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**APhA Unofficial Summary of the Senate Democrats' Health Care Reform Bill
The "Patient Protection and Affordable Care Act"
(H.R. 3590)
As Introduced November 18, 2009**

**TITLE I—QUALITY, AFFORDABLE HEALTH CARE FOR ALL AMERICANS
Subtitle A—Immediate Improvements in Health Care Coverage for All Americans**

**Sec. 1001. Amendments to the Public Health Service Act.
PART A—INDIVIDUAL AND GROUP MARKET REFORMS"
SUBPART II—IMPROVING COVERAGE**

Sec. 2711. No lifetime or annual limits.

Sec. 2712. Prohibition on rescissions.

Sec. 2713. Coverage of preventive health services.

- A group health plan and a health insurance issuer offering group or individual health insurance coverage must provide for coverage for and shall not impose any cost sharing requirements for
 - Evidenced-based items or services that have in effect a rating of 'A' or 'B' in the current recommendations of the United States Preventive Services Task Force;
 - Immunizations that have in effect a recommendation from the Advisory Committee on Immunization Practices of the CDC with respect to the individual involved; and
 - With respect to infants, children and adolescents, evidence-informed preventive care and screenings provided for in the comprehensive guidelines supported by HRSA.
- The Secretary of Health and Human Services (hereinafter referred to as the Secretary) may develop guidelines to permit a group health plan and a health issuer offering group or individual health insurance coverage to utilize value-based insurance designs.

Sec. 2714. Extension of dependent coverage.

Sec. 2715. Development and utilization of uniform explanation of coverage documents and standardized definitions.

- Within 12 months of enactment, the Secretary must develop standards for use by insurers in compiling and providing to enrollees a summary of benefits and coverage explanation that accurately describes the benefits and coverage under the applicable plan or coverage.
- In developing such standards, the Secretary must consult with the National Association of Insurance Commissioners, a working group composed of representatives of health insurance-

related consumer advocacy organizations, health insurance issuers, health care professionals, and patient advocates.

- The standards must address appearance/format, language, and content.
- The Secretary must provide through regulation for the development of standards for the definitions of terms used in health insurance coverage.
 - Defines “medical terms” as, “hospitalization, hospital outpatient care, emergency room care, physician services, prescription drug coverage, durable medical equipment, home health care, skilled nursing care, rehabilitation services, hospice services, emergency medical transportation, and other such terms as the Secretary deems important to help consumer compare benefits.

Sec. 2716. Prohibition of discrimination based on salary.

Sec. 2717. Ensuring the quality of care.

- Within 2 years of enactment, the Secretary, in consultation with experts in health care quality and stakeholders, must develop reporting requirements for use by a group health plan, and a health insurance issuer offering group or individual health insurance coverage, with respect to plan or coverage benefits and health care provider reimbursement structures that
 - Improve health outcomes through the implementation of care activities such as quality reporting, effective case management, care coordination, chronic disease management, and medication and care compliance activities, including through the use of medical homes as defined later in the act;
 - Implement activities to prevent hospital readmissions through a comprehensive program for hospital discharge that includes patient-centered education and counseling, comprehensive discharge planning, and post discharge reinforcement by an appropriate health care professional;
 - Implement activities to improve patient safety and reduce medical errors through the appropriate use of best clinical practices, evidence based medicine, and health information technology under the plan or coverage; and
 - Implement wellness and health promotion activities.
- Annually, group health plans and individual or group health insurance issuers must report to the Secretary and the plan’s/issuer’s enrollees on whether the benefits under the plan satisfy the above elements. Such report will be publically posted on the Internet.
- Defines “wellness and health promotion activities” as activities that may include personalized wellness and prevention services, which are coordinated, maintained or delivered by a health care provider, a wellness and prevention plan manager, or a health, wellness or prevention services organization that conducts health risk assessments or offers ongoing face-to-face, telephonic or Web-based interventions, which may include:
 - Smoking cessation
 - Weight management
 - Stress management
 - Physical fitness
 - Nutrition
 - Heart disease prevention
 - Healthy lifestyle support
 - Diabetes prevention.

Sec. 2718. Bringing down the cost of health care coverage.

- Group or individual health insurance issuers must annually submit to the Secretary a report on the percentage of total premium revenue that such coverage expends
 - On reimbursement for clinical services provided to enrollees under such coverage;
 - For activities that improve health care quality; and
 - On all other non-claims costs.
- Group or individual health insurance issuers who are not found to provide value for the enrollee’s premium payments must provide an annual rebate to each enrollee on a pro rata basis.
- Hospitals must make public a list of the hospital’s standard charges for items and services provided by the hospital.

Sec. 2719. Appeals process.

Sec. 1002. Health insurance consumer information.

Sec. 1003. Ensuring that consumers get value for their dollars.

Sec. 1004. Effective dates.

Subtitle B—Immediate Actions to Preserve and Expand Coverage

Sec. 1101. Immediate access to insurance for uninsured individuals with a preexisting condition.

Sec. 1102. Reinsurance for early retirees.

- Within 90 days of enactment, the Secretary must establish a temporary reinsurance program to provide reimbursement to participating employment-based plans for a portion of the cost of providing health insurance coverage to early retirees.
 - Defines “health benefits” as medical, surgical, hospital, prescription drug, and other such benefits as determined by the Secretary.

Sec. 1103. Immediate information that allows consumers to identify affordable coverage options.

Sec. 1104. Administrative simplification.

- Appears to (KEL must confirm; look up cross references)
 - Demand administrative simplification through the development of uniform standards with the goal of reducing the clerical burden on patients, health care providers, and health plans. In doing so, the Secretary must seek to reduce the number and complexity of forms and data entry required by patients and providers.
 - Require electronic funds transfers (EFT) for Medicare payment. The set of operating rules for EFT and health care payment and remittance advice transactions must
 - Allow for automated reconciliation of the electronic payment with the remittance advice; and
 - Be adopted no later than July 1, 2012 in a manner that ensures the rules are effective no later than January 1, 2014.
 - Require standards and associated operating rules to
 - to the extent feasible and appropriate, enable determination of an individual’s eligibility and financial responsibility for specific services prior to or at the point of care;
 - be comprehensive, requiring minimal augmentation by paper or other communications;
 - provide for timely acknowledgment, response, and status reporting that supports a transparent claims and denial management process (including adjudication and appeals); and

- describe all data elements in unambiguous terms, require that such data elements be required or conditioned upon set values in other fields, and prohibit additional conditions (except where required by law or to protect against fraud, waste and abuse).
- In adopting such rules, the Secretary must consider recommendations for operating rules developed by a qualified nonprofit entity that meets certain, specific requirements.
- The National Committee on Vital and Health Statistics must review and make recommendations about these rules.

Sec. 1105. Effective date.

**Subtitle C—Quality Health Insurance Coverage for All Americans
PART I—HEALTH INSURANCE MARKET REFORMS**

Sec. 1201. Amendment to the Public Health Service Act.

SUBPART I—GENERAL REFORM

Sec. 2701. Fair health insurance premiums.

Sec. 2702. Guaranteed availability of coverage.

Sec. 2703. Guaranteed renewability of coverage.

Sec. 2704. Prohibition of preexisting condition exclusions or other discrimination based on health status.

Sec. 2705. Prohibiting discrimination against individual participants and beneficiaries based on health status.

- No later than July 1, 2014, the Secretary, in consultation with the Secretary of the Treasury and the Secretary of Labor, must establish a 10-state demonstration project under which participating States must apply specific provisions (see subsection j of this section of the bill) to programs of health promotion offered by a health insurance issuer that offers health insurance coverage in the individual market in such State.

Sec. 2706. Non-discrimination in health care.

- A group health plan and a health insurance issuer offering group or individual health insurance coverage must not discriminate with respect to participation under the plan or coverage against any health care provider who is acting within the scope of that provider's license or certification under applicable State law.
- This section does not require that a group health plan or health insurance issuer contract with any health care provider willing to abide by the terms and conditions for participation established by the plan or issuer.
- Nothing in this section shall be construed as preventing a group health plan, a health insurance issuer, or the Secretary from establishing varying reimbursement rates based on quality or performance measures.

Sec. 2707. Comprehensive health insurance coverage.

Sec. 2708. Prohibition on excessive waiting periods.

PART II—OTHER PROVISIONS

Sec. 1251. Preservation of right to maintain existing coverage.

Sec. 1252. Rating reforms must apply uniformly to all health insurance issuers and group health plans.

Sec. 1253. Effective dates.

Subtitle D—Available Coverage Choices for All Americans PART I—ESTABLISHMENT OF QUALIFIED HEALTH PLANS

Sec. 1301. Qualified health plan defined.

Sec. 1302. Essential health benefits requirements.

- The Secretary must define the essential health benefits, which must include at least the following general categories and the items and services covered within the categories:
 - Ambulatory patient services.
 - Emergency services.
 - Hospitalization.
 - Maternity and newborn care.
 - Mental health and substance use disorder services, including behavioral health treatment.
 - Prescription drugs.
 - Rehabilitative and habilitative services and devices.
 - Laboratory services.
 - Preventive and wellness services and chronic disease management.
 - Pediatric services, including oral and vision care.

Sec. 1303. Special rules.

- No individual health care provider or health care facility may be discriminated against because of a willingness or unwillingness, if doing so is contrary to the religious or moral beliefs of the provider or facility, to provide, pay for, provide coverage of, or refer for abortions.
- Nothing in this Act shall be construed to have any effect on Federal laws regarding
 - Conscience protection;
 - Willingness or refusal to provide abortion; and
 - Discrimination on the basis of the willingness or refusal to provide, pay for, cover, or refer for abortion or to provide or participate in training to provide abortion.
- Nothing in this subsection shall alter the rights and obligations of employees and employers under title VII of the Civil Rights Act of 1964.
- Nothing in this Act shall be construed to relieve any health care provider from providing emergency services as required by State or Federal law, including section 18678 of the Social Security Act (popularly known as EMTALA).

Sec. 1304. Related definitions.

PART II—CONSUMER CHOICES AND INSURANCE COMPETITION THROUGH HEALTH BENEFIT EXCHANGES

Sec. 1311. Affordable choices of health benefit plans.

- The Secretary must by regulation establish criteria for the certification of health plans as qualified health plans. Such criteria must require that to be certified a plan must, at a minimum:
 - Ensure a sufficient choice of providers [in a manner consistent with the applicable network adequacy provisions under section 2702(c) of the PHSA] and provide information to enrollees and prospective enrollees on the availability of in-network and out-of-network providers;
 - Etc.
- States may require that a qualified health plan offered in the State offer benefits in addition to the essential health benefits specified above.
 - States must assume the cost of any additional benefit.
- An Exchange must, at a minimum:
 - Maintain an Internet Web site through which enrollees and prospective enrollees of qualified health plans may obtain standardized comparative information on such plans;
 - Utilize a standardized format for presenting health benefits plan options in the Exchange, including the use of the uniform outline of coverage established under section 2715 of the Public Health Service Act.
 - Etc.
- The Secretary, in consultation with experts in health care quality and stakeholders, must develop guidelines concerning the development of a payment structure that provides increased reimbursement or other incentives for:
 - Improving health outcomes through the implementation of activities that shall include quality reporting, effective case management, care coordination, chronic disease management, medication and care compliance initiatives, including through the use of the medical home model, for treatment or services under the plan or coverage;
 - The implementation of activities to prevent hospital readmissions through a comprehensive program for hospital discharge that includes patient-centered education and counseling, comprehensive discharge planning, and post discharge reinforcement by an appropriate health care professional;
 - The implementation of activities to improve patient safety and reduce medical errors through the appropriate use of best clinical practices, evidence based medicine, and health information technology under the plan or coverage; and
 - The implementation of wellness and health promotion activities.
- Beginning January 1, 2015, a qualified health plan may contract with
 - A hospital with greater than 50 beds only if such hospital
 - Utilizes a patient safety evaluation system as described in part C of title IX of the Public Health Service Act; and
 - Implements a mechanism to ensure that each patient receives a comprehensive program for hospital discharge that includes patient-centered education and counseling, comprehensive discharge planning, and post discharge reinforcement by an appropriate health care professional; or
 - A health care provider only if such provider implements such mechanisms to improve health care quality as the Secretary may by regulation require.

- Exchanges must establish a grant program to award grants to entities, including professional associations, that can serve as “navigators” the duties of which include
 - Conducting public education activities to raise awareness of the availability of qualified health plans;
 - Distribute fair and impartial information concerning enrollment, tax credits, and cost-sharing;
 - Facilitate enrollment in qualified health plans;
 - Provide referrals to offices of health insurance consumer assistance or health insurance ombudsman; and
 - Provide information in a manner that is culturally and linguistically appropriate to the needs of the population being served by the Exchange.
- “Navigators” may not be a health insurance issuer; or receive any consideration directly or indirectly from any health insurance issuer in connection with the enrollment of any qualified individuals or employees of a qualified employer in a qualified health plan.

Sec. 1312. Consumer choice.

Sec. 1313. Financial integrity.

- No later than 5 years after the first date on which Exchanges are required to be operational under this title, the Comptroller General (GAO) must conduct an ongoing study of Exchange activities and the enrollees in qualified health plans offered through Exchanges. Such study must review, among other things, how many physicians, by area and specialty, are not taking or accepting new patients enrolled in Federal Government health care programs, and the adequacy of provider networks of Federal Government health care programs.

PART III—STATE FLEXIBILITY RELATING TO EXCHANGES

Sec. 1321. State flexibility in operation and enforcement of Exchanges and related requirements.

Sec. 1322. Federal program to assist establishment and operation of nonprofit, member-run health insurance issuers.

- The Secretary must establish the Consumer Operated and Oriented Plan (CO-OP) program, the purpose of which is to foster the creation of qualified nonprofit health insurance issuers to offer qualified health plans in the individual and small group markets in the States in which issuers are licensed to offer such plans.
- Qualified nonprofit health insurance issuers participating in the CO-OP program may establish a private purchasing council to enter into collective purchasing arrangement for items and services that increase administrative and other cost efficiencies, including claims administration, administrative services, health information technology, and actuarial services.
- The private purchasing council above may not set payment rates for health care facilities or providers participating in health insurance coverage provided by qualified nonprofit health insurance issuers.

Sec. 1323. Community health insurance option.

- The Secretary must establish a community health insurance option to offer, through the Exchanges, health care coverage throughout the United States.

- Nothing in this section shall be construed to require a health care provider or an individual to participate in a community health insurance option or to impose any penalty for non-participation.
- A State may elect to prohibit Exchanges in such State from offering a community health insurance option if such State enacts a law to provide for such prohibition. A State may also repeal such a law to provide for the offering of such an option through an Exchange.
- Except as provided below, a community health insurance option offered under this section shall provide coverage only for the essential benefits described above.
- Nothing in this section shall preclude a State from requiring that benefits in addition to the essential benefits package required above be provided to enrollees of a community health insurance option offered in such State. A State must make payments to or on behalf of an eligible individual to defray the cost of any such additional benefits. Nothing prohibits an individual enrolled in a community health insurance option from paying out-of-pocket the full cost of any item or service not included as an essential health benefit or otherwise covered as a benefit by the health plan. Nothing in this subparagraph prohibits any type of medical provider from accepting an out-of-pocket payment from an individual enrolled in a community health insurance option for a service otherwise not included as an essential health benefit.
- The Secretary shall negotiate rates for the reimbursement of health care providers for benefits covered under a community health insurance option.
- A State Advisory Council may develop or encourage the use of innovative payment policies that promote quality, efficiency, and savings to consumers.
- A State that establishes a State Advisory Council must include as its members representatives of the public and shall include health care consumers and providers.
- To be qualified to offer a community health insurance option, an entity must comply with several criteria including procedures for the use to technology (including front-end, prepayment intelligent data-matching technology similar to that used by hedge funds, investment funds, and banks) to provide real-time data analysis of claims for payment under this title and investigate unusual billing or order practices under this title that could indicate fraud or abuse.
- The Secretary may increase the plan fees based on the extent to which it meets certain performance requirements including the promotion of high quality clinical care.

Sec. 1324. Level playing field.

- Notwithstanding any other provision of law, any health insurance coverage offered by a private health insurance issuer shall not be subject to any Federal or State laws described below if a qualified health plan offered under the CO-OP, a community health insurance option, or a nation-wide qualified health plan is not subject to such law.
- The above mentioned laws relate to:
 - Guaranteed renewal;
 - Rating;
 - Pre-existing conditions;
 - Non-discrimination;
 - Quality improvement and reporting;
 - Fraud and abuse;
 - Solvency and financial requirements;
 - Market conduct;
 - Prompt payment;
 - Appeals and grievances;

- Privacy and confidentiality;
- Licensure; and
- Benefit plan material or information.

PART IV—STATE FLEXIBILITY TO ESTABLISH ALTERNATIVE PROGRAMS

Sec. 1331. State flexibility to establish basic health programs for low-income individuals not eligible for Medicaid.

