary to Reduce, Increase, and Redistribute Residency Positions

The Secretary will have the authority to reduce the number of residency positions among hospitals which are members of the same affiliate group in order to apply resident position limitations. The Secretary may reduce the number of residency positions in programs by 90% of the difference between the otherwise applicable resident limit and the reference resident level, defined as the highest resident level for any of the three most recent cost reporting periods. A hospital may apply to the Secretary in a timely manner and request an increase in its resident level in order to accommodate for an expansion of one of its existing residency training programs. However, the requested increases may not exceed the Secretary's estimate of the aggregate reduction. A hospital qualifies for an increase if it maintains the number of primary care residents, assigns additional resident positions to primary care and if it is fully accredited or is actively applying for full accreditation. When determining whether to grant the request of the increase, the Secretary will take into account the demonstrated likelihood of the hospital filling the positions within the first three cost reporting periods. Further, the Secretary must give preference to qualifying hospitals that have had a reduction, have three-year primary care residency training programs, have a greater emphasis in training in non-provider settings (i.e. health centers, rural clinics, etc.), and provide training in health professional shortage area(s) that have low resident-to-population ratios. The Secretary may not add more than 20 resident positions to any hospital. Hospitals that receive additional resident positions will be required to maintain and periodically report records on the number of primary care residents in its residency training programs and maintain the level of primary care resident positions.

Promotion of Training in Non-Provider Settings

A resident will be able to count time spent in a non-provider setting performing patient care activities toward the determination of full-time equivalency as long as the hospital incurs the costs of compensating the resident. The Secretary may establish a demonstration project in which approved teaching health centers contract with an accredited teaching hospital. The health center will provide inpatient responsibilities to primary care residents in a hospital program but, in turn, will be responsible for paying the hospital for its costs of compensating residents participating in the approved teaching program.

Rules for Counting Resident Time

All time spent by an intern or resident in didactic conferences and seminars, not including non-therapeutic research, will be counted toward the resident's determination of full-time equivalency. Further, vacation, sick leave, and other approved leave which does not prolong the normal duration of the resident's time in the program will also be counted.

Absorbing Residency Positions of Closing Hospitals

The Secretary will establish a process for the resident positions of a closing hospital to be absorbed by other hospitals in the state.

Accountability for Medical Residency Training

The goals of medical residency training programs are: 1) to foster physicians who are prepared and experienced to work effectively in various health care delivery settings; 2) to coordinate patient care within and across settings; 3) to understand various diagnostic and treatment options; 4) to be able to work in inter-professional teams and multi-disciplinary team-based models which enhance safety and improve quality of patient care; 5) to be knowledgeable in identifying systematic errors in health care delivery and in implementing systematic solutions in order to improve health outcomes of the population the physician serves; and 6) to be meaningful electronic health record users so as to deliver care and improve the quality of the health of the community and individuals. A study will evaluate whether medical residency training programs are meeting these goals and whether they have appropriate faculty expertise. This study will also include any recommendations for programs to meet these goals such as development of curriculum requirements and assessment of the accreditation process.

TITLE VI – PROGRAM INTEGRITY

Subtitle A – Increased Funding to Fight Waste, Fraud, and Abuse

Increased Funding to Health Care Fraud and Abuse Control Account

One hundred million dollars will be allocated from the Federal Hospital Insurance Trust fund to the Health Care Fraud and Abuse Control Account. These funds will be used to support the activities of the Fraud and Abuse Program, which include: 1) prosecuting health care matters through criminal, civil, and administrative proceedings; 2) performing audits, investigations, inspections, and other evaluations of health care programs; and 3) educating providers and consumers on compliance with the fraud and abuse provisions set out in Title XI of the Social Security Act (setting forth fraud and false representation provisions and penalties under the Social Security Act and Internal Revenue Code). Additionally, the Secretary is given greater flexibility in carrying out the Medicare Integrity Program by permitting previously non-eligible entities to receive contracts under the program.

Subtitle B – Enhanced Penalties for Fraud and Abuse

False Statements and Inspection Compliance
Fraud or abuse against federal health programs is expanded to include any false statement, omission, or misrepresentation of material fact on the part of a health provider in any application, agreement, bid, or contract with the government. For each such violation, there will be a civil penalty of $50,000 in addition to an amount no more than three times the amount claimed as a result of the fraud. Additionally, any such provider that does not comply with audits, inspections, evaluations, or other statutory functions of the Inspector General in a timely manner will be fined $15,000 for each day in which the provider fails to grant timely access. These new penalties become effective for acts committed on or after January 1, 2010.

Enhanced Hospice Protection Program Safeguards
Hospice programs operating under Medicare, Medicaid, and the Children's Health Insurance Program (CHIP) that are found to provide substandard quality of care or that fail to comply with requirements set by the Secretary shall be subject to sanctions. The sanctions imposed on such programs are to be developed and implemented by the Secretary no later than July 1, 2012, and may include fines, the appointment of temporary management, training, or other corrective action. Fines may not exceed $10,000 for each day of non-compliance, or $25,000 per incident, when applicable. Fines and sanctions are to be based on the severity and length of time that the program is found to be non-compliant, and may be retroactively applied to programs currently meet quality standards but have failed to do so in the past. In the case of deficiencies that put the health or safety of program recipients in jeopardy, the Secretary shall, in addition to any sanctions, take immediate corrective action by appointing new temporary management, revoking certification of the program, or by any other measure deemed necessary.

Enhanced Penalties for Individuals Excluded from Participation
Effective January 1, 2010, any person excluded from participation in a federal health care program who subsequently submits a claim to such a program for medical treatment or equipment provided during the period of exclusion will be fined $50,000 for each claim.

Enhanced Penalties for Provision of False Information or Marketing Violations
Effective January 1, 2010, additional penalties will be imposed on organizations taking part in the Medicare Advantage or Part D program that: 1) misrepresent or falsifies information furnished to the Secretary or another individual or entity; 2) enroll an individual in the plan, or transfer an individual to a different plan, without their consent; 3) fail to submit marketing materials to the Secretary for approval or otherwise violates fair marketing standards; or 4) employ or contract with any individual or entity engaged in sanctionable conduct. For each violation, a maximum fine of $100,000 may be imposed.

Enhanced Penalties for Obstruction of Program Audits
In addition to existing law excluding individuals convicted of a criminal offense related to delivery of care, patient abuse, health care fraud, or controlled substances, the Secretary will be able to exclude those who interfere or obstruct an audit or investigation into any criminal financial misdemeanor (including fraud, theft, embezzlement, or breach of fiduciary responsibility) relating to the delivery of health care.

