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Patient Protection and Affordable Coverage Act of 2010 as amended by the Health Care and Education Reconciliation Act of 2010

Congress has enacted, and the President signed into law on March 23, 2010, the Patient Protection and Affordable Coverage Act of 2010 ("PPACA" or the "Act"). Congress passed and the President signed into law on March 30, 2010 amendments to the Act in the Health Care and Education Reconciliation Act of 2010 (the "Reconciliation Act"). References to PPACA in this summary are to the law as amended by the Reconciliation Act, except as otherwise indicated.

PPACA is a far-reaching nationwide overhaul of health care financing and coverage, with many provisions also affecting the delivery of care. It expands on the individual and group market reforms of the Health Insurance Portability and Accountability Act of 1996 to provide greater access to health insurance, and seeks to create greater competition in the health insurance industry through the creation of State Exchanges. The Act establishes various incentives (including penalties) for insurers and health care providers to provide or arrange for health care more efficiently and effectively and imposes obligations on individuals to maintain health insurance.

This summary is organized by topic, paralleling the Act. Title X of the Act made changes to Titles I through IX. In most cases the Title X changes are summarized within the affected title. However, a number of the Title X changes are discussed separately at the end of this summary. We separately describe some distinct provisions of the Reconciliation Act not relating to or not covered in our summary of specific provisions of the Act.

PATIENT PROTECTION AND AFFORDABLE CARE ACT

RECONCILIATION ACT
Certain Revenue Provisions

Title I Coverage, Medicare, Medicaid and Revenues
Subtitle E – Provisions Relating to Revenue

TITLE I
QUALITY, AFFORDABLE HEALTH CARE FOR ALL AMERICANS

Subtitle A – Immediate Improvements in Health Care Coverage for All Americans- Effective upon enactment.

Except for Sections 1002 and 1003, which are effective March 23, 2010 (the date of the Act's enactment), this subtitle becomes effective for plan years beginning on or after September 23, 2010

Sec. 1001 Amendments to the Public Health Service Act

o Lifetime and annual limits. Group health plans and health insurance issuers offering group or individual coverage (collectively, "Plans") are prohibited from establishing lifetime limits and, beginning January 1, 2014, annual limits, on the dollar value of benefits. Prior to 2014, all such Plans may only establish a restricted annual limit on the dollar value of benefits with respect to essential health benefits (discussed below) as determined by the Secretary of the Department of Health and Human Services ("HHS"). In this determination, the Secretary must ensure access to needed services with minimal impact on premiums. Annual or lifetime beneficiary limits on specific covered benefits that are not "essential health benefits" are allowed to the extent they are otherwise permitted under federal or State law. *(References to the "Secretary" in this summary are to the Secretary of HHS, except where otherwise indicated).*

o Prohibition on rescissions. Plans are prohibited from rescinding coverage of an enrollee, except in instances where the individual has performed an act or practice that constitutes fraud or makes an intentional misrepresentation of material fact as prohibited by the terms of the plan or coverage. Prior notice must be provided in the event of cancellation due to fraud or misrepresentation.

o Coverage of preventive health services. Plans must at a minimum provide coverage, without any cost-sharing requirements, for preventive services and immunizations recommended by the U.S. Preventive Services Task Force and the CDC, certain child preventive services recommended by the Health Resources and Services Administration ("HRSA"), and women's preventive care and screening recommended by HRSA. The Secretary is required to establish a minimum interval, which shall not be less than one year, between the date on which a recommendation or guideline is issued and the plan year to which the recommendation or guideline shall be subject.

o Extension of dependent coverage. Plans that offer dependent coverage must continue to make dependent coverage available to dependents until age 26. Coverage for the dependents of adult children is not required (regardless of marital status).

o Uniform explanation of coverage documents and standardized definitions. Not later than 12 months after enactment of the Act, the Secretary is required to develop standards for use by Plans in compiling and providing to enrollees an accurate summary of benefits and explanation of coverage. The Secretary is required to consult with the National Association of Insurance Commissioners ("NAIC"), a working group composed of health insurance-related consumer advocacy groups, health insurance issuers, health care professionals, and patient advocates, among others. The standards must: (1) ensure a uniform format, (2) ensure the summary is presented in a culturally and linguistically appropriate manner and uses language that is easily understood by the average enrollee, and (3) include uniform definitions of standard insurance and medical terms. The explanation must also describe any cost-sharing, exceptions, reductions, and limitations on coverage, and examples to illustrate common benefits scenarios.

The standards developed by the Secretary preempt any related State standards that provide less information to consumers than that required by the Act, as determined by the Secretary.

Effective not later than 24 months after the Act's enactment, health insurance issuers and Plan sponsors of self-insured plans must provide, prior to any enrollment restriction, a summary of benefits and coverage explanation pursuant to the Secretary's standards to: (1) applicants at the time of application, (2) an enrollee prior to enrollment or reenrollment, and (3) a policyholder or certificate holder at the time of issues of the policy or delivery of the certificate. Notice of any planned coverage changes that are not reflected in the most recently provided summary must be provided to enrollees no less than 60 days prior to the effective date.

An entity that willfully fails to provide information required by this section is subject to a fine of not more than $1,000 for each such failure. Failure to comply with respect to each enrollee is a separate offense.

o Provision of additional information (added by Title X). All group health plans and health insurance issuers are required to comply with the disclosure requirements under the Act applicable to health plans seeking certification as a qualified health plan for the Exchange. These disclosure requirements include, but are not limited to, claims payment policies, rating practices and cost-sharing requirements. Plans that are not offered through the Exchange must submit this information to the Secretary and the State insurance commissioner and make such information available to the public.

o Prohibition of discrimination in favor of highly compensated individuals. Plan sponsors of group health plans (other than self-insured plans) are prohibited from establishing rules related to coverage eligibility (including continued eligibility) of any full-time employee that are based on total hourly or annual salary of the employee or otherwise establish rules that have the effect of discriminating in favor of higher wage employees. An amendment to this section protects Second Amendment gun rights by precluding the collection and disclosure of information related to gun ownership or use for purposes of determining premium rates.

o Ensuring quality of care. Not later than two years after enactment of the Act, the Secretary, in consultation with experts in health care quality of stakeholders, shall develop reporting requirements for use by reporting requirements for use by Plans, with respect to benefits and health care provider reimbursement structures that (1) improve health outcomes through the implementation of activities such as quality reporting, effective case management, care coordination, chronic disease management, and medication and care compliance initiatives, (2) implement activities to prevent hospital readmissions, (3) 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 (4) implement wellness and health promotion activities. Plans will be required to provide reports to the Secretary and enrollees on whether their benefits satisfy these four elements. Reports to enrollees shall be provided during each open enrollment period. These reports will also be available on the Internet.

Wellness and health promotion activities 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 intervention efforts for each of the program's participants, and may include the following wellness and prevention efforts: (1)

smoking cessation, (2) weight management, (3) stress management, (4) physical fitness, (5) nutrition, (6) heart disease prevention, (7) healthy lifestyle support, and (8) diabetes prevention.

o Bringing down the cost of health care coverage (administrative expense ratio caps). Health insurance issuers offering coverage in the group and individual markets (including grandfathered plans but excluding self-insured plans) are required to report their loss ratios to the Secretary. The report must also include the amount of premium revenues spent on clinical services, activities to improve quality, and all other non-claims costs as defined by the NAIC certified by the Secretary of HHS. The reports will be posted on the Internet by the Secretary. Beginning for plan years on or after January 1, 2011, large group plans that spend less than 85 percent of premium revenue and small group and individual market plans that spend less than 80 percent of premium revenue on clinical services and quality must provide an annual rebate to enrollees. States may set higher percentage levels.

In addition, each hospital operating within the United States shall for each year establish and update and make public a list of the hospital's standard charges for items and services provided by the hospital.

o Appeals process. Plans are required to implement an effective internal appeals process of coverage determinations and claims and comply with any applicable State external review process. If the State has not established an external review process or the plan is self-insured, the plan is required to implement an external review process that meets minimum standards established by the Secretary. The Secretary may deem the external review process of a Plan in operation as of enactment to be in compliance with this section.

o Patient protections (added by Title X). Plan enrollees must be allowed to select their primary care provider, or pediatrician in the case of a child, from any available participating primary care provider. In addition, prior authorization or increased cost-sharing requirements for emergency services are prohibited, whether the services are provided by in-network or out-of-network providers. Plans are also precluded from requiring authorization or referral for a patient who seeks coverage for obstetrical or gynecological care by a specialist in these areas.

Sec. 1002. Health insurance consumer information. The Secretary is required to award grants to States to enable them (or their state Exchange) to establish, expand, or provide support for offices of health insurance consumer assistance or health insurance ombudsman programs. These independent offices will assist consumers with filing complaints and appeals, educate consumers on their rights and responsibilities, and collect, track, and quantify consumer problems and inquiries.

Sec. 1003. Ensuring that consumers get value for their dollars. For plan years beginning in 2010, the Secretary and the States will establish a process for the annual review of increases in premiums for health insurance coverage. The process will require issuers to submit to the Secretary and the relevant State a justification for an "unreasonable" premium increase prior to implementation of the increase. Such issuers will be required to post this information on their Internet websites. As a condition for receiving grant money, States will be required to make recommendations to their Exchanges about whether health insurance issuers should be excluded from participation in the Exchanges based on unjustified premium increases.

Subtitle B – Immediate Actions to Preserve and Expand Coverage

Effective upon enactment

Sec. 1101. Immediate access to insurance for people with a preexisting condition. Within 90 days of enactment, the Secretary is required to establish a temporary high risk health insurance pool program to provide health insurance coverage for eligible individuals. An "eligible individual" (1) is a citizen, U.S. national or person lawfully residing in the U.S.; (2) has not been covered under creditable coverage during the six-month period prior to the date on which the individual applies for coverage from the high risk pool; and (3) has a pre-existing condition as determined by the Secretary. The high risk health insurance pool program will end on January 1, 2014 at which time eligible individuals will be transitioned to qualified health plans offered through the Exchange without any lapse in coverage.

The Secretary is authorized to carryout the program directly or through contracts with eligible entities. To be eligible for a contract, an entity must (1) be a State or nonprofit entity; (2) submit an application to the Secretary, and (3) agree to utilize contract funding to establish and administer a qualified high risk pool for eligible individuals.