- The Secretary must establish a basic health program under which a State may enter into contracts to offer one or more standard health plans providing at least the essential health benefits described above.
- A State basic health program must establish a competitive process for entering into contracts with standard health plans. As part of this competitive process, a State must include at least the following:
 - Negotiation with standard health plans for the inclusion of innovative features in the plan including
 - Care coordination and care management for enrollees, especially for those with chronic health conditions;
 - Incentives for use of preventive services; and
 - the establishment of relationships between providers and patients that maximize patient involvement in health care decision-making, including providing incentives for appropriate utilization under the plan.
 - Consideration of, and the making of suitable allowances for, differences in health care needs of enrollees and differences in local availability of, and access to, health care providers. Nothing in this subparagraph shall be construed as allowing discrimination on the basis of pre-existing conditions or other health status-related factors.
 - Contracting with managed care systems, or with systems that offer as many of the attributes of managed care as are feasible in the local health care market.
 - Establishing specific performance measures and standards for issuers of standard health plans that focus on quality of care and improved health outcomes, requiring such plans to report to the State with respect to the measures and standards, and making the performance and quality information available to enrollees in a useful form.

Sec. 1332. Waiver for State innovation.

Sec. 1333. Provisions relating to offering of plans in more than one State.

PART V—REINSURANCE AND RISK ADJUSTMENT

Sec. 1341. Transitional reinsurance program for individual and small group markets in each State.

Sec. 1342. Establishment of risk corridors for plans in individual and small group markets.

Sec. 1343. Risk adjustment.

Subtitle E—Affordable Coverage Choices for All Americans
PART I—PREMIUM TAX CREDITS AND COST-SHARING REDUCTIONS
SUBPART A—PREMIUM TAX CREDITS AND COST-SHARING REDUCTIONS

Sec. 1401. Refundable tax credit providing premium assistance for coverage under a qualified health plan.

Sec. 1402. Reduced cost-sharing for individuals enrolling in qualified health plans.

- The issuer of a qualified health plan must reduce the cost-sharing of a certain eligibles individuals with incomes up to 400% of the federal poverty level.
- Special reductions apply for Indians.

SUBPART B—ELIGIBILITY DETERMINATIONS

Sec. 1411. Procedures for determining eligibility for Exchange participation, premium tax credits and reduced cost-sharing, and individual responsibility exemptions.

Sec. 1412. Advance determination and payment of premium tax credits and cost-sharing reductions.

Sec. 1413. Streamlining of procedures for enrollment through an exchange and State Medicaid, CHIP, and health subsidy programs.

Sec. 1414. Disclosures to carry out eligibility requirements for certain programs.

Sec. 1415. Premium tax credit and cost-sharing reduction payments disregarded for Federal and Federally-assisted programs.

PART II—SMALL BUSINESS TAX CREDIT

Sec. 1421. Credit for employee health insurance expenses of small businesses.

Subtitle F—Shared Responsibility for Health Care
PART I—INDIVIDUAL RESPONSIBILITY

Sec. 1501. Requirement to maintain minimum essential coverage.

Sec. 1502. Reporting of health insurance coverage.

PART II—EMPLOYER RESPONSIBILITIES

Sec. 1511. Automatic enrollment for employees of large employers.

Sec. 1512. Employer requirement to inform employees of coverage options.

Sec. 1513. Shared responsibility for employers.

Sec. 1514. Reporting of employer health insurance coverage.

Sec. 1515. Offering of Exchange-participating qualified health plans through cafeteria plans.

Subtitle G—Miscellaneous Provisions

Sec. 1551. Definitions.

Sec. 1552. Transparency in government.

Sec. 1553. Prohibition against discrimination on assisted suicide.

- The Federal Government, and any State or local government or health care provider that receives Federal financial assistance under this Act (or under an amendment made by this Act) or any health plan created under this Act (or under an amendment made by this Act), may not subject an individual or institutional health care entity to discrimination on the basis that the entity does not provide any health care item or service furnished for the purpose of causing, or for the purpose of assisting in causing, the death of any individual, such as by assisted suicide, euthanasia, or mercy killing.
- In this section, the term “health care entity” includes an individual physician or other health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan.
- Nothing in subsection (a) shall be construed to apply to, or to affect, any limitation relating to—
 - the withholding or withdrawing of medical treatment or medical care;
 - the withholding or withdrawing of nutrition or hydration;
 - abortion; or
 - the use of an item, good, benefit, or service furnished for the purpose of alleviating pain or discomfort, even if such use may increase the risk of death, so long as such item, good, benefit, or service is not also furnished for the purpose of causing, or the purpose of assisting in causing, death, for any reason.
- The Office for Civil Rights of the Department of Health and Human Services is designated to receive complaints of discrimination based on this section.

Sec. 1554. Access to therapies.

- Notwithstanding any other provision of this Act, the Secretary of Health and Human Services shall not promulgate any regulation that—
 - creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care;
 - impedes timely access to health care services;
 - interferes with communications regarding a full range of treatment options between the patient and the provider;
 - restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions;
 - violates the principles of informed consent and the ethical standards of health care professionals; or
 - limits the availability of health care treatment for the full duration of a patient’s medical needs.

Sec. 1555. Freedom not to participate in Federal health insurance programs.

Sec. 1556. Equity for certain eligible survivors.

Sec. 1557. Nondiscrimination.

Sec. 1558. Protections for employees.

Sec. 1559. Oversight.

Sec. 1560. Rules of construction.

Sec. 1561. Health information technology enrollment standards and protocols.

Sec. 1562. Conforming amendments.

TITLE II—ROLE OF PUBLIC PROGRAMS
Subtitle A—Improved Access to Medicaid

Sec. 2001. Medicaid coverage for the lowest income populations.

- Medicaid benchmark benefits must consist of at least minimum essential coverage, including coverage of prescription drugs.

Sec. 2002. Income eligibility for nonelderly determined using modified gross income.

Sec. 2003. Requirement to offer premium assistance for employer-sponsored insurance.

Sec. 2004. Medicaid coverage for former foster care children.

Sec. 2005. Payments to territories.

Sec. 2006. Special adjustment to FMAP determination for certain States recovering from a major disaster.

Sec. 2007. Medicaid Improvement Fund rescission.

Subtitle B—Enhanced Support for the Children’s Health Insurance Program

Sec. 2101. Additional federal financial participation for CHIP.

Sec. 2102. Technical corrections.

Subtitle C—Medicaid and CHIP Enrollment Simplification

Sec. 2201. Enrollment Simplification and coordination with State Health Insurance Exchanges.

Sec. 2202. Permitting hospitals to make presumptive eligibility determinations for all Medicaid eligible populations.

Subtitle D—Improvements to Medicaid Services

Sec. 2301. Coverage for freestanding birth center services.

Sec. 2302. Concurrent care for children.

Sec. 2303. State eligibility option for family planning services.

Sec. 2304. Clarification of definition of medical assistance.

Subtitle E—New Options for States to Provide Long-Term Services and Supports

Sec. 2401. Community First Choice Option.

Sec. 2402. Removal of barriers to providing home and community-based services.

Sec. 2403. Money Follows the Person Rebalancing Demonstration.

Sec. 2404. Protection for recipients of home and community-based services against spousal impoverishment.

Sec. 2405. Funding to expand State Aging and Disability Resource Centers.

Sec. 2406. Sense of the Senate regarding long-term care.

Subtitle F—Medicaid Prescription Drug Coverage

Sec. 2501. Prescription drug rebates.

- Increases the minimum rebate percentage for brand and generic drugs.
- Extends the Medicaid rebate to enrollees of Medicaid managed care organizations.
- Creates new rebates for new formulations of existing drugs.

Sec. 2502. Elimination of exclusion of coverage of certain drugs.

- Removes smoking cessation agents (including FDA-approved, over-the-counter agents), barbiturates, and benzodiazepines from Medicaid's drug exclusion list.

Sec. 2503. Providing adequate pharmacy reimbursement.

- "Fixes" the average manufacturers price (AMP) formula used by the Medicaid program to calculate reimbursement for generic drug products.
 - The Federal upper limit (FUL) is set at no less than 175% of the weighted AMP.
 - Directs the Secretary to implement a smoothing process for AMP.
 - Excludes from the average manufacturer price for a covered outpatient drug:
 - customary prompt pay discounts extended to wholesalers;
 - bona fide service fees paid by manufacturers to wholesalers or retail community pharmacies, including (but not limited to) distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative services agreements and patient care programs (such as medication compliance programs and patient education programs);
 - reimbursement by manufacturers for recalled, damaged, expired, or otherwise unsalable returned goods, including (but not limited to) reimbursement for the cost of the goods and any reimbursement of costs associated with return goods handling and processing, reverse logistics, and drug destruction; and
 - payments received from, and rebates or discounts provided to, pharmacy benefit managers, managed care organizations, health maintenance organizations, insurers, hospitals, clinics, mail order pharmacies, long term care providers, manufacturers, or any other entity that does not conduct business as a wholesaler or a retail community pharmacy.
 - Notwithstanding the clause above, any other discounts, rebates, payments, or other financial transactions that are received by, paid by, or passed through to, retail community pharmacies shall be included in the AMP for a covered outpatient drug.
 - Amends the law so that a generic must be widely available in the United States, not just a single state.
 - Creates new definitions for retail community pharmacy and wholesalers:
 - The term 'retail community pharmacy' means an independent pharmacy, a chain pharmacy, a supermarket pharmacy, or a mass merchandiser pharmacy that is licensed as a pharmacy by the State and that dispenses medications to the general public at retail prices. Such term does not include a pharmacy that dispenses

prescription medications to patients primarily through the mail, nursing home pharmacies, long-term care facility pharmacies, hospital pharmacies, clinics, charitable or not-for-profit pharmacies, government pharmacies, or pharmacy benefit managers.

- The term ‘wholesaler’ means a drug wholesaler that is engaged in wholesale distribution of prescription drugs to retail community pharmacies, including (but not limited to) manufacturers, repackers, distributors, own-label distributors, private-label distributors, jobbers, brokers, warehouses (including manufacturer’s and distributor’s warehouses, chain drug warehouses, and wholesale drug warehouses) independent wholesale drug traders, and retail community pharmacies that conduct wholesale distributions.’’
- Requires public posting of the weighted average of the most recently reported monthly AMP and the average retail survey price determined for each multiple source drug.
- Clarifies that these amendments will take effect the first day of the first calendar year quarter that begins at least 180 days after the date of enactment of this Act, without regard to whether or not final regulations to carry out such amendments have been promulgated by such date.

Subtitle G—Medicaid Disproportionate Share Hospital (DSH) Payments

Sec. 2551. Disproportionate share hospital payments.

Subtitle H—Improved Coordination for Dual Eligible Beneficiaries

Sec. 2601. 5-year period for demonstration projects.

Sec. 2602. Providing Federal coverage and payment coordination for dual eligible beneficiaries.

- No later than March 1, the Secretary must establish a Federal Coordinated Health Care Office for the purposes of better integrating and coordinating the benefits for dual-eligibles under the Medicare and Medicaid programs.

Subtitle I—Improving the Quality of Medicaid for Patients and Providers

Sec. 2701. Adult health quality measures.

- The Secretary must identify and publish a recommended core set of adult health quality measures for Medicaid eligible adults.
- No later than 12 months after the release of the recommended core set of adult health quality measures, the Secretary must establish a Medicaid Quality Measurement Program.

Sec. 2702. Payment Adjustment for Health Care-Acquired Conditions.

- The Secretary must identify current State practices that prohibit payment for health care-acquired conditions and must incorporate the practices identified, or elements of such practices, which the Secretary determines appropriate for application to the Medicaid program.

Sec. 2703. State option to provide health homes for enrollees with chronic conditions.

- Beginning January 1, 2011, through a State plan amendment, a State may provide for medical assistance under Medicaid to eligible individuals with chronic conditions who select a designated provider, a team of health care professionals operating with such a provider, or a health team as the individual's health home for purposes of providing the individual with home health services.
- Defines chronic condition as:
 - A mental health condition.
 - Substance use disorder.
 - Asthma.
 - Diabetes.
 - Heart disease.
 - Being overweight (having a BMI over 25).
- Defines home health services as
 - Comprehensive care management;
 - Care coordination and health promotion;
 - Comprehensive transitional care, including appropriate follow-up, from inpatient to other settings;
 - Patient and family support;
 - Referral to community and social support services; and
 - Use of HIT to link services, as feasible.
- Defines designated provider as a physician, clinical practice or clinical group practice, rural clinic, community health center, community mental health center, home health agency, or any other entity or provider that is determined by the State and approved by the Secretary to be qualified.
- Defines team of health care professionals as a team that may
 - Include physicians and other professionals, such as a nurse care coordinator, nutritionist, social worker, behavioral health professional, or any professionals deemed appropriate by the State; and
 - Be free standing, virtual, or based at a hospital, community health center, community mental health center, rural clinic, clinical practice or clinical group practice, academic health center, or any entity deemed appropriate by the Secretary.
- The Secretary must survey States that have elected this option and report on the nature, extent, and use of such option particularly as it pertains to:
 - Hospital admission rates;
 - Chronic disease management;
 - Coordination of care for individuals with chronic conditions;
 - Assessment of program implementation;
 - Processes and lessons learned;
 - Assessment of quality improvements and clinical outcomes; and
 - Estimates of cost savings.

Sec. 2704. Demonstration project to evaluate integrated care around a hospitalization.

- The Secretary must establish a demonstration project to evaluate the use of bundled payments for the provision of integrated care for a Medicaid beneficiary:
 - With respect to an episode of care that includes a hospitalization; and
 - For concurrent physician services provided during a hospitalization.
- The demonstration project will be conducted in up to 8 States.

- The demonstration project will focus on conditions where there is evidence of an opportunity for providers of services and suppliers to improve the quality of care furnished to Medicaid beneficiaries while reducing total expenditures under the State Medicaid programs selected to participate.
- Hospitals participating in the demonstration project must have or establish robust discharge planning programs to ensure that Medicaid beneficiaries requiring post-acute care are appropriately placed in, or have ready access to, post-acute care settings.

Sec. 2705. Medicaid Global Payment System Demonstration Project.

- The Secretary must, in coordination with the proposed Center for Medicare and Medicaid Innovation, establish a Medicaid Global Payment System Demonstration Project under which a participating State must adjust the payments made to an eligible safety net hospital or network from a fee-for-service payment structure to a global capitated payment model.

Sec. 2706. Pediatric Accountable Care Organization Demonstration Project.

- The Secretary must establish the Pediatric Accountable Care Organization Demonstration Project to authorize a participating State to allow pediatric medical providers that meet specified requirements to be recognized as an accountable care organization.

Sec. 2707. Medicaid emergency psychiatric demonstration project.

Subtitle J—Improvements to the Medicaid and CHIP Payment and Access Commission (MACPAC)

Sec. 2801. MACPAC assessment of policies affecting all Medicaid beneficiaries.

Subtitle K—Protections for American Indians and Alaska Natives

Sec. 2901. Special rules relating to Indians.

Sec. 2902. Elimination of sunset for reimbursement for all Medicare part B services furnished by certain Indian hospitals and clinics.

Subtitle L—Maternal and Child Health Services

Sec. 2951. Maternal, infant, and early childhood home visiting programs.

Sec. 2952. Support, education, and research for postpartum depression.

Sec. 2953. Personal responsibility education.

Sec. 2954. Restoration of funding for abstinence education.

Sec. 2955. Inclusion of information about the importance of having a health care power of attorney in transition planning for children aging out of foster care and independent living programs.

**TITLE III—IMPROVING THE QUALITY AND EFFICIENCY OF
HEALTH CARE**
Subtitle A—Transforming the Health Care Delivery System
**PART I—LINKING PAYMENT TO QUALITY OUTCOMES UNDER THE
MEDICARE PROGRAM**

Sec. 3001. Hospital Value-Based purchasing program.

- The Secretary must establish a hospital value-based purchasing program under which value-based incentive payments are made to hospitals that meet certain performance standards.
- The Secretary must establish a demonstration program under which the Secretary establishes a value-based purchasing program under the Medicare program for critical access hospitals with respect to inpatient critical access hospital services.
- The Secretary must establish a demonstration program under which the Secretary establishes a value-based purchasing program under Medicare for applicable hospitals with respect to inpatient hospital services.

Sec. 3002. Improvements to the physician quality reporting system.

- No later than January 1, 2012, the Secretary must develop a plan to integrate reporting on quality measures under this subsection with reporting requirements relating to the meaningful use of electronic health records.

Sec. 3003. Improvements to the physician feedback program.

Sec. 3004. Quality reporting for long-term care hospitals, inpatient rehabilitation hospitals, and hospice programs.

Sec. 3005. Quality reporting for PPS-exempt cancer hospitals.

Sec. 3006. Plans for a Value-Based purchasing program for skilled nursing facilities and home health agencies.

- The Secretary must develop a plan to implement a value-based purchasing program for payments under the Medicare program for skilled nursing facilities.
- The Secretary must develop a plan to implement a value-based purchasing program for payments under the Medicare program for home health agencies.

Sec. 3007. Value-based payment modifier under the physician fee schedule.

