

**APhA Unofficial Summary of the Senate Finance Committee's
Chairman's Mark of the "America's Healthy Future Act of 2009"
As Released September 16, 2009**

TITLE I—HEALTH CARE COVERAGE (Page 1)

SUBTITLE A—INSURANCE MARKET REFORMS

Rating Rules in the Individual Market

- Establishes Federal rating, issue, renewability, and pre-existing condition rules for the individual market.
 - Premiums could vary based only on: tobacco use, age, and family composition. Specific ratios are provided. Premiums could also vary among, but not within, rating areas to reflect geographic differences.
 - Requires issuers to offer coverage on a guaranteed issue and renewability basis.
 - Prohibits issuers from excluding coverage for pre-existing health conditions and from rescinding health coverage.

Immediate Assistance for Those with Pre-existing Conditions

- Within a year of enactment, any uninsured individual who has been denied health care coverage due to a pre-existing condition can enroll in a high-risk pool.
 - The individual will have had to be uninsured for six months before gaining access to the high-risk pool.
 - The pool will exist until 2013; \$5 billion will be provided to subsidize premiums in the pool.

Rating Rules for Small Group Market

- Applies the individual market rules to the small group market.
 - These would be phased in over a period of up to 5 years, beginning January 1, 2013, as determined by each state with approval from the Secretary.

Cafeteria Plans for Small Employers

- Provides a safe harbor from the non-discrimination requirements for cafeteria plans for an eligible small employer and for specified qualified benefits under the cafeteria plan including group term life insurance, coverage under a self-insured group health plan, and benefits under a dependent care assistance program.
- The safe harbor requires the cafeteria plan to satisfy minimum eligibility and participation requirements and minimum flex-credit contribution requirements. This section is effective for taxable years beginning after December 31, 2010.

Qualified Long-Term Care Insurance

- Authorizes a cafeteria plan to offer as a qualified benefit contributions to a qualified long-term care insurance contract to the extent the amount of such contribution does not exceed the eligible long-term care premiums for such contract. This provision is effective for taxable years beginning after December 31, 2010.

Pooling Requirements for Individual and Small Group Markets

- Requires states to apply the new Federal rating rules to two distinct markets (the individual and small group markets), defined as groups of 1-50 or up to 100 at state option. States would have the option to merge the pooling and rating requirements for the individual and small group markets. This section addresses risk-adjustments, reinsurance, and risk corridors.

State Insurance Commissioners

- Affirms that state insurance commissioners would continue to provide oversight of plans with regard to consumer protections, rate reviews, solvency, reserve requirements, premium taxes, and all requirements imposed on insured plans as specified in this Mark. The Commissioners would also provide oversight of plans with regards to Federal rating rules and any additional state rating rules, would facilitate risk-adjustment within service areas, and would establish rate schedules for broker commissions in the state exchanges.
- Directs the National Association of Insurance Commissioners (NAIC) to devise an NAIC Model Regulation within 12 months of enactment that is consistent with the new Federal law with regards to Federal health insurance rating, issuance and marketing requirements. The model becomes the new Federal minimum without further Congressional action. The Secretary of Health and Human Services (HHS) must promulgate regulations if NAIC does not meet the 12 month deadline. Once completed, states must adopt the new NAIC model (or the HHS regulations if that's the direction taken). States have some flexibility as long as their rule/provision is consistent with the intent of the new Federal law and provides the same level of consumer protections. The Federal law would pre-empt conflicting state laws if the states fail to take action. In such cases, insurers would offer coverage under Federal law and be overseen by HHS until the state adopts the necessary changes.
- Requires states to establish an exchange that complies with Federal law. If the state fails to do so within 24 months of enactment, the Secretary of HHS must contract with a non-governmental entity to establish a state exchange that complies with Federal legislation.

Rating Areas

- Rating areas would be defined by state insurance commissioners and reviewed by the Secretary for adequacy.

Grandfathered Plans

- Individuals and groups wishing to renew an existing policy may do so. Plans could continue to offer coverage in a grandfathered policy, but only to those who were currently enrolled, dependents, or in the case of employers, to new employees and their dependents. No tax credits would be offered for grandfathered plans.
- Beginning January 1, 2013, phases in (over five years) Federal rating rules for grandfathered policies in the small group market, as determined by the state with the Secretary's approval. Plans could continue after the transition period but would be subject to new rating rules.

Interstate Sale of Insurance

- By 2013, directs NAIC to develop model rules for the creation of "health care choice compacts", which states can begin forming in 2015 to allow for the purchase of individual health insurance across state lines. Insurers selling policies through a "compact" would only be subject to the laws and regulations of the state where the policy is written or issued. The state where the consumer lives retains authority to address certain aspects of the plan. Insurers must be licensed in both states or submit to the jurisdiction of each state with regard to these issues. Before selling a policy through a "compact", the insurer must notify the consumer that the policy may not be subject to all the laws and regulations of the state in which the purchaser resides.
- Effective January 1, 2013 unless otherwise noted.

National Plans

- Allows for national plans with uniform benefit packages that are offered across state lines.

- They must be licensed in every state in which they choose to operate, would be regulated by the states in terms of solvency and other key consumer protections, and would offer coverage through the state exchanges.
- They must be compliant with the benefit levels and categories detailed in the Mark, but would preempt state benefit mandates.
- Directs NAIC, in consultation with certain stakeholders, to develop standards on implementing benefit categories (e.g. what constitutes prescription drug coverage). State insurance commissioners will ensure that insurers offering national plans are compliant with the new standards.
- Premiums will be determined based on rating rules in each state and will reflect geographic variation among rating areas.
- Directs national plans to provide “silver” and “gold” benefit levels. Plans must offer the same plan(s) in all the states in which it participates.
- Directs NAIC to also develop harmonization standards for processes of state insurance regulation that pertain to form and rate filing.

SUBTITLE B—EXCHANGE AND CONSUMER ASSISTANCE (Page 14)

State Exchange and Marketing Requirements

- Requires all private insurers in the individual and group markets to be available in newly established state exchanges, if the insurers are licensed by a state.
- Requires states to establish an exchange for the individual market and a “Small Business Health Options Program” (SHOP) exchange in the small group market.
- Directs the Secretary to establish and maintain a database of plan offerings for use by the state exchanges. Authorizes the Secretary to contract out for these services.
- In years 2010 – 2012, prohibits plans with limited benefits and low annual caps from being offered in the state exchanges.
- Beginning 2013, requires all plans offered in the individual and small group market, whether in the exchange, to comply with the rating reforms and benefit options detailed in the Mark.
- Legal U.S. residents may obtain insurance through the exchanges. Parents in the country illegally may not buy insurance for themselves through the exchange, but may buy insurance through the exchange for their children who are U.S. citizens or present legally.
- Details the functions performed by the Secretary and/or States including: developing a standard enrollment application; providing a standardized format for presenting insurance options in the exchange; developing standardized marketing requirements; maintaining a customer support call center; enabling enrollment in hospitals, schools, departments of motor vehicles, social security offices, etc.; developing a model template for a Web portal; conducting eligibility determinations for tax credits and subsidies; establishing procedures for granting annual certifications for individuals that can’t find creditable, affordable coverage; establishing procedures for appeals of eligibility decisions for subsidies; and establishing a plan for publicizing the existence of the exchange and the annual open enrollment period.
- Requires state insurance commissioners to establish procedures for reviewing plans to be offered through the state exchanges and to develop criteria for determining whether certain health benefits can be available for sale in the market.
- Allows for multiple exchanges after certain requirements are met.
- Allows for states to form regional exchanges, subject to the Secretary’s approval.

- Directs states to assist small employers that opt to use the SHOP exchange and the enrollment option for their employees.
- Directs the Secretary to designate an office within the Department to provide technical assistance to states regarding incorporating small businesses into SHOP exchanges.
- In 2017, directs states to develop and submit to the Secretary a phase-in schedule for incorporating firms of various sizes into state exchanges. Directs the Secretary to develop regulations to address the potential for any risk selection issues with allowing larger employers into state exchanges.
- State exchanges would receive initial Federal funding but would be required to be self-sustaining in future years.
- Effective July 1, 2010 unless otherwise indicated.

SUBTITLE C—MAKING COVERAGE AFFORDABLE (Page 17)

Benefit Options

- Allows for four benefit categories: bronze, silver, gold, and platinum. All plans in the individual and small group market must, at a minimum, offer coverage in the silver and gold categories.
- All plans must meet prescribed actuarial standards.
- All plans must provide preventive and primary care, emergency services, hospitalization, physician services, outpatient services, day surgery and related anesthesia, diagnostic imaging and screenings (including x-rays), maternity and newborn care, pediatric services (including dental and vision), medical/surgical care, **prescription drugs**, radiation and chemotherapy, and mental health and substance abuse services that at least meet minimum standards set by Federal and state laws.
- Prohibits plans from charging cost-sharing (e.g., deductibles, copayments) for preventive care services, except in cases where value-based insurance design is used.
- Prohibits plans from including lifetime limits on coverage or annual limits on any benefits.
- Requires insurers that rate on tobacco use to provide coverage for comprehensive tobacco cessation programs including counseling and pharmacotherapy (prescription and non-prescription).
- Plans must apply parity for cost-sharing for treatment of conditions within the following categories of benefits: inpatient hospital; outpatient hospital; physician services; and other items and services except where value-based insurance design is used.
- **Requires plans to meet the class and category of drug coverage requirements specified in Medicare Part D. States may permit some flexibility in plan design to encourage widely agreed upon cost and quality effective services.** These requirements would not add to or change the actuarial value of the benefit designs.
- **Requires insurers in the exchange to charge the same price for the same products in the entire service area** as defined by the state regardless of how the individual purchases the policy (whether inside or outside the state exchange from the carrier or an agent).
- Defines the four benefit packages.
- Requires that a “young invincible” policy must also be available for those 25 years or younger. It would be catastrophic coverage; exempts prevention benefits from the deductible.
- Limits out-of-pocket costs for person between 100-200% and between 200-300% of the federal poverty limit (FPL).

Health Care Affordability Tax Credits

- Provides a refundable tax credit for eligible individuals and families that purchase health insurance through the exchange. The credit will be refundable and payable in advance directly to the insurer.
- Requires verification of personal data to prevent illegal immigrants from accessing the state exchanges obtaining federal health care tax credits.
- Creates a cost-sharing subsidy to buyout any differences in cost-sharing between the insurance purchased and certain, specified actuarial values.

Small Business Tax Credit

- Provides a tax credit for a qualified small employer for contributions to purchase health insurance for its employees. The credit would neither be payable in advance to the taxpayer nor refundable. The credit would be a general business credit and can be carried back for one year and carried forward for twenty years. The credit would be available for tax liability under the alternative minimum tax.
- The credit would be phased in. Initially it would be available to any small employer; but beginning with the taxable years ending after December 31, 2012, the credit would be available only to small employers that purchase insurance through the exchange.
- Specifies how the credit would be calculated.
- Effective January 1, 2013 unless otherwise specified.

Application of State and Federal Laws Regarding Abortion

- Ensures that state laws regarding the prohibition or requirement of coverage or funding of abortions, and state laws involving abortion-related procedural requirements are not preempted.
- Ensures that Federal conscience clause protections and abortion-related anti-discrimination laws are not affected.
- Ensures that the rights and obligations of employees and employers under Title VII of the Civil Rights Act of 1964 are not affected.
- Ensures that state or Federal laws requiring health care providers to provide emergency services are not affected.

Abortion Coverage Prohibited as Part of Minimum Benefits Package

- States that abortion cannot be a mandated benefit as part of a minimum benefits package except in those cases for which Federal funds appropriated for the Department of Health and Human Services (DHHS) are permitted.
- A qualified health plan would not be prohibited from providing coverage of abortions beyond those for which Federal funds appropriated for DHHS are permitted.
- Federal funds continue to be prohibited from being used to pay for abortions unless the pregnancy is due to rape, incest, or if the life of the mother is in danger.

Required Segregation of Public Funds

- Prohibits tax credit or cost-sharing credits from being used to pay for abortions beyond those permitted by the most recent appropriation for DHHS.
- Insurers participating in any state exchange that offers coverage for abortion beyond those permitted by the most recent appropriations for DHHS must segregate any premium and cost-sharing credits an amount of each enrollee's private premium dollars that is determined to be sufficient to cover the provision of such services.

- Directs the Secretary to establish a process using an estimated actuarial value by which insurers that provide coverage for abortions beyond those permitted by the most recent appropriations for DHHS must demonstrate that no federal premium and cost-sharing credits are used for the purpose of paying for such abortions.

Actuarial Value of Optional Service Coverage

- Requires the Secretary to estimate, on an average actuarial basis, the basic per enrollee, per month cost of including coverage of abortions beyond those permitted by the most recent appropriations for DHHS under a basic plan.

Rules Regarding Coverage of and Tax Credits for Specified Services

- Directs the Secretary to ensure that in each state exchange, at least one plan provides coverage of abortions beyond those for which Federal funds appropriated for DHHS are permitted.
- Directs the Secretary to ensure that in each state exchange, at least one plan does not provide coverage of abortions beyond those for which Federal funds appropriated for DHHS are permitted.

No Discrimination on the Basis of Provision of Abortion

- Prohibits health benefits plans participating in state exchanges from discriminating against any individual health care provider or health care facility because of its willingness or unwillingness to provide, pay for, provider coverage for, or refer for abortions.