Exclusion of Certain Individuals and Entities from Participation
The mandatory exclusion criteria will be strengthened such that federal health care programs will make no payment for any item or service furnished (directly or indirectly) by an excluded individual or entity if the person submitting the claim for payment had reason to or should have known of the exclusion. Exception is made for emergency items or services (excepting those furnished in a hospital emergency room), and may be made if a Medicare or Medicaid recipient was mislead or otherwise did not know or have reason to know of the exclusion.

Subtitle C – Enhanced Program and Provider Protections

Enhanced CMS Program Protection Authority
The Secretary will be allowed to conduct screenings of medical service providers or suppliers that pose a significant risk of fraudulent activity. The Secretary will establish a set of procedures for the evaluation of at-risk entities, which may include unannounced site visits, prepayment review, and enhanced claim review. If serious, ongoing fraud is found, the Secretary may impose a moratorium on service providers and suppliers within a certain category, provided that doing so does not adversely impact the individuals receiving care under such programs.

Additionally, any provider of services or supplies who submits an application or renewal for enrollment in Titles XVIII (Medicare), XIX (Medicaid), or XXI (CHIP) of the Social Security Act after July 1, 2011 must disclose any affiliation within the past ten years with a provider of services or supplies that has uncollected debt with an entity that has been suspended or excluded from such program, subject to payment suspension, or has had its billing privileges revoked. If it is believed that such an affiliation poses a risk of fraud, waste, or abuse, the Secretary may call for enhanced oversight. The Secretary may require a state to enforce any determination made by the Secretary relating to findings of fraud among individuals and organizations, and to assist in enforcement of decisions made by the Secretary regarding such entities as a requirement of the state plan under Title XIX (Medicaid) or the child health plan under Title (XXI) (CHIP). For the purpose of enforcement, the Attorney General will have access to all relevant information provided to the Secretary.

Payment Modifier for Certain Evaluation and Management Services
The Secretary will establish a payment modifier for evaluation and management services that result in providers and suppliers ordering additional services, prescribing additional

drugs, furnishing or ordering durable medical equipment, or ordering, furnishing, or prescribing other items and services deemed to pose a high risk of waste, fraud, and abuse. The Secretary may also require providers or suppliers to report such a modifier in payment claims.

Evaluations and Reports Required Under Medicare Integrity Program
Beginning in 2011, eligible entities under contract with the Secretary under the Medicare Integrity Program must provide assurances to the Secretary that they will conduct periodic evaluation of the effectiveness of their activities with respect to the Medicare Integrity Program, and submit an annual report on such activities.

Provider and Supplier Programs to Reduce Waste, Fraud, and Abuse
The Secretary, consulting with the Inspector General, will establish the core elements of a compliance program which health service providers and suppliers will adhere in order to protect against waste, fraud, and abuse, and provide a timeline for adoption of such internal measures. The Secretary may conduct a pilot program before implementing these requirements, and the Administrator for CMS will have the authority to determine whether an entity has satisfied the requirements put forth by the Secretary.

Twelve Month Maximum Period for Medicare Claim Submission
The current maximum period from the time services or items are furnished to the submission of claims is 36 months under Medicare Parts A through D. The period for submission of claims will be reduced to 12 months, except with special exception by the Secretary.

Physicians Who Order Durable Medical Equipment or Home Health Services
Medicare will provide reimbursement for durable medical equipment or home health services only if such items or services are furnished by a Medicare enrolled physician or eligible professional.

Documentation for Referrals to Programs at High Risk of Waste and Abuse
Effective January 1, 2010, the Secretary will be able to disenroll, for a maximum of one year per act, any physician or supplier who fails to maintain and, and supply at the request of the Secretary: 1) documentation relating to written orders or requests for payment for durable medical equipment; 2) certifications for home health services; or 3) referrals for other items or services.

Face to Face Requirement for Home Health Services or DME Certification
Physicians who certify or recertify orders for home health services or durable medical equipment eligible for reimbursement under Medicare, Medicaid, or CHIP, must provide documentation that he or she has met with the patient within the six months preceding such certification.

Extension of Testimonial Subpoena Authority to Program Exclusion Investigations
Effective January 1, 2010, the Secretary may delegate to the Inspector General of HHS and the Administrator of CMS the authority to issue subpoenas to individuals in the course of investigations into the exclusion of individuals or entities from participation in Medicare and state health care programs, encompassing such infractions as fraud, patient abuse, felony convictions relating to health care, or breach of fiduciary responsibility. The Commissioner of Social Security, already vested with such authority to issue subpoenas under the Social Security Act, will also have authority to issue such subpoenas under the program integrity provisions of this Act.

Required Repayments of Medicare and Medicaid Overpayments
If an individual knows of an overpayment on the part of Medicare or Medicaid, such person is required to report and return such amount to the Secretary or appropriate state or intermediary body, as well as provide a reason for the overpayment, no less than 60 days after it is discovered. Doing so does not exclude the individual or entity in question from further liability regarding the same claim.

Expanded Application of Hardship Waivers for OIG Exclusions to Beneficiaries
The authority of the Inspector General of HHS will be extended to grant hardship waivers, which allow excluded entities to continue to receive Medicare payments if the Secretary, in consultation with the Inspector General, determines that exclusion would impose a hardship on individuals receiving care. Currently such waivers are only granted for programs servicing Medicare beneficiaries. Hardship waivers would now be allowed for any federal health care program.

Access to Certain Information on Renal Dialysis Facilities
Renal dialysis facilities operating under Medicare that serve patients with end stage renal disease are required to provide the Secretary access to information relating to ownership or compensation arrangements between the facility and the medical director or any physician for auditing purposes.

Registration of Billing Agents, Clearinghouses, or Other Alternate Payees
Effective January 1, 2012, any agent, clearinghouse, or other entity that submits claims on behalf of a health care provider under Medicare or Medicaid must be registered with the Secretary.

Conforming Civil Monetary Penalties to False Claims Act Amendments
A civil penalty will be applied to any person who conspires to commit a violation of eligibility criteria, or otherwise knowingly submits a false claim for service or materials under a federal health care program. This penalty shall be $50,000 for each false statement or other action involved in the furtherance of the fraud.

Subtitle D—Access to Information Needed to Prevent Fraud, Waste, and Abuse

Access to Information Necessary to Identify Fraud, Waste, and Abuse

The Attorney General will have access to claims and payment data relating to Medicaid and state medical assistance programs for the purpose of law enforcement to the extent that such information is consistent with any applicable disclosure, privacy, and security laws. This information will be provided in consultation with CMS or the owner of such data, and exchange will be facilitated by the Inspector General of HHS.