Sec. 3008. Payment adjustment for conditions acquired in hospitals.

PART II—NATIONAL STRATEGY TO IMPROVE HEALTH CARE QUALITY

Sec. 3011. National strategy.

- The Secretary must establish a national strategy to improve the delivery of health care services, patient health outcomes, and population health.
- The Secretary shall ensure that priorities identified will:
 - Have the greatest potential for improving the health outcomes, efficiency, and patient-centeredness of health care for all populations, including children and vulnerable populations;
 - Identify areas in the delivery of health care services that have the potential for rapid improvement in the quality and efficiency of patient care;

- Address gaps in quality, efficiency, comparative effectiveness information, and health outcomes measures and data aggregation techniques;
- Improve Federal payment policy to emphasize quality and efficiency;
- Enhance the use of health care data to improve quality, efficiency, transparency, and outcomes;
- Address the health care provided to patients with high-cost chronic diseases;
- Improve research and dissemination of strategies and best practices to improve patient safety and reduce medical errors, preventable admissions and readmissions, and health care-associated infections;
- Reduce health disparities across health disparity populations and geographic areas; and
- Address other areas as determined appropriate by the Secretary.

Sec. 3012. Interagency Working Group on Health Care Quality.

Sec. 3013. Quality measure development.

- The Secretary, in consultation with the Director of the Agency for Healthcare Research and Quality and the CMS Administrator, shall identify, not less often than triennially, gaps where no quality measures exist and existing quality measures that need improvement, updating, or expansion, consistent with the national strategy, for use in Federal health programs.
- In awarding grants, contracts, or agreements under this subsection, the Secretary shall give priority to the development of quality measures that allow the assessment of:
 - health outcomes and functional status of patients;
 - the management and coordination of health care across episodes of care and care transitions for patients across the continuum of providers, health care settings, and health plans;
 - the experience, quality, and use of information provided to and used by patients, caregivers, and authorized representatives to inform decision making about treatment options, including the use of shared decision making tools and preference sensitive care;
 - the meaningful use of health information technology;
 - the safety, effectiveness, patient centeredness, appropriateness, and timeliness of care;
 - the efficiency of care;
 - the equity of health services and health disparities across health disparity populations and geographic areas;
 - patient experience and satisfaction;
 - the use of innovative strategies and methodologies; and
 - other areas determined appropriate by the Secretary.
- To be eligible for a grant or contract under this subsection, an entity shall:
 - have demonstrated expertise and capacity in the development and evaluation of quality measures;
 - have adopted procedures to include in the quality measure development process
 - the views of those providers or payers whose performance will be assessed by the measure; and
 - the views of other parties who also will use the quality measures (such as patients, consumers, and health care purchasers);
 - collaborate with the entity with a contract under section 1890(a) of the Social Security Act and other stakeholders, as practicable, and the Secretary so that quality measures developed by the eligible entity will meet the requirements to be considered for endorsement by the entity with a contract under such section 1890(a);

- have transparent policies regarding governance and conflicts of interest; and
- submit an application to the Secretary at such time and in such manner, as the Secretary may require.

Sec. 3014. Quality measurement.

- The Secretary must establish a pre-rulemaking process under which several steps occur with respect to the selection of quality measures including convening a multi-stakeholder group to provide input on the selection of quality measures.

Sec. 3015. Data collection; public reporting.

- The Secretary must collect and aggregate consistent data on quality and resource use measures from information systems used to support health care delivery to implement the public reporting of performance measures and may award grants or contracts for this purpose.
- To be eligible for a grant or contact, an entity must be:
 - A multi-stakeholder entity that coordinates the development of methods and implementation plans for the consistent reporting of summary quality and cost information;
 - An entity capable of submitting summary data for a particular population and providers; or
 - A Federal Indian Health Service program or health program operated by an Indian tribe.
- The Secretary must make available to the public, through standardized Internet Web sites, performance information summarizing data on quality measures. Such data shall be tailored to respond to the differing needs of hospitals and other institutional health care providers, physicians and other clinicians, patients, consumers, researchers, policymakers, States, and other stakeholders as the Secretary may specify.

PART III—ENCOURAGING DEVELOPMENT OF NEW PATIENT CARE MODELS

Sec. 3021. Establishment of Center for Medicare and Medicaid Innovation within CMS.

- Establishes within CMS a Center for Medicare and Medicaid Innovation the purpose of which is to test innovate payment and service delivery models to reduce program expenditures under Medicare and Medicaid while preserving or enhancing the quality of care furnished to individuals in those programs. In selecting such models, the Secretary must give preference to models that also improve the coordination, quality, and efficiency of health care services furnished to applicable individuals.
- The Secretary shall select models to be tested from models where the Secretary determines that there is evidence that the model addresses a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures.
- The models described in this subparagraph are the following models:
 - (i) Promoting broad payment and practice reform in primary care, including patient-centered medical home models for high-need applicable individuals, 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 or salary-based payment.

- (ii) Contracting directly with groups of providers of services and suppliers to promote innovative care delivery models, such as through risk-based comprehensive payment or salary-based payment.
- (iii) Utilizing geriatric assessments and comprehensive care plans to coordinate the care (including through interdisciplinary teams) of applicable individuals with multiple chronic conditions and at least one of the following:
 - An inability to perform 2 or more activities of daily living.
 - Cognitive impairment, including dementia.
- (iv) Promote care coordination between providers of services and suppliers that transition health care providers away from fee-for-service based reimbursement and toward salary-based payment.
- (v) Supporting care coordination for chronically-ill applicable individuals at high risk of hospitalization through a health information technology-enabled provider network that includes care coordinators, a chronic disease registry, and home telehealth technology.
- (vi) Varying payment to physicians who order advanced diagnostic imaging services (as defined in section 1834(e)(1)(B)) 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.
- (vii) Utilizing medication therapy management services, such as those described in section 935 of the Public Health Service Act.
- (viii) Establishing community-based health teams to support small-practice medical homes by assisting the primary care practitioner in chronic care management, including patient self-management, activities.
- (ix) Assisting applicable individuals in making informed health care choices by paying providers of services and suppliers for using patient decision-support tools, including tools that meet the standards developed and identified under section 936(c)(2)(A) of the Public Health Service Act, that improve applicable individual and caregiver understanding of medical treatment options.
- (x) Allowing States to test and evaluate fully integrating care for dual eligible individuals in the State, including the management and oversight of all funds under the applicable titles with respect to such individuals.
- (xi) Allowing States to test and evaluate systems of all-payer payment reform for the medical care of residents of the State, including dual eligible individuals.
- (xii) Aligning nationally recognized, evidence-based guidelines of cancer care with payment incentives under title XVIII in the areas of treatment planning and follow-up care planning for applicable individuals described in clause (i) or (iii) of subsection (a)(4)(A) with cancer, including the identification of gaps in applicable quality measures.
- (xiii) Improving post-acute care through continuing care hospitals that offer inpatient rehabilitation, long-term care hospitals, and home health or skilled nursing care during an inpatient stay and the 30 days immediately following discharge.
- (xiv) Funding home health providers who offer chronic care management services to applicable individuals in cooperation with interdisciplinary teams.
- (xv) Promoting improved quality and reduced cost by developing a collaborative of high-quality, low-cost health care institutions that is responsible for:
 - (I) developing, documenting, and disseminating best practices and proven care methods;

- (II) implementing such best practices and proven care methods within such institutions to demonstrate further improvements in quality and efficiency; and
 - (III) providing assistance to other health care institutions on how best to employ such best practices and proven care methods to improve health care quality and lower costs.
- (xvi) Facilitate inpatient care, including intensive care, of hospitalized applicable individuals at their local hospital through the use of electronic monitoring by specialists, including intensivists and critical care specialists, based at integrated health systems.
- (xvii) Promoting greater efficiencies and timely access to outpatient services (such as outpatient physical therapy services) through models that do not require a physician or other health professional to refer the service or be involved in establishing the plan of care for the service, when such service is furnished by a health professional who has the authority to furnish the service under existing State law.
- (xviii) Establishing comprehensive payments to Healthcare Innovation Zones, consisting of groups of providers that include a teaching hospital, physicians, and other clinical entities, that, through their structure, operations, and joint-activity deliver a full spectrum of integrated and comprehensive health care services to applicable individuals while also incorporating innovative methods for the clinical training of future health care professionals.
- In selecting models for testing, the CMI may consider the following additional factors:
 - (i) Whether the model includes a regular process for monitoring and updating patient care plans in a manner that is consistent with the needs and preferences of applicable individuals.
 - (ii) Whether the model places the applicable individual, including family members and other informal caregivers of the applicable individual, at the center of the care team of the applicable individual.
 - (iii) Whether the model provides for in-person contact with applicable individuals.
 - (iv) Whether the model utilizes technology, such as electronic health records and patient-based remote monitoring systems, to coordinate care over time and across settings.
 - (v) Whether the model provides for the maintenance of a close relationship between care coordinators, primary care practitioners, specialist physicians, community-based organizations, and other providers of services and suppliers.
 - (vi) Whether the model relies on a team-based approach to interventions, such as comprehensive care assessments, care planning, and self-management coaching.
 - (vii) Whether, under the model, providers of services and suppliers are able to share information with patients, caregivers, and other providers of services and suppliers on a real time basis.
- The Secretary shall terminate or modify the design and implementation of a model unless the Secretary determines after testing has begun, that the model is expected to:
 - (i) improve the quality of care without increasing spending under the applicable title;
 - (ii) reduce spending under the applicable title without reducing the quality of care; or
 - (iii) improve the quality of care and reduce spending.

Such termination may occur at any time after such testing has begun and before completion of the testing.
- Taking into account the evaluation under subsection (b)(4), the Secretary may, through rulemaking, expand (including implementation on a nationwide basis) the duration and the scope

of a model that is being tested under subsection (b) or a demonstration project under section 1866C, to the extent determined appropriate by the Secretary, if:

- (1) the Secretary determines that such expansion is expected to:
 - (A) reduce spending under applicable title without reducing the quality of care; or
 - (B) improve the quality of care and reduce spending; and
- (2) the Chief Actuary of CMS certifies that such expansion would reduce program spending under applicable titles.

Sec. 3022. Medicare shared savings program.

- No later than January 1, 2012, the Secretary must establish a shared savings program that promotes accountability for a patient population and coordinates items and services under Medicare Parts A and B, and encourages investment in infrastructure and redesigned care processes for high quality and efficient service delivery. Under this program, groups of providers of services and suppliers meeting certain criteria may work together to manager and coordinate care for Medicare fee-for-service beneficiaries through an accountable care organization (ACO). ACOs that meet quality performance standards are eligible to receive payments for shared savings.
- Eligible ACOs must have established a mechanism for shared governance.
- An ACO professional is defined as a physician and a practitioner as described in section 1842(b)(18)(C)(i).

Sec. 3023. National pilot program on payment bundling.

- The Secretary must establish a pilot program for integrated care during an episode of care provided to an applicable beneficiary around a hospitalization to improve the coordination, quality, and efficiency of health care services under this title.
- Defines “applicable services” as
 - Acute care inpatient services.
 - Physicians’ services delivered in and outside of an acute care hospital setting.
 - Outpatient hospital services, including emergency department services.
 - Post-acute care services, including home health services, skilled nursing services, inpatient rehabilitation services, and inpatient hospital services furnished by a long-term care hospital.
 - Other services that the Secretary determines appropriate.
- “Provider of service” has the meaning given such term in section 1861(u).
- “Supplier” has the meaning given such term in section 1861(d).

Sec. 3024. Independence at home demonstration program.

- The Secretary must conduct a demonstration program to test a payment incentive and service delivery model that utilizes physician and nurse practitioner directed home-based primary care teams designed to reduce expenditures and improve health outcomes in the provision of items and services under this title to applicable beneficiaries.
- The program shall test whether a model results in
 - reducing preventable hospitalizations;
 - preventing hospital readmissions;
 - reducing emergency room visits;
 - improving health outcomes commensurate with the beneficiaries’ stage of chronic illness;
 - improving the efficiency of care, such as by reducing duplicative diagnostic and laboratory tests;
 - reducing the cost of health care services covered under this title; and

- achieving beneficiary and family caregiver satisfaction.
- Defines an “independence at home medical practice” as a legal entity that
 - is comprised of an individual physician or nurse practitioner or group of physicians and nurse practitioners that provides care as part of a team that includes physicians, nurses, physician assistants, pharmacists, and other health and social services staff as appropriate who have experience providing home-based primary care to applicable beneficiaries, make in-home visits, and are available 24 hours per day, 7 days per week to carry out plans of care that are tailored to the individual beneficiary’s chronic conditions and designed to achieve the desired specified results;
 - is organized at least in part for the purpose of providing physicians’ services;
 - has documented experience in providing home-based primary care services to high-cost chronically ill beneficiaries, as determined appropriate by the Secretary;
 - furnishes services to at least 200 applicable beneficiaries during each year of the demonstration program;
 - has entered into an agreement with the Secretary;
 - uses electronic health information systems, remote monitoring, and mobile diagnostic technology; and
 - meets such other criteria as the Secretary determines to be appropriate to participate in the demonstration program.
- Nothing in this subsection shall be construed as preventing an independence at home medical practice from including a provider of services or a participating practitioner described in section 1842(b)(18)(C) that is affiliated with the practice under an arrangement structured so that such provider of services or practitioner participates in the demonstration program and shares in any savings under the demonstration program.

Sec. 3025. Hospital readmissions reduction program.

- The Secretary shall reduce payments that would otherwise be made to hospitals to account for excess readmissions to the hospital.
- No later than two years after the date of enactment, the Secretary shall make available a program for eligible hospitals to improve their readmission rates through the use of patient safety organizations.

Sec. 3026. Community-Based Care Transitions Program.

- The Secretary shall establish a Community-Based Transitions Program under which the Secretary provides funding to eligible entities that furnish improved care transition services to high-risk Medicare beneficiaries.
- Subject other provisions of this subsection, an application to participate shall include a detailed proposal for at least 1 care transition intervention, which may include the following:
 - (i) Initiating care transition services for a high-risk Medicare beneficiary not later than 24 hours prior to the discharge of the beneficiary from the eligible entity.
 - (ii) Arranging timely post-discharge follow-up services to the high-risk Medicare beneficiary to provide the beneficiary (and, as appropriate, the primary caregiver of the beneficiary) with information regarding responding to symptoms that may indicate additional health problems or a deteriorating condition.
 - (iii) Providing the high-risk Medicare beneficiary (and, as appropriate, the primary caregiver of the beneficiary) with assistance to ensure productive and timely interactions between patients and postacute and outpatient providers.

- (iv) Assessing and actively engaging with a high-risk Medicare beneficiary (and, as appropriate, the primary caregiver of the beneficiary) through the provision of self-management support and relevant information that is specific to the beneficiary's condition.
- (v) Conducting comprehensive medication review and management (including, if appropriate, counseling and self-management support).

Sec. 3027. Extension of gain sharing demonstration.

Subtitle B—Improving Medicare for Patients and Providers
PART I—ENSURING BENEFICIARY ACCESS TO PHYSICIAN CARE AND OTHER SERVICES

Sec. 3101. Increase in the physician payment update.

Sec. 3102. Extension of the work geographic index floor and revisions to the practice expense geographic adjustment under the Medicare physician fee schedule.

Sec. 3103. Extension of exceptions process for Medicare therapy caps.

Sec. 3104. Extension of payment for technical component of certain physician pathology services.

Sec. 3105. Extension of ambulance add-ons.

Sec. 3106. Extension of certain payment rules for long-term care hospital services and of moratorium on the establishment of certain hospitals and facilities.

Sec. 3107. Extension of physician fee schedule mental health add-on.

Sec. 3108. Permitting physician assistants to order post-Hospital extended care services.

Sec. 3109. Exemption of certain pharmacies from accreditation requirements.

- The Secretary shall not require a pharmacy to have submitted to the Secretary such evidence of accreditation prior to January 1, 2011.
- With respect to items and services furnished on or after January 1, 2011, in implementing quality standards under this paragraph:
 - (I) subject to subclause (II), in applying such standards and the accreditation requirement of subparagraph (F)(i) with respect to pharmacies described in clause (ii) furnishing such items and services, such standards and accreditation requirement shall not apply to such pharmacies; and
 - (II) the Secretary may apply to such pharmacies an alternative accreditation requirement established by the Secretary if the Secretary determines such alternative accreditation requirement is more appropriate for such pharmacies.
- A pharmacy described in this clause is a pharmacy that meets each of the following criteria:
 - (I) The total billings by the pharmacy for such items and services under this title are less than 5 percent of total pharmacy sales, as determined based on the average total pharmacy sales for the previous 3 calendar years, 3 fiscal years, or other yearly period specified by the Secretary.
 - (II) The pharmacy has been enrolled under section 1866(j) as a supplier of durable medical equipment, prosthetics, orthotics, and supplies, has been issued (which may include the renewal of) a provider number for at least 5 years, and for which a final adverse action has not been imposed in the past 5 years.
 - (III) The pharmacy submits to the Secretary an attestation, in a form and manner, and at a time, specified by the Secretary, that the pharmacy meets the criteria described in

subclauses (I) and (II). Such attestation shall be subject to section 1001 of title 18, United States Code.