A qualified risk pool must: (1) provides to all eligible individuals health insurance coverage that does not impose any preexisting condition exclusion; (2) provide health insurance coverage in which the issuer's share of total allowed costs of benefits is not less than 65 percent of such costs, and has an out of pocket limit not greater than a specified amount; (3) ensure that premium rates charged through the high risk pool vary only as permitted by the Act, and vary on the basis of age by a factor not greater than 4 to 1; and (4) meet any other requirements established by the Secretary.

The Secretary shall set criteria for determining if health insurers and employment-based health plans have improperly discouraged an individual from remaining enrolled in prior coverage based on the individual's health status. The criteria must include at least the following circumstances: (1) in the case of prior employment based coverage, the

provision by the employer, group health plan or issuer of money or other financial consideration for disenrolling from coverage; (2) in the case of prior coverage obtained directly from an issuer or under an employment based health plan— (i) the provision by the issuer or plan of money or other financial consideration for disenrolling from the coverage; or (ii) in the case of an individual whose premium for the prior coverage exceeded the premium required by the program (adjusted based on the age factors applied to the prior coverage)—(I) the prior coverage is a policy that is no longer being actively marketed by the issuer; or (II) the prior coverage is a policy for which duration of coverage form issue or health status are factors that can be considered in determining premiums at renewal.

An issuer or employment-based health plan will be required to reimburse the high risk health insurance program for the medical expenses incurred by the program for an individual who the Secretary, based on the established criteria, finds was encouraged by the issuer to disenroll from health benefits coverage prior to enrolling in coverage through the program.

Sec. 1102. Reinsurance for early retirees. Not later than 90 days after enactment and ending on January 1, 2014, the Secretary is required to establish a temporary reinsurance program to provide reimbursement to participating employment-based plans, including plans sponsored by State and local governments, for part of the cost of providing health benefits to early retirees and their families. The term ''early retirees'' means individuals who are age 55 and older but are not eligible for Medicare, and who are not active employees of an employer that maintains, or currently contributes to, the employment-based plan or of any employer that has made substantial contributions to fund such plan.

An employment-based plan is eligible if the plan—(1) implements programs and procedures to generate cost-savings with respect to participants with chronic and high-cost conditions; (2) provides documentation of the actual cost of medical claims involved; and (3) is certified by the Secretary.

Participating employment-based plan will submit claims for reimbursement to the Secretary. Claims must include documentation of the actual costs of the items and services for which each claim is being submitted. Claims submitted must be based on the actual amount expended by the participating employment-based plan involved within the plan year for the health benefits provided to an early retiree or the family member. In determining the amount of a claim, the participating plan must take into account any negotiated price concessions (such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations) obtained by such plan. For purposes of determining the amount of any such claim, the costs paid by the early retiree or family member in the form of deductibles, co-payments, or co-insurance are included in the amounts paid by the participating employment-based plan.

The program will reimburse participating employment-based plans for 80 percent of the cost of benefits provided per enrollee in excess of $15,000 and below $90,000. The plans are required to use the funds to lower costs borne directly by participants and beneficiaries, and the program incentivizes plans to implement programs and procedures to better manage chronic conditions.

Sec. 1103. Immediate information that allows consumers to identify affordable coverage options. Not later than July 1, 2010, the Secretary, in consultation with the States, will establish a mechanism, including an Internet website, through which a resident of or small business in any State may identify affordance health insurance options in that State. The Internet website shall, to the extent practicable, provide ways for residents of any State to receive information on at least the following coverage options: comprehensive health insurance coverage, Medicaid, State Children's Health Insurance Programs, State health benefits high risk pools; and coverage under a qualified high risk pool established under the Act. Information to be made available in standardized format established by the Secretary will include eligibility, availability, premium rates, cost sharing, and the percentage of total premium revenues spent on health care, rather than administrative expenses, by the issuer.

Sec. 1104. Administrative simplification. The Act accelerates HHS' adoption of uniform standards and operating rules for the electronic transactions that occur between providers and health plans that are governed under the Health Insurance Portability and Accountability Act ("HIPAA") (such as benefit eligibility verification, prior authorization and electronic funds transfer payments). The goal of this section is to make the health system more efficient by reducing the clerical burden on providers, patients, and health plans.

Specifically, the Secretary is required to promulgate (1) effective not later than October 1, 2012, a final rule to establish a unique health plan identifier, which may be done on an interim final basis; (2) a final rule to establish a standard for electronic funds transfers. The Secretary do this on an interim final basis and adopt such standard not later than January 1, 2012, in a manner ensuring that such standard is effective not later than January 1, 2014; and (3) a final rule to establish a transaction standard and a single set of associated operating rules for health claims attachments that is consistent with the X12 Version 5010 transaction standards. The Secretary may do so on an interim final basis and shall adopt a transaction standard and a single set of associated operating rules not later than January 1, 2014, in a manner ensuring that such standard is effective not later than January 1, 2016.

The standards and associated operating rules shall (1) 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; (2) be comprehensive, requiring minimal augmentation by paper or other communications; (3) provide for timely acknowledgment, response, and status reporting that supports a transparent claims and denial management process (including adjudication and appeals); and (4) describe all data elements (including reason and remark codes) in unambiguous terms, require that such data elements be required or conditioned upon set values in other fields, and prohibit additional conditions (except where necessary to implement State or Federal law, or to protect against fraud and abuse).

"Operating rules" are defined as necessary business rules and guidelines for the electronic exchange of information that are not defined by a standard or its implementation specifications. A process is established to regularly update the standards and operating rules for electronic transactions. Not later than December 31, 2013, health plans shall certify compliance with the standards and operating rules for electronic funds transfer, eligibility for a health, health claim status, and health care payment and remittance advice. Not later than December 31, 2015, health plans shall certify compliance with the standards and operating rules for health claims or equivalent encounter information, enrollment and disenrollment in a health plan, health plan premium payments, health claims attachments, and referral certification and authorization.

Health plans shall be required to ensure that any entities that provide services pursuant to a contract with a health plan complies with applicable certification and compliance requirements.

Not later than April 1, 2014, and annually thereafter, the Secretary is required to assess financial penalties against non-compliant health plans.

Subtitle C – Quality Health Insurance for All Americans

All provisions in this subtitle take effect on January 1, 2014. Section 10103 of Title X clarifies that the grandfathering takes effect on the date of enactment and applies the prohibition on pre-existing condition exclusions with respect to children effective six months after enactment.

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PART I –HEALTH INSURANCE MARKET REFORMS

Sec. 1201. Further amendments to the Public Health Service Act.

o Fair health insurance premiums. Premium rates charged in the individual and small group markets may vary only by family structure, rating area, age (limited to a ratio of 3 to 1 for adults), and tobacco use (limited to a ratio of 1.5 to 1). No other factors are permitted in premium rate setting. Each State is required to establish one or more rating areas within the State for purposes of applying the foregoing rating requirements. Permissible age bands are to be established by the Secretary in consultation with the NAIC. For States that permit issuers in the large group market to offer such coverage through the Exchange, the premium requirements of this section will apply to coverage offered in the large group market in that State.

o Guaranteed availability of coverage. Each health insurance issuer that offers coverage in the individual or group market in a State must accept every individual and employer in that State that applies for coverage, provided that the health insurance issuer may restrict enrollment on a guaranteed availability basis to open or special enrollment periods or for qualifying special events.

o Guaranteed renewability of coverage. Each health insurance issuer that offers coverage in the individual or group market must continue in force such coverage at the option of the plan sponsor, or individual, as applicable.

o Prohibition of preexisting condition exclusions or other discrimination based on health status. Plans are prohibited from imposing any preexisting condition exclusion.

o Prohibiting discrimination against individual participants and beneficiaries based on health status. The law prohibits plans from setting eligibility (including continued eligibility) rules based on health status, medical condition, claims experience, receipt of health care, medical history, genetic information, or evidence of insurability – including acts of domestic violence or disability. The law permits employers to vary insurance premiums by as much as 30 percent for employee participation in certain wellness programs. A 10-State demonstration is authorized to apply a health promotion prevention program in the individual market.

o Non-discrimination in health care. No group health plan or health insurance issuer in the individual or group market may discriminate with respect to participation under the plan or coverage against any health care provider acting within the scope of the provider's license or certification under applicable State law. The full implications of this prohibition are not clear. The section does not, though, require plans to contract with any willing provider. The section also does not prohibit a plan or the Secretary

from establishing varying provider reimbursement rates based on quality or performance measures.

o Comprehensive health insurance coverage. Health insurance issuers in the small group and individual markets must ensure that such coverage includes the essential health benefits package required under section 1302(a) of the Act. In addition, group health plans must comply with the Act's limitations on allowable cost-sharing.

The Act also provides for child-only plans. Specifically, if a health insurer offers health insurance at the Bronze, Silver, Gold or Platinum level as described in section 1302(d), the issuer must also offer such coverage in that level as a plan in which the only enrollees are individuals who, as of the beginning of a plan year, have not reached age 21.

o Prohibition on excessive waiting periods. Plans may not apply any waiting period that exceeds 90 days.

o Coverage for individuals participating in approved clinical trials (added by Title X). Plans that provide coverage to a "qualified individual," may not (1) deny the individual participation in a clinical trial, (2) deny (or limit or impose additional conditions on) the coverage of routine patient costs for items and services furnished in connection with a clinical trial, and (3) discriminate against the individual on the basis of the individual's participation in a clinical trial.

A "qualified individual" means an enrollee who meets the following conditions: (1) is eligible to participate in an approved clinical trial according to the trial protocol with respect to treatment of cancer or other life threatening disease or condition. (2) Either—(A) the referring health care professional is a participating health care provider and has concluded that the individual's participation in such trial would be appropriate based upon the individual meeting the conditions described in (1) above; or (B) the enrollee provides medical and scientific information establishing that the individual's participation in such trial would be appropriate based upon the individual meeting the conditions described in (1) above.

If one or more participating providers are participating in a clinical trial, the Act does not prohibit a plan from requiring that a qualified individual participate in the trial through such a participating provider if the provider will accept the individual as a participant in the trial. However, the non-discrimination provisions apply to a qualified individual participating in an approved clinical trial that is conducted outside of the State in which the qualified individual resides.

The coverage mandated by this section applies to health plans offered under the Federal Employees Health Benefits Program.

PART II – OTHER PROVISIONS

Sec. 1251. Preservation of right to maintain existing coverage (as amended by Title X and the Reconciliation Act). The Act confirms that no individual shall be required to terminate group coverage in which such individual was enrolled on the date of the Act's enactment. The section provides that the requirements of Subtitle A (Immediate Improvements in Health Care Coverage for All Americans) and Subtitle C (Quality Health Insurance Coverage for All Americans) shall not apply to a group health plan or health insurance coverage in which an individual was enrolled on the date of the Act's enactment, regardless of whether the individual renews such coverage after the date of enactment.