Elimination of Duplication

The Secretary will begin a program to eliminate duplication between the Healthcare Integrity and Protection Data Bank (HIPDB) and the National Practitioner Data Bank (NPDB) by ensuring that all information formerly available through the HIPDB is made available through the NPDB. Upon completion of this process, the Secretary will discontinue HIPDB and transfer all relevant data collection responsibilities to the NPDB. In doing so, the Inspector General for HHS is relieved of the responsibility of collecting such information. Additionally, for one year following the decommissioning of the HIPDB, the Secretary of Veterans Affairs will have access to any information contained in the NPDB which would formerly be part of the HIPDB without charge.

Compliance With HIPPA Privacy and Security Standards

Privacy standards set forth in HIPAA Sections 262(a) (establishment of standards and requirements for the electronic transmission of certain health information for administrative simplification) and 264 (requirements with respect to privacy of certain health information including rights of individuals who are the subject of individually identifiable health information, procedures to exercise such rights, and authorized or required uses and disclosures of such information) and the Privacy Act of 1974 (establishment of a code of fair information practice that governs the collection, maintenance, use, and dissemination of personally identifiable information about individuals that is maintained in systems of records by federal agencies), as well as regulations and standards enacted pursuant with these acts, will apply.

TITLE VII – MEDICAID AND CHIP

Subtitle A – Medicaid and Health Reform

Medicaid Eligibility Expanded to 133-1/3% of the Federal Poverty Level

Medicaid eligibility is expanded to individuals under 65 who have incomes below 133 and 1/3% of the poverty level. Authorizes 100% federal matching funds for medical coverage for newborns and other nontraditional Medicaid eligible individuals and certain traditional Medicaid eligible individuals.

State Medicaid Memorandum of Understanding with Health Choices Commissioner
The state shall enter into a Medicaid memorandum of understanding with the Commissioner, acting in consultation with the Secretary, to coordinate the implementation of this Act with the state's Medicaid program. If the Commissioner determines that an individual is eligible, then the state is responsible for enrolling the individual in the state Medicaid program.

Children's Health Insurance Program Eligibility and Program Termination
CHIP programs may not employ more stringent eligibility standards on children covered than those in effect as of June 16, 2009, and will not be eligible for reimbursement under Medicaid if they do so. States may limit expenditures for its CHIP program to those for which federal financial participation is available for that fiscal year. Additionally, CHIP will terminate on January 1, 2013 if the Commissioner determines that the Exchange is capable of supporting eligible CHIP enrollees and the Secretary determines that it is possible to ensure a timely transition without interruption of coverage.

Reduction in Expenditures to Disproportionate Share Hospital Program
No later than January 1, 2016, the Secretary must submit a report to Congress on the extent to which this Act has reduced the number of uninsured persons, including a determination as to whether there continues to be a role for the Disproportionate Share Hospital (DSH) program under Medicaid. Pursuant with this, the Secretary will develop a methodology to identify the degree to which reductions in the DSH program can be made. In total, the Secretary shall reduce DSH expenditures to all states by $1.5 million in FY 2017, $2.5 million in FY 2018, and $6 million in FY 2019.

Subtitle B – Prevention

Coverage of Preventive Services
Tobacco cessation products approved by the FDA will no longer be excluded from covered outpatient drugs and state Medicaid programs will have the option to cover nursing home visitation services and family planning services.

Subtitle C – Access

Payments to Primary Care Practitioners
Effective January 1, 2010, state plans for medical assistance operating under Medicaid must provide payments for primary care physicians (or services that would qualify as primary care if furnished by such a physician) at a rate of 80% of the amount paid under Part B of Title XVIII (Medicare) for 2010, 90% for 2011, and 100% for 2012 and each subsequent year.

Medical Home Pilot Program
The Secretary shall establish a Medical Home Pilot Program for the purpose of evaluating the feasibility of reimbursing qualified patient-centered medical homes for

furnishing medical home services to high need beneficiaries who are eligible for assistance under Title XIX (Medicaid) (including medically fragile children and high-risk pregnant women). A maximum aggregate amount of $1.235 billion shall be made available to states applying for the program, which may run for a maximum of five years. The Secretary must submit a report to Congress containing an evaluation of the program no less than 60 days after such evaluation is completed.

Translation or Interpretation Services
Beginning January 1, 2010, translation and interpretation services will be provided to all qualifying individuals for whom English is not a first language.

Optional Coverage for Freestanding Birth Centers
Eligible individuals will be able to receive medical assistance for services provided in freestanding birth centers. Freestanding birth centers are health facilities where childbirth is planned to occur by a licensed birth attendant (away from the pregnant woman's residence).

Inclusion of Public Health Clinics Under the Vaccines for Children Program
Vaccines will be allowed to be administered to eligible children at public health clinics under the Vaccines for Children Program.

Subtitle D – Coverage

Optional Medicaid Coverage of Low-Income HIV-Infected Individuals
States will be able to provide Medicaid services to individuals who have HIV and whose income and resources do not exceed the maximum eligibility under Medicaid.

Extending Transitional Medicaid Assistance (TMA)
The Transitional Medicaid Assistance Program (health insurance program for families leaving or diverted from welfare) is extended until December 31, 2012.

Continuous Coverage For Certain CHIP Programs
Effective January 1, 2010, for children whose family income is below 200% of the poverty line, a 12-month period of continuous coverage is required.

Subtitle E – Financing

Payments to Pharmacists
Effective January 1, 2010, the Secretary shall calculate the upper reimbursement limit of the Average Manufacturer Price (AMP) as 130% of the weighted average of monthly average manufacturer prices. Manufacturers are also required to report information to the Secretary to be used in this calculation.

Prescription Drug Rebates
Effective for drugs dispensed after December 31, 2009, the rebate rate given by state health programs will be increased for prescription drugs that are either a line extension of a single source drug (a new, time-release formulation of an existing drug for which there are no generic formulations) or an innovator multiple source drug (a new formulation of an existing drug originally marketed under a new drug application and approved by the FDA for which there are generic formulations). Additionally, the minimum rebate rate for single source drugs (existing drugs for which there are no generic formulations) is increased to 22.1%.

Extension of Prescription Drug Discounts to Medicaid Managed Care Enrollees
Prescription drug discounts to Medicaid managed care enrollees are extended with the additional requirement that entities receiving Medicare funds shall report to the state information on outpatient drugs dispensed to Medicaid enrollees in a timely manner on a periodic basis set forth by the Secretary.