- (IV) The pharmacy agrees to submit materials as requested by the Secretary, or during the course of an audit conducted on a random sample of pharmacies selected annually, to verify that the pharmacy meets the criteria described in subclauses (I) and (II). Materials submitted under the preceding sentence shall include a certification by an accountant on behalf of the pharmacy or the submission of tax returns filed by the pharmacy during the relevant periods, as requested by the Secretary.
- Notwithstanding any other provision of law, the Secretary may implement the amendments made by subsection (a) by program instruction or otherwise.
- Nothing in the provisions of or amendments made by this section shall be construed as affecting the application of an accreditation requirement for pharmacies to qualify for bidding in a competitive acquisition area under the Medicare program.

Sec. 3110. Part B special enrollment period for disabled TRICARE beneficiaries.

Sec. 3111. Payment for bone density tests.

Sec. 3112. Revision to the Medicare Improvement Fund.

Sec. 3113. Treatment of certain complex diagnostic laboratory tests.

Sec. 3114. Improved access for certified nurse-midwife services.

PART II—RURAL PROTECTIONS

Sec. 3121. Extension of outpatient hold harmless provision.

Sec. 3122. Extension of Medicare reasonable costs payments for certain clinical diagnostic laboratory tests furnished to hospital patients in certain rural areas.

Sec. 3123. Extension of the Rural Community Hospital Demonstration Program.

Sec. 3124. Extension of the Medicare-dependent hospital (MDH) program.

Sec. 3125. Temporary improvements to the Medicare inpatient hospital payment adjustment for low-volume hospitals.

Sec. 3126. Improvements to the demonstration project on community health integration models in certain rural counties.

Sec. 3127. MedPAC study on adequacy of Medicare payments for health care providers serving in rural areas.

- The Medicare Payment Advisory Commission shall conduct a study on the adequacy of payments for items and services furnished by providers of services and suppliers in rural areas under the Medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.). Such study shall include an analysis of:
 - (1) any adjustments in payments to providers of services and suppliers that furnish items and services in rural areas;
 - (2) access by Medicare beneficiaries to items and services in rural areas;
 - (3) the adequacy of payments to providers of services and suppliers that furnish items and services in rural areas; and
 - (4) the quality of care furnished in rural areas.

Sec. 3128. Technical correction related to critical access hospital services.

Sec. 3129. Extension of and revisions to Medicare rural hospital flexibility program.

PART III—IMPROVING PAYMENT ACCURACY

Sec. 3131. Payment adjustments for home health care.

- Adjusts Medicare payments for home health services to reflect such factors as changes in the number of visits in an episode, the mix of services in an episode, the level of intensity of services in an episode, the average cost of providing care per episode, and other factors that the Secretary considers to be relevant. In conducting the analysis under the preceding sentence, the Secretary may consider differences between hospitalbased and freestanding agencies, between for-profit and nonprofit agencies, and between the resource costs of urban and rural agencies.
- The Medicare Payment Advisory Commission shall conduct a study on the implementation of these amendments. Such study shall include an analysis of the impact of such amendments on:
 - (i) access to care;
 - (ii) quality outcomes;
 - (iii) the number of home health agencies; and
 - (iv) rural agencies, urban agencies, for-profit agencies, and nonprofit agencies.
- The Secretary shall conduct a study to evaluate the costs and quality of care among efficient home health agencies relative to other such agencies in providing ongoing access to care and in treating Medicare beneficiaries with varying severity levels of illness. Such study shall include an analysis of the following:
 - (A) Methods to revise the home health prospective payment system under section 1895 of the Social Security Act (42 U.S.C. 1395fff) to more accurately account for the costs related to patient severity of illness or to improving beneficiary access to care, including:
 - (i) payment adjustments for services that may be under- or over-valued;
 - (ii) necessary changes to reflect the resource use relative to providing home health services to low-income Medicare beneficiaries or Medicare beneficiaries living in medically underserved areas;
 - (iii) ways the outlier payment may be improved to more accurately reflect the cost of treating Medicare beneficiaries with high severity levels of illness;
 - (iv) the role of quality of care incentives and penalties in driving provider and patient behavior;
 - (v) improvements in the application of a wage index; and
 - (vi) other areas determined appropriate by the Secretary.
 - (B) The validity and reliability of responses on the OASIS instrument with particular emphasis on questions that relate to higher payment under the home health prospective payment system and higher outcome scores under Home Care Compare.
 - (C) Additional research or payment revisions under the home health prospective payment system that may be necessary to set the payment rates for home health services based on costs of high-quality and efficient home health agencies or to improve Medicare beneficiary access to care.
 - (D) A timetable for implementation of any appropriate changes based on the analysis of the matters described in subparagraphs (A), (B), and (C).
 - (E) Other areas determined appropriate by the Secretary.
- In conducting this study, the Secretary shall consider whether certain factors should be used to measure patient severity of illness and access to care, such as:
 - (A) population density and relative patient access to care;

- (B) variations in service costs for providing care to individuals who are dually eligible under the Medicare and Medicaid programs;
- (C) the presence of severe or chronic diseases, as evidenced by multiple, discontinuous home health episodes;
- (D) poverty status, as evidenced by the receipt of Supplemental Security Income under title XVI of the Social Security Act;
- (E) the absence of caregivers;
- (F) language barriers;
- (G) atypical transportation costs;
- (H) security costs; and
- (I) other factors determined appropriate by the Secretary.

Sec. 3132. Hospice reform.

Sec. 3133. Improvement to Medicare disproportionate share hospital (DSH) payments.

Sec. 3134. Misvalued codes under the physician fee schedule.

Sec. 3135. Modification of equipment utilization factor for advanced imaging services.

Sec. 3136. Revision of payment for power-driven wheelchairs.

Sec. 3137. Hospital wage index improvement.

Sec. 3138. Treatment of certain cancer hospitals.

Sec. 3139. Payment for biosimilar biological products.

- Establishes the payment for biosimilars at 106% of ASP.

Sec. 3140. Medicare hospice concurrent care demonstration program.

Sec. 3141. Application of budget neutrality on a national basis in the calculation of the Medicare hospital wage index floor.

Sec. 3142. HHS study on urban Medicare-dependent hospitals.

Subtitle C—Provisions Relating to Part C

Sec. 3201. Medicare Advantage payment.

- Establishes a care coordination and management performance bonus for Medicare Advantage plans. These programs include:
 - (i) Care management programs that:
 - (I) target individuals with 1 or more chronic conditions;
 - (II) identify gaps in care; and
 - (III) facilitate improved care by using additional resources like nurses, nurse practitioners, and physician assistants.
 - (ii) Programs that focus on patient education and self-management of health conditions, including interventions that:
 - (I) help manage chronic conditions;
 - (II) reduce declines in health status; and
 - (III) foster patient and provider collaboration.
 - (iii) 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.

- (iv) Patient safety programs, including provisions for hospital-based patient safety programs in contracts that the Medicare Advantage organization offering the MA plan has with hospitals.
- (v) Financial policies that promote systematic coordination of care by primary care physicians across the full spectrum of specialties and sites of care, such as medical homes, capitation arrangements, or pay-for-performance programs.
- (vi) Programs that address, identify, and ameliorate health care disparities among principal at-risk subpopulations.
- (vii) Medication therapy management programs that are more extensive than is required under section 1860D–4(c).
- (viii) Health information technology programs, including clinical decision support and other tools to facilitate data collection and ensure patient-centered, appropriate care.
- (ix) Such other care management and coordination programs as the Secretary determines appropriate.

Sec. 3202. Benefit protection and simplification.

Sec. 3203. Application of coding intensity adjustment during MA payment transition.

Sec. 3204. Simplification of annual beneficiary election periods.

Sec. 3205. Extension for specialized MA plans for special needs individuals.

Sec. 3206. Extension of reasonable cost contracts.

Sec. 3207. Technical correction to MA private fee-for-service plans.

Sec. 3208. Making senior housing facility demonstration permanent.

Sec. 3209. Authority to deny plan bids.

Sec. 3210. Development of new standards for certain Medigap plans.

Subtitle D—Medicare Part D Improvements for Prescription Drug Plans and MA–PD Plans

Sec. 3301. Medicare coverage gap discount program.

- The Secretary must establish a Medicare coverage gap discount program by July 1, 2010. Under the program, the Secretary shall enter into agreements with manufacturers that require the manufacturer to provide applicable beneficiaries access to discounted prices for applicable drugs of the manufacturer.
- Such discounted prices shall be provided to the applicable beneficiary at the pharmacy or by the mail-order service at the point-of-sale of an applicable drug. From July 1, 2010 to December 31, 2011, if it is not practicable to provide the discounted prices at the point-of-sale, then procedures must be established to provide the discounted prices as soon as practicable after the point-of-sale.
- Procedures must be established to ensure that, no later than the applicable number of calendar days after the dispensing of an applicable drug by a pharmacy or mail-order service, the pharmacy or mail-order service is reimbursed for an amount equal to the difference between:
 - The negotiated price of the applicable drug; and
 - The discounted price of the applicable drug.
- The Secretary shall enter in a contract with one or more third parties to administer the requirements established by the Secretary to carry out this section.

Sec. 3302. Improvement in determination of Medicare part D low-income benchmark premium.

Sec. 3303. Voluntary de minimis policy for subsidy eligible individuals under prescription drug plans and MA–PD plans.

Sec. 3304. Special rule for widows and widowers regarding eligibility for low income assistance.

Sec. 3305. Improved information for subsidy eligible individuals reassigned to prescription drug plans and MA–PD plans.

- No later than January 1, 2011, the Secretary shall, in the case of a subsidy eligible individual who is enrolled in one prescription drug plan and is subsequently reassigned by the Secretary to another drug program, provide the individual within 30 days of such reassignment:
 - Information on formulary differences between the individual’s former plan and the plan to which the individual is reassigned with respect to the individual’s drug regimens; and
 - A description of the individual’s right to request a coverage determination, exception, or reconsideration, bring an appeal, or resolve a grievance.

Sec. 3306. Funding outreach and assistance for low-income programs.

Sec. 3307. Improving formulary requirements for prescription drug plans and MA–PD plans with respect to certain categories or classes of drugs.

- Amends the Medicare Part D law regarding the process for determining what categories or classes of drugs are considered protected (and therefore included in total in formularies).
 - (i)Formulary requirements
 - (I) A PDP sponsor offering a prescription drug plan shall be required to include all covered part D drugs in the categories and classes identified by the Secretary under clause (ii)(I).
 - (II) The Secretary may establish exceptions that permit a PDP sponsor offering a prescription drug plan to exclude from its formulary a particular covered part D drug in a category or class that is otherwise required to be included in the formulary under subclause (I) (or to otherwise limit access to such a drug, including through prior authorization or utilization management).
 - (ii)Identification of drugs
 - (I) Subject to 10 clause (iv), the Secretary shall identify, as appropriate, categories and classes of drugs for which the Secretary determines are of clinical concern.
 - (II)The Secretary shall use criteria established by the Secretary in making any determination under subclause (I).
 - (iii) The Secretary shall establish the criteria under clause (ii)(II) and any exceptions under clause (i)(II) through the promulgation of a regulation which includes a public notice and comment period.
 - (iv) Until such time as the Secretary establishes the criteria under clause (ii)(II) the following categories and classes of drugs shall be identified under clause (ii)(I):
 - (I) Anticonvulsants.
 - (II) Antidepressants.
 - (III) Antineoplastics.
 - (IV) Antipsychotics.
 - (V) Antiretrovirals.
 - (VI) Immunosuppressants for the treatment of transplant rejection.

Sec. 3308. Reducing part D premium subsidy for high-income beneficiaries.

Sec. 3309. Elimination of cost sharing for certain dual eligible individuals.

- The Social Security Act is amended to adjust the cost sharing for certain dual eligible individuals who would be an institutionalized individual or couple, if the full-benefit dual eligible individual were not receiving services under a home and community-based waiver or services provided through enrollment in a Medicaid managed care organization.

Sec. 3310. Reducing wasteful dispensing of outpatient prescription drugs in long-term care facilities under prescription drug plans and MA–PD plans.

- The Secretary shall require PDP sponsors of prescription drug plans to utilize specific, uniform dispensing techniques, as determined by the Secretary, in consultation with relevant stakeholders (including representatives of nursing facilities, residents of nursing facilities, pharmacists, the pharmacy industry (including retail and long-term care pharmacy), prescription drug plans, MA–PD plans, and any other stakeholders the Secretary determines appropriate), such as weekly, daily, or automated dose dispensing, when dispensing covered part D drugs to enrollees who reside in a long-term care facility in order to reduce waste associated with 30-day fills.
- This requirement shall apply to plan years beginning on or after January 1, 2012.

Sec. 3311. Improved Medicare prescription drug plan and MA–PD plan complaint system.

Sec. 3312. Uniform exceptions and appeals process for prescription drug plans and MA–PD plans.

- Medicare Part D is amended by requiring each PDP sponsor of a prescription drug plan to:
 - use a single, uniform exceptions and appeals process (including, to the extent the Secretary determines feasible, a single, uniform model form for use under such process) with respect to the determination of prescription drug coverage for an enrollee under the plan; and
 - provide instant access to such process by enrollees through a toll-free telephone number and an Internet website.

Sec. 3313. Office of the Inspector General studies and reports.

- The Inspector General of the Department of Health and Human Services shall conduct a study of the extent to which formularies used by prescription drug plans and MA–PD plans under Part D include drugs commonly used by full-benefit dual eligible individuals.
 - No later than July 17 of each year (beginning with 2011), the Inspector General shall submit to Congress a report on the study conducted under paragraph (1), together with such recommendations as the Inspector General determines appropriate.
- The Inspector General of the Department of Health and Human Services shall conduct a study on prices for covered part D drugs under the Medicare prescription drug program under part D and for covered outpatient drugs under title XIX. Such study shall include the following:
 - A comparison, with respect to the 200 most frequently dispensed covered part D drugs under such program and covered outpatient drugs under such title (as determined by the Inspector General based on volume and expenditures), of
 - (I) the prices paid for covered part D drugs by PDP sponsors of prescription drug plans and Medicare Advantage organizations offering MA- PD plans; and
 - (II) the prices paid for covered outpatient drugs by a State plan under Medicaid.
 - An assessment of—
 - (I) the financial impact of any discrepancies in such prices on the Federal Government; and
 - (II) the financial impact of any such discrepancies on enrollees under part D or individuals eligible for Medicaid.
 - Notwithstanding any other provision of law, the Inspector General of the Department of Health and Human Services shall be able to collect any information related to the prices of covered part D drugs under such program and covered outpatient drugs under Medicaid necessary to carry out the comparison under subparagraph (A).

Sec. 3314. Including costs incurred by AIDS drug assistance programs and Indian Health Service in providing prescription drugs toward the annual out-of-pocket threshold under part D.

Sec. 3315. Immediate reduction in coverage gap in 2010.

- Reduces the Medicare Part D coverage gap by, beginning with January 1, 2010, increasing the initial coverage limit by \$500.
- The Secretary must establish procedures, which may include a reconciliation process, to fully reimburse PDP and MA-PD plans for the reduction in beneficiary cost sharing associated with the application of this change.
- The Secretary shall establish a procedure for retroactive reimbursement of Part D eligible individuals who are covered under such a plan for costs which are incurred before the date of initial implementation.

Subtitle E—Ensuring Medicare Sustainability

Sec. 3401. Revision of certain market basket updates and incorporation of productivity improvements into market basket updates that do not already incorporate such improvements.

Sec. 3402. Temporary adjustment to the calculation of part B premiums.

Sec. 3403. Independent Medicare Advisory Board.

- Establishes the Independent Medicare Advisory Board to make recommendations to reduce the per capita rate growth in Medicare spending. The Secretary is required to implement such proposals unless Congress enacts legislation.
- The Board must submit a draft copy of each of their proposals to the Medicare Payment Advisory Commission for its review. The Board must also submit a draft copy of each proposal to the Secretary for his review and comment.
- Provides for detailed guidance on how the report is handled by Congress.
- The appointed membership of the Board shall include individuals with national recognition for their expertise in health finance and economics, actuarial science, health facility management, health plans and integrated delivery systems, reimbursement of health facilities, allopathic and osteopathic physicians, and other providers of health services, and other related fields, who provide a mix of different professionals, broad geographic representation, and a balance between urban and rural representatives.
- The appointed membership of the Board shall include (but not be limited to) physicians and other health professionals, experts in the area of pharmaco-economics or prescription drug benefit programs, employers, third-party payers, individuals skilled in the conduct and interpretation of biomedical, health services, and health economics research and expertise in outcomes and effectiveness research and technology assessment. Such membership shall also include representatives of consumers and the elderly.

Subtitle F—Health Care Quality Improvements

Sec. 3501. Health care delivery system research; Quality improvement technical assistance.