SUBTITLE D—SHARED RESPONSIBILITY (Page 27)

Personal Responsibility Requirement

- Beginning in 2013, all U.S. citizens and legal residents must purchase coverage through the individual market, a public program (e.g. Medicare, Medicaid, the Children’s Health Insurance Program, Veteran’s Health Care Program, or TRICARE), or through an employer (as an employee or dependent) in the small group market, meeting at least the requirements of a bronze plan; or in the large group market, in a plan with first dollar coverage for prevention-related services as recommend by the U.S. Preventive Services Task Force. Certain exceptions are allowed related to value-based insurance design and for religious objections. Individuals enrolled in grandfathered plans are deemed to have met this requirement.
- Compliance would be ensured through individuals reporting on their Federal income taxes and by insurer reports.
- The initial open-enrollment period for eligible individuals in the individual and small group markets would be from September 1, 2012 through November 30, 2012. Thereafter, the open-enrollment period would be from October 15 through November 30. Special enrollment periods are allowed.
- An excise tax would apply for any period for which the individual is not covered by a health plan with the minimum requirement benefit. The tax would be prorated for partial years of noncompliance. Certain individuals would be exempt from the tax based upon their finances.
- Employers with 200 or more employees must automatically enroll employees into health insurance plans offered by their employer. Employees may opt out if they can demonstrate other credible coverage. States will have the option to establish a process for auto-enrollment of individuals and families into policies offered in the individual and small group markets. These state programs must be approved by the Secretary.

Employer-Provided Health Insurance Coverage

- Employers are not required to offer health insurance coverage. Specifics are provided regarding tax credits when employees accept their employer's offer of health insurance coverage.
- A Medicaid-eligible individual can always choose to leave the employer's coverage and enroll in Medicaid.
- Employers with more than 50 employees that do not offer coverage must pay a fee for each employee who receives a tax credit for health insurance through a state exchange.
- Effective January 1, 2013 unless otherwise noted.

SUBTITLE E—CREATION OF HEALTH CARE COOPERATIVES (Page 32)

Taxation of Insurance Companies & Tax Exemption for Certain Organizations

- Authorizes \$6 billion in funding the Consumer Operated and Oriented Plan (CO-OP) program to foster the creation of non-profit, member-run health insurance companies that serve individuals in one or more states. CO-OP grantees would compete in the reformed individual and small group markets.
- To be eligible for Federal funds (loans for start-up costs, grants to meet state solvency requirements), an organization must meet the following requirements:
 - Organized as a non-profit.
 - Must not be an existing insurer or an affiliate of one.
 - Its governing documents must include ethics and conflict of interest standards.
 - It must not be sponsored by any government instrument.
 - Substantially all of its activities must consist of issuing qualified health plans in the individual and small group markets.
 - Its governance must be subject to a majority vote of its members.
 - Per regulations promulgated by the Secretary of HHS, it must operate with a strong consumer focus.
 - Profits must be used to lower premiums, improve benefits, or for programs intended to improve the quality of health care delivered to its members.
- Participating organizations may enter into collective purchasing agreements for services and items to increase administrative and other efficiencies. A purchasing council may be established to execute these agreements. The council is prohibited from setting rates for health care facilities and providers. The council may not include government or insurer representatives and is subject to anti-trust statutes.
- Grants and loans provided by the Secretary of HHS will be based upon recommendations from an advisory board chaired by the Secretary and made up of members of the House and Senate. Priority in awarding grants will be given to statewide proposals, integrated care models, and applications with significant private support. In making awards, the Secretary must ensure that there is sufficient funding for at least one CO-OP in all 50 states and the District of Columbia. Multiple awards per state are allowed. The Secretary must begin distributing funds no later than January 1, 2012. The board will sunset upon completion of their duties, but no later than December 31, 2015.
- Organizations receiving loans or grants qualify for Federal income tax exemptions. Certain restrictions would apply.
- Grants and loans must be repaid (with interest) for violations that are not corrected within a reasonable period of time.

SUBTITLE F—TRANSPARENCY AND ACCOUNTABILITY (Page 38)

Ombudsmen Program

- In 2010, requires states to establish an ombudsman office to act as a consumer advocate for those with private coverage in the individual and small group markets.

Health Insurance Consumer Assistance Grants

- Authorizes \$30 million to establish a new competitive grant program to support consumer assistance organizations in each state.

Transparency

- Beginning in 2010, requires plans to report the proportion of premium dollars that are spent on items other than medical care. Requires hospitals to list standard charges for all services and Medicare DRGs.

Standardization

- Mandates the development and utilization of uniform outline of coverage documents. The Secretary will request that the NAIC develop standards for use by health insurers in compiling and providing to enrollees an outline of coverage that accurately describes the coverage under the plan. If the NAIC fails to act in a timely manner, the Secretary shall proceed with standards making via the rulemaking process. The standards shall preempt any related State standards. Failure to comply with the standards will result in a fine not to exceed \$1,000 for each failure.

SUBTITLE G—ROLE OF PUBLIC PROGRAMS (Page 41)

PART I—MEDICAID COVERAGE FOR THE LOWEST INCOME POPULATIONS

Eligibility Standards and Methodology

- Creates a new eligibility category for all non-elderly non-pregnant individuals (childless adults) otherwise ineligible for Medicaid. In 2011, states would have the option to cover childless adults through a state plan amendment.
- Beginning January 1, 2014, establishes 133% of the federal poverty (FPL) limit as the new mandatory minimum Medicaid income eligibility level for all non-elderly individuals. Existing law for pregnant women would not change.
- Addresses when eligibility levels can change, how income would be measured, benefit packages, and the applicability of tax credits. All newly-eligible, non-pregnant adults would receive a benchmark benefit package, which would have to meet requirements for minimum creditable coverage. For benchmark-equivalent plans, **prescription drugs** would be added to the list of benefits that must have the same actuarial value as the benchmark.
- States would have to ensure that all children of parents who choose the state exchange coverage would continue to receive the benefits, including EPSDT benefits, to which children are entitled under Medicaid.

Medicaid Program Payments

- States would continue to receive Federal financial assistance as determined by FMAP. Beginning in 2014, additional Federal financial assistance would be provided to states to defray the costs of covering newly-eligible beneficiaries. The proposal details the schedule and criteria for additional assistance.

Medicaid and Employer-Sponsored Insurance

- Effective January 1, 2013, states must offer premium assistance and wrap-around benefits to Medicaid beneficiaries who are offered employer-sponsored insurance if it is cost-effective to do so, consistent with current law requirements.

Treatment of the Territories

- Beginning on January 1, 2011, increases the spending caps for territories by 30 percent and the applicable FMAP by five percentage points, to 55%. The cost of covering newly eligibles would not count towards the spending caps.

PART II—CHILDREN’S HEALTH INSURANCE PROGRAM (Page 45)

- Restructures the Children’s Health Insurance Program (CHIP). On September 30, 2013 (when the current authorization expires) or when the state exchange is fully operational, whichever occurs later, a new Federal floor for CHIP eligibility is established at 250% of FPL – requiring states to offer CHIP to all children between 134 and 250% of FPL.
- After this date, CHIP income eligibility would be based on modified adjusted gross income, the same measurement that would be used in Medicaid and the state exchanges.
- After this date, the CHIP benefit package would include state exchange coverage and state wrap-around benefits.
- CHIP enrollees would receive tax credits in the state exchanges.
- As in current law, states would be reimbursed at the enhanced CHIP match for the cost of this coverage.

PART III—ENROLLMENT SIMPLIFICATION (Page 47)

Enrollment Coordination with the State Exchange

- Requires states to establish a Medicaid enrollment Web site to promote seamless enrollment in Medicaid should a Medicaid eligible individual apply for tax credits through a state exchange Web site or vice versa.

Presumptive Eligibility

- Effective January 1, 2014, permits hospitals that participate in Medicaid to make presumptive eligibility determinations, in addition to providers currently eligible to do so. Hospitals and other providers could make such determinations for all Medicaid eligible populations as long as the state agency verifies the hospital or provider is capable of doing so.

Waiver Transparency

- Imposes statutory requirements regarding transparency in the development, implementation, and evaluation of Medicaid and CHIP section 1115 demonstration programs that impact eligibility, enrollment, benefits, cost-sharing, or financing. Imposes additional transparency-related statutory requirements on the Secretary. Adds transparency-related statutory requirements to the state plan amendment process for proposals that limit benefits.

PART IV—MEDICAID SERVICES (Page 49)

Free-Standing Birth Centers

- Requires free-standing birth centers recognized as Medicaid providers.

Curative and Palliative Care for Children in Medicaid

- Allows children who are eligible for Medicaid to receive hospice services without forgoing any other service to which the child is entitled under Medicaid.

Long Term Services and Support

- Beginning in fiscal year 2010 for five years, allocates \$10 million for each fiscal year to continue funding the Aging and Disability Resource Center.

Money Follows the Person Rebalancing Demonstration

- Extends the Money Follows the Person Rebalancing Demonstration through September 30, 2016.

PART V—MEDICAID PRESCRIPTION DRUG COVERAGE (Page 51)

Make Prescription Drugs a Mandatory Benefit

- Effective January 1, 2014, makes prescription drugs a mandatory benefit for the categorically and medically needy.

Change the Status of Some Excludible Drugs

- Effective January 1, 2014, removes smoking cessation drugs, barbiturates, and benzodiazepines from Medicaid's excluded drug list.

Increase the Brand-Name Drug Rebate Amount

- Increases the flat rebate percentage used to calculate Medicaid's basic rebate for outpatient brand name prescription drugs from 15.1% to 23.1% except for clotting factors that receive a furnishing fee and outpatient drugs that are approved by FDA exclusively for pediatric indications, for which the basic rebate would increase to 17.1%.
- Limits the total rebate liability on an individual single source or innovator multiple source drug to 100% of AMP for that product.

Increase Generic Drug Rebate Amount

- Increases the rebate for non-innovator, multiple source drugs to 13% of AMP.

Extend to and Collect Rebates on Behalf of Managed Care Organizations (MCO)

- Requires brand name and generic prescription drug manufacturers to pay rebates for beneficiaries who receive care under risk-based agreements similar to the way rebates are now required for fee-for-service (FFS) beneficiaries. Requires manufacturers to pay the MCO rebates directly to states. Nothing prohibits MCOs from negotiating with manufacturers and wholesalers for rebates above Medicaid statutory rebates.

Application of Rebates to New Formulations of Existing Drugs

- For purposes of calculating Medicaid's additional drug rebate, treats new formulations of existing brand name drugs as if they were the original product. When a new version of an existing drug is introduced, the additional rebate obligation for that new drug would be calculated on the original drug's baseline AMP. New formulations of orphan drugs are exempt.

Changes to Medicaid Payment for Prescription Drugs

- Changes the FUL to 175% of the weighted average (determined based on utilization) of the most recent AMPs for pharmaceutically and therapeutically equivalent multiple source drugs available nationally through commercial pharmacies. Clarifies what transactions, discounts, and other price adjustments are included in the definition of AMP. Clarifies that retail survey prices do not include mail order and long term care pharmacies. Expands the disclosure requirement to include monthly average AMPs and retail survey prices.

PART VI—MEDICAID DISPROPORTIONATE SHARE (DSH) PAYMENTS (Page 55)

- State DSH allotments would remain intact until a state trigger is tripped, which would occur once a state's uninsured rate decreases by 50% compared to an initial uninsured rate on the date of

enactment. Once the trigger is tripped, allotments would decrease by 50%. Low DSH state allotments would be decreased by 25%. Further reductions in the uninsured would result in additional DHS allotment decreases.

PART VII—DUAL ELIGIBLES (Page 57)

Waiver Authority for Dual Eligible Demonstrations

- Clarifies that Medicaid demonstration authority for coordinating care for dual eligibles is as long as five years.

Office of Coordination for Dual Eligible Beneficiaries

- Establishes a new office within CMS, the Office of Coordination for Dual Eligible Beneficiaries (OCDEB), which would be responsible for identifying and leading agency efforts to align Medicare and Medicaid financing, administration, oversight rules, and policies for dual eligibles. OCDEB would submit a report to Congress that would include a statistically valid sample of indicators on the quality of care provided to dual eligibles.

PART VIII—MEDICAID QUALITY (Page 58)

Medicaid Quality Measures

- Directs the Secretary of HHS, in consultation with states, to develop an initial set of health care quality measures specific to adults who are eligible for Medicaid.
- Establishes the Medicaid Quality Measurement Program to expand upon existing quality measures, identify gaps in current quality measurement, establish priorities for the development and advancement of quality measures, and consult with relevant stakeholders.
- The Secretary would regularly report to Congress on progress made.
- States would receive grant funding to support the development and reporting of quality measures.

Medicaid Reimbursement for Health Care Acquired Conditions

- Effective July 1, 2011, prohibits Federal payments to states for Medicaid services related to health care acquired conditions. The Secretary would define such conditions.

Medicaid Bundled Payments Demonstration Project

- Establishes a bundled payment demonstration project under Medicaid in up to eight states. The unit of payment for acute care provided in hospitals would be redefined and expanded to include post-acute care provided in acute care hospitals and nonhospital settings, and/or hospital and concurrent physicians' services. Hospitals would receive a single bundled payment for such services. The demonstration would begin October 1, 2011.

PART IX—MEDICAID AND CHIP PAYMENT AND ACCESS COMMISSION (MACPAC) (Page 61)

- Authorizes \$11 million for MACPAC for fiscal year 2010. Of this, \$9 million would come from Medicaid funds and \$2 million would come from CHIP funds. Funding in subsequent years would be subject to appropriations.
- Expands MACPAC's mission to include assessment of adult services in Medicaid and more detailed reporting requirements to states and Congress. Changes reporting dates too.

PART X—AMERICAN INDIANS AND ALASKA NATIVES (Page 62)

Premiums and Cost-Sharing

- Prohibits cost-sharing (including premiums, deductibles, copayments, co-insurance, etc.) for all American Indians and Alaska Natives with incomes at or below 300% of FPL for state exchange and plans and public programs.

Payer of Last Resort

- Ensures that Indian tribes, tribal organizations, and urban Indian organizations (I/T/Us) are the payers of last resort.