Title X amended section 1251 to apply the Act's requirements for medical loss ratios and uniform coverage documents to grandfathered plans. The Reconciliation Act further amended Section 1251 to apply the following requirements of the Act to grandfathered plans: (1) section 2708 (relating to excessive waiting periods); (2) provisions of section 2711 (relating to lifetime limits); (3) section 2712 (relating to rescissions); and (4) section 2714 (relating to extension of dependent coverage). In addition, the following provisions of the Act only apply to grandfathered group health plans: (1) those provisions of section 2711 (relating to annual limits), and (2) the provisions of section 2704 (relating to pre-existing condition exclusions). Finally, for plan years beginning before January 1, 2014, the provisions of section 2714 (relating to extension of dependent coverage) will apply in the case of an adult child with respect to a grandfathered health plan that is a group health plan only if such adult child is not eligible to enroll in an eligible employer-sponsored health plan other than the grandfathered health plan.

Family members of an individual referred to above are permitted to enroll in such plan or coverage if enrollment was permitted under the terms of the plan in effect as of the date of the Act's enactment.

The section also allows a group health plan that provides coverage on the date of enactment to enroll new employees and their families and the requirements of Subtitles A and C shall not apply to such plan and new employees and their families. For health insurance coverage provided pursuant to one or more collective bargaining agreements Subtitles A and C do not apply until the last of the collective bargaining agreements terminates.

Any group health plan or health insurance coverage subject to this section is referred to as a "grandfathered plan."

Sec. 1252. Rating reforms must apply uniformly to all health insurance issuers and group health plans. The standards and requirements adopted by a State pursuant to Title I, Quality, Affordable Health Care for All Americans, are required to be applied uniformly to all health plans in each insurance market to which the standard and requirements apply. The uniformity requirement also applies to a State standard or requirement relating to the Title I standard or requirement that is not the same as the Title I standard or requirement and is not preempted under section 1321(d).

Sec. 1253. Annual report on self-insured plans (added by Title X). Not later than 1 year after the date of enactment of the Act, and annually thereafter, the Secretary of Labor shall prepare and submit to Congress an aggregate annual report, using data collected from the Department of Labor Form 5500, that includes general information on self-insured group health plans (including plan type, number of participants, benefits offered, funding arrangements, and benefit arrangements) as well as data from the financial filings of self-insured employers (including information on assets, liabilities, contributions, investments, and expenses).

Sec. 1254. Study of Large Group Market (added by Title X). The Secretary is required to conduct a study of the fully-insured and self-insured group health plan markets to (1) compare the characteristics of employers (including industry, size, and other characteristics as determined appropriate by the Secretary), health plan benefits, financial solvency, capital reserve levels, and the risks of becoming insolvent; and (2) determine the extent to which new insurance market reforms are likely to cause adverse selection in the large group market or to encourage small and midsize employers to self-insure. The Secretary, in coordination with the Secretary of Labor, is required to collect information and analyze (1) the extent to which self-insured group health plans can offer less costly coverage and, if so, whether lower costs are due to more efficient plan administration and lower overhead or to the denial of claims and the offering very limited benefit packages; (2) claim denial rates, plan benefit fluctuations (to evaluate the extent that plans scale back health benefits during economic downturns), and the impact of the limited recourse options on consumers; and (3) any potential conflict of interest as it relates to the health care needs of self-insured enrollees and self-insured employer's financial contribution or profit margin, and the impact of such conflict on administration of the health plan. A report on the study results shall be submitted to Congress no later than 1 year after the date of enactment of the Act.

Subtitle D – Available Coverage Choices for All Americans

PART I – ESTABLISHMENT OF QUALIFIED HEALTH PLANS

Sec. 1301. Qualified health plans. The Act focuses heavily on health plans that satisfy requirements to be a "Qualified Health Plan" ("QHP"). QHPs must be (1) certified by a State Exchange as described below, (2) provide a package of "essential health benefits," and (3) be offered by a health insurance issuer that (i) is licensed and in good standing in the Exchange State, (ii) agrees to offer at least one Silver and one Gold plan, as defined, in each Exchange in which it participates, and (iii) agrees to charge the same premium for each QHP of the issuer whether the plan is offered through an Exchange or offered directly from the issuer or through an agent. The Act does not provide further detail on this requirement of uniform pricing both within and outside the Exchange. QHPs also include approved plans offered through a new "CO-OP" program described in Section 1322.

QHPs can provide coverage through a "qualified direct primary care medical home plan" that meets regulatory criteria if the services the medical home plan covers are coordinated with the entity offering the QHP. QHPs may vary premiums by rating area.

The term "health plan" in this Title of PPACA means health insurance coverage and a group health plan, but does not include group health plans or multiple employer welfare arrangements outside state insurance regulation under the Employee Retirement Income Security Act of 1974 ("ERISA"). In other words, self-insured ERISA plans are not health plans whose coverage is regulated the regulation of QHPs.

Sec. 1302. Essential health benefits requirements. Exchange health plans must at a minimum provide an "essential benefit package" set by the Secretary. Essential health benefits must include at least: 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; and pediatric services, including oral and vision care. Essential health benefits packages will provide bronze, silver, gold or platinum levels of coverage as established by the Secretary. Plans are permitted to provide more than the essential benefits.

The scope of essential health benefits must equal the scope of benefits provided under a typical employer plan, as determined by the Secretary. The Secretary of Labor is to conduct a survey of employer-sponsored coverage to determine the benefits typically covered by employers, including multiemployer plans, and provide a report on that survey to the Secretary.

The Secretary is required to make an appropriate balance among the categories so that benefits are not unduly weighted toward any category. The Secretary also may not make coverage decisions, determine reimbursement rates, establish incentive programs, or design benefits in ways that discriminate against individuals because of their age, disability, or expected length of life. The Secretary is to take into account the health care needs of diverse population segments and ensure that essential health benefits are not subject to denial against an individual's wishes on the basis of the age, expected length of life, or present or predicted disability, degree of medical dependency, or quality of life. To provide essential health benefits, a QHP must provide coverage for emergency department services without any different requirement for prior authorization of services, copayment or coinsurance rate, or limit on coverage based on whether the provider is a network provider. If a stand-alone dental benefits plan is offered through an Exchange, another Exchange health plan does not lose qualification because it does not offer that set of benefits.

Cost sharing is defined as any copayment, coinsurance deductible or "any other expenditure required of an insured individual which is a qualified medical expense (within the meaning of section 223(d)(2) of the Internal Revenue Code of 1986) (the "IRC") with respect to essential health benefits covered under the plan," but does not include premiums, balance billing by non-network providers and payments for non-covered services. In 2014, enrollee cost sharing may not exceed the annual limits in Section 223(c)(2)(A)(ii) of the IRC. In subsequent years, the annual limit shall be adjusted by a percentage formula, and then rounded upwards to the nearest $50. No deductible may apply to any preventive health benefits required to be covered under the Act's amendments to the Public Health Service Act.

Employer sponsored plans in the small group market may not have deductibles higher than $2,000 for individual coverage and $4,000 for family. These amounts may be increased by the maximum amounts reasonably available to individuals under flexible spending plans. This cap is increased by a percentage formula for years after 2014 and then rounded up to the nearest $50 increment.

Plans will be offered at bronze, silver, gold and platinum levels, representing, respectively, 60, 70, 80 and 90% actuarial value of the full actuarial value of the benefits covered. (i.e., if there were no cost sharing provisions). This will be in accordance with regulations and on the basis of a "standard" population, rather than the population actually enrolled with the issuer. Regulations will permit employer contributions to HSAs to be counted for purposes of determining the actuarial value of a plan. De minimis variation will be permitted to account for differences in actuarial estimation.

If a qualified plan is offered through the Exchange at any of the four levels, the issuer must also offer it as a separate qualified plan for individuals under the age of 21.

A plan offered in the individual market can still be a qualified plan, without being one of these four level type plans, if it meets specified criteria as a catastrophic plan. Such a plan, apart from offering at least three primary care visits annually, may not provide coverage until the covered individual has incurred cost-sharing obligations satisfying a specified threshold. It may only cover an individual who is either under 30 or who satisfies hardship or prior uninsured status requirements.

Payments by QHPs to a federally qualified health center shall be amounts "not less than the amount of payment" would have been made under Medicaid to the center.

PART II CONSUMER CHOICES AND INSURANCE COMPETITION THROUGH HEALTH BENEFIT EXCHANGES

Sec. 1311. Affordable choices of health benefit plans. PPACA calls for each State's establishment by January 1, 2014 of an American Health Benefit Exchange ("Exchange") that will make "qualified health plans" ("QHPs") available to individuals and small groups. A State can have a separate exchange for individual coverage and a distinct Small Business Health Options Program (''SHOP Exchange'') or may merge them into one Exchange. An Exchange can be either a government agency or a non-profit entity "established by" the State. States that agree can set up a multi-state Exchange.

A "large group" is an employer group that in the previous year averaged 100 or more employees. A "small group" means an employer that in the previous year averaged 1 or more employees but not more than 100. Until 2016, a State can substitute 50 for 100 in these definitions. Also, if a small employer is in the exchange, but gets bigger, it will continue to be treated as small until it leaves the exchange.

The Secretary will set minimum standards Exchanges must use in certifying and recertifying QHPs for participation. These will include requirements covering: marketing; network adequacy; inclusion of "essential community providers" willing to accept the "generally applicable payment rates" of the plan; accreditation; quality improvement; uniform enrollment forms; and a standardized benefit presentation format permitting consumer comparisons.

The Secretary will also develop a rating system for assessment of QHP prices and quality as well as an enrollee satisfaction survey system. Rating and enrollee satisfaction information will be posted by each Exchange on an Internet portal. The Exchanges will have initial and annual open enrollment periods, and special open enrollment periods upon specified events.

The Secretary will establish a core set of "essential health benefits" that each QHP must offer. Financial incentives will discourage States from requiring Exchange plans to offer additional benefits. If a State imposes a mandate for any additional benefits, it must provide payment to the individual, or to the plan on the individual's behalf, for the incremental premium cost attributable to the extra mandated benefit.

Participating QHPs will have to provide to enrollees, upon request, the amount of cost-sharing under the individual's plan with respect to specific services by a participating provider.