- Amends the Public Health Service Act by adding a section on health care delivery system research to enable the Director to identify, develop, evaluate, disseminate, and providing training

in innovative methodologies and strategies for quality improvement practices in the delivery of health care services that represent best practices in health care, quality, safety and value.

- The Center for Quality Improvement and Patient Safety of the Agency for Healthcare Research and Quality or any other relevant agency or department designated by the Director, shall—
 - (1) carry out its functions using research from a variety of disciplines, which may include epidemiology, health services, sociology, psychology, human factors engineering, biostatistics, health economics, clinical research, and health informatics;
 - (2) conduct or support activities consistent with the purposes described in subsection (a), and for:
 - (A) best practices for quality improvement practices in the delivery of health care services; and
 - (B) that include changes in processes of care and the redesign of systems used by providers that will reliably result in intended health outcomes, improve patient safety, and reduce medical errors (such as skill development for health care providers in team-based health care delivery and rapid cycle process improvement) and facilitate adoption of improved workflow;
 - (3) identify health care providers, including health care systems, single institutions, and individual providers, that:
 - (A) deliver consistently high-quality, efficient health care services; and
 - (B) employ best practices that are adaptable and scalable to diverse health care settings or effective in improving care across diverse settings;
 - (4) assess research, evidence, and knowledge about what strategies and methodologies are most effective in improving health care delivery;
 - (5) find ways to translate such information rapidly and effectively into practice, and document the sustainability of those improvements;
 - (6) create strategies for quality improvement through the development of tools, methodologies, and interventions that can successfully reduce variations in the delivery of health care;
 - (7) identify, measure, and improve organizational, human, or other causative factors, including those related to the culture and system design of a health care organization, that contribute to the success and sustainability of specific quality improvement and patient safety strategies;
 - (8) provide for the development of best practices in the delivery of health care services that:
 - (A) have a high likelihood of success, based on structured review of empirical evidence;
 - (B) are specified with sufficient detail of the individual processes, steps, training, skills, and knowledge required for implementation and incorporation into workflow of health care practitioners in a variety of settings;
 - (C) are designed to be readily adapted by health care providers in a variety of settings; and
 - (D) where applicable, assist health care providers in working with other health care providers across the continuum of care and in engaging patients and their families in improving the care and patient health outcomes;
 - (9) provide for the funding of the activities of organizations with recognized expertise and excellence in improving the delivery of health care services, including children's

- health care, by involving multiple disciplines, managers of health care entities, broad development and training, patients, caregivers and families, and frontline health care workers, including activities for the examination of strategies to share best quality improvement practices and to promote excellence in the delivery of health care services; and
- (10) build capacity at the State and community level to lead quality and safety efforts through education, training, and mentoring programs to carry out the activities under paragraphs (1) through (9).
 - The Center shall support, such as through a contract or other mechanism, research on health care delivery system improvement and the development of tools to facilitate adoption of best practices that improve the quality, safety, and efficiency of health care delivery services. Such support may include establishing a Quality Improvement Network Research Program for the purpose of testing, scaling, and disseminating of interventions to improve quality and efficiency in health care. Recipients of funding under the Program may include national, State, multi-State, or multi-site quality improvement networks. This research shall:
 - (A) address the priorities identified by the Secretary in the national strategic plan established under section 399HH;
 - (B) identify areas in which evidence is insufficient to identify strategies and methodologies, taking into consideration areas of insufficient evidence identified by the entity with a contract under section 1890(a) of the Social Security Act in the report required under section 399JJ;
 - (C) address concerns identified by health care institutions and providers and communicated through the Center pursuant to subsection (d);
 - (D) reduce preventable morbidity, mortality, and associated costs of morbidity and mortality by building capacity for patient safety research;
 - (E) support the discovery of processes for the reliable, safe, efficient, and responsive delivery of health care, taking into account discoveries from clinical research and comparative effectiveness research;
 - (F) allow communication of research findings and translate evidence into practice recommendations that are adaptable to a variety of settings, and which, as soon as practicable after the establishment of the Center, shall include:
 - (i) the implementation of a national application of Intensive Care Unit improvement projects relating to the adult (including geriatric), pediatric, and neonatal patient populations;
 - (ii) practical methods for addressing health care associated infections, including Methicillin-Resistant Staphylococcus Aureus and Vancomycin-Resistant Enterococcus infections and other emerging infections; and
 - (iii) practical methods for reducing preventable hospital admissions and readmissions;
 - (G) expand demonstration projects for improving the quality of children's health care and the use of health information technology, such as through Pediatric Quality Improvement Collaboratives and Learning Networks, consistent with provisions of section 1139A of the Social Security Act for assessing and improving quality, where applicable;
 - (H) identify and mitigate hazards by:
 - (i) analyzing events reported to patient safety reporting systems and patient safety organizations; and

- (ii) using the results of such analyses to develop scientific methods of response to such events;
 - (I) include the conduct of systematic reviews of existing practices that improve the quality, safety, and efficiency of health care delivery, as well as new research on improving such practices; and
 - (J) include the examination of how to measure and evaluate the progress of quality and patient safety activities.

Sec. 3502. Establishing community health teams to support the patient-centered medical home.

- The Secretary shall establish a program to provide grants to or enter into contracts with eligible entities to establish community-based interdisciplinary, interprofessional teams (“health teams”) to support primary care practices, including obstetrics and gynecology practices, within the hospital service areas served by the eligible entities. Grants or contracts shall be used to:
 - (1) establish health teams to provide support services to primary care providers; and
 - (2) provide capitated payments to primary care providers as determined by the Secretary.
- To be eligible to receive a grant or contract under subsection (a), an entity shall:
 - (1)(A) be a State or State-designated entity; or
 - (B) be an Indian tribe or tribal organization, as defined in section 4 of the Indian Health Care Improvement Act;
 - (2) submit a plan for achieving long-term financial sustainability within 3 years;
 - (3) submit a plan for incorporating prevention initiatives and patient education and care management resources into the delivery of health care that is integrated with community-based prevention and treatment resources, where available;
 - (4) ensure that the health team established by the entity includes an interdisciplinary, interprofessional team of health care providers, as determined by the Secretary; such team may include medical specialists, nurses, pharmacists, nutritionists, dieticians, social workers, behavioral and mental health providers (including substance use disorder prevention and treatment providers), doctors of chiropractic, licensed complementary and alternative medicine practitioners, and physicians’ assistants;
 - (5) agree to provide services to eligible individuals with chronic conditions, as described in section 1945 of the Social Security Act (as added by section 2703), in accordance with the payment methodology established under subsection (c) of such section; and
 - (6) submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.
- A health team established pursuant to a grant or contract under subsection (a) shall:
 - (1) establish contractual agreements with primary care providers to provide support services;
 - (2) support patient-centered medical homes, defined as a mode of care that includes:
 - (A) personal physicians;
 - (B) whole person orientation;
 - (C) coordinated and integrated care;
 - (D) safe and high-quality care through evidence-informed medicine, appropriate use of health information technology, and continuous quality improvements;
 - (E) expanded access to care; and
 - (F) payment that recognizes added value from additional components of patient-centered care;

- (3) collaborate with local primary care providers and existing State and community based resources to coordinate disease prevention, chronic disease management, transitioning between health care providers and settings and case management for patients, including children, with priority given to those amenable to prevention and with chronic diseases or conditions identified by the Secretary;
- (4) in collaboration with local health care providers, develop and implement interdisciplinary, interprofessional care plans that integrate clinical and community preventive and health promotion services for patients, including children, with a priority given to those amenable to prevention and with chronic diseases or conditions identified by the Secretary;
- (5) incorporate health care providers, patients, caregivers, and authorized representatives in program design and oversight;
- (6) provide support necessary for local primary care providers to:
 - (A) coordinate and provide access to high quality health care services;
 - (B) coordinate and provide access to preventive and health promotion services;
 - (C) provide access to appropriate specialty care and inpatient services;
 - (D) provide quality-driven, cost-effective, culturally appropriate, and patient- and family centered health care;
 - (E) provide access to pharmacist-delivered medication management services, including medication reconciliation;
 - (F) provide coordination of the appropriate use of complementary and alternative (CAM) services to those who request such services;
 - (G) promote effective strategies for treatment planning, monitoring health outcomes and resource use, sharing information, treatment decision support, and organizing care to avoid duplication of service and other medical management approaches intended to improve quality and value of health care services;
 - (H) provide local access to the continuum of health care services in the most appropriate setting, including access to individuals that implement the care plans of patients and coordinate care, such as integrative health care practitioners;
 - (I) collect and report data that permits evaluation of the success of the collaborative effort on patient outcomes, including collection of data on patient experience of care, and identification of areas for improvement; and
 - (J) establish a coordinated system of early identification and referral for children at risk for developmental or behavioral problems such as through the use of infolines, health information technology, or other means as determined by the Secretary;
- (7) provide 24-hour care management and support during transitions in care settings including:
 - (A) a transitional care program that provides onsite visits from the care coordinator, assists with the development of discharge plans and medication reconciliation upon admission to and discharge from the hospitals, nursing home, or other institution setting;
 - (B) discharge planning and counseling support to providers, patients, caregivers, and authorized representatives;
 - (C) assuring that post-discharge care plans include medication management, as appropriate;

- (D) referrals for mental and behavioral health services, which may include the use of info lines; and
 - (E) transitional health care needs from adolescence to adulthood;
- (8) serve as a liaison to community prevention and treatment programs;
- (9) demonstrate a capacity to implement and maintain health information technology that meets the requirements of certified EHR technology (as defined in section 3000 of the Public Health Service Act (42 U.S.C. 300jj)) to facilitate coordination among members of the applicable care team and affiliated primary care practices; and
- (10) where applicable, report to the Secretary information on quality measures used under section 399JJ of the Public Health Service Act.
- (d) A provider who contracts with a care team shall:
 - (1) provide a care plan to the care team for each patient participant;
 - (2) provide access to participant health records; and
 - (3) meet regularly with the care team to ensure integration of care.

Sec. 3503. Medication management services in treatment of chronic disease.

- The Secretary, acting through the Patient Safety Research Center established in section 933 (referred to in this section as the ‘Center’) [see section 3501 above] , shall establish a program to provide grants or contracts to eligible entities to implement medication management (‘MTM’) services provided by licensed pharmacists, as a collaborative, multidisciplinary, interprofessional approach to the treatment of chronic diseases for targeted individuals, to improve the quality of care and reduce overall cost in the treatment of such diseases. The Secretary shall commence the program under this section not later than May 1, 2010.
- To be eligible to receive a grant or contract under subsection (a), an entity shall:
 - (1) provide a setting appropriate for MTM services, as recommended by the experts described in subsection (e);
 - (2) submit to the Secretary a plan for achieving long-term financial sustainability;
 - (3) where applicable, submit a plan for coordinating MTM services through local community health teams established in section 3502 of the Patient Protection and Affordable Care Act or in collaboration with primary care extension programs established in section 399W;
 - (4) submit a plan for meeting the requirements under subsection (c); and
 - (5) submit to the Secretary such other information as the Secretary may require.
- (c) The MTM services provided with the assistance of a grant or contract awarded under subsection (a) shall, as allowed by State law including applicable collaborative pharmacy practice agreements, include:
 - (1) performing or obtaining necessary assessments of the health and functional status of each patient receiving such MTM services;
 - (2) formulating a medication treatment plan according to therapeutic goals agreed upon by the prescriber and the patient or caregiver or authorized representative of the patient;
 - (3) selecting, initiating, modifying, recommending changes to, or administering medication therapy;
 - (4) monitoring, which may include access to, ordering, or performing laboratory assessments, and evaluating the response of the patient to therapy, including safety and effectiveness;
 - (5) performing an initial comprehensive medication review to identify, resolve, and prevent medication-related problems, including adverse drug events, quarterly targeted

- medication reviews for ongoing monitoring, and additional follow up interventions on a schedule developed collaboratively with the prescriber;
- (6) documenting the care delivered and communicating essential information about such care, including a summary of the medication review, and the recommendations of the pharmacist to other appropriate health care providers of the patient in a timely fashion;
 - (7) providing education and training designed to enhance the understanding and appropriate use of the medications by the patient, caregiver, and other authorized representative;
 - (8) providing information, support services, and resources and strategies designed to enhance patient adherence with therapeutic regimens;
 - (9) coordinating and integrating MTM services within the broader health care management services provided to the patient; and
 - (10) such other patient care services allowed under pharmacist scopes of practice in use in other Federal programs that have implemented MTM services.
- (d) MTM services provided by licensed pharmacists under a grant or contract awarded under subsection (a) shall be offered to targeted individuals who:
 - (1) take 4 or more prescribed medications (including over-the-counter medications and dietary supplements);
 - (2) take any ‘high risk’ medications;
 - (3) have 2 or more chronic diseases, as identified by the Secretary; or
 - (4) have undergone a transition of care, or other factors, as determined by the Secretary, that are likely to create a high risk of medication-related problems.
 - (e) In designing and implementing MTM services provided under grants or contracts awarded under subsection (a), the Secretary shall consult with Federal, State, private, public-private, and academic entities, pharmacy and pharmacist organizations, health care organizations, consumer advocates, chronic disease groups, and other stakeholders involved with the research, dissemination, and implementation of pharmacist-delivered MTM services, as the Secretary determines appropriate. The Secretary, in collaboration with this group, shall determine whether it is possible to incorporate rapid cycle process improvement concepts in use in other Federal programs that have implemented MTM services.
 - (f) An entity that receives a grant or contract under subsection (a) shall submit to the Secretary a report that describes and evaluates, as requested by the Secretary, the activities carried out under subsection (c), including quality measures endorsed by the entity with a contract under section 1890 of the Social Security Act, as determined by the Secretary.
 - (g) The Secretary shall submit to the relevant committees of Congress a report which shall:
 - (1) assess the clinical effectiveness of pharmacist-provided services under the MTM services program, as compared to usual care, including an evaluation of whether enrollees maintained better health with fewer hospitalizations and emergency room visits than similar patients not enrolled in the program;
 - (2) assess changes in overall health care resource use by targeted individuals;
 - (3) assess patient and prescriber satisfaction with MTM services;
 - (4) assess the impact of patient-cost sharing requirements on medication adherence and recommendations for modifications;
 - (5) identify and evaluate other factors that may impact clinical and economic outcomes, including demographic characteristics, clinical characteristics, and health services use of

the patient, as well as characteristics of the regimen, pharmacy benefit, and MTM services provided; and

- (6) evaluate the extent to which participating pharmacists who maintain a dispensing role have a conflict of interest in the provision of MTM services, and if such conflict is found, provide recommendations on how such a conflict might be appropriately addressed.
- (h) The Secretary may, through the quality measure development program under section 931 of the Public Health Service Act, award grants or contracts to eligible entities for the purpose of funding the development of performance measures that assess the use and effectiveness of medication therapy management services.

Sec. 3504. Design and implementation of regionalized systems for emergency care.

Sec. 3505. Trauma care centers and service availability.

Sec. 3506. Program to facilitate shared decision making.

Sec. 3507. Presentation of prescription drug benefit and risk information.

- The Secretary, acting through the Commissioner of FDA, shall determine whether the addition of quantitative summaries of the benefits and risks of prescription drugs in a standardized format (such as a table or drug facts box) to the promotional labeling or print advertising of such drugs would improve health care decision making by clinicians and patients and consumers.
- In making the determination under subsection (a), the Secretary shall review all available scientific evidence and research on decision making and social and cognitive psychology and consult with drug manufacturers, clinicians, patients and consumers, experts in health literacy, representatives of racial and ethnic minorities, and experts in women's and pediatric health.
- Not later than 1 year after the date of enactment of this Act, the Secretary shall submit to Congress a report that provides:
 - (1) the determination by the Secretary under subsection (a); and
 - (2) the reasoning and analysis underlying that determination.
- If the Secretary determines under subsection (a) that the addition of quantitative summaries of the benefits and risks of prescription drugs in a standardized format (such as a table or drug facts box) to the promotional labeling or print advertising of such drugs would improve health care decision making by clinicians and patients and consumers, then the Secretary, not later than 3 years after the date of submission of the report under subsection (c), shall promulgate proposed regulations as necessary to implement such format.
- Nothing in this section shall be construed to restrict the existing authorities of the Secretary with respect to benefit and risk information.

Sec. 3508. Demonstration program to integrate quality improvement and patient safety training into clinical education of health professionals.

- The Secretary may award grants to eligible entities or consortia under this section to carry out demonstration projects to develop and implement academic curricula that integrates quality improvement and patient safety in the clinical education of health professionals. Such awards shall be made on a competitive basis and pursuant to peer review.
- To be eligible to receive a grant under subsection (a), an entity or consortium shall:
 - submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require;
 - be or include:
 - a health professions school;
 - a school of public health;
 - a school of social work;

- a school of nursing;
- a school of pharmacy;
- an institution with a graduate medical education program; or
- a school of health care administration;
- collaborate in the development of curricula described in subsection (a) with an organization that accredits such school or institution;
- provide for the collection of data regarding the effectiveness of the demonstration project; and
- provide matching funds in accordance with subsection (c).