Eligibility Determination

- Adds I/T/Us to the definition of an Express Lane Agency. Also allows tribes to accept applications for public programs and state exchange plans.

American Indian and Alaska Native Providers (AI/ANs) and Medicare Part B

- Removes the sunset in current law to allow I/T/Us to continue to receive payment for certain Medicare covered items and services.

Other Policies Related to State Exchange Coverage

- Subjects AI/ANs to the responsibility to obtain insurance but exempts them from the penalty for failing to do so. Authorizes monthly special enrollment periods for AI/ANs in state exchanges.

SUBTITLE H—ADDRESSING HEALTH DISPARITIES (Page 64)

Standardized Collection of Data

- Establishes uniform categories for collecting data on race and ethnicity, gender and primary language.
- Requires CMS to collect data on individuals with disabilities.

Sufficient Disparities Data

- Requires that Federally-funded population surveys collect sufficient data on racial and ethnic subgroups to generate statistically reliable results in studies comparing health disparities populations.
- Ensures that quality reporting requirements include provisions to collect data on patients by race, ethnicity, gender, primary language, and disability.
- Extends the MIPPA provisions regarding the collection of health disparities data on the Medicare population to Medicaid and CHIP.

Data Sharing

- Requires HHS to share health disparities data, measures, and analyses with other relevant agencies.

Privacy and Security

- Requires the Secretary of HHS to ensure all appropriate privacy and security safeguards are followed for activities relating to health disparities data collection, analysis, and sharing.

SUBTITLE I—MATERNAL, INFANT, AND EARLY CHILDHOOD VISITATION PROGRAMS (Page 67)

- Requires states, as a condition of receiving the Maternal and Child Health block grant, to conduct a needs assessment to identify communities that are at risk for poor maternal and child health and have few quality home visitation programs.
- Establishes a new state grant program for early childhood home visitation. Provides certain core components for the home visitation programs.

- Directs the Secretary to appoint an expert panel to design the evaluation of the home visitations grants program; and by grant, contract or interagency agreement, conduct an evaluation of the statewide needs assessments, home visitation programs, and the progress made by grantees' towards their benchmarks. The results of these evaluations would be reported to Congress.
- Specifies appropriations to fund the program.
- Defines eligible entities as states, Indian tribes, tribal organizations or urban Indian organizations.

TITLE II—PROMOTING DISEASE PREVENTION AND WELLNESS (Page 69)

SUBTITLE A—MEDICARE

Annual Wellness Visit

- Beginning in 2011, Medicare beneficiaries would have access to a comprehensive health risk assessment (HRA) based on guidelines developed by the Secretary in consultation with relevant groups and entities. The assessment would identify chronic diseases, modifiable risk factors, and emergency or urgent health needs. The assessment could be provided through an interactive telephonic or Web-based program or during an encounter with a health professional.
- Within six months of completing the HRA, payments are authorized for a visit to a primary care provider to create a personalized prevention plan. The plan would include the following elements: review and update of medical and family history; age, gender, and risk-appropriate measurements (height, weight, BMI, and blood pressure); a schedule and referral for recommended, covered preventive services and immunizations; a strategy to address identified conditions and risk factors; a list of all medications currently prescribed and all providers regularly involved in the patient's care; and health advice and referral to Medicare-covered health education and preventive counseling or referral to community-based interventions to address modifiable risk factors such as weight, physical activity, smoking and nutrition. Optional elements could include cognitive impairment screening and administration of or referral for appropriate Medicare-covered immunizations and screening tests.
- All beneficiaries would be eligible for the wellness visit once every year. No co-payment or deductible would apply.

Removing Barriers to Preventive Services

- Encourages beneficiaries to receive preventive screenings by removing cost-sharing for services covered by Medicare and recommended (rated "A" and "B") by the U.S. Preventive Services Task Force (USPSTF).

Evidence-Based Coverage of Preventive Services

- Encourages evidence-based coverage of preventive services by giving the Secretary the authority to use the same standards of evidence that apply to any new preventive services to existing preventive services.
- Authorizes the Secretary to modify coverage of existing preventive services to the extent that the modification is consistent with the USPSTF recommendations. Allows the Secretary to withdraw Medicare coverage for services rated "D" or harmful by USPSTF.
- Provides funding for CMS to improve provider education and patient awareness of covered preventive services.
- Requires GAO to determine if any barriers exist that prevent the optimal utilization of covered primary, secondary, and tertiary preventive services.

Study on Beneficiary Access to Immunizations

- Requires a GAO study and report to Congress on the impact of the coverage of adult immunizations and Part D on access to those immunizations by Medicare beneficiaries.

Incentives for Healthy Lifestyles

- Authorizes and appropriates \$100 million over five years for the Secretary to establish an initiative to provide incentives to Medicare beneficiaries who successfully complete certain healthy lifestyle programs. Programs would target: high blood pressure, high cholesterol, tobacco use, overweight or obesity, diabetes and falls.
- The initiative would be implemented January 1, 2011.

SUBTITLE B—MEDICAID (Page 72)

Improving Access to Preventive Services for Eligible Adults

- Encourages states to improve coverage of and access to recommended preventive services and immunizations.
- Requires states to provide Medicaid coverage for comprehensive tobacco cessation services for pregnant women without cost-sharing for such services.
- A state would receive a one percent increase in the Federal share of its FMAP for certain services.

Incentives for Healthy Lifestyles

- Directs the Secretary to develop criteria for healthy lifestyle programs.
- The programs must be comprehensive and uniquely suited to address the needs of Medicaid eligible beneficiaries and have demonstrated success in helping individuals lower or control cholesterol and/or blood pressure, lose weight, quit smoking and/or manage or prevent diabetes, and may address co-morbidities, such as depression, associated with these conditions.
- States could apply for funds to provide incentives for Medicaid enrollees who successfully complete healthy lifestyle programs.
- States may collaborate with community-based programs, non-profit organizations, providers, and faith-based groups among others.
- \$100 million is authorized for these grants during a five-year period beginning January 1, 2011.

Medicaid State Plan Option Promoting Health Homes and Integrated Care

- Creates a new Medicaid state plan option under which Medicaid enrollees with at least two chronic conditions or with one chronic condition and at risk of developing another could designate a provider as their health home.
- Qualifying providers must meet standards established by the Secretary.
- The provider or team would offer: comprehensive care management; care coordination and health promotion; comprehensive transitional care, including appropriate follow-up, from inpatient to other settings; patient and family support; and referral to community and social support services, if relevant and as feasible use health information technology to link such services.
- Teams of providers could be free-standing, virtual, or based at a hospital, community health center, clinic, physician's office, or a physician group practice.
- The state plan amendment would include a plan for tracking avoidable hospital readmissions and plan for producing savings resulting from improved chronic care coordination and management.
- States that take up this option will have an enhanced match of 90% of FMAP for two years.

- Small planning grants may be available to states intending to take up this option.
- Requires the Secretary to survey states and report to Congress on the nature, extent, and use of this option especially as it pertains to hospital admission rates, chronic disease management, and coordination of care for the chronically ill.
- The state option would be available beginning January 1, 2011.
- After two years, there would be a evaluation of the impact of this option on reducing hospital admissions.

Appropriations for Childhood Obesity Demonstration Project

- Appropriates \$25 million for the Secretary to carry out the demonstration project.

TITLE III—IMPROVING THE QUALITY AND EFFICIENCY OF HEALTH CARE (Page 75)

SUBTITLE A—TRANSFORMING THE HEALTH CARE DELIVERY SYSTEM

PART I—LINKING PAYMENT TO QUALITY OUTCOMES IN THE MEDICARE PROGRAM

Hospital Value-Based Purchasing

- Establishes a Hospital Value-Based Purchasing (VBP) program in Medicare that moves beyond pay-for-reporting on quality measures to paying for hospitals' actual performance on these measures.
- Measures would be selected from measures used in the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program and would focus on the same areas as RHQDAPU: heart attack; heart failure; pneumonia; surgical care activities; and patient perception of care.
- By fiscal year 2014, the Secretary is required to expand the categories to include efficiency measures.
- Funding for the program would be generated through reducing Medicare IPPS payments to the hospitals. Requires the Secretary to ensure that all funds reduced from hospital payments to fund the program are returned to the hospital in the form of value-based incentive payments in that same year.
- IPPS add-on payments such as DHS payments and IME would not be affected.
- Hospital performance on each specific quality measure, on each condition or procedure, and on total performance would be publicly reported.
- Establishes an appeals process.
- The development of the program would be transparent and done through rulemaking.
- Directs the Secretary and GAO to conduct ongoing monitoring and submit reports to Congress.
- Provides the Secretary the funds necessary to administer the program (amount to be determined).
- Establishes three-year demonstration programs to test VBP models tailored towards critical access hospitals and small hospitals that otherwise would not qualify to participate in the VBP program.

Physician Value-Based Purchasing

- Establishes a new Physician Quality Reporting Initiative (PQRI) option.
- Beginning with the 2011 reporting period, requires CMS to make PQRI incentive payments available for two successive years to eligible professionals who voluntarily complete certain certifications and practice assessments.
- Requires CMS to make two additional enhancements to the PQRI program. First, it requires CMS to provide timely feedback to eligible professionals on their performance with respect to

satisfactorily submitting data on quality measures. Second, it requires CMS to establish an appeals process for providers.

- Extends the PQRI incentive payments beyond 2010.
- Requires CMS to develop a plan to integrate the PQRI program with the standards for meaningful use of certified electronic health records as created in ARRA.
- Beginning in 2012, requires the Secretary to provide reports to physicians that compare their resource use with their peers. Beginning in 2015, payment would be reduced by 5% if an aggregation of the physician's resource use is at or above the 90th percentile of national utilization. After five years, the Secretary may convert the 90th percentile threshold to a standard measure of utilization.

Medicare Inpatient Rehabilitation Facility, Long Term Care Acute Hospital and Hospice Quality Reporting

- Directs the Secretary to establish quality reporting programs for inpatient rehabilitation facilities, long term care hospitals, and hospices.
- Failure to report quality measures would result in reduction of annual market basket update by 2%.

Medicare IPPS Exempt Cancer Hospital Quality Reporting

- Directs the Secretary to establish quality reporting programs for IPPS-exempt cancer hospitals.

Medicare Home Health Agency and Skilled Nursing Facility Value-based Purchasing Implementation Plans

- Directs the Secretary to complete and submit to Congress Medicare value-based purchasing implementation plans for home health agencies and skilled nursing facilities by 2011 and 2012, respectively.

Reducing Hospital Acquired Conditions

- Applies a new payment adjustment to hospitals ranked in the top quartile of national, risk-adjusted hospital acquired condition (HAC) rates.
- Beginning in fiscal year 2013, the Secretary would share these data with hospitals, and the data would be publicly reported on the Hospital Compare Web site.
- Starting October 1, 2014, hospitals in the top quartile of national HAC rates would receive 99% of their otherwise applicable Medicare payments.

PART II—STRENGTHENING THE QUALITY INFRASTRUCTURE (Page 84)

Quality Infrastructure

- Provides additional resources to HHS to strengthen and improve quality measure development processes for purposes of improving quality, informing patients and purchasers, and guiding payment under Federal health programs.
- AHRQ and CMS would implement the provisions in this proposal.
- Directs the Secretary to establish a national quality improvement strategy that includes priorities to improve the delivery of health care services, patient health outcomes, and population health through a transparent and collaborative process.
- In developing the priorities, directs the Secretary to consider how they would: address health care needs of those with high-cost chronic diseases; improve strategies and best practices to improve patient safety and reduce medical errors, preventable hospital admissions and readmissions, and health care-associated infections; have the greatest potential for improve the health outcomes, efficiency and patient-centeredness of health care; reduce health care disparities

across populations and geographic areas; address gaps in quality, efficiency and outcomes measures and data aggregation techniques; identify areas in the delivery of health care services that have the potential for rapid improvement in the quality and efficiency of patient care; improve payment policy under Federal health programs to emphasize quality and efficiency; enhance the use of health care data to improve quality, efficiency, transparency, and outcomes; and other areas as determined appropriate by the Secretary.

- The national strategy would also include a strategic plan to achieve the above priorities.
- In developing the national strategy and priorities, the Secretary will take into consideration recommendations submitted by a qualified consensus-based entity as set forth in Medicare Improvements for Patients and Providers Act (MIPPA). To develop these recommendations, this entity would convene a multi-stakeholder group. Stakeholders would include, but not be limited to representatives of hospitals, physicians, post-acute providers, quality alliances, nurses and other health care practitioners, health plans, consumer representatives, life sciences industry, employers and public purchasers, labor organizations, licensing, credentialing and accrediting bodies, relevant government agency representatives, and others that the Secretary deems appropriate.
- Directs the President to convene a working group of relevant Federal departments and agencies to collaborate and consult on fulfilling the national strategy.
- Directs the Secretary to identify, no less than triennially, gaps where no quality measures exist or where current measures need improvement. The report would also include information on the economic and quality impact of the use of the endorsed measures.
- Directs the Secretary to develop measures to fill identified gaps.
- An entity that receives a grant under this section would use the funds to develop quality measures that build on measures already required to be reported per the Social Security Act, can be collected using HIT (to the extent practicable), is free of charge to users, and is publicly available on the Web.
- Measures developed would focus at a minimum on the following areas: patient outcomes and functional status; coordination of care across episodes of care and care transitions; meaningful use of health information technology; safety, effectiveness, patient centeredness, appropriateness and timeliness of care; efficiency of care; equity of health services and health disparities; patient experience and satisfaction; and other areas the Secretary deems appropriate.
- Authorizes \$75 million to DHHS for each fiscal year, 2010-2014 to carry out this section.