From now through 2014, HHS is to provide funding to the States to establish the Exchanges. Exchanges are also permitted to charge insurers assessments or user fees.

Although an Exchange may not exclude a plan "through the imposition of premium price controls," they are authorized to review premium increases, must require insurers to submit justifications for increases and may consider those justifications in deciding whether to make a plan available on the Exchange. Justification information will be made public.

The Exchanges are to encourage plans to provide incentives for improved health outcomes through such measures as quality reporting, care coordination and chronic disease management, in particular the "medical home" model, patient- centered education, strengthened discharge planning, evidence-based medicine, health promotion activities, and addressing health disparities.

Exchanges will award grants to "Navigators," such as trade and professional associations, consumer organizations, unions, chambers of commerce, insurance agents and brokers, and resource partners of the Small Business Administration. The Navigators will conduct public education activities, distribute fair and impartial information about QHPs and the availability of premium tax credits and cost-sharing reductions for eligible individuals, facilitate enrollment, provide referrals to health insurance consumer assistance or health insurance ombudsman or any other appropriate State agency for enrollees with grievances or complaints, or questions about their health plan or coverage or a claim determination. Navigators will need to meet standards, and may not be health insurance issuers.

The recently enacted Mental Health Parity law will apply to QHPs just as it does for group health plans and health insurance issuers.

Sec. 1312. Consumer choice. Any person qualifies for individual Exchange QHP coverage if he or she lives in the State, is not incarcerated (except for those awaiting disposition of charges) and is a citizen or an alien anticipated to be lawfully in the country for the entire enrollment period sought. Any small employer can participate if it makes all full-time employees eligible for coverage in the Exchange. Starting in 2017, a State may permit health insurance issuers to provide coverage for large employers through the State's Exchange.

Each health insurance issuer will consider all its individual market enrollees in the State (other than grandfathered health plans), including those who do not enroll through the Exchange, to be members of a single risk pool. All an issuer's small group enrollees in a State are also (other than those in grandfathered plans) to be considered a single risk pool. A State may require these individual and small group pools to be combined.

Individuals and employers may obtain non-Exchange health plans from health insurance issuers and employers may opt to self-insure outside any Exchange. There is no impact on State coverage mandates outside of Exchange plans.

Sec. 1313. Financial integrity. The Act makes important changes in the federal fraud and abuse laws, both with regard to Exchange programs and more generally.

Payments made by or through or in connection with an Exchange, if the payments include any federal funds, are subject to the federal False Claims Act (the "FCA"). In addition, compliance with the requirements of PPACA concerning eligibility for a health insurance issuer to participate in the Exchange shall be a material condition of an issuer's entitlement to receive payments, including payments of premium tax credits and cost-sharing reductions, through the Exchange.

Section 1313 applies the FCA to "Payments made by, through, or in connection with an Exchange . . . if those payments include any Federal funds." It further provides that "Compliance with the requirements of this Act concerning eligibility for a health insurance issuer to participate in the Exchange shall be a material condition of an issuer's entitlement to receive payments". So a health insurance issuer's knowing request for payment while not in compliance with participation eligibility requirements is made automatically actionable under the FCA regardless of how material that compliance failure is; compliance is deemed a material condition for payment.

Section 1313 also increases the FCA damages by permitting an award of up to six times the actual damages that the Government suffers by reason of a false claim in connection with an Exchange. It describes this as a modification of the "civil penalty assessed under the False Claims Act", but the civil penalty and treble damage provisions of the FCA are distinct. This confusion could give rise to litigation, and a six times actual damage penalty may challenged on the ground that it punitive in nature. Finally, since some of the payments that a health insurance issuer may receive will be in the form of tax credits, the application of the FCA in that circumstance may be in doubt because it does not apply to claims or statements made under the IRC.

PART III - STATE FLEXIBILITY RELATING TO EXCHANGES

Sec. 1321. State flexibility in operation and enforcement of Exchanges and related requirements. If a State's Exchange enrollment meets expectations based on HHS projection norms, then it shall, subject to rebuttal, be presumed to be compliance with various federally imposed requirements.

The Act also provides there shall be no preemption of state law that does not prevent the application of the provisions of the health insurance reform title of the Act.

Sec. 1322. Federal program to assist establishment and operation of nonprofit, member-run health insurance issuers. PPACA provides up to $6 billion in loan and grant money to seed new non-profit "Consumer Operated and Oriented Plans" ("CO–OPs") to offer QHPs in the individual and small group markets. The initiative is similar to the funding approach first taken for non-profit health plans in the early 1970s with the federal Health Maintenance Organization Act. The Secretary is to ensure that there is enough funding to establish at least one new nonprofit health insurance issuer in each State. The Secretary may also award grants to encourage establishment of a CO-OP plan in any State where no issuer participates in the Exchange. Grants and loans are to be made by July 1, 2013. An insurer will not be eligible for CO-OP funding if it, a related entity, or any predecessor entity was already an insurer as of July 16, 2009, or if it is owned or sponsored by any government body or political subdivision. CO-OP plan governance must be subject to a majority vote of its members and governing documents must incorporate ethics and conflict of interest standards protecting against insurance industry involvement and interference.

CO-OP plans may collaborate to form a private purchasing council to do collective purchasing that increases administrative and other cost efficiencies, including claims administration, administrative services, health information technology, and actuarial services. The private purchasing council shall not set payment rates for health care facilities or providers and the authorization of these councils is not intended to limit the application of the antitrust laws to the activities of the private purchasing councils or the CO-OP plans.

The Secretary shall not participate in any negotiations between qualified nonprofit health insurance issuers (or a private purchasing council) and any health care facilities or providers, including any drug manufacturer, pharmacy, or hospital; and shall not establish or maintain a price structure for reimbursement of any health benefits covered by such issuers. Nothing in this section shall be construed as authorizing the Secretary to interfere with the competitive nature of providing health benefits through qualified nonprofit health insurance issuers.

CO-OP plans with a loan or grant will be covered by a newly created Section 501(c)(29) tax exemption so long as they are in compliance with grant or loan terms.

Sec. 1324. Level playing field. Coverage by private health insurance issuers will not be subject to federal or state laws on a broad range of topics if a QHP under the CO-OP Program or a new Exchange multi-state qualified plan is not subject to the same law. The topics are: guaranteed renewal, rating, preexisting 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. The full scope of this preemption is not yet clear.

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 will set up a "basic health program" under which each State may contract to offer one or more standard health plans providing at least essential health benefits to eligible individuals in lieu of offering such coverage through an Exchange. The State would have to demonstrate that the premiums do not exceed what would have been required, taking into account premium tax credits and subsidized cost sharing reductions, in the individual's rating area if they had enrolled in the second lowest silver plan and the cost-sharing does not exceed the platinum plan levels for individuals with household income at 150% or less of the federal poverty line; or gold plan levels for other enrollees. In the case of a plan that provides this standard health plan coverage through a health insurance issuer, the plan must have a medical loss ratio of at least 85 percent.

The state contracting process for standard health plans must be a "competitive process", including negotiation of premiums and cost sharing and of any benefits beyond the essential benefits. Persons eligible to offer standard health plans under a basic health program can include HMOs, health insurance insurer or a "network of health care providers established to offer services under the program." The State shall negotiate for innovative features, including care coordination, incentives for preventive care, and maximization of patient involvement in health care decision-making, including incentives for appropriate utilization. It shall give consideration to difference in health care needs of enrollees and local differences in availability of providers, employing managed care systems or plan attributes, and specific performance measures.

States shall seek to have multiple standard health plans available, They may also negotiate regional compacts to include multi-state coverage by the same standard health plan.

HHS will provide funding for States with operating standard health plans, set to be 95% of the amount of premium tax credits and cost sharing reduction subsidies that would have been provided by HHS if the individual had joined an Exchange plan based on specific criteria outlined and to be certified by the Chief Actuary of the Centers for Medicare and Medicaid Services ("CMS"). The funding will be used to reduce premiums and cost sharing, or provide additional benefits, for eligible individuals in standard health plans.

"Eligible individuals" means persons resident in a State not eligible for Medicaid benefits that at a minimum consist of essential health benefits; whose household income exceeds 133 percent but does not exceed 200 percent of the poverty line; are not eligible for minimum essential coverage (section 5000A(f) of IRC) or are eligible for an employer-sponsored plan that is not "affordable" under those IRC provisions; and who are not 65. Lawful aliens can be eligible individuals if their household income is not greater than 133 percent of the poverty line and they are ineligible for Medicaid on account of alien status. Eligible individuals do not include anyone who is not a qualified individual under section 1312 who is eligible to be covered by a QHP through the Exchange. Eligible individuals are not eligible for Exchange plan coverage.

Sec. 1332. Waivers for State Innovation. For plan years starting in 2017, States can apply for waivers from certain requirements with respect to health insurance coverage. Waiver requests must demonstrate budget neutrality for the federal government. The waiver-eligible requirements are those imposed starting January 1, 2014 under this subtitle of the Act, under Part II of subtitle D; Section 1402; and under sections 36B, 4980H and 5000A of the IRC. Depending on the requirements sought to be waived, the waiver request will be considered by the Secretary or the Secretary of the Treasury.

If the effect of a state waiver would be to prevent individuals and small employers from qualifying for premium tax credits, cost sharing reductions or small business credits, HHS is to provide an alternative means for providing the aggregate value of those credits and reductions to the State for purposes of implementing the state plan operating with the waiver.

To qualify for a waiver, the state plan must provide coverage as least comprehensive as essential health benefits under Exchange plans, that will provide coverage to a comparable number of residents as the federal scheme, will provide protection against excessive out of pocket spending and will not increase the federal deficit.

Sec. 1333. Provisions relating to offering plans in more than one state. In consultation with NAIC, the Secretary will by July 1, 2013 issue regulations for creation of "health care choice compacts." Under these, multiple states may, following passage of authorizing state legislation, agree that a QHP could be offered in the individual market in each of the States, but be for the most part subject to the laws and regulations only of the State "in which the plan was written or issued" (i.e., not where it was delivered). Each participating State's laws would continue to apply as regards market conduct, unfair trade practices, network adequacy and consumer protection standards. Issuers would either have to be licensed in each participating State, or else submit to the jurisdiction of each State on the above subjects. Notice to consumers about the limited reach of their State's laws to the policy would be required.

Compact agreements are subject to approval by the Secretary for compliance with requirements for adequacy of coverage, protection against excessive cost sharing, numerosity of coverage, and avoidance of federal deficit requirements, the same criteria as apply to State waiver requests.