Sec. 3509. Improving women’s health.

Sec. 3510. Patient navigator program.

Sec. 3511. Authorization of appropriations.

TITLE IV—PREVENTION OF CHRONIC DISEASE AND IMPROVING PUBLIC HEALTH
Subtitle A—Modernizing Disease Prevention and Public Health Systems

Sec. 4001. National Prevention, Health Promotion and Public Health Council.

- The President shall establish, within the Department of Health and Human Services, a council to be known as the “National Prevention, Health Promotion and Public Health Council” (referred to in this section as the “Council”).
- The Council shall:
 - (1) provide coordination and leadership at the Federal level, and among all Federal departments and agencies, with respect to prevention, wellness and health promotion practices, the public health system, and integrative health care in the United States;
 - (2) after obtaining input from relevant stakeholders, develop a national prevention, health promotion, public health, and integrative health care strategy that incorporates the most effective and achievable means of improving the health status of Americans and reducing the incidence of preventable illness and disability in the United States;
 - (3) provide recommendations to the President and Congress concerning the most pressing health issues confronting the United States and changes in Federal policy to achieve national wellness, health promotion, and public health goals, including the reduction of tobacco use, sedentary behavior, and poor nutrition;
 - (4) consider and propose evidence-based models, policies, and innovative approaches for the promotion of transformative models of prevention, integrative health, and public health on individual and community levels across the United States;
 - (5) establish processes for continual public input, including input from State, regional, and local leadership communities and other relevant stakeholders, including Indian tribes and tribal organizations;
 - (6) submit the reports required under subsection (g); and
 - (7) carry out other activities determined appropriate by the President.

Sec. 4002. Prevention and Public Health Fund.

Sec. 4003. Clinical and community preventive services.

- The Director shall convene an independent Preventive Services Task Force (referred to in this subsection as the ‘Task Force’) to be composed of individuals with appropriate expertise. Such Task Force shall review the scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of clinical preventive services for the purpose of developing recommendations

for the health care community, and updating previous clinical preventive recommendations, to be published in the Guide to Clinical Preventive Services (referred to in this section as the ‘Guide’). Such recommendations shall consider clinical preventive best practice recommendations from the AHRQ, the NIH, the CDC, the IOM, specialty medical associations, patient groups, and scientific societies.

- The Director of the CDC shall convene an independent Community Preventive Services Task Force (referred to in this subsection as the ‘Task Force’) to be composed of individuals with appropriate expertise. Such Task Force shall review the scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of community preventive interventions for the purpose of developing recommendations, to be published in the Guide to Community Preventive Services (referred to in this section as the ‘Guide’), for individuals and organizations delivering population-based services, including primary care professionals, health care systems, professional societies, employers, community organizations, non-profit organizations, schools, governmental public health agencies, Indian tribes, tribal organizations and urban Indian organizations, medical groups, Congress and other policy-makers. Community preventive services include any policies, programs, processes or activities designed to affect or otherwise affecting health at the population level.

Sec. 4004. Education and outreach campaign regarding preventive benefits.

Subtitle B—Increasing Access to Clinical Preventive Services

Sec. 4101. School-based health centers.

Sec. 4102. Oral healthcare prevention activities.

Sec. 4103. Medicare coverage of annual wellness visit providing a personalized prevention plan.

- Provides Medicare coverage of an annual personal prevention plan that includes a health assessment of the individual. Such assessment may include a screening schedule for the next 5 to 10 years as appropriate based on recommendations of the U.S. Preventive Services Task Force and the Advisory Committee on Immunization Practices, and the individual’s health status, screening history, and age-appropriate preventive services covered under Medicare.

Sec. 4104. Removal of barriers to preventive services in Medicare.

- Waives copays and deductibles for certain preventive services.

Sec. 4105. Evidence-based coverage of preventive services in Medicare.

Sec. 4106. Improving access to preventive services for eligible adults in Medicaid.

Sec. 4107. Coverage of comprehensive tobacco cessation services for pregnant women in Medicaid.

- Requires Medicaid coverage of counseling and pharmacotherapy (including prescription and non-prescription FDA approved tobacco cessation agents) for cessation of tobacco use by pregnant women.
- The services are furnished
 - By or under the supervision of a physician; or
 - By any other health care professional who
 - Is legally authorized to furnish such services under State law (or other State regulatory mechanism provided by State law) of the State in which the services are furnished; and
 - Is authorized to receive payment for other services under this title or is designated by the Secretary for this purpose.

- Removes cost-sharing for these services and products.

Sec. 4108. Incentives for prevention of chronic diseases in Medicaid.

- The Secretary shall award grants to States to carry out initiatives to provide incentives to Medicaid beneficiaries who
 - Successfully participate in a program described below; and
 - Upon completion of such program demonstrate changes in health risk and outcomes, including the adoption and maintenance of healthy behaviors by meeting specific targets.
- A program described in this paragraph is a comprehensive, evidence based, widely available, and easily accessible program, proposed by the State and approved by the Secretary, that is designed and uniquely suited to address the needs of Medicaid beneficiaries and has demonstrated success in helping individuals achieve one or more of the following:
 - Ceasing use of tobacco products.
 - Controlling or reducing their weight.
 - Lowering their cholesterol.
 - Lowering their blood pressure.
 - Avoiding the onset of diabetes or, in the case of a diabetic, improving the management of that condition.

Subtitle C—Creating Healthier Communities

Sec. 4201. Community transformation grants.

- The Secretary, acting through the Director of the CDC, shall award competitive grants to State and local governmental agencies and community-based organizations for the implementation, evaluation, and dissemination of evidence-based community preventive health activities in order to reduce chronic disease rates, prevent the development of secondary conditions, address health disparities, and develop a stronger evidence-base of effective prevention programming.
- Activities within a plan may focus on (but not be limited to):
 - creating healthier school environments, including increasing healthy food options, physical activity opportunities, promotion of healthy lifestyle, emotional wellness, and prevention curricula, and activities to prevent chronic diseases;
 - creating the infrastructure to support active living and access to nutritious foods in a safe environment;
 - developing and promoting programs targeting a variety of age levels to increase access to nutrition, physical activity and smoking cessation, improve social and emotional wellness, enhance safety in a community, or address any other chronic disease priority area identified by the grantee;
 - assessing and implementing worksite wellness programming and incentives;
 - working to highlight healthy options at restaurants and other food venues;
 - prioritizing strategies to reduce racial and ethnic disparities, including social, economic, and geographic determinants of health; and
 - addressing special populations needs, including all age groups and individuals with disabilities, and individuals in both urban and rural areas.

Sec. 4202. Healthy aging, living well; evaluation of community-based prevention and wellness programs for Medicare beneficiaries.

- The Secretary, acting through the CDC Director, shall award grants to State or local health departments and Indian tribes to carry out 5-year pilot programs to provide public health community interventions, screenings, and where necessary, clinical referrals for individuals who are between 55 and 64 years of age.
 - A State or local health department shall use the funds to conduct
 - Public health interventions such as efforts to improve nutrition, increase physical activity, reduce tobacco use and substance abuse, improve mental health, and promote healthy lifestyles among the target population.
 - A State or local health department shall enter into contracts with community health centers or rural health clinics and mental health and substance use disorder service providers to assist in the referral/treatment of at risk patients to community resources for clinical follow-up and help determine eligibility for other public programs.
 - Community preventive screenings to identify risk factors for cardiovascular disease, cancer, stroke, and diabetes.
- The Secretary shall conduct an evaluation of community-based prevention and wellness programs and develop a plan for promoting healthy lifestyles and chronic disease self-management for Medicare beneficiaries.

Sec. 4203. Removing barriers and improving access to wellness for individuals with disabilities.

Sec. 4204. Immunizations.

- The Secretary may negotiate and enter into contracts with manufacturers of vaccines for the purchase and delivery of vaccines for adults as provided under subsection (e).
- A State may obtain additional quantities of such adult vaccines through the purchase of vaccines from manufacturers at the applicable price negotiated by the Secretary under this subsection.
- The Secretary, acting through the CDC Director shall establish a demonstration program to award grants to States to improve the provision of recommended immunizations for children, adolescents, and adults through the use of evidence-based, population-based interventions for high-risk populations.
 - Funds received under a grant under this subsection shall be used to implement interventions that are recommended by the Task Force on Community Preventive Services (as established by the Secretary, acting through the Director of the Centers for Disease Control and Prevention) or other evidence-based interventions, including:
 - (A) providing immunization reminders or recalls for target populations of clients, patients, and consumers;
 - (B) educating targeted populations and health care providers concerning immunizations in combination with one or more other interventions;
 - (C) reducing out-of-pocket costs for families for vaccines and their administration;
 - (D) carrying out immunization-promoting strategies for participants or clients of public programs, including assessments of immunization status, referrals to health care providers, education, provision of on-site immunizations, or incentives for immunization;
 - (E) providing for home visits that promote immunization through education, assessments of need, referrals, provision of immunizations, or other services;
 - (F) providing reminders or recalls for immunization providers;

- (G) conducting assessments of, and providing feedback to, immunization providers;
- (H) any combination of one or more interventions described in this paragraph; or
- (I) immunization information systems to allow all States to have electronic databases for immunization records.

Sec. 4205. Nutrition labeling of standard menu items at chain restaurants.

Sec. 4206. Demonstration project concerning individualized wellness plan.

Sec. 4207. Reasonable break time for nursing mothers.

Subtitle D—Support for Prevention and Public Health Innovation

Sec. 4301. Research on optimizing the delivery of public health services.

Sec. 4302. Understanding health disparities: data collection and analysis.

Sec. 4303. CDC and employer-based wellness programs.

- Directs the Secretary to provide employers with technical assistance, consultation, tools, and other resources in evaluating such employers' employer-based wellness program including:
 - (A) measuring the participation and methods to increase participation of employees in such programs;
 - (B) developing standardized measures that assess policy, environmental and systems changes necessary to have a positive health impact on employees' health behaviors, health outcomes, and health care expenditures; and
 - (C) evaluating such programs as they relate to changes in the health status of employees, the absenteeism of employees, the productivity of employees, the rate of workplace injury, and the medical costs incurred by employees.

Sec. 4304. Epidemiology-Laboratory Capacity Grants.

Sec. 4305. Advancing research and treatment for pain care management.

- The Secretary shall seek to enter into an agreement with the IOM to convene a Conference on Pain to:
 - (A) increase the recognition of pain as a significant public health problem in the United States;
 - (B) evaluate the adequacy of assessment, diagnosis, treatment, and management of acute and chronic pain in the general population, and in identified racial, ethnic, gender, age, and other demographic groups that may be disproportionately affected by inadequacies in the assessment, diagnosis, treatment, and management of pain;
 - (C) identify barriers to appropriate pain care;
 - (D) establish an agenda for action in both the public and private sectors that will reduce such barriers and significantly improve the state of pain care research, education, and clinical care in the United States.
- The Director of NIH is encouraged to continue and expand, through the Pain Consortium, an aggressive program of basic and clinical research on the causes of and potential treatments for pain.
 - Not less than annually, the Pain Consortium, in consultation with the Division of Program Coordination, Planning, and Strategic Initiatives, shall develop and submit to the Director of NIH recommendations on appropriate pain research initiatives that could be

undertaken with funds reserved under section 402A(c)(1) for the Common Fund or otherwise available for such initiatives.

- The Secretary shall establish not later than 1 year after the date of the enactment of this section and as necessary maintain a committee, to be known as the Interagency Pain Research Coordinating Committee, to coordinate all efforts within the Department of Health and Human Services and other Federal agencies that relate to pain research.
- The Committee shall be composed of the following voting members:
 - (i) Not more than 7 voting Federal representatives appoint by the Secretary from agencies that conduct pain care research and treatment.
 - ii) 12 additional voting members appointed under subparagraph (B).
 - The Committee shall include additional voting members appointed by the Secretary as follows:
 - 6 non-Federal members shall be appointed from among scientists, physicians, and other health professionals.
 - 6 members shall be appointed from members of the general public, who are representatives of leading research, advocacy, and service organizations for individuals with pain-related conditions.
 - The Committee shall include such nonvoting members as the Secretary determines to be appropriate.
- The Committee shall:
 - (A) develop a summary of advances in pain care research supported or conducted by the Federal agencies relevant to the diagnosis, prevention, and treatment of pain and diseases and disorders associated with pain;
 - (B) identify critical gaps in basic and clinical research on the symptoms and causes of pain;
 - (C) make recommendations to ensure that the activities of the National Institutes of Health and other Federal agencies are free of unnecessary duplication of effort;
 - (D) make recommendations on how best to disseminate information on pain care; and
 - (E) make recommendations on how to expand partnerships between public entities and private entities to expand collaborative, crosscutting research.
- The Secretary may make awards of grants, cooperative agreements, and contracts to health professions schools, hospices, and other public and private entities for the development and implementation of programs to provide education and training to health care professionals in pain care.
 - An award may be made under subsection (a) only if the applicant for the award agrees that the program carried out with the award will include information and education on:
 - (1) recognized means for assessing, diagnosing, treating, and managing pain and related signs and symptoms, including the medically appropriate use of controlled substances;
 - (2) applicable laws, regulations, rules, and policies on controlled substances, including the degree to which misconceptions and concerns regarding such laws, regulations, rules, and policies, or the enforcement thereof, may create barriers to patient access to appropriate and effective pain care;

- (3) interdisciplinary approaches to the delivery of pain care, including delivery through specialized centers providing comprehensive pain care treatment expertise;
- (4) cultural, linguistic, literacy, geographic, and other barriers to care in underserved populations; and
- (5) recent findings, developments, and improvements in the provision of pain care.

Sec. 4306. Funding for Childhood Obesity Demonstration Project.

Subtitle E—Miscellaneous Provisions

Sec. 4401. Sense of the Senate concerning CBO scoring.

Sec. 4402. Effectiveness of Federal health and wellness initiatives.

TITLE V—HEALTH CARE WORKFORCE
Subtitle A—Purpose and Definitions

Sec. 5001. Purpose.

Sec. 5002. Definitions.

Subtitle B—Innovations in the Health Care Workforce

Sec. 5101. National health care workforce commission.

- Establishes the National Health Care Workforce Commission whose purpose includes
 - Developing and commissioning evaluations of education and training activities to determine whether the demand for health care workers is being met; and
 - Identifying barriers to improved coordination at the Federal, State and local levels and recommending ways to address such barriers.
- Members of the Commission include providers of health care services.
- Specific topics to be reviewed include:
 - Current health care workforce supply and distribution;
 - Health care workforce education and training capacity; the education and training infrastructure; and the education and training demands;
 - The education loan and grant programs;
 - The implications of new and existing federal policies which affect the health care workforce;
 - The health care workforce needs of special populations; and
 - Recommendations creating or revising national loan repayment programs and scholarship programs to require low-income, minority medical students to serve in their home communities, if designated a medical underserved community.
- Defines health care workforce as “all health care providers with direct patient care and support responsibilities, such as physicians, nurses...pharmacists...”
- Defines health professionals as including:

- “dentists, nurses...clinical pharmacists...”
- National representatives of health professionals;
- Representatives of “schools of medicine...nursing...pharmacists...”
- Representatives of public and private teaching hospitals, and ambulatory health facilities, including Federal medical facilities; and
- Any other health professional the Comptroller General determines appropriate.

Sec. 5102. State health care workforce development grants.

Sec. 5103. Health care workforce assessment.

- The Secretary shall establish the National Center for Health Workforce Analysis.
- The Center shall collaborate with Federal agencies and relevant professional and education organizations or societies to link data regarding grants awarded under this title.

Subtitle C—Increasing the Supply of the Health Care Workforce

Sec. 5201. Federally supported student loan funds.

Sec. 5202. Nursing student loan program.

Sec. 5203. Health care workforce loan repayment programs.

Sec. 5204. Public health workforce recruitment and retention programs.

- Establishes the Public Health Workforce Loan Repayment Program to assure an adequate supply of public health professionals to eliminate critical public health workforce shortages in Federal, State, local and tribal public health agencies.
- To be eligible to participate, an individual shall
 - Be accepted for enrollment or be enrolled as a student in an accredited academic educational institution in a State or territory in the final year of a course of study or program leading to a public health or health professions degree or certificate; and have accepted employment with a Federal, State, local, or tribal public health agency, or a related training fellowship, as recognized by the Secretary, to commence upon graduation;
 - have graduated, during the preceding 10-year period, from an accredited educational institution in a State or territory and received a public health or health professions degree or certificate; and
 - be employed by, or have accepted employment with, a Federal, State, local, or tribal public health agency or a related training fellowship, as recognized by the Secretary;
 - be a United States citizen; and
 - submit an application to the Secretary to participate in the Program;
 - execute a written contract as required in subsection (c); and
 - not have received, for the same service, a reduction of loan obligations under section 455(m), 428J, 428K, 428L, or 460 of the Higher Education Act of 1965.

Sec. 5205. Allied health workforce recruitment and retention programs.