PART III—ENCOURAGING DEVELOPMENT OF THE NEW PATIENT CARE MODELS

(Page 88)

Accountable Care Organizations

- In the Medicare program, allows groups of providers who meet certain criteria to be recognized as accountable care organizations (ACOs) and be eligible to share in the cost-savings that they achieve for the Medicare program.
- Beginning January 1, 2012, eligible ACOs have the opportunity for an incentive bonus.
- Defines eligible ACOs as groups of providers and suppliers that have an established mechanism for joint decision making. The following providers and suppliers would be eligible: practitioners in group practice arrangements; networks of practices; partnerships or joint-venture arrangements between hospitals and practitioners; hospitals employing practitioners; and such other groups of providers of services and suppliers as the Secretary determines appropriate.

Defines practitioners as physicians, nurse practitioners, physician assistants, clinical nurse specialists, and **other practitioners** or suppliers as the Secretary determines appropriate.

- To qualify as an ACO requires an organization to meet at least the following criteria:
 - Agree to become accountable for the overall care of their Medicare fee-for-service beneficiaries;
 - Agree to a minimum three-year participation;
 - Have a formal legal structure that would allow the organization to receive and distribute bonuses to participating providers;
 - Include the primary care physicians for at least 5,000 Medicare fee-for-service beneficiaries;
 - Provide CMS with information regarding primary care and specialist physicians participating in the ACO as the Secretary deems appropriate;
 - Have arrangements in place with a core group of specialist physicians;
 - Have in place a leadership and management structure, including with regard to clinical and administrative systems;
 - Define processes to promote evidence-based medicine, report on quality and costs measure, and coordinate care; and
 - Demonstrate to the Secretary that it meets patient-centeredness criteria determined by the Secretary, such as use of patient and caregiver assessments or the use of individualized care plans.
- To earn the incentive payment requires the organization to meet certain quality thresholds. In determining the quality of care furnished by an ACO, the Secretary would be required to use measures such as:
 - Clinical processes and outcomes;
 - Patient and caregiver perspectives on care; and
 - Utilization and costs (such as rates of ambulatory-sensitive admissions and readmissions).
- Requires ACOs to submit data, at the group and individual provider level, on measures the Secretary determines necessary to evaluate the quality of care furnished by the ACO. Requires the Secretary to establish performance standards for measures of the quality of care furnished by ACOs. Requires the Secretary to seek to improve the quality of care furnished by ACOs over time by specifying higher standards for purposes of assessing quality of care.
- Authorizes the Secretary to incorporate reporting requirements and incentive payments and penalties related to the physician quality reporting initiative (PQRI), electronic prescribing, electronic health records, and other similar initiatives into the reporting requirements for ACOs.
- Directs CMS to assign Medicare fee-for-service beneficiaries to ACOs based on their use of Medicare items and services in preceding periods. The achievement thresholds and rewards for the ACO would be as follows. The spending baseline would be determined on an organizational level by using the most recent three years of total per beneficiary spending for those beneficiaries assigned to the ACO. The target would be set by the baseline amount plus a flat-dollar amount that is equal to the risk-adjusted average expenditure growth per beneficiary nationally. Baselines would be re-set at end of the three-year period.
- ACOs with three-year average Medicare expenditures that are determined by CMS to be below their benchmark for the corresponding period would be eligible for shared savings at a rate determined appropriate by the Secretary. Requires the Secretary to set a minimum threshold of

savings that would need to be achieved by an ACO before savings would be shared. Authorizes the Secretary to adjust the savings thresholds to account for the varying sizes of participating ACOs. If the Secretary determines that an ACO has taken steps to avoid at-risk patients in order to reduce the likelihood of increasing costs, authorizes the Secretary to impose an appropriate sanction, including terminating agreements with participating ACOs.

CMS Innovation Center

- Requires the Secretary to create an Innovation Center within CMS. The Center is authorized to test, evaluate, and expand different payment structures and methodologies which aim to foster patient-centered care, improve quality, and slow the rate of Medicare cost growth.
- Makes permanent the authority granted to the Secretary under Section 646 of the MMA (section 1866C of the Social Security Act).
- Requires the Center would to conduct an evaluation of each model tested, including an analysis of the extent to which the model results in:
 - Coordination of health care services across treatment settings;
 - Reduction of preventable hospitalizations;
 - Prevention of hospital readmissions;
 - Reduction of emergency room visits;
 - Improvement in quality and health outcomes;
 - Improvement in the efficiency of care;
 - Reduction in the cost of health care services covered under this title; and
 - Achievement of beneficiary and family-caregiver satisfaction.
- To facilitate the timely design, implementation, and evaluation of payment models by the Center, exempts the Center from budget-neutrality requirements for an initial testing period. Authorizes the Center to terminate or modify the design of models at any time during a testing period.
- Requires the Center to consult regularly with outside experts and stakeholders, including the Medicare Payment Advisory Commission (MedPAC), health professionals with demonstrated expertise in chronic care management of older adults, and representatives of patients and caregivers.
- Authorizes the Secretary to expand the duration or the scope of any project undertaken by the Center if the Secretary determines that doing so would improve the quality of patient care and reduce the rate of growth of Medicare fee-for-service expenditures. The expected reduction in future Medicare expenditures must be certified by the CMS Office of the Actuary before an expansion could occur.
- Requires the Center to test and evaluate patient-centered delivery and payment models. The Center would review models that have shown evidence of success in the Medicare population. The Center would consider models that target beneficiaries who are dually-eligible for both Medicare and Medicaid, and beneficiaries with multiple chronic conditions and at least one of the following: (1) an inability to perform 2 or more activities of daily living; and (2) a cognitive impairment, including dementia.
- Requires the Center to consider for testing, at a minimum, models that achieve at least one of the following criteria:
 - Promote broad payment and practice reform in primary care, including patient-centered medical home models for high-need beneficiaries, medical homes that address women's unique health care needs, and models that transition primary care practices away from fee-for-service based reimbursement and toward comprehensive payment;

- Contract directly with groups of providers and suppliers to promote innovative care delivery models, such as through risk-based comprehensive payments;
- Support care coordination for chronically-ill Medicare beneficiaries at high risk of hospitalization through a health IT-enabled network that includes a chronic disease registry, home tele-health technology, and care oversight by the beneficiary's treating physician;
- Vary payment to physicians ordering advanced diagnostic imaging services according to the physician's adherence to appropriateness criteria for the ordering of such services, as determined in consultation with physician specialty groups and other relevant stakeholders;
- Utilize medication therapy management services.
- Establish community-based health teams to support small-practice medical homes by assisting the principal primary care practitioner in chronic care management activities;
- Fund physician, nurse practitioner, or physician assistant-led home-based primary care programs with demonstrated experience in serving high-cost beneficiaries with multiple chronic illnesses and functional disabilities.
- Establish a program to assist beneficiaries in making informed health care choices by paying providers for using patient decision-support tools that improve beneficiary and caregiver understanding of their medical treatment options;
- Allow states to test and evaluate fully integrating care for dually eligible members, including the management and oversight of all Medicare and Medicaid funds for this population;
- Allows states to test and evaluate systems of all-payer payment reform for medical care of residents in each participating State, including individuals dually eligible for Medicare and Medicaid;
- Align nationally-recognized, evidence-based guidelines of cancer care with Medicare payment incentives in the areas of treatment planning and follow-up care planning for Medicare beneficiaries with cancer, including the identification of gaps in current quality measures;
- Improve post-acute care through continuing care hospitals that offer inpatient rehabilitation, long-term care hospital, and home health or skilled nursing care during an inpatient stay and the 30 days immediately following discharge;
- Fund home health providers who offer chronic care management services to Medicare beneficiaries in cooperation with the interdisciplinary teams.
- In selecting models for testing, the Secretary shall also consider the extent to which models meet the following criteria:
 - Foster care coordination for high-cost, chronically ill Medicare beneficiaries who are at highest risk for hospitalization or readmission;
 - Place the patient, including family members and other informal caregivers, at the center of the care team;
 - Include, but are not limited to, in-person contact with beneficiaries;
 - Utilize technology, such as electronic health records and patient-based remote monitoring systems, to coordinate care over time;
 - Maintain a close relationship between care coordinators and primary care practitioners;

- Rely on team-based approach to interventions such as comprehensive care assessments, care planning, and self-management coaching.
- To be approved for expansion, requires models to demonstrate that they meet patient-centered criteria as determined by the Secretary, such as the use of patient and caregiver assessments or the use of individualized care plans.
- Within 18 months of enactment, requires the Center to post on the CMS Web site a report on the Center's initial consideration of the models listed above, as well as a detailed plan for the continuing work of the Center.
- Appropriates \$10 billion from the Part A and Part B Trust Funds to the Center over 10 years. The costs of otherwise uncovered benefits delivered under this authority would be counted against the Center's overall funding level. Requires the Center to directly allocate a portion of such funding for the Centers' evaluation activities.

National Pilot Program on Payment Bundling

- Requires the Secretary to develop, test and evaluate alternative payment methodologies through a national, voluntary pilot program that is designed to provide incentives for providers to coordinate patient care across the continuum and to be jointly accountable for the entire episode of care starting in 2013.
- The Secretary would determine which patient assessment tool to use and what quality measures to use.
- The Secretary would select eight conditions to be included in the pilot program by considering the following factors: a mix of chronic and acute conditions; a mix of surgical and medical conditions; conditions for which there is evidence of opportunity for providers to improve quality of care while reducing total expenditures; conditions with significant variation in readmissions and post acute care spending; conditions with high-volume or high post acute care spending; and conditions that are deemed most amenable to bundling across spectrum of care given current practice patterns.
- The pilot may cover the following services: acute care inpatient hospitalizations; physician services delivered inside and outside of the acute care hospital setting; outpatient hospital services, including emergency department visits; services associated with acute care hospital readmissions; PAC services including home health, skilled nursing, inpatient rehabilitation, long term care hospital; and other services the Secretary deems appropriate.
- The Secretary would test alternative payment methodologies, which would include bundled payments or arrangements in which providers continue to receive reimbursement under current payment systems but are held jointly accountable for the quality and cost of care provided to Medicare patients. The payment methodology would also take into account the provision of services such as care coordination, medication reconciliation, discharge planning, and transitional care services and other patient-centered activities as defined by the Secretary.
- Any Medicare provider, including hospitals, physicians groups, or post-acute entities interested in assuming responsibility for the bundled payment would be able to apply to participate in the pilot program. All services provided under the bundle would be required to be provided or directed by Medicare-participating providers.
- Directs the Secretary to establish quality measures related to care provided across all providers participating in the pilot.
- Requires the Secretary to conduct an independent evaluation of the pilot program and report to Congress. If the Secretary finds that the pilot results in significant improvements in quality and

outcomes and reductions in cost, then the Secretary is required to submit an implementation plan to Congress with regards to making the program a permanent Medicare program.

Reducing Avoidable Hospital Admissions

- Directs CMS to calculate national and hospital-specific data on the readmission rates of Medicare participating hospitals for eight conditions that the Secretary would choose based on spending and readmission rates. Starting in fiscal year 2012, this data would be shared with hospitals and publicly reported on the Hospital Compare Web site.
- Starting in fiscal year 2013, readmission rates above a certain threshold would result in a 20% reduction in reimbursement if a patient is rehospitalized with a preventable readmission within 7 days; if it is within 15 days, then the reimbursement drops 10%.

Transitional Care Program to Reduce Preventable Readmissions

- Establishes a three-year Medicare pilot program, the “Community Care Transitions Program.” Beginning in 2011, the Secretary would fund eligible hospitals and community-based partnership organizations to provide patient-centered, evidence-based care transition services to Medicare beneficiaries at the highest risk of preventable hospital readmissions.
- Examples of core intervention elements for care transition services could include:
 - Initiating care transition services for targeted high-risk beneficiaries no later than 24 hours prior to the beneficiary being discharged from the participating hospital;
 - Assessment and active engagement with patient and caregiver focusing on coaching, self-management support when appropriate, and providing information specific to the patient’s health, functional, social, and environmental conditions;
 - Comprehensive medication review and management, including patient self-management when appropriate;
 - Assisting patient and caregiver to engage in productive interactions with post-acute and outpatient providers in a timely manner; and
 - Arrangement of timely follow-up in order to educate patient and/or caregiver about health symptoms that indicate a worsening condition and how to respond.
- Sets the programs funding at \$500 million over three years.
- Authorizes the Secretary to continue or expand the scope and duration of the program if the Secretary determined that expansion would improve quality of care and the CMS Office of the Actuary certified that expansion would reduce projected Medicare spending.

Extension of Gainsharing Demonstration

- Extends the authority to conduct the gainsharing demonstration (per Public Law 109-171) until September 30, 2011. Extends report deadlines too.
- Authorizes \$1.6 million in fiscal year 2010.

PART IV—STRENGTHENING PRIMARY CARE AND OTHER WORKFORCE IMPROVEMENTS (Page 101)

Primary Care/General Surgery Bonus

- Establishes a new 10% bonus on select evaluation and management codes under the Medicare fee schedule for five years, beginning January 1, 2011.
- The group codes include office visits, home visits, nursing facility visits, and domiciliary, rest home, or custodial care services.
- Makes the bonus available to certain primary care providers. General surgeons providing care in a health professions shortage area (HPSA) would also be eligible.

- Half of the cost of the bonuses would be offset through an across-the-board reduction to all other codes, except for physicians who provide services in a HPSA zip code.

Redistribution of Unused GME slots to Increase Access to Primary Care and Generalist Physicians

- Establishes a policy to redistribute unused residency training slots as a way to encourage increased training, particularly in the areas of primary care and general surgery.
- Requires the Secretary to increase the otherwise applicable resident limit for each qualifying hospital that submits a timely application by such number determined by the Secretary.

Promoting Greater Flexibility for Residency Training Programs

- Provides increased flexibility in laws and regulations governing medical education funding in the Medicare program. The goal is to promote training in outpatient settings and to ensure the availability of residency programs in rural and underserved areas.
- Addresses what of the resident's time spent counts towards Medicare direct and indirect medical education payments.
- Ambulatory and outpatient training sites are considered eligible sites.