Sec. 1334. Multi-State Plans (added by Title X). PPACA requires the Director of the Office of Personnel Management ("OPM") to contract with health insurance issuers, which can include a group of issuers affiliated by common ownership and control or by common use of a nationally licensed service mark (e.g., Blue Cross Blue Shield plans), to offer two multi-state qualified health plans through each Exchange, without regard to federal laws regarding competitive bidding. At least one of the contracts shall be with a non-profit entity.

Administration will be similar to the FEHBP, including negotiation of a medical loss ratio, a profit margin, and the premiums to be charged. This language suggests that the comparison is to the service benefit fee-for-service or experience rated program under the FEHBP, rather then the community rated carrier approach used by some plans, since the latter do not involve negotiation of a medical loss ratio or profit margin. OPM is to ensure that at least one multi-state qualified plan does not offer coverage for abortion services that cannot be federally funded.

Health insurers are eligible if they are licensed in each State, and comply with non-preempted State laws, and comply with the minimum standards for carriers offering plans under the FEHBP, to the extent not inconsistent with the new federal scheme.

A multi-state qualified health plan must offer a benefits package that is uniform in each State and "consists of the essential benefits," meets requirements for QHPs, including bronze, silver and gold levels of coverage and catastrophic coverage in each State Exchange; determine premiums on the basis of rating requirements set out in the health reform legislation in amendments to the Public Health Service Act, and the issuer offers the plan "in all geographic regions, and in all States that have adopted adjusted community rating before the date of enactment of this Act." The latter reference appears to be the rating methodology required under the health insurance reforms of the Act.

States can require additional benefits to be offered, so long as enrollees get the same credits and cost sharing assistance as are given to persons joining a QHP through an Exchange. States must defray the cost of any such additional benefits for any persons enrolling. This will be a sharp disincentive to States imposing any such expanded benefit requirement.

If a State requires an age rating requirement lower than 3:1, it can requires that Exchanges in its State only permit multi-state plans to operate if they comply with the more protective age rating requirement.

Approved multi-state plans are deemed certified for Exchange participation.

In its first year, a multi-state issuer must offer its coverage plan in at least 60 percent of the States, at least 70 percent for the second year, 85 percent for the third, and in all States thereafter. FEHBP requirements applicable to health benefit plans shall apply to multi-state plans except to the extent inconsistent with other provisions of the reform law.

PART V - REINSURANCE AND RISK ADJUSTMENT

Sec. 1341. Transitional reinsurance program for individual market. By January 1, 2014 each State shall establish or contract with reinsurance entities for a program under which health insurers, and TPAs on behalf of group health plans, are required to make payments to an applicable reinsurance entity, except for those plans that have a "grandfather" exception. The premium amounts collected will be paid out to participating health insurance issuers that cover "high risk individuals" in the individual market. Note that this mechanism will thereby include funding of a risk adjustment fund benefiting insurers issuing individual policies by assessments against group coverage, including insurance carriers and self-insured plans.

High risk individuals will be identified by reference to a list of at least 50 but not more than 100 high risk medical conditions, which may be based on identification of diagnostic and procedure codes or a comparable objective method recommended by the American Academy of Actuaries.

The reinsurance payment formula will equitably allocate the available funds to provide a schedule of payments that will be paid for each of the identified conditions or some other method recommended by the American Academy of Actuaries that encourages use of care coordination and care management. So, the "reinsurance" is in the nature of a risk-adjuster payment, rather than coverage to be provided based on the actual claims incurred by the health insurance issuer.

The contribution amounts for any plan year may be based on the percentage of revenue of each issuer and total costs of providing benefits to enrollees in self-insured plans or on a specified amount per enrollee.

The contribution amount should proportionally reflect each issuer's fully insured commercial book of business for major medical products and the total value of fees charged by the issuer and the costs of coverage administered by the issuer as a TPA. Additional amounts may be assessed to fund the reinsurance entity's administrative expenses. The aggregate contribution amounts shall equal $10 billion for plan years beginning in 2014, $6 billion for 2015, and $4 billion for plan years starting in 2016. Contributors will also be assessed for their proportionate share of an additional $2 billion for 2014, $2 billion for 2015, and $1 billion for 2016 that will be deposited into the general fund of the Treasury and which is not to be used as part of the reinsurance entity initiative.

States can collect more, and pay out more, from health insurance issuers on a voluntary basis.

The reinsurance entity must be a non-profit organization whose purpose is to help stabilize premiums for coverage in the individual market during the first three years of operation of the State's Exchange. A State can recognize more than one reinsurance entity, and two or more States may jointly engage a reinsurance entity to serve their States. The reinsurance entities will be exempt from taxation under chapter 1 of the IRC, except for unrelated business income.

States must eliminate or modify any State high risk pool as necessary to effectuate the new reinsurance program.

Sec. 1342. Establishment of risk corridors for plans in individual and small group markets. HHS will set up a program of risk corridors for 2014, 2015 and 2016 for QHPs offered in the individual or small group market. Health insurers will participate in a payment adjustment system based on the ratio of allowable costs to the plan's aggregate premium. The program will be based on the program for "regional participating provider organizations" under Medicare Part D. If a plan's allowable costs for a plan year are more than 103% but not more than 108% of the target amount, HHS will pay the plan 50 percent of the excess in costs over 103% of the target amount. If a plan's allowable costs are more than 108% of the target, HHS will pay the plan 2.5% of the target amount, plus 80% of the allowable costs exceeding 108% of the target amount.

Plans will pay HHS a portion of any savings in claims relative to target amounts. If the plan's allowable costs are less than 97% of target, but not less than 92% of target, the plan will pay HHS 50% of the excess of 97% of the target amount over the allowable costs. If the plan's allowable costs are less than 92% of the target amount, the plan will pay HHS 2.5% of the target amount, plus 80% of the excess of 92% of the target amount over the allowable costs. Allowable costs do not include administrative costs. Allowable cost are reduced by any risk adjustment and reinsurance payments under

sections 1341 and 1343. "Target" amount is premiums, including any premium subsidies, reduced by administrative costs.

Sec. 1343. Risk adjustment. Each State will assess a charge on "low actuarial risk plans" -- health plan and health insurance issuers (with respect to health insurance coverage) where the actuarial risk of their enrollees is less than the average actuarial risk for all enrollees in plans or coverage in the State that are not self-insured group health plans. The State will make a corresponding payment to "high actuarial risk plans" whose enrollments' actuarial risk is higher than the average. HHS will set criteria, in consultation with the States, and may use methods similar to those under Medicare Part C and D. This risk adjustment process will apply to health plans and health insurance issuers providing individual or small group coverage in a State.

The risk adjustment provisions do not apply to "grandfathered health plans" or the issuers of a "grandfathered health plan".

Sec. 1303. Special Rules (Abortion Services). PPACA focuses closely on the degree and manner by which abortion service may be covered by an Exchange plan. The Act differentiates between abortion services performed in circumstances where under current law the abortion may be funded by federal dollars, such as Medicaid dollars, and abortion services in circumstances where no federal funding is currently allowed.

First, PPACA does not require QHPs to cover abortion services as part of essential health services, whether the abortion services are those that are otherwise permitted to be federally funded or not. Second, if a QHP covers abortion services not otherwise permitted to be federally funded, it cannot use funds derived from the tax credit and federal government subsidies for member cost sharing reductions established elsewhere in PPACA to pay for those abortions. Third, such QHPs must collect from the enrollee separate payments (without regard to age, sex or family status) to be paid directly by the enrollee for his or her contribution toward the rest of the plan's coverage and a payment for the actuarial value of the coverage for those abortion services. The actuarial value for that abortion coverage may not be less than $1 per enrollee per month. Finally, the payments received shall be allocated to separate segregated accounts to be used to pay claims.

QHPs that provide this coverage must provide a notice to enrollees, only as part of the summary of benefits and coverage explanation, at the time of enrollment, of such coverage. The notice, and any advertising or other communications, shall provide information only with respect to the total amount of the combined payments. This suggests, oddly, that the billing sent to enrollees will require issuance of separate payments by the enrollees, while prior communications to the enrollees will not have explained that there will such separate charges.

No individual health care provider or health care facility may be discriminated against because of a willingness or an unwillingness to provide, pay for, provide coverage of, or refer for abortions if doing so is contrary to the religious or moral beliefs of the provider or facility

PPACA does not preempt State laws prohibiting or requiring coverage or State laws setting procedural requirements on abortions, including parental notification or consent for the performance of an abortion on a minor. Nor does it alter Title VII of the federal civil rights laws, any emergency care obligations of providers under EMTALA or federal laws addressing (i) conscience protection, (ii) willingness or refusal to provide abortion; or (iii) 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.

A State may prohibit abortion coverage in QHPs offered through an Exchange if the State does so by enactment of a law.

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 plan. The IRC is amended to add a new section that generally allows tax credits against the tax imposed by this subtitle equal to the "premium assistance credit" amount of the taxpayer for the taxable year. The "premium assistance credit" is determined as the lesser of: (1) the monthly premiums of a QHP plan offered within a particular State or (2) the excess (if any) of (i) the adjusted monthly premium for such month for the applicable second-lowest cost silver plan with respect to the taxpayer, over (ii) an amount equal to 1/12 of the product of the applicable percentage and the taxpayer's household income for the taxable year.

"Applicable percentage" is defined in the statute, and there are special rules for taxpayers under 133% of the poverty line. "Applicable second-lowest cost silver plan" is defined as the second-lowest cost silver plan of the individual market in the entire rating area in which the taxpayer resides that meets certain criteria. "Adjusted monthly premium" is the monthly premium which would have been charged for the plan if each individual covered under a qualified health plan were covered by such silver plan and the premium was adjusted only for the age of each such individual in the manner allowed in the Public Health Service Act.

Eligible taxpayers are those whose household income for the taxable year exceed 100% but do not exceed 400% of an amount equal to the poverty line for a family of the size involved. There are special rules for legal aliens and married couples, and dependents shall not be issued credits. Credits shall be reduced to a taxpayer who has as a dependent or dependents a person who is not lawfully present in the United States. The Secretary is charged with promulgating regulations to carry out the credit process.

Sec. 1402. Reduced cost-sharing for individuals enrolling in qualified health plans. For eligible insureds enrolled in a QHP, the Secretary shall notify the issuer of the plan of such eligibility and the issuer shall reduce the cost-sharing under the plan at the level and in the manner specified. An "eligible insured" is a person who enrolls in a qualified health plan in the silver level of coverage in the individual market offered through an Exchange, and whose household income exceeds 100% but does not exceed 400% of the poverty line for a family of the size involved.