Payments for Graduate Medical Education
States will provide the Secretary with information on medical assistance programs for graduate medical education carried out with federal funding. The Secretary must make this information available to the Advisory Committee on Health Workforce Evaluation and Assessment, and work independently to review the information to take into account state and local workforce need areas.

Subtitle F – Waste, Fraud, and Abuse

Health Acquired Conditions
Beginning in 2010, certain miscellaneous provisions seeking to reduce waste, fraud and abuse are added to existing federal anti-fraud law. Several provisions disallow federal reimbursement for certain expenditures deemed avoidable, such as health-care acquired conditions or litigation related misconduct, or to programs which have been excluded from participation in Medicaid or CHIP due to delinquency in overpayment obligations, or failure to meet CHIP obligations.

Evaluations and Reports
Contractors will be required to conduct periodic evaluations on the effectiveness of Medicaid integrity program activities. Providers, other than physicians and nursing facilities, will be required to establish compliance programs to reduce waste, fraud and abuse.

Overpayments
The timeframe for state reimbursement of the federal component of a Medicaid overpayment is extended to one year in the event of overpayment due to fraud. Medicaid managed care organizations are required to maintain a minimum 85% medical loss ratio, or more, if required by regulation, and are also required to provide the state with patient

encounter data as specified by the Secretary.

Reporting on Expanding Data Sets
States are required to expand the data elements under MMIS for the purpose of detection of fraud and abuse. Entities such as billing agents, clearinghouses or alternate payees will be required to register with the state and federal government.

Subtitle G – Puerto Rico and the Territories

Increase in Cap on Spending for Federal Health Programs in U.S. Territories
Effective October 1, 2010, the cap on spending will be increased for federal health programs in U.S. territories–Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa–from 2011 onwards. The amount of the increase is to total an estimated $10.35 billion for fiscal years 2011 through 2019, and is to be allocated by the Secretary in the form of a percentage of the total for each territory. Beginning with FY 2020, the Secretary shall provide an amount equal to the same percentage of this total, rounded to the nearest $10,000 (or $100,000 in the case of Puerto Rico), on an ongoing basis. The 50% limit for federal contributions to Medicaid programs in U.S. territories (as set forth in Section 1905(b)(2) of the Social Security Act) is removed.

Subtitle H – Miscellaneous

Extension of Medicare Qualified Individual Program
The Medicare Qualified Individual (QI) program will be extended from December 2010 to December 2012. Effective January 1, 2011, the QI program will no longer be "first come first serve," but rather will pay Medicare Part B premiums for all eligible individuals (those with incomes between 120% and 135% of the federal poverty level).

TITLE VIII – REVENUE-RELATED PROVISIONS

Disclosures to Identify Ineligibility for Medicare Prescription Drug Program
Upon written request from the Commissioner of Social Security to the Internal Revenue Service for the purpose of identifying eligibility and ineligibility for Medicare's prescription drug program, the Internal Revenue Service may provide to officers or employees of the Social Security Administration an individual's tax return information or payments of retirement income, unearned income information and income information of the taxpayer from partnerships, trusts, estates, and corporations for the applicable year, and such other return information relating to the individual (or the individual's spouse in the case of a joint return) as is prescribed by the Secretary by regulation as might indicate that the individual is likely to be ineligible for a low-income prescription drug subsidy.

Comparative Effectiveness Research Trust Fund
There will be established in the Treasury of the United States the Health Care Comparative Effectiveness Research Trust Fund (CERTF). The amounts appropriated

will be transferred from the Federal Hospital Insurance Trust Fund and from the Federal Supplementary Medical Insurance Trust Fund and from the Medicare Prescription Drug Account within such Trust Fund, in amounts equivalent to the fair share per capita amount computed for the fiscal year multiplied by the average number of individuals entitled to Medicare benefits under Part A, or enrolled under Part B. The fair share per capita amount will be computed by the Secretary, and should result in revenues to the CERTF of $75,000,000 for FY 2013. Expenditures from the fund will be available to the Comparative Effectiveness Research Commission.

CERTF Financing From Fees on Insured and Self-Insured Health Plans
A fee equal to the fair share per capita multiplied by the average number of lives covered under the policy will be imposed against insured and self-insured health plans to be paid each year by the issuer of the policy for insured policies and paid by the plan sponsor for self-insured health plans. The fees imposed will be treated as if they were taxes for policies and plans beginning on or after October 1, 2012.

TITLE IX – MISCELLANEOUS PROVISIONS

Repeal of Trigger Provisions
The 45% trigger provision of the Medicare Prescription Drug, Improvement and Modernization Act (MMA) will be repealed. This trigger provision mandated that if more than 45% of Medicare expenditures were projected to come from general revenues within a seven-year period, the Medicare Trustees would issue a warning. Two consecutive years of warning would require the President to offer reform legislation and Congress to give that legislation expedited consideration.

Repeal of Comparative Cost Adjustment Program
The Comparative Cost Adjustment Program mandated by the MMA that would require traditional Medicare to compete with MA plans in a number of locations around the country will be repealed.

Extension of Gainsharing Application
The Gainsharing Demonstration of the Deficit Reduction Act of 2005 will be extended from December 31, 2009 to September 30, 2011. An additional $1.6 million will be appropriated for FY 2010, to remain available for expenditure through FY 2014. The demonstration permits the testing of various hospital/physician alignment options without the application of the physician self-referral or other federal fraud and abuse laws.

DIVISION C – PUBLIC HEALTH AND WORKFORCE DEVELOPMENT

Creation of Public Health Investment Fund
A new Public Health Investment Fund will be established with deposit amounts set for 2010 to 2019. Deposits to the Fund will be derived from general revenues of the Treasury and will be allocated to community health centers, the National Health Service

Corps program, the National Health Service Corps Scholarship and Loan Repayment Programs, primary care educations programs, nursing workforce development, the National Center for Health Statistics, and AHRQ. Reports for each program are generally required to be submitted to Congress in each title by the Secretary or Advisory Committee on Health Workforce to keep Congress apprised on the state of the programs and status of the health workforce.

TITLE I – COMMUNITY HEALTH CENTERS

Increased Funding to Community Health Centers

Funding appropriations will be authorized from the Public Health Investment Fund to Community Health Centers in sums as may be necessary for each of fiscal years 2013 and 2019 and additional funds set forth for each year from 2010 to 2019.