Rules for Counting Resident Time for Didactic and Scholarly Activities and Other Activities

- Specifies what Medicare counts when determining time residents spend in certain non-patient care activities including didactic conferences and seminars.

Preservation of Resident Cap Positions from Closed and Acquired Hospitals

- Directs the Secretary to promulgate regulations to establish a process where the residency allotments in a hospital with an approved medical residency program that closes could be used to increase the otherwise applicable residency limit for other hospitals.
- Establishes the order of priority for distribution.
- Establishes a special rule for acquired hospitals.

Proposal on Development of a National Workforce Strategy

- Directs the Secretary to create a Workforce Advisory Committee to be comprised of external stakeholders and representatives of health professionals, schools of higher education for health care professionals, public health experts, health insurers, business, labor, state or local workforce investment boards, and any other health professional organization or practice that the Secretary determines appropriate.
- Directs the stakeholders to develop and present a national workforce strategy to the Secretary and Congress that would address recruiting, training and retraining a health workforce, and meeting the nation's current and future health care needs.
- Directs the Committee to consult with Federal agencies such as HRSA and the VA to avoid duplication of effort and to review government wide Federal workforce policies. The Committee would also consult with state and local entities.
- Directs the Committee to examine the current and projected health care workforce supply; the current and projected demand for health professionals; the health care workforce education training capacity; the implications of new and existing Federal policies which will affect the health care workforce; and the health care workforce needs of specific populations, including minorities, rural and urban populations, and medically underserved populations.
- Directs the Committee to report on specific high-priority topics including efforts to integrate the health care workforce into a reformed delivery system, the implications for the health care

workforce as a result of greater utilization of HIT, nursing workforce capacity, mental and behavioral health workforce capacity, and the geographic distribution of health care providers.

Demonstration Project to Address Health Professions Workforce Needs

- Establishes demonstration grants to address needs in the health professions workforce. Competitive grants would provide aid and support services to low-income individuals with the opportunity to obtain education and training for occupations in the health care field that pay well and are expected to experience labor shortages or be in high demand.
- The grants would be made available by the Secretary of HHS, in consultation with the Secretary of Labor, states, Indian tribes, tribal organizations, institutions of higher education, local workforce investment boards under the Workforce Investment Act, or community-based organizations.
- The demonstration program would provide, when appropriate, financial aid, child care, case management, and supportive services.
- Also establishes a demonstration program to competitively award grants to up to six states for three years to develop core training competencies and certification programs for personal and home care aides.
- Appropriates \$85 million per year for five years (fiscal years 2010-2014), with no more than \$5 million per year for three years (fiscal years 2010-2012).

Extension of Family-to-Family Health Information Centers

- Extends funding for family-to-family health information centers at \$5 million for fiscal year 2010 through 2012.

SUBTITLE B—IMPROVING MEDICARE FOR PATIENTS AND PROVIDERS (Page 110)

PART I—ENSURING BENEFICIARY ACCESS TO PHYSICIAN CARE AND OTHER SERVICES

Sustainable Growth Rate

- Sets the annual update to the conversion factor used in the determination of the Medicare fee schedule at 0.5% in 2010. The conversion factor for 2011 and beyond would be computed as if the increase in 2010 had never applied.

Extension of Floor on Medicare Work Geographic Adjustment

- Extends the 1.00 floor for the geographic index for physician work for an additional two years through December, 2012.

Misvalued Relative Value Units (RVUs)

- Directs the Secretary to periodically identify physician services as being potentially misvalued, and make appropriate adjustments to the relative values of such services under the Medicare physician fee schedule.
- Subjects adjustments to misvalued procedures to budget neutrality requirements.

Therapy Caps

- Extends the exceptions process for therapy caps for two years, through December 31, 2011.

Extension of Treatment of Certain Physician Pathology Services under Medicare

- Extends the provision until January 1, 2012

Extension of Increased Payments for Ambulance Services under Medicare

- Extends the provision until January 1, 2012.

Extension of Long Term Care Hospital Provisions

- Extends the Medicare, Medicaid and SCHIP Extension Act of 2007 (Public Law 110-173), Sections 114 (c) and (d) by two years.

Extension of Payment Adjustments for Medicare Mental Health Services

- Extends the provision until January 1, 2012.

Permitting Physician Assistants to Order Post-Hospital Extended Care Services

- Authorizes physician assistants who do not have a direct or indirect employment relationship with a skilled nursing facility, but who are working in collaboration with a physician, to certify the need for post-hospital extended care services for Medicare payment purposes.
- Applies to items and services furnished on or after January 1, 2010.

Recognizing Attending Physician Assistants as Attending Physicians to Serve Hospice Patients

- For the purposes of a hospice written plan of care, includes a physician assistant in the definition of an attending physician. Physician assistants continue to be excluded from the authority to certify an individual as terminally ill.
- Applies to items and services furnished on or after January 1, 2010.

Medicare Diabetes Self-Management Training

- Provides for the recognition of state-licensed or registered health care professionals who are certified diabetes educators (CDEs) as Medicare providers of diabetes outpatient self-management training services (DSMT).
- CDEs would still provide DSMT services according to physician referral, but would be able to provide such services in appropriate, non-hospital locations to meet current needs.

Medicare Improvement Fund

- Eliminates the funding.

Medicare Part B Special Enrollment Period for Disabled TRICARE Beneficiaries

- Creates a twelve-month special enrollment period (SEP) for military retirees, their spouses (including widows/widowers) and dependent children, who are otherwise eligible for TRICARE and entitled to Medicare Part A based on disability or ESRD, but who have declined Medicare Part B.
- This SEP would be available once in the individual's lifetime.
- Specifies when the twelve-month period would begin, whether they may choose retroactive Part B coverage, and any late enrollment penalties.
- Effective the date of enactment.

PART II—RURAL PROTECTIONS (Page 117)

Extend Medicare Rural Hospital Flexibility Program

- Extends the FLEX program two years, until 2012.

Extend Hospital Outpatient Department Hold Harmless for Small Rural Hospitals; Extend and Expand Hospital Outpatient Department Hold Harmless for Sole Community Hospitals

- Establishes that small rural hospitals would receive 85% of the payment difference in calendar year (CY) 2010 and CY2011. Sole community hospitals with not more than 100 would receive 85% of the payment difference in CY2010 and CY2011.

Extend Reasonable Cost Reimbursement for Laboratory Services in Small Rural Hospitals

- Reinstates reasonable cost reimbursements for clinical diagnostic laboratory service for qualifying rural hospitals with under 50 beds from July 1, 2010 and extends it for two years, ending July 1, 2012.

Extend Rural Community Hospital Demonstration Programs

- Extends the demonstration program for an additional two years, expands the maximum number of participating hospitals to 30, and expands eligible sites to rural areas in all states until January 1, 2012.

Extend Medicare Dependent Hospital Program

- Extends the Medicare Dependent Hospital classification by two years, until September 30, 2013.

Temporary Improvements to the Medicare Inpatient Hospital Payment Adjustment for Low-Volume Hospitals

- Creates a temporary adjustment that would increase payment in fiscal year (FY) 2011 and FY2012 for certain low-volume hospitals.

Revisions to the Demonstration Project on Community Health Integration Models in Certain Rural Counties

- Strikes the limitation on the number of eligible counties that may participate in the demonstration program within the qualifying states.
- Deletes references to rural health clinic services and replaces these with a requirement that physician services may also be included within the scope of the demonstration project.

MedPAC Study on Adequacy of Medicare Payments for Health Care Providers Serving Rural Areas

- Requires MedPAC to review payment adequacy for rural health care providers serving the Medicare program and provide a report to Congress by January 1, 2011.
- The report must include an analysis of the rural payment adjustments outlined in this section and an analysis of the beneficiaries' access to care in rural communities, adequacy of Medicare payments to rural providers, and quality of care.
- Requires MedPAC to provide recommendations on appropriate modifications to the rural payment adjustments outlined in this section.

PART III—MEDICARE PART D IMPROVEMENTS (Page 121)

Improving Coverage in the Part D Coverage Gap

- Establishes a discount program for beneficiaries who enroll in Part D and have drug spending that falls into the coverage gap. Drug manufacturers would provide discounts on brand-name drugs that are covered under Part D and are on plan formularies or treated as being on plan formularies through exceptions and appeals processes. The discount would apply to sole-source and multiple source brand-name drugs.
- The discount would be available during the entire gap and ends once the catastrophic portion of beneficiary coverage applies.
- The program would apply to Medicare beneficiaries enrolled in Part D, do not qualify for the low-income subsidy, are not enrolled in an employer-sponsored retiree drug plan, and do not have an annual income that exceeds the Part B income thresholds as determined under current law (\$85,000 for singles and \$170,000 for couples in 2009).
- Beginning July 1, 2010, eligible beneficiaries would automatically receive a 50% discount off of the negotiated price for brand-name prescription drugs. The negotiated price would be the same as the price that plans pay to pharmacies minus the amount of price concessions (i.e. rebates and

discounts) that plans pass on to beneficiaries. **Dispensing fees would be excluded from the negotiated price and the discount. Thus, beneficiaries who receive the discount would continue to pay pharmacy dispensing fees as under current law.**

- Allows 100% of the negotiated price of discounted drugs (excluding dispensing fees) to count toward the annual out-of-pocket threshold that is used to define the coverage gap each year. This is also referred to as the “true out-of-pocket” spending.
- Stipulates that drugs sold and marketed in the U.S. by a manufacturer would not be covered under Part D unless they participate in this discount program. There are exceptions for extenuating circumstances.
- Requires manufacturers to discount drug prices at the pharmacy or through a mail order service. The Secretary would be allowed to provide for the discount after the point-of-sale for a temporary period until the necessary data systems are in place to implement the discount at the point-of-sale.
- Requires manufacturers to collect and have available data to demonstrate their compliance with the program.
- Provides parameters for the length of the agreement with the manufacturer and potential terminations of agreements.
- Allows the Secretary to contract with a third party to administer the drug discount. Directs the Secretary to establish performance requirements and data standards for the third-party contractor to coordinate benefits with Medicare prescription drug plans. Requires manufacturers that participate in the Part D discount program to be audited for compliance by the third-party administrator. Lack of compliance can result in fines.

Improving the Determination of Part D Low-Income Benchmarks

- Requires the Secretary to exclude Medicare Advantage rebates and bonus payments from the MA-PDP premium amount when calculating the regional LIS benchmark amounts. The goal is to increase the number of plans that can serve LIS beneficiaries at fully subsidized or \$0 premiums.
- Takes effect in 2011.

Voluntary De Minimis Policy for Low-Income Subsidy Plans

- Beginning in 2011, authorizes a policy through which plans that bid a nominal amount above the regional low-income subsidy (LIS) benchmark amount can choose to absorb the cost of the small difference between their bid and the LIS benchmark in order to qualify as a LIS-eligible plan.
- Provides the Secretary discretion to auto-enroll LIS beneficiaries into these plans in order to maintain adequate LIS plan choices.
- The de minimis threshold amount would be established by the Secretary.

Special Rule for Widows and Widowers Regarding Eligibility for Low-Income Assistance

- Beginning in 2011, requires that the surviving spouse of an LIS-eligible couple undergo a redetermination of his or her eligibility status no earlier than one year from the next redetermination that would have occurred after the death of a spouse. The LIS widow/widower would be determined or redetermined, as appropriate, for LIS on the same basis as other LIS-eligible beneficiaries.

Facilitation of Reassignments of Beneficiaries in Low-Income Subsidy Plans

- Requires plans whose bids exceeds the regional benchmark amount and whose LIS beneficiaries are reassigned to other plans by CMS to transmit recent drug utilization data to the beneficiary’s new plan within thirty days of notification of the reassignment.

- Within thirty days of receiving the drug utilization information, plans that are reassigned LIS beneficiaries are required to provide these beneficiaries with information about formulary differences between the old and new plan with respect to their drug regimen, as well as a description of the new plan's appeals process, grievance mechanisms and coverage determination/redetermination process.
- Requires the Secretary to develop a standard format for plans to provide this information to beneficiaries.

Funding Outreach and Education of Low-Income Programs

- Extends MIPPA (Public Law 110-275) Section 119 and provides \$45 million for outreach and education activities related to Medicare low-income assistance programs, including the Part D LIS program and the Medicare Savings Program.
- Funds would be allocated to State Health Insurance Programs, the Administration on Aging for Area Agencies on Aging, Aging Disability Resource Centers and for the contract for the National Center for Benefits Outreach and Enrollment in the same proportion as MIPPA.
- Funds are available for obligation through 2012.
- Authorizes the Secretary to enlist the support of these entities to conduct outreach activities aimed at preventing disease and promoting wellness as an additional use of these funds.

Strengthening Formularies with Respect to Certain Categories or Classes of Drugs

- Removes the criteria (specified in Section 176 of MIPPA) that would have been used by the Secretary to identify protected classes of drugs.
- Gives the Secretary authority to identify classes of clinical concern as defined by the Secretary.
- Codifies the current six classes of clinical concern as they are currently specified through sub-regulatory guidance until the Secretary issues a rule regarding classes of clinical concern to be protected on plan formularies.

Reducing the Part D Premium Subsidy for High-Income Beneficiaries

- Beginning in 2011, reduces the Medicare premium amount for beneficiaries.
- Inflates the income thresholds by the consumer price index, except for the period between 2010 and 2019 when the income thresholds would not be updated.
- Expands the current authority for IRS to disclose income information to SSA for purposes of adjusting the Part B subsidy to include the Part D subsidy adjustments and related appeals.