- The purpose of this section is to assure an adequate supply of allied health professionals to eliminate critical allied health workforce shortages in Federal, State, local, and tribal public health agencies or in settings where patients might require health care services, including acute care facilities, ambulatory care facilities, personal residences and other settings, as recognized by the Secretary by authorizing an Allied Health Loan Forgiveness Program.

- The term ‘allied health professional’ means an allied health professional as defined in section 799B(5) of the Public Health Service Act (42 U.S.C. 295p(5)) who:
 - (A) has graduated and received an allied health professions degree or certificate from an institution of higher education; and
 - (B) is employed with a Federal, State, local or tribal public health agency, or in a setting where patients might require health care services, including acute care facilities, ambulatory care facilities, personal residences and other settings located in health professional shortage areas, medically underserved areas, or medically underserved populations, as recognized by the Secretary,

Sec. 5206. Grants for State and local programs.

- The Secretary may make grants to, or enter into contracts with, any eligible entity to award scholarships to eligible individuals to enroll in degree or professional training programs for the purpose of enabling mid-career professionals in the public health and allied health workforce to receive additional training in the field of public health and allied health.
- The term ‘eligible entity’ indicates an accredited educational institution that offers a course of study, certificate program, or professional training program in public or allied health or a related discipline, as determined by the Secretary
- The term ‘eligible individuals’ includes those individuals employed in public and allied health positions at the Federal, State, tribal, or local level who are interested in retaining or upgrading their education.

Sec. 5207. Funding for National Health Service Corps.

Sec. 5208. Nurse-managed health clinics.

Sec. 5209. Elimination of cap on commissioned corps.

Sec. 5210. Establishing a Ready Reserve Corps.

Subtitle D—Enhancing Health Care Workforce Education and Training

Sec. 5301. Training in family medicine, general internal medicine, general pediatrics, and physician assistantship.

- The Secretary may make grants to or enter into contracts with accredited schools of medicine or osteopathic medicine to establish, maintain, or improve:
 - (A) academic units or programs that improve clinical teaching and research in fields defined in subsection (a)(1)(A); or
 - (B) programs that integrate academic administrative units in fields defined in subsection (a)(1)(A) to enhance interdisciplinary recruitment, training, and faculty development.
- In awarding the above grants, the Secretary shall give priority to qualified applicants that:
 - (A) proposes a collaborative project between academic administrative units of primary care;
 - (B) proposes innovative approaches to clinical teaching using models of primary care, such as the patient centered medical home, team management of chronic disease, and interprofessional integrated models of health care that incorporate transitions in health care settings and integration physical and mental health provision;
 - (C) have a record of training the greatest percentage of providers, or that have demonstrated significant improvements in the percentage of providers trained, who enter and remain in primary care practice;

- (D) have a record of training individuals who are from underrepresented minority groups or from a rural or disadvantaged background;
- (E) provide training in the care of vulnerable populations such as children, older adults, homeless individuals, victims of abuse or trauma, individuals with mental health or substance-related disorders, individuals with HIV/AIDS, and individuals with disabilities;
- (F) establish formal relationships and submit joint applications with federally qualified health centers, rural health clinics, area health education centers, or clinics located in underserved areas or that serve underserved populations;
- (G) teach trainees the skills to provide interprofessional, integrated care through collaboration among health professionals;
- (H) provide training in enhanced communication with patients, evidence-based practice, chronic disease management, preventive care, health information technology, or other competencies as recommended by the Advisory Committee on Training in Primary Care Medicine and Dentistry and the National Health Care Workforce Commission established in section 5101 of the Patient Protection and Affordable Care Act; or
- (I) provide training in cultural competency and health literacy.

Sec. 5302. Training opportunities for direct care workers.

Sec. 5303. Training in general, pediatric, and public health dentistry.

Sec. 5304. Alternative dental health care providers demonstration project.

Sec. 5305. Geriatric education and training; career awards; comprehensive geriatric education.

- A geriatric education center that receives an award under this subsection shall use such funds to offer short-term intensive courses that focus on geriatrics, chronic care management, and long-term care that provide supplemental training for faculty members in medical schools and other health professions schools with programs in psychology, pharmacy, nursing, social work, dentistry, public health, allied health, or other health disciplines, as approved by the Secretary.
- Such a fellowship shall be open to current faculty, and appropriately credentialed volunteer faculty and practitioners, who do not have formal training in geriatrics, to upgrade their knowledge and clinical skills for the care of older adults and adults with functional limitations and to enhance their interdisciplinary teaching skills.
- The Secretary shall award grants or contracts under this section to individuals described in paragraph (2) to foster greater interest among a variety of health professionals in entering the field of geriatrics, long-term care, and chronic care management.
 - To be eligible to received an award under paragraph (1), an individual shall:
 - (A) be an advanced practice nurse, a clinical social worker, a pharmacist, or student of psychology who is pursuing a doctorate or other advanced degree in geriatrics or related fields in an accredited health professions school; and
 - (B) submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.
- Expands eligibility for geriatric academic career awards. Amends the Public Health Service Act regarding eligible individuals:
 - to receive an Award under paragraph (1), an individual shall:
 - (A) be board certified or board eligible in internal medicine, family practice, psychiatry, or licensed dentistry, or have completed any required training in a discipline and employed in an accredited health professions school that is approved by the Secretary

- (B) have completed an approved fellowship program in geriatrics or have completed specialty training in geriatrics as required by the discipline and any addition geriatrics training as required by the Secretary; and
- (C) have a junior (non-tenured) faculty appointment at an accredited (as determined by the Secretary) school of medicine, osteopathic medicine, nursing, social work, psychology, dentistry, pharmacy, or other allied health disciplines in an accredited health professions school that is approved by the Secretary.

Sec. 5306. Mental and behavioral health education and training grants.

Sec. 5307. Cultural competency, prevention, and public health and individuals with disabilities training.

- In carrying out this subsection, the Secretary shall collaborate with health professional societies, licensing and accreditation entities, health professions schools, and experts in minority health and cultural competency, prevention, and public health and disability groups, community-based organizations, and other organizations as determined appropriate by the Secretary. The Secretary shall coordinate with curricula and research and demonstration projects developed under section 807.

Sec. 5308. Advanced nursing education grants.

Sec. 5309. Nurse education, practice, and retention grants.

Sec. 5310. Loan repayment and scholarship program.

Sec. 5311. Nurse faculty loan program.

Sec. 5312. Authorization of appropriations for parts B through D of title VIII.

Sec. 5313. Grants to promote the community health workforce.

Sec. 5314. Fellowship training in public health.

Sec. 5315. United States Public Health Sciences Track.

- Authorizes to be established a United States Public Health Sciences Track, at sites to be selected by the Secretary, with authority to grant appropriate advanced degrees in a manner that uniquely emphasizes team based service, public health, epidemiology, and emergency preparedness and response. It shall be so organized as to graduate not less than:
 - (A) 150 medical students annually, 10 of whom shall be awarded studentships to the Uniformed Services University of Health Sciences;
 - (B) 100 dental students annually;
 - (C) 250 nursing students annually;
 - (D) 100 public health students annually;
 - (E) 100 behavioral and mental health professional students annually;
 - (F) 100 physician assistant or nurse practitioner students annually; and
 - (G) 50 pharmacy students annually.
- Medical, dental, physician assistant, pharmacy, behavioral and mental health, public health, and nursing students at the Track shall be selected under procedures prescribed by the Surgeon General. In so prescribing, the Surgeon General shall consider the recommendations of the National Health Care Workforce Commission.
 - In developing such admissions procedures, the Surgeon General shall ensure that such procedures give priority to applicant medical, dental, physician assistant, pharmacy, behavioral and mental health, public health, and nursing students from rural communities and underrepresented minorities.
- Upon being admitted to the Track, a medical, dental, physician assistant, pharmacy, behavioral and mental health, public health, or nursing student shall enter into a written contract with the Surgeon General that shall contain:

- (A) an agreement under which:
 - (i) subject to subparagraph (B), the Surgeon General agrees to provide the student with tuition (or tuition remission) and a student stipend in each school year for a period of years (not to exceed 4 school years) determined by the student, during which period the student is enrolled in the Track at an affiliated or other participating health professions institution pursuant to an agreement between the Track and such institution; and
 - (ii) subject to subparagraph (B), the student agrees:
 - (I) to accept the provision of such tuition and student stipend to the student;
 - (II) to maintain enrollment at the Track until the student completes the course of study involved;
 - (III) while enrolled in such course of study, to maintain an acceptable level of academic standing;
 - (IV) if pursuing a degree from a school of medicine or osteopathic medicine, dental, public health, or nursing school or a physician assistant, pharmacy, or behavioral and mental health professional program, to complete a residency or internship in a specialty that the Surgeon General determines is appropriate; and
 - (V) to serve for a period of time within the Commissioned Corps of the Public Health Service equal to 2 years for each school year during which such individual was enrolled at the College, reduced as provided for in paragraph (3);
- (B) a provision that any financial obligation of the United States arising out of a contract entered into under this part and any obligation of the student which is conditioned thereon, is contingent upon funds being appropriated to carry out this part;
- (C) a statement of the damages to which the United States is entitled for the student's breach of the contract; and
- (D) such other statements of the rights and liabilities of the Secretary and of the individual, not inconsistent with the provisions of this part.
- The Surgeon General, based on the recommendations of the National Health Care Workforce Commission, shall establish Federal tuition remission rates to be used by the Track to provide reimbursement to affiliated and other participating health professions institutions for the cost of educational services provided by such institutions to Track students. The agreement entered into by such participating institutions under paragraph (1)(A)(i) shall contain an agreement to accept as payment in full the established remission rate under this subparagraph.
 - The Surgeon General, based on the recommendations of the National Health Care Workforce Commission, shall establish and update Federal stipend rates for payment to students under this part.
- The period of obligated service under paragraph (1)(A)(ii)(V) shall be reduced:
 - (A) in the case of a student who elects to participate in a high-needs specialty residency by 3 months for each year of such participation (not to exceed a total of 12 months); and
 - (B) in the case of a student who, upon completion of their residency, elects to practice in a Federal medical facility that is located in a health professional shortage area, by 3 months for year of full-time practice in such a facility (not to exceed a total of 12 months).

- During the third and fourth years in which a medical, dental, physician assistant, pharmacy, behavioral and mental health, public health, or nursing student is enrolled in the Track, training should be designed to prioritize clinical rotations in Federal medical facilities in health professional shortage areas, and emphasize a balance of hospital and community-based experiences, and training within interdisciplinary teams.
- The Surgeon General shall establish provisions applicable with respect to dental, physician assistant, pharmacy, behavioral and mental health, public health, and nursing students that are comparable to those for medical students under this section, including service obligations, tuition support, and stipend support. The Surgeon General shall give priority to health professions training institutions that train medical, dental, physician assistant, pharmacy, behavioral and mental health, public health, and nursing students for some significant period of time together, but at a minimum have a discrete and shared core curriculum.
- The Surgeon General, in consultation with the Secretary, the Director of the Centers for Disease Control and Prevention, and other appropriate military and Federal government agencies, shall develop criteria for the appointment of highly qualified Track faculty, medical, dental, physician assistant, pharmacy, behavioral and mental health, public health, and nursing students, and graduates to elite Federal disaster preparedness teams to train and to respond to public health emergencies, natural disasters, bioterrorism events, and other emergencies.
- A medical, dental, physician assistant, pharmacy, behavioral and mental health, public health, or nursing student who, under regulations prescribed by the Surgeon General, is dropped from the Track in an affiliated school for deficiency in conduct or studies, or for other reasons, shall be liable to the United States for all tuition and stipend support provided to the student.

Subtitle E—Supporting the Existing Health Care Workforce

Sec. 5401. Centers of excellence.

- Provides grant monies for health professions schools that meet certain conditions.

Sec. 5402. Health care professionals training for diversity.

Sec. 5403. Interdisciplinary, community-based linkages.

- The Secretary shall make the following 2 types of awards in accordance with this section:
 - (1) INFRASTRUCTURE DEVELOPMENT AWARD.—The Secretary shall make awards to eligible entities to enable such entities to initiate health care workforce educational programs or to continue to carry out comparable programs that are operating at the time the award is made by planning, developing, operating, and evaluating an area health education center program.
 - (2) POINT OF SERVICE MAINTENANCE AND ENHANCEMENT AWARD.—The Secretary shall make awards to eligible entities to maintain and improve the effectiveness and capabilities of an existing area health education center program, and make other modifications to the program that are appropriate due to changes in demographics, needs of the populations served, or other similar issues affecting the area health education center program.
- An eligible entity shall use amounts awarded under a grant to carry out various activities, including:
 - (A) Conduct and participate in interdisciplinary training that involves physicians, physician assistants, nurse practitioners, nurse midwives, dentists, psychologists,

pharmacists, optometrists, community health workers, public and allied health professionals, or other health professionals, as practicable.

- The Secretary shall make grants to, and enter into contracts with, eligible entities to improve health care, increase retention, increase representation of minority faculty members, enhance the practice environment, and provide information dissemination and educational support to reduce professional isolation through the timely dissemination of research findings using relevant resources.
 - For purposes of this section, the term ‘eligible entity’ means an entity described in **section 799(b)**.

Sec. 5404. Workforce diversity grants.

Sec. 5405. Primary care extension program.

Subtitle F—Strengthening Primary Care and Other Workforce Improvements

Sec. 5501. Expanding access to primary care services and general surgery services.

Sec. 5502. Medicare Federally qualified health center improvements.

- The Secretary shall develop a prospective payment system for payment for Federally qualified health services furnished by Federally qualified health centers under this title. Such system shall include a process for appropriately describing the services furnished by Federally qualified health centers.

Sec. 5503. Distribution of additional residency positions.

Sec. 5504. Counting resident time in outpatient settings and allowing flexibility for jointly operated residency training programs.

Sec. 5505. Rules for counting resident time for didactic and scholarly activities and other activities.

Sec. 5506. Preservation of resident cap positions from closed hospitals.

Sec. 5507. Demonstration projects To address health professions workforce needs; extension of family-to-family health information centers.

- The Secretary, in consultation with the Secretary of Labor, shall award grants to eligible entities to conduct demonstration projects that are designed to provide low income eligible individuals with the opportunity to obtain education and training for occupations in the health care field that pay well and are expected to either experience labor shortages or be in high demand.

Sec. 5508. Increasing teaching capacity.

Sec. 5509. Graduate nurse education demonstration.

Subtitle G—Improving Access to Health Care Services

Sec. 5601. Spending for Federally Qualified Health Centers (FQHCs).

Sec. 5602. Negotiated rulemaking for development of methodology and criteria for designating medically underserved populations and health professions shortage areas.

Sec. 5603. Reauthorization of the Wakefield Emergency Medical Services for Children Program.

Sec. 5604. Co-locating primary and specialty care in community-based mental health settings.

Sec. 5605. Key National indicators.

Subtitle H—General Provisions

Sec. 5701. Reports.

TITLE VI—TRANSPARENCY AND PROGRAM INTEGRITY Subtitle A—Physician Ownership and Other Transparency

Sec. 6001. Limitation on Medicare exception to the prohibition on certain physician referrals for hospitals.

Sec. 6002. Transparency reports and reporting of physician ownership or investment interests.

Sec. 6003. Disclosure requirements for in-office ancillary services exception to the prohibition on physician self-referral for certain imaging services.

Sec. 6004. Prescription drug sample transparency.

- Not later than April 1 of each year (beginning with 2012), each manufacturer and authorized distributor of record of an applicable drug shall submit to the Secretary (in a form and manner specified by the Secretary) the following information with respect to the preceding year:
 - (1) In the case of a manufacturer or authorized distributor of record which makes distributions by mail or common carrier under subsection (d)(2) of section 503 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353), the identity and quantity of drug samples requested and the identity and quantity of drug samples distributed under such subsection during that year, aggregated by:
 - (A) the name, address, professional designation, and signature of the practitioner making the request under subparagraph (A)(i) of such subsection, or of any individual who makes or signs for the request on behalf of the practitioner; and
 - (B) any other category of information determined appropriate by the Secretary.
 - (2) In the case of a manufacturer or authorized distributor of record which makes distributions by means other than mail or common carrier under subsection (d)(3) of such section 503, the identity and quantity of drug samples requested and the identity and quantity of drug samples distributed under such subsection during that year, aggregated by:
 - (A) the name, address, professional designation, and signature of the practitioner making the request under subparagraph (A)(i) of such subsection, or of any individual who makes or signs for the request on behalf of the practitioner; and
 - (B) any other category of information determined appropriate by the Secretary.
- The term ‘applicable drug’ means a drug:
 - which is subject to subsection (b) of such section 503; and
 - for which payment is available under title XVIII or a State plan under title XIX or XXI (or a waiver of such a plan).
- The term ‘authorized distributor of record’ has the meaning given that term in subsection (e)(3)(A) of such section.
- The term ‘manufacturer’ has the meaning given that term for purposes of subsection (d) of such section.

Sec. 6005. Pharmacy benefit managers transparency requirements.