The cost sharing shall be first achieved by a reduction in the applicable out of pocket limit under section 1302(c)(1) by two thirds, one half, and one thirds, depending on what level the family's income exceeds the poverty level. The Secretary shall ensure that the reduction does not increase the plan's share of the total allowed costs of benefits by certain levels. Furthermore, there are additional provisions for the reduction of costs for lower-income insureds.

Issuers of QHPs making reductions shall notify the Secretary of such reductions and the Secretary shall make payments to the issuer equal to the value of the reductions. The Secretary may establish a capitated payment system. The repayments to the issuers shall not take into account any benefits required by any plan or State that requires benefits additional to those required to be provided. These cost-sharing provisions shall not apply for individuals not lawfully present in the United States.

SUBPART B – ELIGIBILITY DETERMINATIONS

Sec. 1411. Procedures for determining eligibility for Exchange participation, premium tax credits, and reduced cost-sharing, and individual responsibility exemptions. The Secretary is charged with setting up a program to determine whether individuals applying for coverage in the individual market by a QHP offered through an Exchange are citizens or nationals of the United States or are aliens lawfully present in the United States. The Secretary must also ensure that the income and coverage requirements are met for individuals applying. The Secretary must also set up a system to determine whether to grant a certification that an individual is entitled to an exemption from the individual responsibility requirement or the penalty imposed by the Act.

Sec. 1412. Advance determination and payment of premium tax credits and cost-sharing reductions. Premium assistance tax credits and cost-sharing reductions for eligible individuals may be paid in advance. Payments may not be made to persons who are not lawfully present in the United States. States are permitted the flexibility to make payments to or on behalf of an individual for coverage under a qualified health plan offered through an Exchange that are in addition to any credits or cost-sharing reductions allowable to the individual under this subtitle.

Sec. 1413. Streamlining of procedures for enrollment through an Exchange and State Medicaid, CHIP, and health subsidy programs. The Secretary must establish a system for enrollment and participation in applicable State health subsidy programs. The program must also address determinations of eligibility. The system must be designed to ensure that individuals applying to the Exchange are found eligible for Medicaid or a CHIP program. The Secretary will promulgate standards governing the timing, contents, and procedures for data matching, and such standards shall take into account administrative and other costs.

Sec. 1414. Disclosures to carry out eligibility requirements for certain programs. There is authorized a limited disclosure of tax return information in order to ensure that eligibility requirements for certain programs are carried out effectively.

Sec. 1415. Premium tax credit and cost-sharing reduction payments disregarded for federal and federally-assisted programs. Tax credits and cost-sharing reductions shall not be counted as income for determining eligibility for any federal program or under any State or local program financed with federal funds in whole or in part.

Sec. 1416. Study of geographic variation in application of federal poverty level -- as Added by Title X Amendment. The Secretary is charged with conducting a study to examine the feasibility and implication of adjusting the application of the federal poverty level for different geographic areas to reflect the variations in cost-of-living among different areas within the United States. The Secretary must, by January 1, 2013, submit a report to Congress on the study and include such recommendations as the Secretary determines appropriate. The Secretary must include the Territories -- Puerto Rico, Virgin Islands, Guam, Northern Marina Islands, etc. -- in the study.

PART II – SMALL BUSINESS TAX CREDIT

Sec. 1421. Credit for employee health expenses of small businesses. The IRC is amended to add a new section that provides for the determination of insurance tax credits given to small businesses for their employees. The amount shall be equal to 50% (35% in the case of a tax-exempt eligible employer) of the lesser of: (1) the aggregate

amount of nonelective contributions the employer made on behalf of its employees during the taxable year for qualified health plans, or (2) the aggregate amount of nonelective contributions that the employer would have made during the taxable year if each employee taken into account under paragraph (1) had enrolled in a qualified health plan that had a specific health plan premium (based on the small group market in the rating area). There are certain formulas within the Act that provide for the reduction of the credit amount based on number of employees and average wages.

"Eligible small employers" must have no more than 25 full-time equivalent employees for the taxable year and annual wages must not exceed an amount equal to twice the dollar amount in effect in subsection (3)(B), which, as amended by Title X, is $25,000 for years 2011, 2012, and 2013. Thereafter, the "dollar amount" is determined by cost of living adjustments starting with that base level of $25,000. "Employee" excludes certain individuals, including an employee within the meaning of 401(c)(1); any 2% shareholder of an eligible small business which is an S corporation; and, any 5% owner of an eligible small business.

The credit is made available to tax-exempt eligible small employers -- those described in section 501(c) -- at the lesser of (1) the amount of the credit determined under this section with respect to such employer, or (2) the amount of the payroll taxes of the employer during the calendar year in which the taxable year begins.

There are alterations to these standard provisions for taxable years 2011, 2012, and 2013, and "no credit period shall be treated as beginning with a taxable year beginning before 2014." The Secretary shall prescribe regulations as are necessary to carry out this section.

Subtitle F – Shared Responsibility for Health Care

PART I – INDIVIDUAL RESPONSIBILITY

Sec. 1501. Requirement to maintain minimum essential coverage (as amended by the Reconciliation Act). Beginning January 1, 2014, most U.S. citizens and legal residents must obtain and maintain "minimum essential" health insurance coverage. "Minimum essential coverage" is coverage under government sponsored programs (including the Medicare, Medicaid, SCHIP, TRICARE for Life, and veteran's programs), eligible employer-sponsored plans, plans sold in State individual health insurance markets, and coverage offered by State high-risk pools. "Eligible employer-sponsored plans" include group health coverage offered by employers that are either governmental plans or any other plan offered in a State small or large group market.

Individuals must obtain coverage for themselves and any dependents, or pay a penalty. The penalty is the greater of $695 per year per family, up to a maximum of three times that amount, or 2.5% of taxable household income. The penalty will be phased in over three years as follows: $95 or 1% of taxable income in 2014, $325 or 2% of taxable income in 2015, and $695 or 2.5% of taxable income in 2016. Thereafter the penalty increases annually by the cost of living adjustment. Penalties will be collected by the Internal Revenue Service ("IRS").

Certain individuals are exempt from the coverage mandate, including religious objectors, individuals not lawfully present in the United States, and prison inmates. Other individuals are exempt from the penalty provisions, including people whose lowest cost coverage option exceeds eight percent of household income, individuals with income below the federal income tax filing threshold, members of Indian tribes, individuals who were uninsured for less than three months, and individuals who have received a hardship waiver from the Secretary.

Sec. 1502. Reporting of health insurance coverage. Every person who provides minimum essential coverage to any individual must report various information to the government including:

1. The name and taxpayer identification number each individual who has coverage under the policy;
2. The dates during which the individual was covered during a calendar year;
3. Whether the coverage is a qualified health plan offered through a State Exchange;
4. The amount of any advance payment of cost-sharing reductions or tax credits under Section 1402 or 36B;
5. If the coverage is provided through an employer-sponsored group health plan, the employer's name and identification number and the employer's portion of the premium.

The IRS, in collaboration with HHS, must notify each person who files an individual tax return and who is not enrolled in minimum essential coverage to provide information to the individual about the individual's coverage options available through his or her State Exchange.

PART II – EMPLOYER RESPONSIBILITIES

Sec. 1511. Automatic enrollment for employees of large employers – as amended by the Reconciliation Act. Employers with more than 200 employees and who offer enrollment in one or more health benefit plans must (1) automatically enroll new full-time employees in one of the offered plans and (2) continue the enrollment of current

employees. The automatic enrollment requirement is subject to any applicable waiting period authorized by law. Employers must notify employees of their ability to opt out of the employer-sponsored coverage.

Sec 1512. Employer requirement to inform employees of coverage options. Employers must notify each employee about coverage options through a State Exchange and how to contact the Exchange for assistance. Employers must also notify employees of their possible eligibility for premium tax credits or cost sharing reductions, if the employer's premium contribution is less than sixty percent and the employee purchases coverage through the Exchange. Finally, employers must inform employees that, if they choose to purchase coverage through a State Exchange, that the employee will lose any employer contribution towards coverage sponsored by the employer. These provisions are effective beginning January 1, 2014.

Sec. 1513. Shared responsibility for employers. Section 1513 imposes tax penalties on large employers who have at least one full-time employee who receives a premium tax credit or cost sharing reduction. An employer is a "large" employer if it employs an average of at least fifty full-time employees. For large employers who do not offer their employees the opportunity to enroll in employer-sponsored coverage, the employer will be assessed a $2,000 penalty per employee, not including the first thirty employees. For large employers who do offer employees the opportunity to enroll in employer-sponsored coverage, the employer will be assessed a $3,000 penalty per employee who receives the tax credit, not including the first 30 employees. The penalty for employers who do offer coverage is capped at $2,000 for every full-time employee. These provisions are effective beginning January 1, 2014.

Sec. 1514. Reporting of employer health insurance coverage. Large employers must report various information to the government including:

1. Whether the employer offers its full-time employees the opportunity to enroll in employer-sponsored minimum essential coverage;;
2. If the employer does offer minimum essential coverage, information about the availability, cost, and the amount of the employer's contribution of such coverage;
3. The number of the employer's full-time employees; and
4. The name, address, and tax identification number of each full-time employee and the months during which the employee and his or her dependents were covered under the employer-sponsored plan.

These requirements are effective beginning January 1, 2014.

Sec. 1515. Offering of Exchange-participating qualified health plans through cafeteria plans. A QHP offered through a State Exchange is not a "qualified benefit" (a benefit that does not defer compensation and is excludable from an employee's gross income) under an employer-sponsored cafeteria plan. There is an exception for small employers who offer their employees a choice of plans through the Exchange. This exception is extended to large employers in electing States beginning in 2017. Otherwise, the provisions of this section are effective January 1, 2014.

Subtitle G – Miscellaneous Provisions

Sec. 1551. Definitions. The definitions used in section 2791 of the Public Health Service Act shall apply to this title.

Sec. 1552. Transparency in government. Not later than 30 days after the date of enactment of this Act, the Secretary shall post on the internet website of HHS a list of all the authorities provided to the Secretary under this Act (and its amendments).

Sec. 1553. Prohibition against discrimination on assisted suicide. The federal government and any other government receiving funding under this Act, or any health plan created by this Act, shall 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.

These provisions do not apply to or 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 any item, good, benefit, or service furnished for the purpose of alleviating pain even if such use may induce death. HHS Office of Civil Rights is charged with receiving complaints of discrimination based on this section.