Simplifying Part D Information

- Beginning in 2011, requires the Secretary to establish two or more categories of prescription drug plans offered by Part D sponsors based on ranges of the actuarial values of the prescription drug benefits provided under the plans.
- Requires the Secretary to develop standardized nomenclature, definitions, and language to describe and present the benefit categories on the Part D plan finder and in other relevant beneficiary communications. For example, the Secretary could establish three categories of benefit levels – bronze, silver, and gold. Plans would be required to indicate the benefit category of each plan in the name of the product. The Secretary would be required to ensure that there are meaningful differences between the benefit categories.

Limitation on Removal or Change of Coverage of Covered Part D Drugs Under a Formulary Under a Prescription Drug Plan or a MA-PD

- Beginning in 2011, prohibits Part D sponsors from removing a covered drug from a plan formulary, apply a cost or utilization management tool that imposes a restriction or limitation on

the coverage of such a drug (such as through the application of a preferred status, usage restriction, step therapy, prior authorization, or quantity limitation), or increase the cost sharing of such a drug (such as through the placement of a drug on a tier that would result in higher cost sharing for a beneficiary) other than the date on which the Part D sponsors may begin marketing their plans with respect to the immediately succeeding plan year.

- Allows for exceptions if the change is in regard to a brand name drug for which a generic drug was approved during the plan year, or if the change is in regard to a safety issue determined by the plan's Pharmacy and Therapeutic Committee or by FDA.
- During the annual open enrollment period, requires Part D sponsors to provide each enrollee a notice of any change in the formulary or other restrictions or limitations on coverage of a drug for the upcoming plan year.

SUBTITLE C—MEDICARE ADVANTAGE (Page 132)

Medicare Advantage Payment

- Bases the calculation of Medicare Advantage (MA) benchmarks on actual plan costs as reflected in plan bids rather than statutorily set rates.
- As under current law, would risk adjust total payments to plans.
- Requires MA plans to use 100% of any rebate amount to provide additional benefits to their enrollees. As under current law, plans may still offer supplemental benefits for which they would charge beneficiaries an added premium.
- Establishes bidding rules, including requiring bid information submitted by MA plans to be certified by a member of the American Academy of Actuaries.
- Requires the Secretary to establish new MA payment areas for urban areas for plan years beginning in 2012.
- Establishes two new bonus payments for local and regional MA plans.
 - **The first is for care coordination and management activities conducted by the plans.** Plans may earn ½ % of the U.S. Per Capita Costs of Medicare (USPCC) for each of the following areas; they can receive a maximum of 4% of the USPCC for demonstrating that they conduct activities in four of the following eight areas:
 - Care management programs that target individuals with one or more chronic conditions, identify gaps in care, and facilitate improved care by using additional resources like nurse, nurse practitioners, and physician assistants.
 - Programs that focus on patient education and self-management of health conditions, including interventions that help manage chronic conditions, reduce declines in health status, and foster patient/provider collaboration.
 - Transitional care interventions that focus on care provided around a hospital inpatient episode, including programs that target post-discharge patient care in order to reduce unnecessary health complications and readmissions.
 - Patient safety programs, including provisions for hospital-based patient safety programs in their contracts with hospitals.
 - Financial policies that promote systematic coordination of care by primary care physicians across the full spectrum of specialists and sites of care, such as medical homes, capitation arrangements or pay-for-performance programs.

- Medication therapy management programs that focus on poly-pharmacy and medication reconciliation, periodic review of drug regimens, and integration of medical and pharmacy care for chronically-ill, high-cost beneficiaries.
 - Health information technology programs, including electronic health records, clinical decision support and other tools to facilitate data collection and ensure patient-centered, appropriate care.
 - Programs that address identify and ameliorate health care disparities among principal at risk populations.
 - The second bonus would be for prior year achievement or improvement in plan quality performance. Performance would be based on a ranking system that measures clinical quality and enrollee satisfaction at the contract or plan level as feasible.
 - Both bonus payments would be risk adjusted to reflect the demographics and actual health status of each enrollee.
- Requires MA plans to use 100% of bonus payment amounts to cover the costs of additional benefits offered to their enrollees. Plans may still offer supplemental benefits for which they charge beneficiaries an added premium, as under current law.
- Directs the Chairman to create an efficiency bonus for local and regional MA plans that bid significantly below per capita fee-for-service costs. Bonus payments would be risk adjusted to reflect the demographics and actual health status of each enrollee.

Benefit Protection and Simplification

- Includes several protections for beneficiaries with respect to the cost sharing amounts charged by MA plans. Prohibits cost sharing that is greater than the cost sharing under the original Medicare program for certain services for which beneficiaries need the highest level of predictability and transparency, such as chemotherapy, renal dialysis, and skilled nursing care. MA plans could still charge cost sharing for Medicare-covered services where there is no cost sharing under the traditional program.
- Makes additional benefits offered by MA plans and paid for by rebates and bonus payments more consistent across plans by establishing a list of priorities of additional benefits.
- Directs the Secretary to categorize MA plans in each payment area into two or more distinct categories according to the share that rebates, bonuses, and supplemental premiums are of each plan's bid.

Simplification of Annual Beneficiary Election Periods

- Effective 2011, shifts the annual enrollment period dates for MA and Part D to October 15 to December 7.
- Eliminates the open enrollment period (January 1 through March 31) for MA plans.

Extension for Specialized MA Plans for Special Need Individuals

- Extends special need plan (SNP) authority through December 31, 2013.
- By January 1, 2013, requires SNPs to have beneficiaries enrolled in their plans that meet the definitions for each type of SNP.
- Requires the Secretary to transition beneficiaries enrolled in SNPs to other Ma plans or original Medicare if they do not meet the definitions established for such plans by 2013. There are some exceptions to provide beneficiaries time to transition to other plans.
- Requires all dual-eligible SNPs to have established contracts with state Medicaid programs by January 1, 2013.

- All MA changes related to payment, rebates and bonuses, and payment and service areas apply to SNPs.
- Creates a new payment adjustment for fully-integrated dual-eligible SNPs. Specifically, it gives the Secretary authority to provide a frailty adjustment for fully-integrated dual-eligible SNPs that have similar average level of frail beneficiaries as PACE plans.
- Gives the Secretary discretion to require SNPs to be certified or otherwise approved by NCQA in order to participate in the MA program.
- Beginning in 2011, directs the Secretary to use a risk score for new enrollees in SNPs that reflects the known underlying risk profile and chronic health status of each enrollee.
- For 2011 and periodically thereafter, the Secretary would evaluate and revise the methodology used to risk adjust MA plan payments to account for higher medical and care coordination costs associated with frailty, persons with multiple, co-morbid chronic conditions, enrollees with mental illness diagnosis, and to account for costs that may be associated with higher concentrations of beneficiaries with these conditions.

Extension of Reasonable Cost Contracts

- Extends for three years – from January 1, 2010 to January 1, 2013 – the length of time reasonable cost plans may continue operating regardless of any other MA plans serving the area.

MA Private Fee-for-Service (PFFS) Plans

- Clarifies that in defining areas in which PFFS plans (not sponsored by employers) must establish contracted networks of providers, a network area would be defined as an area served by two or more MA organizations.
- Allows the Secretary to grant employer-based PFFS plans a waiver from the network requirements in a manner similar to the Secretary’s authority to waive or modify other MA requirements for employer-based coordinated care plans.

Erickson Demonstration

- Allows Erickson demonstrations (MA demonstration project) to be a type of MA Special Need Plan, beginning in 2011, if they serve beneficiaries who reside in continuous care environments, have sufficient number of on-site primary care providers, supply transportation benefits to other providers, and were in existence under a demonstration for at least one year.

Medigap

- Requests that NAIC create new model plans for C and F that include nominal cost sharing to encourage the use of appropriate Part B physician services. The cost sharing must be based on evidence either published or from integrated delivery systems, of how cost sharing affects utilization or appropriate physician care. The new models would be available in 2015.

SUBTITLE D—IMPROVING PAYMENT ACCURACY (Page 144)

Home Health Payment Changes

Updating Home Health Payments through Rebasing

- Starting in CY2013, directs the Secretary to rebase payments to reflect the number and mix of home health services, level of intensity of services, and the average cost of providing care.
- Directs MedPAC to report to Congress in CY2014 and CY2016 on the implementation of the new system, with particular emphasis on how rebasing changes impact: access to care for beneficiaries, quality outcomes, supply of home health providers, and any differential financial impacts on rural, urban, non-profit and for-profit providers.

Provider-Specific Cap on Home Health Outlier Payments

- Starting in CY2011, directs the Secretary to establish a provider-specific annual cap of 10% of revenues that a home health agency may be reimbursed in a given year from outlier payments.

Reinstatement of Rural Home Health Payment Adjustment

- Between CY2010 and CY2015, directs the Secretary to provide for a 3% add-on payment for home health providers serving rural areas.

Study Regarding the Development of Home Health Payment Reforms to Ensure Access to Care and Quality Services

- Directs the Secretary to conduct a study to evaluate the costs and quality of care among efficient home health providers relative to their peers in providing ongoing access to care and in treating beneficiaries with varying severity levels of illness and develop recommendations on ways to reform home health payments and case mix adjustments based on this analysis.
- No later than January 1, 2012, based on the findings of this report and if the Secretary deems appropriate, directs the Secretary to establish a temporary Medicare payment adjustment targeted toward ensuring access to care for beneficiaries with high severity of illness or to improve access to care for low-income or underserved beneficiaries.

Hospice Payment Reforms

- Requires the Secretary to collect additional data and information in order to revise payments for hospice care after consulting with hospice providers and the MedPAC.
- Requires the Secretary to implement changes to the payment methodology for hospice care as appropriate based on the additional data and information collected.
- Directs the Secretary to impose certain requirements on hospice providers regarding patient eligibility beyond the 180th day.

Medicare DSH Changes

- No later than 2015, and continuing on an annual basis, directs the Secretary to make disproportionate share (DSH) payments equal to 25% of the DSH payments that would otherwise be made, a payment that represents the empirically justified amount as determined by MedPAC in its March 2007 Report to Congress.
- An additional payment would be made to reflect hospitals' continued uncompensated care costs.

Plan to Reform Medicare Hospital Wage Index

- By December 31, 2011, requires the Secretary to provide a plan to Congress on how to comprehensively reform the Medicare wage index system. The plan must take into account the goals set forth in the MedPAC June 2007 report including establishing a new hospital compensation index system.

Extend Section 508 Reclassifications

- Extends current section 508 reclassifications until September 30, 2011.

Advanced Diagnostic Imaging Services

- Increases the utilization rate assumption for calculating the payment for advanced imaging equipment from 50% to 5% for 2010 through 2013. The rate would be increased to 75% in 2014.
- Directs the Secretary to conduct a study by January 1, 2013 on the estimated impact of the utilization rate change on beneficiary access, utilization of services, and savings to the Medicare program from 2010 through 2019.
- Increases the technical component payment reduction for sequential imaging services on contiguous body parts during the same visit from 25% to 50%.

Durable Medical Equipment

- Eliminates the 2014 add-on payment.
- Starting in 2010, limits the option to purchase a power-driven wheelchair with a lump-sum payment only to complex, rehabilitative power wheelchairs.
- Eliminates the lump-sum purchase option for replacing wheelchair for all chairs except complex, rehabilitative power wheelchairs.
- Makes pharmacies eligible for an exemption from the accreditation requirements under the following circumstances:
 - The pharmacy has had no adverse determination against it for the last 5 years due to fraud;
 - The pharmacy submits an attestation that its total Medicare DMEPOS billings are and continue to be less than a rolling three year average of 5% of total pharmacy sales; and
 - The pharmacy is willing to submit documentation to the Secretary (based on a random sample of pharmacies) that would allow the Secretary to verify the information above. This documentation could consist of an accountant certification or filing of tax returns by the pharmacy.
- Allows the Secretary to determine accreditation standards that are more appropriate for pharmacies.

Treatment of Certain Cancer Hospitals

- Requires the Secretary to conduct a study to determine if the outpatient costs incurred by prospective payment system (PPS)-exempt cancer hospitals with respect to Medicare's ambulatory payment classifications exceed those costs incurred by other hospitals reimbursed under the outpatient PPS.
- If the costs are found to be excessive, requires the Secretary to provide for an appropriate adjustment for services furnished starting January 1, 2011.

SUBTITLE E—ENSURING MEDICARE SUSTAINABILITY (Page 154)

Market Basket Cuts

- Reduces market basket updates for home health providers by 1% in 2011 and 2012.
- Reduces market basket updates for hospice providers by 0.5% in 2013-2019 in addition to the productivity adjustments.
- Reduces market basket updates for hospitals by .25% in 2010 and 2011 for inpatient and outpatient hospitals, inpatient psychiatric facilities, inpatient rehabilitation and long term care hospitals.
- Implements an additional .2% market basket reduction for inpatient and outpatient hospitals, inpatient psychiatric facilities, inpatient rehabilitation facilities and long term care hospitals from 2012-2019.
- Regarding the .2% and .5% reductions for hospitals and hospice providers, if in any year from 2014-2019 the previous year's total percentage of insured population is more than 5 percentage points below projections at time of bill enactment, then the Secretary will "give back" this payment reduction via an adjustment to the otherwise applicable market basket increase in the current year.

Productivity

- Provides for updates based on the market basket (MB) or consumer price index (CPI) minus full productivity estimates for all Parts A and B providers who are subject to a MB or CPI update

(inpatient and outpatient hospital services, inpatient psychiatric facilities, inpatient rehabilitation, long term care hospital services, nursing homes, hospice providers, home health providers, etc.).

Temporary Adjustment to the Income-Related Premium for Part B of Medicare

- Freezes the current income threshold for the period of 2011 through 2019.