TITLE II – WORKFORCE

Subtitle A – Primary Care Workforce

National Health Service Corps Scholarship and Loan Repayment Program

The Secretary will be allowed to grant waivers for individuals who have entered into a contract for obligated service under the National Health Service Corps Scholarship Program or Loan Repayment Program to allow individuals to meet their service requirement by providing clinical practice on a half-time basis to either double the length of service or half the full-time award amount. The Secretary may increase loans given through the Loan Repayment Program from $35,000 to $50,000 plus an additional amount beginning with FY 2012, reflecting inflation and to be determined by the Secretary. For up to 20% of obligated service under the National Health Service Corps Scholarship Program or Loan Repayment Program, teaching may now qualify as clinical practice.

Establishment of Frontline Health Providers Loan Repayment Program

The Frontline Health Providers Loan Repayment Program is created to assist health professional needs areas through loan repayments for individuals participating in the program who will serve for two years or longer in health professional needs areas. To be eligible to participate in the Frontline Health Providers Loan Repayment Program, an individual must: 1) hold a degree or be enrolled in an accredited school of medicine, dentistry, osteopathic medicine, pharmacy, optometry, podiatric medicine, veterinary medicine, or chiropractic, excluding schools of public health; 2) hold a degree from or be enrolled in an accredited graduate program in clinical social work, marriage and family therapy, professional counseling, behavioral health and mental health practices, or school of allied health; 3) be a physician assistant, nurse practitioner, clinical nurse specialist, registered nurse anesthetist, certified nurse-midwife, clinical social worker, clinical psychologist, registered dietitian or nutrition professional, or a physical occupational therapist, speech language pathologist, or audiologist; or 4) be a practitioner in the field

of respiratory therapy, medical technology, or radiologic technology. Individuals participating in the program may satisfy their service requirement through employment in a solo or group practice, clinic, accredited public or private nonprofit hospital, or any other health care entity deemed appropriate by the Secretary.

Primary Care Training Programs

The Primary Care Training and Capacity Building Program will provide grants and contracts to support and develop primary care training programs with funding for: 1) accredited professional training programs, including accredited residency or internship programs in the field of family medicine, general internal medicine, general pediatrics, or geriatrics for medical students, interns, residents, or practicing physicians; 2) traineeships and fellowships to medical students, interns, residents, or practicing physicians who are participants and who plan to specialize or work in these fields; 3) accredited programs for the training of physicians who plan to teach in programs in these fields, including in community-based settings; 4) traineeships and fellowships to practicing physicians who are participants in any such program and who plan to teach in training program in these fields; and 5) accredited programs for physician assistant education and training those who will teach such training. Preference for grants and contracts will be given to entities that have a demonstrated record of: 1) training the greatest percentage, or significantly improving the percentage, of health care professionals who provide primary care; 2) training individuals who are from underrepresented minority groups or disadvantaged backgrounds; 3) a high rate of placing graduates in practice settings that principally focus on serving underserved areas or populations experiencing health disparities, and; 4) supporting teaching programs that address the health care needs of vulnerable populations.

Training of Medical Residents in Community Based Settings

Grants and contracts will be available to eligible entities to plan and develop new primary care residency training programs or to operate established programs. In awarding grants and contracts under this program, preference will be given to medical education and teaching health center entities that support teaching programs that address the health care needs of vulnerable populations, or are a federally qualified health center, or a rural health clinic. For established primary care training programs, additional preference will be given to entities that have a demonstrated record of training a high or a significantly improved percentage of health care professionals who provide primary care, individuals who are from underrepresented minority groups or disadvantaged backgrounds, or individuals who principally serve underserved areas or populations experiencing health disparities. Grants or contracts will not exceed three years for new primary care residency training programs and cannot be renewed or five years for existing programs.

Support and Development of Dental Training Programs

Grants and contracts will be awarded to accredited schools of dentistry, training programs in dental hygiene, and public and private nonprofit entities to support and train oral health professionals in the fields of general, pediatric, or public health dentistry and dental

hygiene. These grants and contracts will be used to: 1) support professional training programs; 2) provide financial assistance to individual practitioners, traineeships and fellowships; 3) support training programs and provide financial assistance for those who plan to teach in such fields; 4) establish, maintain, or improve academic administrative and clinical teaching units; 5) support pre- and postdoctoral training programs or loan repayment programs for full-time faculty; and 6) provide technical assistance in developing and implementing instruction with regard to the oral health status, dental care needs, and risk-based clinical disease management of all pediatric populations with an emphasis on underserved children. In awarding grants and contracts, preference will be given to entities that have demonstrated record similar to those stated for the primary care and medical resident training program grants and contracts or a record of supporting teaching programs that provide instruction regarding the oral health status, dental care needs, and risk-based clinical disease management of pediatric populations with an emphasis on underserved children.

Subtitle B – Nursing Workforce

Nurse-Managed Health Centers

The term "Nurse-Managed Health Center" is added to the definitions in the Public Health Service Act and is defined as a nurse-practice arrangement, managed by advanced practice nurses, that provides primary care or wellness services to underserved or vulnerable populations and is associated with an accredited school of nursing, Federally qualified health center, or independent nonprofit health or social services agency.

Grants and Loans for Nursing Students

Additional traineeship consideration will be given to entities that agree to expend awards to increase diversity among advanced education nurses. Grants and contracts will be available to eligible entities that provide coordinated and quality care rather than those that provide managed care and quality improvement. The maximum amount a student may receive in the form of loans from nursing programs is also increased. Loans may be extended to qualifying individuals who wish to satisfy the terms of their loan by teaching as faculty at an accredited school of nursing.

Subtitle C – Public Health Workforce

Creation of Public Health Workforce Corps

A Public Health Workforce Corps is created to ensure an adequate supply of public health professionals in the country. The Director of the CDC will develop a methodology for assigning Public Health Workforce Corps participants to state, local, and tribal health departments and federally qualified health centers to address the needs of medically underserved populations. A scholarship program will provide scholarships for the corps to eligible participants who: 1) are accepted for enrollment or enrolled in an approved course of study or program at an accredited graduate school or program of public health; 2) have demonstrated expertise in public health and enrolled or accepted

for enrollment at an accredited graduate school or program of nursing; health administration, management, or policy, preventive medicine, laboratory science, veterinary medicine, dental medicine, or another accredited graduate school or program deemed appropriate by the Secretary; 3) eligible for or hold an appointment as a commissioned officer in the Regular or Reserve Corps of the Service or selection for civilian service in the Corps; and 4) sign and submit to the Secretary a written contract to serve full-time as a public health professional upon completion of the course of study or program involved.