Sec. 1554. Access to therapies. The Secretary may not promulgate any regulations that create unreasonable barriers to the ability of individuals to obtain appropriate medical care; that impede with timely access to health care services; that interfere with communications regarding treatment potions between patient and provider; that restrict the ability of health care providers to provide full disclosure of all relevant information; that violate the principles of informed consent and medical ethics; and that limit the availability of health care treatment for the full duration of a patient's needs.

Sec. 1555. Freedom not to participate in federal health insurance programs. No individual, company, business, or other entity shall be required to participate in any federal health insurance program created under this Act.

Sec. 1556. Equity for certain eligible survivors. The Black Lung Benefits Act is amended in certain respects.

Sec. 1557. Nondiscrimination. An individual shall not, pursuant to the various federal nondiscrimination laws, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity that is receiving federal financial assistance under this Title. The enforcement mechanisms available under Title VI of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, the Age Discrimination Act, or section 504 of the Rehabilitation Act shall apply for purposes of this subsection. The Secretary may promulgate regulations.

Sec. 1558. Protections for employees. The Fair Labor Standards Act of 1938 is amended by inserting after section 18B (as added by section 1512) the following: "Protections for Employees" **--** discrimination or negative employment action is prohibited on the basis that the employee has received certain credits provided for in the Act, provides or has provided information to the government about violations of this law, has testified or will testify about violations of this law, assisted or participated in such a proceeding, or objected to or refused to participate in an act that the employee reasonably believed to be a violation of this law. The Act establishes a complaint procedure.

Sec. 1559. Oversight. The HHS Inspector General has oversight authority with respect to the implementation and administration of this Title as it relates to the HHS.

Sec. 1560. Rules of construction. Nothing in this title shall be construed to modify, impair, or supersede the operation of the antitrust laws. Also, nothing in the title shall modify or limit the application of the exemption for Hawaii's Prepaid Health Care Act as provided for under section 514(b)(5) of ERISA. Higher education institutions are not prohibited from offering insurance plans. Nothing in this title shall be construed to modify any existing Federal requirement concerning the State agency responsible for determining eligibility for programs identified in section 1413 (*e.g.*, Medicaid, CHIP, and health subsidy programs).

Sec. 1561. Health information technology enrollment standards and protocols. Title XXX of the Public Health Service Act is amended by adding the following:

> **o Health information technology enrollment standards and protocols.** Not later than 180 days after the enactment of this title, the Secretary, along with the HIT Policy Committee, shall develop standards and protocols that facilitate enrollment of individuals in federal and state health and human services programs. This shall include the provision to individuals or representatives of individuals notice of eligibility and verification of eligibility required under such programs.
>
> The standards shall account for the following: (1) electronic matching against existing federal and state data, including vital records, employment history, enrollment systems, tax records, and other data determined appropriate by the Secretary; (2) simplification and submission of electronic documentation, etc.; (3) reuse of stored eligibility information to assist with retention of eligible individuals; (4) capability for individuals to apply, recertify, and manage their eligibility information online; (5) ability to expand the enrollment system to integrate new programs, rules, and functionalities, etc.; (6) notification of eligibility, recertification, and other needed communication, including via e-mail and cell phones; (7) other functionalities. The Secretary shall notify the States and may condition the receipt of federal funding on compliance with such standards. Grants may be awarded to States and political subdivisions according to the standards set forth within the Act.

Sec. 1562. GAO study regarding the rate of denial of coverage and enrollment by health insurance issuers and group health plans. The Comptroller General shall conduct a study of the incidence of denials of coverage for medical services and denials of applications to enroll in health insurance plans by group health plans and health insurance issuers. The Comptroller must submit the report to the Secretaries of HHS and Labor no later than one year after the date of enactment of this Act.

Sec. 1563. Small business procurement. Part 19 of the Federal Acquisition Regulation, section 15 of the Small Business Act, and any other applicable laws or regulations establishing procurement requirements relating to small business concerns (as defined in section 3 of the Small Business Act) may not be waived with respect to any contract awarded under any program or other authority under this Act or an amendment made by this Act.

TITLE II

ROLE OF PUBLIC PROGRAMS

Subtitle A - Improved Access to Medicaid

Sec. 2001. Medicaid coverage for the lowest income populations. On January 1, 2014, eligible individuals whose income does not exceed 133% of the poverty line will receive medical assistance. States are given the option to offer coverage earlier to all non-elderly individuals above 133% of the poverty line, and children are required to have coverage before their parents would be eligible. Newly-eligible individuals would receive benchmark or benchmark-equivalent coverage consistent with the requirements of section 1937 of the Social Security Act.

During the period that begins on January 1, 2014 and ends on December 31, 2016, the federal medical assistance percentage ("FMAP") determined for a State shall be 100% of the cost of covering newly-eligible individuals. In 2017 and 2018, States that initially covered less of the newly-eligible population would receive more assistance than those States that covered at least some non-elderly, non-pregnant individuals. Section 10201 of the Act applies pre-2017 matching rate to subsequent years in Nebraska. States must maintain the same income eligibility levels through 2013 for all adults and through September 30, 2019 for all children currently covered in Medicaid or CHIP.

Sec. 2002. Income eligibility for non-elderly determined using modified gross income. For purposes of determining income eligibility for medical assistance under the state plan or under any waiver of a state plan, a State must use the modified gross income of an individual and, if the individual is in a family greater than one, the

household income of the family. The State must establish income eligibility thresholds for populations to be eligible for medical assistance under the state plan (or a waiver of the plan) that are not less than the effective income eligibility levels that applied under the state plan or waiver before the date of enactment of the Act. States cannot apply any assets or resources test for the purpose of determining eligibility. Exceptions to the income rule would apply to groups such as those eligible for other federal or state assistance, individuals 65 or older, the blind or disabled, and the medically needy.

Sec. 2003. Requirements to offer premium assistance for employer-sponsored insurance. A State may not require, as a condition of an individual being or remaining eligible for medical assistance, that the individual apply for enrollment in qualified employer-sponsored coverage.

Sec. 2004. Medicaid coverage for former foster care children. The State must cover former foster children in Medicaid, but only those children who have aged out of the foster care system as of the date of enactment.

Sec. 2005. Payment to territories. The bill amends the Social Security Act to increase the limits of payment by 30% to territories and to increase the FMAP to 55%.

Sec. 2006. Special adjustment to FMAP determination for certain states recovering from a major disaster. The FMAP projected decreases would be reduced for States recovering from a major disaster.

Sec. 2007. Medicaid Improvement Fund rescission. Any amounts available to the Medicaid Improvement Fund for fiscal years 2014 through 2018 that are available for expenditure from the fund but not obligated on the date of enactment are rescinded.

Subtitle B - Enhanced Support for the Children's Health Insurance Program

Sec. 2101. Additional federal financial participation from CHIP. From 2016 through 2019, the enhanced FMAP determined for a State for a fiscal year will be increased by 23 percentage points, but will not exceed 100 percent. States must maintain eligibility standards for CHIP through September 30, 2019. If the allotments provided are not sufficient to provide coverage to all children who are eligible, a State must establish procedures to ensure that such children are provided coverage through an Exchange. Income eligibility is determined by using modified gross income and household income.

Subtitle C- Medicaid and CHIP Enrollment Simplification

Sec. 2201. Enrollment simplification and coordination with state health insurance exchanges. Each State, as a condition of receiving federal financial assistance, must establish procedures for enabling individuals, through an Internet website, to apply for medical assistance; enrolling individuals who are identified by an Exchange as being eligible; ensuring that individuals who apply for but are determined to be ineligible for medical assistance are screened for eligibility in qualified health plans; ensuring that the state agency and an Exchange utilize a secure electronic interface; coordinating the provision of medical assistance; and conducting outreach to vulnerable, eligible populations.

Sec. 2202. Permitting hospitals to make presumptive eligibility determinations for all Medicaid eligible populations. Any hospital that is a participating provider under the state plan may elect to be a qualified entity for purposes of determining whether an individual is eligible for medical assistance under the state plan or under a waiver.

Subtitle D - Improvements to Medicaid Services

Sec. 2301. Coverage for freestanding birth center services. States must provide separate payments to providers administering prenatal labor and delivery or postpartum care in a freestanding birth center.

Sec. 2302. Concurrent care for children. A voluntary election to receive hospice care for a child will not constitute a waiver of any rights of the child to be provided with services related to the treatment of the condition.

Sec. 2303. State eligibility option for family planning services. A new optional, categorically-needy group may receive benefits limited to family planning services and supplies. The eligible group would include women who are not pregnant and whose income does not exceed the level applicable to pregnant women covered under Medicaid or CHIP and individuals eligible under the standards of section 1115 waivers.

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

Sec. 2401. Community first choice option. A State may offer home and community-based attendant services and support for disabled individuals eligible for Medicaid. The State would provide home and community-based attendant services and support to eligible individuals, as needed, to assist in everyday activities and health-related tasks. Prohibited services include room and board; special education; assistive technology devices; medical supplies; and home modifications. The services would include expenditures for transition costs and expenditures relating to a need identified in an individual's person-centered plan of services.

Sec. 2402. Removal of barriers to providing home and community-based services. States may provide more types of home and community-based services through a state plan amendment to individuals with higher levels of need. States would develop service systems designed to allocate resources, provide support and coordination for beneficiary services, and improve coordination among providers of such services. The provision of services may target specific populations, and the services may differ by type, amount, duration, and scope.

Sec. 2403. Money Follows the Person Rebalancing Demonstration. The Money Follows the Person Rebalancing Demonstration is extended through fiscal year 2016.

Sec. 2404. Protection for recipients of home and community-based services against spousal impoverishment. States must apply spousal impoverishment rules to beneficiaries who receive home and community-based services.

Sec. 2405. Funding to expand state aging and disability resource centers. Congress appropriated $10 million to the Secretary for each of fiscal years 2010 through 2014 to carry out Aging and Disability Resource Center Initiatives.

Sec. 2406. Sense of the Senate regarding long-term care. Congress should address long-term services and supports in a comprehensive way that guarantees elderly and disabled individuals the care they need; and long-term services and supports should be made available in the community in addition to institutions.