Medicare Commission

- Establishes an independent Medicare Commission that would develop and submit proposals to Congress aimed at extending the solvency of Medicare, slowing Medicare cost-growth, and improving the quality of care delivered to Medicare beneficiaries.
- It would be composed of 15 members, appointed by the President and confirmed by the Senate. Recommendations would come from Congressional leadership. Qualifications for the members would be similar to qualifications for MedPAC.
- MedPAC would continue to exist in its current form as an advisory body to Congress.
- The Commission would be tasked with presenting proposals to Congress that would reduce Medicare spending by targeted amounts compared to the trajectory of Medicare spending under current law. The scope of the proposals should (to the extent feasible):
 - Target reductions to sources of excess cost growth;
 - Improve the health care delivery system, including the promotion of integrated care, care coordination, prevention and wellness, and quality improvement;
 - Protect beneficiary access to care, including rural and frontier areas;
 - Consider the effects of benefit changes on beneficiaries;
 - Consider the effects of proposals on any provider who has, or is projected to have, negative profit margins; and
 - Not impact providers scheduled to receive a reduction to their inflationary payment updates in excess of a reduction due to productivity in a year in which the Commission's proposals would take effect.
- The Commission would be prohibited from presenting proposals that would ration care, increase revenues, or otherwise change Medicare cost-sharing, benefits, or eligibility standards.
- Beginning with the 2013 report of the Medicare Trustees, requires the CMS Office of the Actuary to project whether the Medicare per-capita growth rate in 2015 will exceed the average of the growth rates in the CPI and CPI for medical care projected for 2015. If the projected excess cost growth is estimated to be greater than the average, then the Commission must submit a proposal to reduce growth. If the Commission fails to submit a proposal, then the Secretary must submit one to Congress.
- In 2019, Congress must pass a joint resolution to continue further proposals and subsequent action by the Commission.

SUBTITLE F—PATIENT-CENTERED OUTCOMES RESEARCH (Page 158)

Patient-Centered Outcomes Research Act of 2009

- Authorizes the establishment of a private, non-profit corporation that would be known as the “Patient-Centered Outcomes Research Institute” to assist patients, clinicians, purchasers, and policymakers in making informed health decisions by advancing the quality and relevance of clinical evidence through research and evidence synthesis.
- Research would focus on the manner in which diseases, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed. It

would compare the clinical effectiveness, risk and benefits of two or more medical treatments, services or items.

- Treatment, services or devices is defined as: health care interventions, protocols for treatment, care management and delivery, procedures, medical devices, diagnostics tools, pharmaceuticals, and any strategies or items used in the treatment, management, and diagnosis or prevention of illness or injury in patients.
- The duties of the Institute include: identifying research priorities and establishing an agenda; carrying out the agenda; studying and reporting on the feasibility of in-house research; collecting data from CMS; appointing advisory panels; supporting patient and consumer representatives; establishing a methodology committee; providing for a peer-review process for primary research; disseminating research findings; adopting priorities, standards, processes and protocols; coordinating research and resources and building capacity for research; and submitting an annual report to Congress, the President, and the public.
- Establishes a Board of Governors for the Institute. The 21 members would include representatives of HHS, AHRQ, NIH, patients and health care consumers, physicians, agencies administering public health programs, private payers, manufacturers, and others.
- Charges the Institute with identifying national priorities for comparative clinical effectiveness research and establishing a research project agenda. The Institute would design research to take into account potential differences in outcomes among different subpopulations.
- Establishes a standing methodology committee to serve the Institute that would be responsible for developing and improving the science and methods of comparative effectiveness research. Directs the committee to also establish and maintain standards regarding clinical outcomes measures, risk-adjustment, and other aspects of research and assessment. Requires the committee to contract with IOM to examine methods by which aspects of health care delivery systems, such as benefit design, could be assessed and compared for effectiveness, risks, benefits, advantages, and disadvantages in a scientifically valid and standardized way; and methods by which efficiency and value could be assessed in a scientifically valid and standardized way.
- Requires the Institute to disseminate the findings of research to clinicians, patients, and the public in a comprehensible manner and form so that they are useful to patients and providers in making health care decisions.
- Limits the use of the Institute's findings. Prohibits HHS from denying coverage based solely on an Institute study. Prohibits the Secretary from using the Institute's research in determining coverage for a treatment in ways that treat extending the life of an elderly, disabled or terminally ill patient of lower value than extending the life of a person who is younger, non-disabled, or not terminally ill. Prohibits the Institute from developing or employing a dollars per quality adjusted life year (or similar measure that discounts the value of a life because of a person's disability) as a threshold to establish what health care is cost-effective or recommended.
- Creates a Patient-Centered Outcomes Research Trust Fund. Funds would come from general funds in the Treasury, the Medicare Federal Hospital Insurance and Federal Supplemental Medical Trust Funds, ARRA (the stimulus package), and fees on health plans.

SUBTITLE G—ADMINISTRATIVE SIMPLIFICATION (Page 168)

- Establishes a timeline for accelerating the development, adoption and implementation of a set of operating rules for each HIPAA transaction for which there is an existing standard.

- Adds the electronic funds transfer (EFT) of health claims payments as a HIPAA transaction and provides for the adoption and enforcement of a standard EFT.
- Requires the Secretary to adopt a single set of operating rules for eligibility verification, claims status, claims remittance/payment, and EFT. The Secretary would rely on recommendations for operating rules developed by a qualified non-profit entity.
- Requires National Committee on Vital and Health Statistics to review operating rules for HIPAA standards that are developed by the non-profit entity.
- Requires the Secretary to adopt operating rules for eligibility and health plan claims status transactions no later than July 1, 2011 to be effective by January 1, 2013. The rules may address the use of a machine readable identification card.
- Directs the Secretary to issue a rule to create unique health plan identifiers.
- Requires health plans to certify that they are in compliance with certain requirements.
- Provides for a process to periodically update HIPAA standards including operating rules.
- Prohibits, as of January 1, 2014, Medicare payment for benefits delivered under Part A or Part B other than by EFT or an electronic remittance in a form specified in the payment/remittance advice HIPAA standard.
- Defines operating rules as the necessary business rules and guidelines for the electronic exchange of information that are not defined by the electronic standards themselves.

SUBTITLE H—SENSE OF THE SENATE REGARDING MEDICAL MALPRACTICE (Page 174)

- Expresses the Sense of the Senate that health care reform presents an opportunity to address issues related to medical malpractice and medical liability insurance. Furthermore, that states should be encouraged to develop and test alternatives to the current civil litigation system as a way of improving patient safety, reducing medical errors, encouraging the efficient resolution of disputes, increasing the availability of prompt and fair resolution of disputes, and improving access to liability insurance, while preserving an individual’s right to seek redress in court. Expresses the Sense of the Senate that Congress should consider establishing a state demonstration program to evaluate alternatives to the current litigation system.

TITLE IV—TRANSPARENCY AND PROGRAM INTEGRITY (Page 174)

Limitation on Medicare Exception to the Prohibition on Certain Physician Referrals for Hospitals

- No later than 18 months after enactment, exempts only hospitals meeting certain requirements from the prohibition on self-referral. An exempt hospital would:
 - Submit an annual report containing the identity of each physician owner and any other information on the nature and extent of all ownership interests in the hospital;
 - Have procedures in place to require that any referring physician owner disclose to each patient their ownership in the hospital and any such ownership interest of the treating physician;
 - Not condition ownership on the physician owners making or influencing referrals to the hospital;
 - Disclose that the hospital is owned in whole or in part by physicians on any public Web site for the hospital and in public advertising for the hospital.
- Establishes requirements to ensure bona fide investments and proportional returns.
- Addresses patient safety by disclosing the lack of 24 hour physician services.

- Prohibits exempt hospitals from increasing the number of operating rooms, procedure rooms or beds for which the hospital is licensed after the date of enactment.

Physician Payment Sunshine

- Seeks to provide transparency in the relationship between physicians and applicable manufacturers with respect to payments and other transfers of value and physician ownership or investment interests in manufacturers.
- Calls for annual transparency reports, penalties for noncompliance, procedures for the submission of information and public availability of this information.
- Preempts state laws or regulations that require manufacturers to disclose the type of information required under this provision regarding payments or transfers to covered recipients. Does not preempt any state law or regulation that required the disclosure of: information not required under this provision; the types of information excluded from reporting requirements under this provision, with some exceptions; information by an person or entity not described above; and information reported to a Federal, state, or local government for public health purposes.

Prescription Drug Samples

- Requires drug manufacturers and authorized distributors to report the information required under the Prescription Drug Marketing Act of 1987 to the Secretary of HHS. This includes information on the practitioner making the request, drug sample information, manufacturer information, and the date of the request.
- This would include samples provided to **pharmacies of hospitals** or other health care entities.

Nursing Home Transparency

- Makes a number of changes aimed at improving transparency of information about SNF and nursing homes, enforcement of SNF and nursing home standards and rules, and training of SNF and nursing home staff.
- Requires SNFs and nursing facilities to make available on request by the Secretary, the HHS Office of Inspector General, the state, the state long term care ombudsman, information on ownership and additional structure of the facility.
- Directs the Secretary and states to develop a standardized format through regulation for facilities to report information about ownership and additional disclosable parties.
- Directs the Secretary to make information about ownership and additional disclosable parties available to the public.
- Requires SNFs and nursing homes to develop and implement compliance and ethics programs by their employees and agents.
- Directs the Secretary to create regulations on quality assurance and performance improvement plans.
- Requires the Secretary to include additional information on the Medicare Nursing Home Compare Web site. Requires the Secretary to review the information for accuracy, etc.
- Requires states to submit survey information to the Secretary no later than when they send the information to the facility and requires the Secretary to use the information to update the Web site. Establishes record keeping requirements.
- Requires SNFs and nursing homes to report expenditures for wages and benefits for direct care staff on facility cost reports.
- Requires the Secretary to develop a standardized form for SNF and nursing facility residents and their representatives to use in submitting quality of care complaints.

- Requires the Secretary to establish a process to require SNF and nursing facilities to regularly report staffing data, including agency and contract staff, by staff position categories.
- Requires the Secretary to promulgate regulations providing facilities with the opportunity for participation in an independent informal dispute resolution process that would produce a written record and occur within 30 days of imposition of the penalty. Provides the Secretary authority to impose civil monetary penalties if deficiencies are cited at the level of actual harm and immediate jeopardy.
- Requires the Secretary to develop, test, and implement a two-year pilot for an independent monitor program to oversee large interstate and intrastate SNF and nursing home chains. Directs the Secretary to develop protocols for addressing quality and safety problems at the corporate management level. Requires chains that receive a report containing findings and recommendations from the independent monitor to communicate what actions will be taken to address the situation. Authorizes the Secretary to waive Medicare and Medicaid laws to carry out the independent monitor pilot program. The HHS Office of Inspector General will evaluate the pilot and determine the feasibility of establishing a permanent independent monitor program.
- Requires SNFs and nursing homes to notify in a timely manner state, Federal, and stakeholder officials as well as residents and their representatives of an impending nursing facility closure. Requires facilities to issue a plan for the transfer and relocation of residents. Requires the state to approve the plan and ensure the safe transfer of residents. When the Secretary terminates a facility's participation, requires the Secretary to provide written notification to state, Federal, and stakeholder officials as well as residents and their representatives.
- Requires the Secretary to conduct two demonstration projects for nursing homes and SNF: for the development of best practices for facilities involved in culture change; and for the development of best practices in facilities for the use of information technology to improve resident care. Requires the Secretary to report to Congress the results of the projects and any recommended legislation or administrative actions.
- Adds staff training requirements for SNF and nursing homes.

Imaging Self-referral Sunshine

- The in-office ancillary exception would include a requirement that with respect to magnetic resonance imaging, computed tomography, positron emission tomography, and any other designated health services as determined by the Secretary, the referring physician must inform the individual at the time of the referral that the individual may obtain the services from a person other than the referring physician, a physician who is a member of the same group practice as the referring physician, or an individual who is directly supervised by the physician or by another physician in the group practice. The individual must be provided with a written list of suppliers who furnish services in the area in which the individual resides.
- Applies to services furnished after January 1, 2010.

Hospital Average Charge Information

- Beginning in 2011, establishes a national requirement for acute care hospitals to make their charges for each Medicare diagnostic related group (DRG) available to the public and upon request to any patient served by the facility. Requires hospitals to provide the average charge and the range between the 2nd and 4th quintiles of charges across all commercial payers and for self-pay patients for each DRG; hospitals would update their information annually. Authorizes the Secretary to impose a civil monetary penalty on noncompliant facilities in the amount of \$50,000.

TITLE V—FRAUD, WASTE, AND ABUSE (Page 184)

Provider Screening

- Requires the Secretary to screen all providers and suppliers before granting Medicare billing privileges (at a minimum, licensure checks). Certain groups of providers and suppliers would be subject to additional screening measures according to risk, as defined by the Secretary. Imposes an application fee of \$350 on providers and suppliers to cover the screening costs. Discounts the fee for current providers to \$250 if they pay within 12 months of enactment.
- Requires all providers, including physicians, to be Medicare enrolled before ordering or prescribing services that incur any costs to Medicare. Some new providers or suppliers could be subject to enhanced oversight, such as prepayment review and payment caps for a provisional period of 6 to 12 months.
- Imposes new disclosure requirements on providers and suppliers enrolling in Medicare. Requires applicants to disclose affiliations with any enrolled entity that has uncollected Medicare or Medicaid debt. Authorizes the Secretary to deny enrollment in Medicare if these affiliations pose an undue risk to the program. Also authorizes the Secretary to require surety bonds up to \$500,000 (depending on the volume of billing) and to impose moratoria on the enrollment of certain groups of new providers or suppliers to prevent fraud. Establishes permissive exclusions and/or civil penalties for false statements on provider and supplier enrollment applications.
- Authorizes states to impose similar screening procedures in Medicaid. Subjects states failing to create effective screening programs to a financial penalty through a reduction in their Federal Medical Assistance Percentage (FMAP). Requires states to initiate termination proceedings for providers or suppliers excluded from Medicare or any other state's Medicaid program.