Public Health Workforce Corps Scholarship and Loan Repayment Requirements
Scholarships will be available for a period of up to four years to pursue an approved course of study or program for preparation in the public health workforce. Scholarship recipients will serve full-time as a public health professional for either two years or at least one year for each academic year in which the student was enrolled. A loan repayment program will be available to individuals who hold a graduate degree or are enrolled in a graduate degree program from an accredited school or program of public health or who have demonstrated expertise in public health and have a graduate degree from an accredited school of nursing; health administration, management, or policy; preventive medicine; laboratory science; veterinary medicine; dental medicine; or another accredited program approved by the Secretary. The loan repayment beneficiary will serve full-time as a public health professional for no less than two years. Repayments may consist of the principal and interest for government and commercial loans for reasonable educational expenses no more than $35,000 for each year of obligated service.

Public Health Workforce Training and Enhancement Program
A Public Health Workforce Training and Enhancement Program will be established, awarding grants and contracts to accredited health profession schools, state, local or tribal health departments and public or private nonprofit entities to support accredited professional training programs in the field of public health, including programs in nursing; health administration, management, or policy; preventive medicine; laboratory science; veterinary medicine; and dental medicine, for members of the public health workforce including mid-career professionals. Grants and contracts will also provide financial assistance for traineeships and fellowships to students in these programs who plan to specialize in public health and support programs for the training of public health professionals who plan to teach in these areas. Preference in awarding grants and contracts will be given to entities that have a demonstrated record of training professionals who serve in underserved communities, who are from underrepresented minority groups, who enter specialties experiencing shortage, and who serve the federal, state, local or tribal government.

Preventive Medicine and Public Health Training Grant Program
The Administrator of the Health Resources and Services Administration (HRSA) in consultation with the CDC Director will award grants or contracts to eligible entities to provide training to graduate medical residents in preventive medicine specialties. To be

eligible for a grant or contract under the program, an entity shall be: 1) an accredited school of public health, medicine, or osteopathic medicine; 2) an accredited public or private hospital; or 3) a state, local, or tribal health department. Funds will be used to support residency or internship program in preventive medicine or public health, or to help defray the costs of practicum experiences in such programs and to establish, maintain, or improve academic administrative units in preventive medicine and public health, or programs that improve clinical teaching in these fields.

Subtitle D – Adapting Workforce to Evolving Health System Needs

Increase in Maximum Amount for Scholarships and Loan Repayments

The maximum amount of principal and interest for educational loans given annually to qualifying individuals is increased from $20,000 to $35,000, plus an additional amount (determined to reflect inflation) beginning with FY 2012 for disadvantaged students, loan repayments and fellowships for faculty positions, and educational assistance in health professions for individuals from disadvantaged backgrounds.

Cultural and Linguistic Competency Training for Health Care Professionals

A Cultural and Linguistic Competency Training Program will be developed for health care professionals, including nurse professionals. Grants and contracts will be awarded to health professions schools, academic health centers or other public or private nonprofit entity in order to test, develop, evaluate, and implement models of cultural and linguistic competency training for health professionals. Preference for grants and contracts will be given to entities that have a demonstrated record of addressing cultural and linguistic competency needs, health disparities, and placing health professionals in regions with significant changes in cultural and linguistic demographics.

Interdisciplinary Training Programs

The Innovations in Interdisciplinary Care Training Program will award grants and contracts to eligible entities to test, develop, evaluate and implement health professional training programs designed to promote the delivery of health services through interdisciplinary and team-based models and coordination of care within and across settings, including health care institutions, community-based settings, and the patient's home. Eligible entities include accredited health profession programs, academic health centers, or public or private nonprofit entities. Preference shall be given to entities that have a demonstrated record of training the greatest percentage, or significantly increasing the percentage, of health professionals who serve in underserved communities, using broad interdisciplinary team-based collaborations, and addressing health disparities.

Advisory Committee on Health Workforce Evaluation and Assessment

A permanent advisory committee on the health workforce will be created and will have the following responsibilities: 1) submit recommendations to the Secretary on classifications of the health workforce to ensure consistency of data collection on the workforce, and standardized methodologies and procedures to enumerate the workforce;

and 2) submit policy recommendations to the Secretary on the supply, diversity, and geographic distribution of the workforce and workforce retention. Members of the committee shall possess expertise in at least one of the following areas: 1) conducting and interpreting health workforce market and labor analysis; 2) conducting and interpreting health finance and economics research; 3) delivering and administering health care services; and 4) delivering and administering health workforce education and training. Members of the Advisory Committee will not receive pay for their services.

TITLE III – PREVENTION AND WELLNESS

Addition of Prevention and Wellness to the Public Health Service Act

A new title will be added to the Public Health Service Act regarding prevention and wellness and creating a prevention and wellness trust. Appropriations will be available to: 1) establish prevention task forces; 2) support prevention and wellness research; 3) support the delivery of community preventive and wellness services; 4) fund core public health infrastructure for state, local and tribal health departments; and 5) fund core public health infrastructure for the CDC. The Secretary will submit to Congress within one year after enactment and then at least every two years a national strategy to improve public health through evidence-based clinical and community prevention and wellness activities. The National Prevention and Wellness Strategy will include: 1) identification of specific national goals and objectives in prevention and wellness activities; 2) establishment of national priorities for prevention and wellness; 3) establishment of national priorities for research on prevention and wellness; 4) identification of health disparities in prevention and wellness; and 5) a plan for addressing and implementing these goals.

Task Force on Clinical Preventive Services

A permanent task force for clinical preventive services will be developed to identify areas for research and review the scientific evidence related to clinical services identified for the purpose of developing and disseminating evidence-based recommendations on their use. The task force will take health care disparities into account in developing the recommendations. The task force will consult with a stakeholders board and the Task Force on Community Preventive Services. The task force will be composed of 30 members appointed by the Secretary for six year terms, with a 12-year limit. Members will possess expertise in at least one of the following areas: 1) health promotion and disease prevention; 2) evaluation of research and systematic evidence reviews; 3) applications of systematic evidence reviews to clinical decision-making or health policy; 4) clinical primary care in child and adolescent health; 5) clinical primary care in adult health, including women's health; 6) clinical primary care in geriatrics; and 7) clinical counseling and behavioral services for primary care patients.

Clinical Prevention Stakeholders Board

The Task Force on Clinical Preventive Services will convene a clinical prevention stakeholders board to advise the task force. The members of the board will include

representatives of: 1) health care consumers and patient groups; 2) providers of clinical preventive services, including community-based providers; 3) federal departments and agencies; and 4) private health care payers. The board will: 1) recommend clinical preventive services for review by the task force; 2) suggest scientific evidence for consideration related to reviews; 3) provide feedback regarding draft recommendations; and 4) assist with dissemination of recommendations by the Director of AHRQ. Members of the task force and board will not receive pay for their service.