- A health benefits plan or any entity that provides pharmacy benefits management services on behalf of a health benefits plan that manages prescription drug coverage under a contract with:
 - (1) a PDP sponsor of a prescription drug plan or an MA organization offering an MA–PD plan under part D of title XVIII; or
 - (2) a qualified health benefits plan offered through an exchange established by a State under section 1311 of the Patient Protection and Affordable Care Act, shall provide the information described in subsection (b) to the Secretary and, in the case of a PBM, to the plan with which the PBM is under contract with, at such times, and in such form and manner, as the Secretary shall specify.
- The information described in this subsection is the following with respect to services provided by a health benefits plan or PBM for a contract year:
 - (1) The percentage of all prescriptions that were provided through retail pharmacies compared to mail order pharmacies, and the percentage of prescriptions for which a generic drug was available and dispensed (generic dispensing rate), by pharmacy type (which includes an independent pharmacy, chain pharmacy, supermarket pharmacy, or mass merchandiser pharmacy that is licensed as a pharmacy by the State and that dispenses medication to the general public), that is paid by the health benefits plan or PBM under the contract.
 - (2) The aggregate amount, and the type of rebates, discounts, or price concessions (excluding bona fide service fees, which include but are not limited to distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative services agreements and patient care programs (such as medication compliance programs and patient education programs)) that the PBM negotiates that are attributable to patient utilization under the plan, and the aggregate amount of the rebates, discounts, or price concessions that are passed through to the plan sponsor, and the total number of prescriptions that were dispensed.
 - (3) The aggregate amount of the difference between the amount the health benefits plan pays the PBM and the amount that the PBM pays retail pharmacies, and mail order pharmacies, and the total number of prescriptions that were dispensed.
- Information disclosed by a health benefits plan or PBM under this section is confidential and shall not be disclosed by the Secretary or by a plan receiving the information, except that the Secretary may disclose the information in a form which does not disclose the identity of a specific PBM, plan, or prices charged for drugs, for the following purposes:
 - (1) As the Secretary determines to be necessary to carry out this section or part D of title XVIII.
 - (2) To permit the Comptroller General to review the information provided.
 - (3) To permit the Director of the Congressional Budget Office to review the information provided.
 - (4) To States to carry out section 1311 of the Patient Protection and Affordable Care Act.
- The provisions of subsection (b)(3)(C) of section 1927 shall apply to a health benefits plan or PBM that fails to provide information required under subsection (a) on a timely basis or that knowingly provides false information in the same manner as such provisions apply to a manufacturer with an agreement under that section.

Subtitle B—Nursing Home Transparency and Improvement
PART I—IMPROVING TRANSPARENCY OF INFORMATION

- Sec. 6101. Required disclosure of ownership and additional disclosable parties' information.
- Sec. 6102. Accountability requirements for skilled nursing facilities and nursing facilities.
- Sec. 6103. Nursing home compare Medicare website.
- Sec. 6104. Reporting of expenditures.
- Sec. 6105. Standardized complaint form.
- Sec. 6106. Ensuring staffing accountability.
- Sec. 6107. GAO study and report on Five-Star Quality Rating System.

PART II—TARGETING ENFORCEMENT

- Sec. 6111. Civil money penalties.
- Sec. 6112. National independent monitor demonstration project.
- Sec. 6113. Notification of facility closure.
- Sec. 6114. National demonstration projects on culture change and use of information technology in nursing homes.

PART III—IMPROVING STAFF TRAINING

- Sec. 6121. Dementia and abuse prevention training.

**Subtitle C—Nationwide Program for National and State Background Checks
on Direct Patient Access Employees of Long-term Care Facilities and Providers**

- Sec. 6201. Nationwide program for National and State background checks on direct patient access employees of long-term care facilities and providers.

Subtitle D—Patient-Centered Outcomes Research

- Sec. 6301. Patient-Centered Outcomes Research.
 - There is authorized to be established a nonprofit corporation, to be known as the 'Patient-Centered Outcomes Research Institute' which is neither an agency nor establishment of the United States Government.
 - The purpose of the Institute is to assist patients, clinicians, purchasers, and policy-makers in making informed health decisions by advancing the quality and relevance of evidence concerning the manner in which diseases, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed through research and evidence synthesis that considers variations in patient subpopulations, and the dissemination

of research findings with respect to the relative health outcomes, clinical effectiveness, and appropriateness of the medical treatments, services, and items described in subsection (a)(2)(B).

- The Institute shall have a Board of Governors, which shall consist of the following members:
 - (A) The Director of Agency for Healthcare Research and Quality.
 - (B) The Director of the National Institutes of Health.
 - (C) Seventeen members appointed, not later than 6 months after the date of enactment of this section, by the Comptroller General of the United States as follows:
 - (i) 3 members representing patients and health care consumers.
 - (ii) 5 members representing physicians and providers, including at least 1 surgeon, nurse, State-licensed integrative health care practitioner, and representative of a hospital.
 - (iii) 3 members representing private payers, of whom at least 1 member shall represent health insurance issuers and at least 1 member shall represent employers who self-insure employee benefits.
 - (iv) 3 members representing pharmaceutical, device, and diagnostic manufacturers or developers.
 - (v) 1 member representing quality improvement or independent health service researchers.
 - (vi) 2 members representing the Federal Government or the States, including at least 1 member representing a Federal health program or agency.
- The Board shall represent a broad range of perspectives and collectively have scientific expertise in clinical health sciences research, including epidemiology, decisions sciences, health economics, and statistics. In appointing the Board, the Comptroller General of the United States shall consider and disclose any conflicts of interest in accordance with subsection (h)(4)(B).

Sec. 6302. Federal coordinating council for comparative effectiveness research.

Subtitle E—Medicare, Medicaid, and CHIP Program Integrity Provisions

Sec. 6401. Provider screening and other enrollment requirements under Medicare, Medicaid, and CHIP.

- Not later than 180 days after the date of enactment of this paragraph, the Secretary, in consultation with the Inspector General of the Department of Health and Human Services, shall establish procedures under which screening is conducted with respect to providers of medical or other items or services and suppliers under the program under this title, the Medicaid program under title XIX, and the CHIP program under title XXI.
- The Secretary shall determine the level of screening conducted under this paragraph according to the risk of fraud, waste, and abuse, as determined by the Secretary, with respect to the category of provider of medical or other items or services or supplier. Such screening:
 - (i) shall include a licensure check, which may include such checks across States; and
 - (ii) may, as the Secretary determines appropriate based on the risk of fraud, waste, and abuse described in the preceding sentence, include:
 - (I) a criminal background check;
 - (II) fingerprinting;
 - (III) unscheduled and unannounced site visits, including pre-enrollment site visits;
 - (IV) database checks (including such checks across States); and
 - (V) such other screening as the Secretary determines appropriate.

- Except as provided in clause (iii), the Secretary shall impose a fee on each individual provider of medical or other items or services or supplier (such as a physician, physician assistant, nurse practitioner, or clinical nurse specialist) with respect to which screening is conducted under this paragraph in an amount equal to:
 - (I) for 2010, \$200; and
 - (II) for 2011 and each subsequent year, the amount determined under this clause for the preceding year, adjusted by the percentage change in the consumer price index for all urban consumers (all items; United States city average) for the 12-month period ending with June of the previous year.
- Except as provided in clause (iii), the Secretary shall impose a fee on each institutional provider of medical or other items or services or supplier (such as a hospital or skilled nursing facility) with respect to which screening is conducted under this paragraph in an amount equal to:
 - (I) for 2010, \$500; and
 - (II) for 2011 and each subsequent year, the amount determined under this clause for the preceding year, adjusted by the percentage change in the consumer price index for all urban consumers (all items; United States city average) for the 12-month period ending with June of the previous year.
- (iii) The Secretary may, on a case-by-case basis, exempt a provider of medical or other items or services or supplier from the imposition of an application fee under this subparagraph if the Secretary determines that the imposition of the application fee would result in a hardship. The Secretary may waive the application fee under this subparagraph for providers enrolled in a State Medicaid program for which the State demonstrates that imposition of the fee would impede beneficiary access to care.
- The Secretary shall establish procedures to provide for a provisional period of not less than 30 days and not more than 1 year during which new providers of medical or other items or services and suppliers, as the Secretary determines appropriate, including categories of providers or suppliers, would be subject to enhanced oversight, such as prepayment review and payment caps, under the program under this title, the Medicaid program under title XIX, and the CHIP program under title XXI.
- The Secretary may establish by program instruction or otherwise the procedures under this paragraph.
- A provider of medical or other items or services or supplier who submits an application for enrollment or revalidation of enrollment in the program under this title, title XIX, or title XXI on or after the date that is 1 year after the date of enactment of this paragraph shall disclose any current or previous affiliation (directly or indirectly) with a provider of medical or other items or services or supplier that has uncollected debt, has been or is subject to a payment suspension under a Federal health care program (as defined in section 1128B(f)), has been excluded from participation under the program under this title, the Medicaid program under title XIX, or the CHIP program under title XXI, or has had its billing privileges denied or revoked.
- If the Secretary determines that such previous affiliation poses an undue risk of fraud, waste, or abuse, the Secretary may deny such application. Such a denial shall be subject to appeal in accordance with paragraph (7).
- Notwithstanding any other provision of this title, in the case of an applicable provider of services or supplier, the Secretary may make any necessary adjustments to payments to the applicable provider of services or supplier under the program under this title in order to satisfy any past-due obligations described in subparagraph (B) (ii) of an obligated provider of services or supplier.

- The term ‘applicable provider of services or supplier’ means a provider of services or supplier that has the same taxpayer identification number assigned under section 6109 of the Internal Revenue Code of 1986 as is assigned to the obligated provider of services or supplier under such section, regardless of whether the applicable provider of services or supplier is assigned a different billing number or national provider identification number under the program under this title than is assigned to the obligated provider of services or supplier.
- The term ‘obligated provider of services or supplier’ means a provider of services or supplier that owes a past-due obligation under the program under this title (as determined by the Secretary).
- The Secretary may impose a temporary moratorium on the enrollment of new providers of services and suppliers, including categories of providers of services and suppliers, in the program under this title, under the Medicaid program under title XIX, or under the CHIP program under title XXI if the Secretary determines such moratorium is necessary to prevent or combat fraud, waste, or abuse under either such program.
- On or after the date of implementation determined by the Secretary under subparagraph (C), a provider of medical or other items or services or supplier within a particular industry sector or category shall, as a condition of enrollment in the program under this title, title XIX, or title XXI, establish a compliance program that contains the core elements established under subparagraph (B) with respect to that provider or supplier and industry or category.
- The Secretary, in consultation with the Inspector General of the Department of Health and Human Services, shall establish core elements for a compliance program under subparagraph (A) for providers or suppliers within a particular industry or category.
- Requires State Medicaid programs to comply with the above provisions.

Sec. 6402. Enhanced Medicare and Medicaid program integrity provisions.

- The Secretary may require a provider of services or supplier to provide the Secretary on a continuing basis with a surety bond in a form specific by the Secretary in an amount (not less than \$50,000) that the Secretary determines is commensurate with the volume of the billing of the provider of services or supplier. The Secretary may waive this requirement if the provider or supplier provides a comparable surety bond under State law.
- The Secretary may suspend payments to a provider of services or supplier under this title pending an investigation of a credible allegation of fraud against the provider of services or supplier, unless the Secretary determines there is good cause not to suspend such payments.

Sec. 6403. Elimination of duplication between the Healthcare Integrity and Protection Data Bank and the National Practitioner Data Bank.

Sec. 6404. Maximum period for submission of Medicare claims reduced to not more than 12 months.

Sec. 6405. Physicians who order items or services required to be Medicare enrolled physicians or eligible professionals.

Sec. 6406. Requirement for physicians to provide documentation on referrals to programs at high risk of waste and abuse.

Sec. 6407. Face to face encounter with patient required before physicians may certify eligibility for home health services or durable medical equipment under Medicare.

Sec. 6408. Enhanced penalties.

- Enhances penalties for making false statements or delaying inspections.
- Enhances penalties for Medicare Part D plan marketing violations.

Sec. 6409. Medicare self-referral disclosure protocol.

Sec. 6410. Adjustments to the Medicare durable medical equipment, prosthetics, orthotics, and supplies competitive acquisition program.

- Expands Round 2 of the DME competitive bidding program by including the next 21 largest metropolitan statistical areas by total population in the round.
- Requires the Secretary to either competitively bid areas or use competitive bid prices by 2016.

Sec. 6411. Expansion of the Recovery Audit Contractor (RAC) program.

Subtitle F—Additional Medicaid Program Integrity Provisions

Sec. 6501. Termination of provider participation under Medicaid if terminated under Medicare or other State plan.

Sec. 6502. Medicaid exclusion from participation relating to certain ownership, control, and management affiliations.

- Directs Medicaid to exclude, with respect to a period, any individual or entity from participation in the program under the State plan if such individual or entity owns, controls, or manages an entity that (or if such entity is owned, controlled, or managed by an individual or entity that):
 - has unpaid overpayments under this title during such period determined by the Secretary or the State agency to be delinquent;
 - is suspended or excluded from participation under or whose participation is terminated under this title during such period; or
 - is affiliated with an individual or entity that has been suspended or excluded from participation under this title or whose participation is terminated under this title during such period.

Sec. 6503. Billing agents, clearinghouses, or other alternate payees required to register under Medicaid.

Sec. 6504. Requirement to report expanded set of data elements under MMIS to detect fraud and abuse.

Sec. 6505. Prohibition on payments to institutions or entities located outside of the United States.

Sec. 6506. Overpayments.

Sec. 6507. Mandatory State use of national correct coding initiative.

Sec. 6508. General effective date.

Subtitle G—Additional Program Integrity Provisions

Sec. 6601. Prohibition on false statements and representations.

Sec. 6602. Clarifying definition.

Sec. 6603. Development of model uniform report form.

Sec. 6604. Applicability of State law to combat fraud and abuse.

Sec. 6605. Enabling the Department of Labor to issue administrative summary cease and desist orders and summary seizures orders against plans that are in financially hazardous condition.

Sec. 6606. MEWA plan registration with Department of Labor.

Sec. 6607. Permitting evidentiary privilege and confidential communications.

Subtitle H—Elder Justice Act

- Sec. 6701. Short title of subtitle.
- Sec. 6702. Definitions.
- Sec. 6703. Elder Justice.

Subtitle I—Sense of the Senate Regarding Medical Malpractice

- Sec. 6801. Sense of the Senate regarding medical malpractice.
 - Encourages states to develop and test alternatives to the existing 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.

TITLE VII—IMPROVING ACCESS TO INNOVATIVE MEDICAL THERAPIES
Subtitle A—Biologics Price Competition and Innovation

- Sec. 7001. Short title.
- Sec. 7002. Approval pathway for biosimilar biological products.
- Sec. 7003. Savings.

Subtitle B—More Affordable Medicines for Children and Underserved Communities

- Sec. 7101. Expanded participation in 340B program.
- Sec. 7102. Improvements to 340B program integrity.
- Sec. 7103. GAO study to make recommendations on improving the 340B program.

TITLE VIII—CLASS ACT

- Sec. 8001. Short title of title.
- Sec. 8002. Establishment of national voluntary insurance program for purchasing community living assistance services and support.

TITLE IX—REVENUE PROVISIONS
Subtitle A—Revenue Offset Provisions

- Sec. 9001. Excise tax on high cost employer-sponsored health coverage.
- Sec. 9002. Inclusion of cost of employer-sponsored health coverage on W-2.
- Sec. 9003. Distributions for medicine qualified only if for prescribed drug or insulin.

- Limits medication-related reimbursements from health savings accounts, Archer medical savings accounts, health flexible spending arrangements and health reimbursement arrangements to expenses incurred for prescribed drug or insulin.

Sec. 9004. Increase in additional tax on distributions from HSAs and Archer MSAs not used for qualified medical expenses.

Sec. 9005. Limitation on health flexible spending arrangements under cafeteria plans.

Sec. 9006. Expansion of information reporting requirements.

Sec. 9007. Additional requirements for charitable hospitals.

Sec. 9008. Imposition of annual fee on branded prescription pharmaceutical manufacturers and importers.

Sec. 9009. Imposition of annual fee on medical device manufacturers and importers.

Sec. 9010. Imposition of annual fee on health insurance providers.

Sec. 9011. Study and report of effect on veterans health care.

Sec. 9012. Elimination of deduction for expenses allocable to Medicare Part D subsidy.

Sec. 9013. Modification of itemized deduction for medical expenses.

Sec. 9014. Limitation on excessive remuneration paid by certain health insurance providers.

Sec. 9015. Additional hospital insurance tax on high-income taxpayers.

Sec. 9016. Modification of section 833 treatment of certain health organizations.

Sec. 9017. Excise tax on elective cosmetic medical procedures.

Subtitle B—Other Provisions

Sec. 9021. Exclusion of health benefits provided by Indian tribal governments.

Sec. 9022. Establishment of simple cafeteria plans for small businesses.

Sec. 9023. Qualifying therapeutic discovery project credit.