Data Matching

- Requires CMS to complete development of the comprehensive “One PI” Integrated Data Repository (IDR), which would expand existing program integrity data sources and expand data sharing and data matching across Federal health care claims and payment data. Also would enable existing and new data sources to be integrated, such as: quality of care under fee-for-service, managed care and waivers; Medicaid encounter data; health plan performance; ownership, control, and business relationships; survey and certification; resident/patient neglect or abuse; adverse actions; site visits; penalties and settlements; and data on results from other program monitoring.
- Provides additional authority for HHS Office of Inspector General and Department of Justice to use these data to identify and investigate potential fraud and abuse.
- Imposes new civil penalties for intentional submission of erroneous data to the IDR.
- Subjects states that fail to report encounter data to a reduction in their Federal financial participation under Medicaid.

Consolidate and Expand Existing Provider Databases

- Expands and consolidates the existing provider databases (HIPDB, NPDB, and LEIE) with a national patient abuse/neglect registry into a centralized sanctions data system. The system would include information on providers in Medicare and all state Medicaid programs, including provider ownership and business relationships, history of adverse actions, and results of site visits or other monitoring by any program. Data on fraud settlements would be reported to the database. Authorizes access for state licensure boards and Federal and state law enforcement

agencies. Requires Medicare and Medicaid programs to verify any applicant's status in the provider database prior to issuing provider/supplier numbers.

- Requires states to regularly report to CMS information from their Medicaid Management Information Systems databases. Subjects states that fail to do so to a financial penalty through a reduction in their FMAP.

Provider Compliance and Penalties

- Requires Medicare and Medicaid providers and suppliers to implement compliance programs as a Condition of Participation. Directs the Secretary, in consultation with the HHS Office of Inspector General and CMS, to establish core elements for inclusion in a compliance program.
- Requires physicians and other suppliers to keep documentation on referrals to programs at high risk for fraud and abuse and to provide access to such documentation upon request of the Secretary. Inability to provide such documentation could result in disenrollment.
- As a condition of payment, requires physicians to have a face-to-face encounter with the patient before making a referral for home health or **durable medical equipment**.
- Establishes intermediate sanctions and program safeguards to provide greater flexibility to CMS and law enforcement to address problems.
- Reduces the maximum period for submission of Medicare claims to not more than 12 months. Authorizes the Secretary, in consultation with the HHS Office of Inspector General and CMS, to suspend payments to providers and suppliers pending an investigation of credible allegations of fraud.
- Modifies the 60 days providers and suppliers have to repay Medicare overpayments to either 60 days after the date on which the overpayment was made or the date the corresponding cost report is due. Requires providers and suppliers to repay any Medicare or Medicaid overpayment identified through an internal compliance audit. Requires any person who knows of an overpayment to return it to the Secretary, the state, or a Medicare contractor and notify the aforementioned party in writing to whom the overpayment was returned.
- Amends the civil monetary penalty (CMP) laws to increase penalties and extend use of CMPs. Establishes a CMP for each instance of a hospital's failure to report an adverse action affecting the clinical privileges of a physician. Amends the beneficiary inducement CMP to tailor the prohibition to address harmful conduct and relieve the burden on certain charitable and other innocuous programs currently covered by the broad reach of the statute. Authorizes a CMP on an excluded person who orders or prescribes (rather than directly furnishes) items or services reimbursed by Federal health care programs. Increases penalties for submitting false claims and for submitting false statements material to a false claim. Enhances penalties for delaying inspections and for obstructing program audits. For Medicare Advantage and Medicare Part D, enhances penalties for misrepresentation or submission of falsified information as well as for marketing violations. Extends the subpoena authority to program exclusion investigations.
- Amends the Anti-Kickback statute to define "willfully" as "a person acted voluntarily and purposefully to what the law forbids and the person need not have actual knowledge of the law or specific intent to violate the law."
- Within 180 days, requires the Secretary to establish a mechanism for providers to voluntarily disclose specific information regarding actual and potential violations of the physician self-referral law. The mechanism would offer an incentive to encourage providers to participate, such as a damage calculation near the lower-end of the statutory spectrum. Authorizes the Secretary to create disclosure requirements similar to those set forth by the HHS Office of

Inspector General (OIG) in an April 15, 2008 open letter to health care providers. The mechanism would include an information sharing strategy to apply to the HHS OIG and the Department of Justice (DOJ).

- Does not require the Secretary to resolve all disclosed matters. But does require the Secretary to work closely with providers that come forward in good faith seeking resolution. Neither the HHS OIG nor DOJ would be precluded from opening an investigation into a provider while the disclosure protocol is being implemented. Any resolution entered into by the Secretary and the provider would not be binding on the DOJ or other Federal or state agency.
- Authorizes the Secretary to promulgate the necessary regulations to fulfill these requirements.
- Within a year of enactment, requires the Secretary to submit a report to the appropriate committees in Congress on the use of the protocol.

Program Exclusions

- Amends the law to clarify that hardship waivers of an HHS Office of Inspector General exclusion can be based on hardship imposed on beneficiaries of any Federal health care program.
- Recovery Audit Contractors (RAC)
- Extends the RAC program to Medicare Parts C and D, and Medicaid.

Program Integrity Funding and Reporting Requirements

- Increases the Health Care Fraud and Abuse Control (HCFAC) program funding by \$10 million each year for ten years, and would be available until expended. The provision permanently applies the CPI adjustment to HCFAC funding.
- Amends the Medicare and Medicaid Integrity Program (MIP) evaluation requirements by establishing reporting requirements for Medicare MIP contractors, modeled on those established for the Medicaid MIP.

Adjustments to the Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Competitive Acquisition Program

- Requires the Secretary to expand the number of areas to be included in Round Two of the program from 79 of the largest metropolitan statistical areas (MSAs) to 100 of the largest MSAs by including the next 21 largest MSAs by population.
- Requires the Secretary to extend the competitive acquisition program, or apply competitively-bid rates, to the remaining areas by 2016.

TITLE VI—REVENUE ITEMS (Page 195)

Excise Tax on High Cost Insurance

- Imposes an excise tax on insurers if the aggregate value of employer-sponsored health coverage for an employee exceeds a threshold amount.

Calculation and Pro Ration of Excise Tax and Reporting Requirements

- Requires an employer to disclose the value of the benefit provided by the employer for each employee's health insurance coverage on the employee's annual Form W-2.
- Regarding the method for determining the value of employer-provided health insurance coverage, uses the same calculation as is currently used in determining the employer-provided portion of the applicable premiums for the taxable year for the employee determined under the rules for COBRA continuation coverage.
- Effective beginning the first taxable year after December 31, 2009

Modify the Definition of Qualified Medical Expenses

- The amount of excise tax imposed is not deductible for Federal income tax purposes.
- Effective for taxable years beginning after December 31, 2012.

Employer Health Insurance Reporting

- With respect to medicine, the definition of medical expense for purposes of employer provided health coverage, HSAs, and Archer MSAs generally is conformed to the definition for purposes of the itemized deduction for medical expenses. **This does not apply to doctor prescribed over-the-counter medicine. Thus, the cost of over-the-counter medicine (other than doctor prescribed) may not be reimbursed on a tax-free basis through a HSA or Archer MSA.**
- Effective for taxable years beginning after December 31, 2009

Health Savings Accounts

- Increases the additional tax on distributions from an HSA that are not used for qualified medical expenses to 20% of the disbursed amount.

Limiting Flexible Spending Arrangements under Cafeteria Plans

- Limits salary reductions by an employee for a taxable year for purposes of coverage under a Health FSA under a cafeteria plan to \$2,000. There are no limits to the exclusion for health coverage offered through an HRA.
- Effective for taxable years beginning after December 31, 2012.

Corporate Information Reporting

- Modifies the general information reporting requirement by eliminating the exception for payments to corporations. Clarifies the class of payments with respect to which reporting is required to include gross proceeds for both property and services. Authorizes the Secretary to promulgate regulations necessary to avoid duplicative information reporting.
- Effective for payments made in taxable years beginning after December 31, 2011.

Requirements for Section 501(c)(3) Hospitals

- Establishes new requirements applicable to section 501(c)(3) hospitals.
 - Requires each hospital facility to conduct a community health needs assessment at least once every three years and to adopt an implementation strategy to meet the community needs identified through the assessment. Failure to complete the assessment would result in a penalty on the organization of up to \$50,000.
 - Requires each hospital facility to adopt, implement, and widely publicize a written financial assistance policy.
 - Requires each facility to adopt and implement a policy to provide emergency medical treatment to individuals that prevents discrimination in the provision of emergency medical treatment.
 - Requires each facility to bill patients who qualify for financial assistance no more than the amount generally billed to insured patients. A hospital facility may not use gross charges when billing individuals who qualify for financial assistance. Amounts billed to those who qualify for financial assistance may be based on either the best, or an average of the three best, negotiated commercial rates, or Medicare rates.
 - Requires a hospital facility (or its affiliates) to follow current Medicare law and regulations regarding collection of debts, but may not undertake certain extraordinary collection actions (even if otherwise permitted by law) against a patient without first making reasonable attempts to inform the patient about the hospitals' financial assistance

policy. Directs the Secretary to issue guidance concerning what attempts to determine eligibility for financial assistance constitute “reasonable attempts.”

- Requires the IRS to review information about a hospital’s community benefit activities at least once every three years. Requires each organization to which this proposal applies to make its audited financial statements widely available. If an organization or facility is included in consolidated financial statements, the consolidated entity’s audited financial statements must also be widely available.
- Requires the Secretary and the Secretary of HHS to annually report to Congress the levels of charity care, bad debt expenses, unreimbursed costs of means-tested government programs, and unreimbursed costs of non-means tested government programs incurred by private tax-exempt, taxable, and governmental hospitals as well as the cost of community benefit activities incurred by private tax-exempt hospitals. The secretaries must study the trends in these amounts and report to Congress on their findings.
- Effective for taxable years beginning after the date of enactment.

Annual Fee on Manufacturers and Importers of Branded Drugs

- Imposes a fee on any person that manufactures or imports prescription drugs for sale in the United States. The fee would be apportioned among the covered entities each year based on their relative market share of covered domestic sales for the prior year. The fee would be paid annually. The aggregate fee would be \$2.3 billion.
- Applies to domestic and foreign manufacturers or importers of certain drugs or biologics offered for sale under prescription in the U.S. Covered sales include sales of branded prescription drugs made to or funded by “specific government programs”. Branded drugs includes single source or innovator multiple source drugs, but excludes orphan drugs.
- Specified government programs include Medicare, Medicaid, Veterans Administration and TRICARE.
- The fees assessed would not be deductible for U.S. income tax purposes.
- Effective for calendar year 2010 and thereafter, with respect to domestic covered sales in calendar year 2009 and thereafter.

Annual Fee on Manufacturers and Importers of Medical Devices

- Imposes a fee on any person that manufactures or imports medical devices offered for sale in the United States. The fee would be apportioned among the covered entities each year based on their relative market share of covered domestic sales for the prior year. The fee would be paid annually. The aggregate fee would be \$4 billion.
- Applies to domestic and foreign manufacturers or importers of medical devices offered for sale under prescription in the U.S. Entities include a parent, its affiliates, and other related parties.
- Covered domestic sales include U.S. sales of medical devices regulated by FDA as a medical device and subject to premarketing and postmarketing regulatory controls. The term does not include sales attributable to Class I products nor sales of products intended for use on animals.
- Directs the Secretary of the Treasury to require any covered entity to file an annual report of its covered domestic sales of the prior calendar year.
- The fees assessed would not be deductible for U.S. income tax purposes.
- Effective for calendar year 2010 and thereafter, with respect to domestic covered sales in calendar year 2009 and thereafter.

Annual Fee for Health Insurance Providers

- Applies an annual fee to any U.S. health insurance provider with respect to health insurance. The aggregate fee would be \$6 billion.
- Federal, state, or other governmental entities are not considered U.S. health insurance providers but a company or organization that underwrites policies for government-funded insurance is considered a U.S. health insurance provider. An employer that self-insures its employees' health risks is not considered a U.S. health insurance provider for purposes of this proposal.
- The aggregate annual fee for all U.S. health insurance providers is \$6 billion and is apportioned among the providers based on relative market share.
- Requires a U.S. health insurance provider to file with the Treasury Department an annual report of the amount of its "net premiums written" with respect to health insurance for the prior calendar year.
- The fees assessed would not be deductible for U.S. income tax purposes.
- Effective for calendar year 2010 and thereafter, with respect to health insurance premiums written in 2009 and thereafter.

Annual Fee on Clinical Laboratories

- Imposes a fee on any covered entity offering clinical laboratory services in the United States.
- The aggregate fee would be apportioned among the covered entities each year based on each entity's relative market share of covered domestic laboratory service revenue for the prior year. The fee would be paid annually. The aggregate fee would be \$750 million.
- Defines a covered entity as any company that provides services for the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. The term covered entity includes a parent, its affiliates, and other related parties.
- Covered domestic laboratory service revenue would not include revenue from laboratory services performed by a hospital for inpatients of the hospital.
- Directs the Secretary of the Treasury to require any covered entity to file an annual report of its covered domestic laboratory service revenue for the prior calendar year.
- The fees assessed would not be deductible for U.S. income tax purposes.
- Effective for calendar year 2010 and thereafter, with respect to covered domestic laboratory service revenue in 2009 and thereafter.

Repeal Business Deduction for Federal Subsidies for Certain Retiree Prescription Drug Plans

- Eliminates the rule that the exclusion for subsidy payments is not taken into account for purposes of determining whether a deduction is allowable with respect to retiree prescription drug expenses.
- Effective for taxable years beginning after December 31, 2010.