Task Force on Community Preventive Services

A permanent task force on community preventive services will be established to: 1) identify community preventive services for review; 2) review the scientific evidence related to the community preventive services identified for the purpose of developing and disseminating evidence-based recommendations; 3) take health care disparities into account in developing the recommendations; 4) identify gaps in community preventive services research and recommend priority areas for research; 5) consult with the Community Prevention Stakeholders Board; 6) consult with the Task Force on Clinical Preventive Services; and 7) take into consideration the national wellness and prevention strategy. The task force will be composed of 30 members appointed by the Secretary for six year terms, with a two-term limit. Members of the task force must possess expertise in at least one of the following areas: 1) public health; 2) evaluation of research and systematic evidence reviews; and 3) disciplines relevant to community preventive services, including health promotion, disease prevention, chronic disease, worksite health, qualitative and quantitative analysis, and health economics, policy, law, and statistics. The Secretary will ensure that all areas of expertise are represented and the members of the task force include sufficient representations of state and local health officers and health care and public health practitioners. The Secretary must also appoint individuals with expertise in health disparities.

Community Prevention Stakeholders Board

The Task Force on Community Preventive Services will convene a community prevention stakeholders, with members including representatives of: 1) health care consumers and patient groups; 2) providers of community preventive services, including community-based providers; 3) federal departments and agencies; and 4) private health care payers. The board will: 1) recommend community preventive services for review by the task force; 2) suggest scientific evidence for consideration related to reviews; 3) provide feedback regarding draft recommendations; and 4) assist with dissemination of recommendations. Members of the task force and board will not receive pay.

Community Prevention and Wellness Research Service Grants

The CDC Director, the Director of the National Institutes of Health, and the heads of other agencies within HHS conducting or supporting research, must take into consideration the national prevention and wellness strategy and the recommendations of the Task Forces on Clinical Preventive Services and Community Preventive Services when conducting or supporting research on prevention and wellness. For FY 2013 and

subsequent years, the Secretary will award grants only for services recommended by the Task Force on Community Preventive Services or deemed effective as determined by the Director of the CDC. Grants may not be used: 1) to build or for property or for construction; 2) for services or planning that has been paid by an insurance policy, federal or state health benefits program, or an entity which provides health services on a prepaid basis.

Formula Grants to State Health Departments

Grants will be awarded to state, local, or tribal health departments in order to address core public health infrastructure needs. Not less than 50% of the total amount of funds will be for grants to state health departments. The Secretary will award grants according to: 1) a formula based on size, burden of preventable disease and disability, and core public health infrastructure gaps; and 2) application requirements established by the Secretary including that the state will submit a plan that addresses its highest priority core public health infrastructure needs and allocate funds to local health departments. Competitive grants to state, local, and tribal health departments will be awarded to applicants demonstrating core public health infrastructure needs.

Establishment of a Public Health Accreditation Program

Standards will be reviewed, developed, and implemented for accreditation of state, local, and tribal health departments and public health laboratories to advance their quality and performance. The Secretary may enter into a cooperative agreement with a nonprofit entity to achieve this and must submit to Congress an annual report on progress being made to accredit entities.

Core Public Health Infrastructure and Activities for the CDC

The core public health infrastructure and activities of the CDC will be improved and expanded to address unmet and emerging public health needs. The Secretary must submit to Congress an annual report regarding these activities.

TITLE IV – QUALITY AND SURVEILLANCE

Implementation of Best Practices in the Delivery of Health Care

A Center for Quality Improvement will be established. The Director will: 1) identify, develop, evaluate, and implement best practices for quality improvement; 2) ensure that such practices are consistent with standards adopted by the Secretary for health information technology used in the collection and reporting of quality information; and 3) provide for the dissemination of information and reporting. The Secretary shall identify best practices that are: 1) currently used by health care providers that deliver consistently high-quality, efficient health care services; and 2) easily adapted for use by other health care providers and for use across a variety of health care settings.

The Director will enter into arrangements with entities to implement best practices. Such implementation: 1) may include forming collaborative multi-institutional teams; and

2) shall include an evaluation of the best practices being implemented, including the measurement of patient outcomes throughout the process. The Director will provide for the public dissemination of information with respect to best practices. The Director shall submit an annual report to Congress. Not later than 18 months after the enactment of this Act, the AHRQ Director will submit a report to Congress on the impact of nurse-to-patient ratio on quality of care and patient outcomes, including recommendations for further integration into quality measurement.

Assistant Secretary for Health Information

An Assistant Secretary for Health Information is established within HHS, appointed by the Secretary. The Assistant Secretary will: 1) ensure the collection, reporting, and publishing of information on key health indicators and all other information regarding the nation's health; 2) develop standards for the collection of data and ensure appropriate specificity and standardization at the national, regional, state, and local levels, including standards for the collection of data by race, ethnicity, primary language, sex, sexual orientation, gender identity, disability, socioeconomic status, rural, urban, or other geographic setting, and any other population or subpopulation determined appropriate by the Secretary; 3) ensure consistency with the 1997 Office of Management and Budget Standards for Data on Race and Ethnicity; and 4) develop standards for the collection of data with respect to primary language. The Assistant Secretary also will: 1) provide support and facilitate sharing of information to federal departments whose programs have a significant impact upon health; 2) ensure the sharing of information among the HHS agencies; 3) indentify gaps in information and the agency or entity to address the gaps; 4) facilitate identification and monitoring of health disparities; 5) facilitate public accessibility of datasets by means of the Internet; and 6) award grants or contracts for the collection and collation of information.

The Assistant Secretary will coordinate with: 1) public and private entities that collect and disseminate information on health and health care, including foundations; and 2) the head of the Office of the National Technology to ensure optimal use of health information technology. The Assistant Secretary will submit to the Secretary and the Congress an annual report containing: 1) a description of national, regional, or state changes in health or health care, as reflected by key health indicators; 2) a description of gaps in the information and a plan for actions to be taken and recommendations; and 3) a description of analyses of health disparities, including the results of analyses, the status of longitudinal studies, and proposed or planned research.

TITLE V – OTHER PROVISIONS

Subtitle A – Drug Discount for Rural and Other Hospitals

Expanded Participation in 340B Program

Eligibility for the 340B drug pricing program will be expanded to children's hospitals, which are excluded from the Medicare prospective payment system, critical access

hospitals, certain maternal and child health service providers, certain comprehensive community mental health service providers, certain substance abuse providers, certain

rural hospitals, certain community hospitals, and certain rural referral centers.

Prohibition on Group Purchasing Arrangements by Hospitals
Hospitals owned or operated by the state, which have disproportionate share adjustment percentages greater than 11.75%, children's hospitals, Medicare-dependent small rural hospitals, sole community hospitals, and rural referral centers may not obtain covered outpatient drugs through a group purchasing organization. Exceptions permitted by the Secretary will include: 1) a covered outpatient drug that is unavailable through the drug discount program due to a shortage, manufacturer non-compliance, or a reason beyond the hospital's control; 2) to facilitate substitution when a generic drug is available at a lower price; and 3) to reduce administrative burdens of managing both drug inventories.

Extension of Discounts to Inpatient Drugs, Medicaid Credits on Inpatient Drugs
Discounts will be extended to inpatient covered drugs for the hospitals prohibited from group purchasing arrangements. The term "covered drug" means: 1) a covered outpatient drug; and 2) drugs used in connection with inpatient or outpatient services provided by hospitals owned or operated by the state. Hospitals must provide to each state under its Medicaid plan a credit on the estimated annual costs to such hospital of single source and innovator multiple source drugs and a credit on the estimated annual costs to such hospital of non-innovator multiple source drugs provided to Medicaid beneficiaries for inpatient use. Not later than 30 days after the date of the filing of the hospital's Medicare cost report, the hospital is required to provide the state with: 1) the annual value of single source and innovator multiple source drugs purchased by the hospital based on the drugs' average manufacturer price; and 2) the estimated percentage of the hospital's drug purchases attributable to Medicaid beneficiaries for inpatient use. For each drug purchased during the cost reporting period, the hospital must provide the dosage form, strength, package size, date of purchase and number of units purchased. The Medicaid credits provided by hospitals to states must be paid within 60 days of the hospital calculating those credits. A hospital is not required to provide Medicaid credits to states if it can demonstrate to the state that it will lose reimbursement under the state plan resulting from the extension of discounts to inpatient drugs.

Subtitle B – School-Based Health Clinics

Grants Available for School-Based Health Clinics
A School-Based Health Clinics Program will be established. The Secretary will award grants to school-based health clinics affiliated with a school and providing comprehensive primary health services during school hours to children by health professionals in accordance with state and local laws. School-based health clinics will apply for the grants, providing evidence of local need. Funds awarded under the grant program may be used for: 1) providing training related to the provision of comprehensive

primary health services and additional health services; 2) the management and operation of clinic programs; and 3) the payment of salaries for health professionals and other appropriate clinic personnel.

In awarding grants for the school-based health clinic program the Secretary will give preference to clinics that have: 1) a high percentage of medically underserved children and adolescents; 2) communities or populations in which children and adolescents have difficulty accessing health and mental health services; and 3) communities with high percentages of children and adolescents who are uninsured, underinsured, or eligible for medical assistance under federal or state health benefits programs including Medicaid and CHIP. The clinic must agree to provide, from non-federal sources, an amount equal to 20% of the amount of the grant to carry out the activities supported by the grant. The clinic must demonstrate that funds received through the grant will be expended only to supplement, not supplant, non-federal and federal funds otherwise available to the clinic for operations.

The Secretary will issue regulations regarding the reimbursement for health services provided by school-based health clinics including reimbursement under any insurance policy or any federal or state health benefits program including Medicaid or CHIP. The Secretary also will provide technical assistance for the clinics, develop and implement a plan for evaluating quality performance and submit an annual report to Congress on the School-Based Health Clinics Program.

Subtitle C – National Medical Device Registry

Establishment of a National Medical Device Registry

A National Medical Device Registry will be established. The registry will facilitate analysis of postmarket safety and outcomes data on each implantable or life supporting or life sustaining device. In developing the registry the Secretary, in consultation with HHS agency directors will: 1) determine best methods for including information in the registry to identify each device by type, model, and serial number or other unique identifier; 2) validate methods for analyzing patient safety and outcomes data from multiple sources and for linking data with the information in the registry; 3) integrate registry activities with other activities relating to active postmarket risk identification, advanced analysis of drug safety data, and other postmarket device surveillance activities; and 4) provide public access to the data and analysis collected or developed through the registry in a manner and form that protects patient privacy.

To facilitate analyses of postmarket safety and patient outcomes for devices, the Secretary is required to collaborate with public, academic, and private entities in developing methods to obtain access and to link sources of patient safety and outcomes data including: 1) federal health-related electronic data such as data from Medicare or from the Department of Veterans Affairs; and 2) private sector health-related electronic data such as pharmaceutical purchase data and health insurance claims data. The

Secretary will promulgate regulations for establishment and operation of the registry. Device manufacturers will be required to submit identifying information to the registry for each device.

Subtitle D – Grants for Comprehensive Programs to Provide Education to Nurses and Create a Pipeline to Nursing

Grant Program to Address the Projected Shortage of Nurses

Grants will be available for nurse education programs to address the projected shortage of nurses, increase the capacity for educating nurses by increasing both nurse faculty and clinical opportunities, and provide training programs. The Secretary of Labor will establish a partnership program to award grants to eligible entities. Grant awards shall include one or more of the following: 1) preparing workers to return to the classroom; 2) providing tuition assistance; 3) providing assistance in preparing for and meeting all nursing licensure tests and requirements; 4) carrying out orientation and mentorship programs to assist newly graduated nurses to ensure their short-and long-term retention; 5) providing stipends for release time and continued health coverage; 6) funding programs that enable incumbent nurses interested in teaching to return to school; 7) establishing incentives for advanced degree bedside nurses who wish to teach so that they can obtain a leave without loss of salary or benefits; or 8) collaborating with accredited schools of nursing for nurses to carry out innovative nursing programs which meet the needs of bedside nursing and health care providers.

The Secretary of Labor may not make a grant unless the applicant agrees to make non-federal contributions toward the costs of the program in an amount equal to not less than one dollar for each dollar of federal funds provided in the grant. The Secretary of Labor will submit a report to Congress two years after enactment, using data and information from reports received by entities that have received grant awards, concerning the overall effectiveness of the program.

Subtitle E – States Failing To Adhere to Certain Employment Obligations

Limitation on Federal Funds for States Failing to Adhere to Obligations

A state will only be eligible for federal funds under the provisions of the Public Health Service Act if the state agrees to be subject in its capacity as an employer to each obligation of Division A of this Act and amendments applicable to employers (regarding health insurance plans or contribution to health insurance plans for employees) and if the state assures that all political subdivisions in the state will do the same.