Subtitle F – Medicaid Prescription Drug Coverage

Sec. 2501. Prescription drug rebates. The provision increases the flat rebate for most single source and innovator multiple source outpatient prescription from 15.1 percent to 23.1 percent. The rebate for clotting factors and outpatient pediatric drugs will increase to 17.1 percent. The provision increases the basic rebate percentage for multi-source, non-innovator drugs from 11 percent to 13 percent. The law specifically and clearly requires for the first time that manufacturers pay rebates for drugs dispensed to Medicaid beneficiaries who receive care through a Medicaid managed care organization. This provision could have the effect of shifting rebate payments by manufacturers from private managed care organizations to the States.

Total rebate liability would be limited to 100 percent of the average manufacturer price ("AMP").

Finally, the increased rebates to the States are accompanied by a corresponding decrease in federal matching funds.

Sec. 2502. Elimination of exclusion of coverage of certain drugs. Effective January 1, 2014, barbiturates, benzodiazepines, and drugs for smoking cessation may not be excluded from Medicaid coverage.

Sec. 2503. Providing adequate pharmacy reimbursement. This provision amends 42 U.S.C. 1396r-8(e) establishing the federal upper limit ("FUL") for reimbursement of pharmacies by state Medicaid programs. The revised FUL is no less than 175 percent of the weighted average (determined on the basis of utilization) of the most recently reported monthly AMP for pharmaceutically and therapeutically equivalent multiple source drugs available nationally through commercial pharmacies. The definition of AMP under 42 U.S.C. 1396r-8(k) is also amended to clarify which types of sales are not required to be included, and what types of discounts may be excluded, in calculating the AMP.

Subtitle G – Medicaid Disproportionate Share (DSH) Payments

Sec. 2551. Medicaid Disproportionate Share Hospital ("DSH") Payments (as amended by the Reconciliation Act). These lengthy section addresses changes to be made in the future to reduce Medicaid DSH allotments to states for FYs 2014 through 2020 in light of the reduction in the number of uninsured anticipated as a result of the implementation of the PPACA. They also expand certain DSH allotments for FYs 2012 and 2013 (with special rules for Hawaii) and address payments under the QUEST Demonstration Project.

Subtitle H – Improved Coordination for Dual Eligible Beneficiaries

Sec. 2601. 5-year period for demonstration projects. This provision clarifies that the Secretary can authorize Medicaid waivers for coordinating care for dual eligible beneficiaries for as long as five years, and may reauthorize such waivers for subsequent five year periods.

Sec. 2602. Providing Federal coverage and payment coordination for dual eligible beneficiaries. This provision provides for the creation of a Federal Coordinated Health Care Office ("CHCO") within CMS. The CHCO's mission is to facilitate Medicare and Medicaid program officials to better integrate benefits under the two programs, and through coordination between the Federal and State officials, to provide individuals better access to benefits under both Medicare and Medicaid by, among other things, simplifying processes, and eliminating regulatory conflicts and cost shifting between programs.

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

Sec. 2701. Adult health quality measures. This provision directs the Secretary of HHS to develop a set of quality measures for Medicaid eligible adults that is similar to the quality measurement program for children enacted in the Children's Health Insurance Program Reauthorization Act of 2009 ("CHIP") that should be recommended by January 1, 2011 and final by January 1, 2012. By January 1, 2013, The Secretary and the States shall develop a standardized format for the reporting of the information with the aim to encourage State voluntary reporting of information on the quality of health care for Medicaid eligible adults. The States are to report annually State-specific adult health quality measures used by the State for the purposes of analysis and publication by the Secretary. Establishes the Medicaid Quality Measurement Program by January 1, 2012, which is to model the pediatric quality measures program under CHIP and include the same amount of funding for awarding grants and contracts relating to the development, testing, and validation of emerging an innovative evidence-based measures.

Sec. 2702. Payment adjustment for health care-acquired conditions. Effective July 1, 2011, this provision prohibits Medicaid payment for services related to a health care-acquired condition, a diagnosed medical condition that could be identified by a secondary diagnostic code. The Secretary will develop a list of health care-acquired conditions for Medicaid based on those defined under Medicare as well as current State practices.

Sec. 2703. State option to provide health homes for enrollees with chronic conditions. By January 1, 2011, this provision provides States the option, through a state plan amendment, of enrolling Medicaid beneficiaries with chronic conditions into a health home. "Chronic condition" is defined under the statute, but not limited to a mental health condition, substance use disorder, asthma, diabetes, heart disease, and being overweight with a BMI over 25. States may be awarded grants for purposes of developing a state plan amendment under this section and the state plan amendment would have to include a provision requiring hospitals to refer eligible individuals who seek treatment in the emergency department to designated providers. Health homes would be composed of a team of health professionals, would provide a comprehensive set of medical services, including care coordination, and would have to meet standards established by the Secretary to be eligible.

Payments made to the team of health professionals would be considered medical assistance, but would be limited to 90% during the first 2 years that the state plan amendment would be in effect. The methodology for determining payment would not be limited to per-member per-month. A designated provider's payment under this

section would be conditioned on reporting to the State all applicable measures for determining quality of services as specified by the Secretary. Reports and independent evaluations will be conducted on all States that include this option, in order to determine its success by various measures included the possible affect on the amount of hospital admissions.

Sec. 2704. Demonstration project to evaluate integrated care around a hospitalization. This provision establishes a demonstration project, in up to eight States, to study the use of bundled payments for hospital and physicians services under Medicaid between January 1, 2012 through December 31, 2016 in an effort to reduce cost and increase quality. The demonstration project should be as representative as possible of the demographic and geographic composition of Medicaid beneficiaries nationally.

Sec. 2705. Medicaid global payment system demonstration project. This provision establishes a demonstration project between fiscal years 2010 through 2012, in coordination with the CMS Innovation Center, in up to five States that would allow participating States to adjust their current payment structure for safety net hospitals from a fee-for-service model to a global capitated payment structure.

Sec. 2706. Pediatric Accountable Care Organization demonstration project. This provision establishes a demonstration project to take place between January 1, 2012 through December 31, 2016 that allows qualified pediatric providers to be recognized and receive payments as Accountable Care Organizations ("ACO") under Medicaid. The pediatric ACO would be required to meet certain performance guidelines. Pediatric ACOs that met these guidelines and provided services at a lower cost of an amount determined by the Secretary would share in a proportion of those savings as determined by the Secretary.

Sec. 2707. Medicaid emergency psychiatric demonstration project. This provision requires the Secretary of HHS to establish a consecutive three-year Medicaid demonstration project in up to eight States. Participating States would be required to reimburse certain institutions for mental disease ("IMDs") that are not publicly owned or operated for services provided to Medicaid beneficiaries between the ages of 21 and 65 who are in need of medical assistance to stabilize an emergency psychiatric condition. Such an emergency condition is defined as an individual who expresses suicidal or homicidal thoughts or gestures when determined to be dangerous to one's self or others. States will specify in their application a mechanism to determine whether such individuals have actually been stabilized and would be put into effect before the third day of inpatient stay.

Subtitle J – Improvements to the Medicaid and CHIP Payment and Access Commission

Sec. 2801. MACPAC assessment of policies affecting all Medicaid beneficiaries. This provision clarifies the topics to be reviewed by the Medicaid and CHIP Payment and Access Commission ("MACPAC"), in consultation with the Medicare Payment Advisory Commission ("MedPAC") as necessary, such as factors affecting the efficient provision of items and services including the process for updating payments to various providers and managed care entities and how such factors enable beneficiaries to obtain the service for which they are eligible, affect provider supply, and providers that serve a disproportionate share of low-income and other vulnerable populations. Additionally, MACPAC will now review Medicaid and CHIP eligibility policies, enrollment and retention policies, coverage policies, and the quality of care provided under these programs.

MACPAC will be assessing the interactions of policies under the Medicaid and Medicare program, reviewing Federal Medicaid and CHIP regulations, making additional reports and recommendations of State-specific data, and an assessment of adult services in Medicaid. The provision would also authorize $11 million to fund MACPAC for FY 2010.

Subtitle K - Protections for American Indians and Alaska Natives

Sec. 2901. Special rules relating to Indians. This provision prohibits cost-sharing for Indians with income at or below 300 percent of the poverty level who are enrolled in a QHP plan in the individual market through a State Exchange. Also, health programs operated by the Indian Health Service ("HIS") and Indian, Tribal, and Urban Indian facilities ("I/T/Us") will generally be the payer of last resort for services provided by the same. Facilities operated by the IHS and I/T/Us would be added to the list of agencies that could serve as an "Express Lane" agency able to make Medicaid and CHIP eligibility determinations.

Sec. 2902. Elimination of sunset for reimbursement for all Medicare Part B services furnished by certain Indian hospitals and clinics. This provision removes the sunset provision, allowing IHS and I/T/U services to continue to be reimbursed by Medicare Part B.

Subtitle L - Maternal and Child Health Services

Sec. 2951. Maternal, infant, and early childhood home visiting programs. Each State, as a condition of receiving payments from an allotment, must conduct a statewide needs assessment that identifies communities with concentrations of poor infant

outcomes, poverty, crime, domestic violence, high rates of high school drop-outs, substance abuse, unemployment, or child maltreatment. The State must also identify the quality and capacity of existing programs or initiatives for early childhood home visitation. These results must be submitted to the Secretary, along with a description of how the State intends to address needs identified by the assessment.

The Secretary will then make grants to States, Indian tribes, territories, and nonprofit organizations to enable the entities to deliver services under early childhood visitation programs in order to promote improvements in maternal and prenatal health, infant health, child health and development, parenting related to child development outcomes, school readiness, and the socioeconomic status of such families. The requirements for an early childhood visitation program conducted with a grant are subject to a quantifiable 3- and 5-year benchmark for demonstrating that the program results in improvements for eligible families. The program must include, in part, a service delivery model(s), competent staff, high quality supervision, and organizational capacity. The eligible entity must give priority to providing services under the program to high-risk populations.

Sec. 2952. Support, education, and research for postpartum depression. Congress encourages the Secretary to continue activities on postpartum conditions, including research to expand the understanding of the causes of, and treatment for, these conditions. These activities include basic research, epidemiological studies, improved screening, clinical research, and educational programs for health care professionals and the public. The Secretary may make grants to eligible entities for the establishment and operation of systems for the delivery of essential services to individuals with or at risk for postpartum conditions. Specifically, the Secretary shall ensure these projects provide education and services with respect to the diagnosis and management of postpartum conditions, such as delivering outpatient home-based health and support services.

Sec. 2953. Personal responsibility education. The Secretary will allot a portion of the $75 million (per year through fiscal year 2014) to each State to enable the State to carry out personal responsibility education programs. A personal responsibility program is a program designed to educate adolescents on both abstinence and contraception and at least three adult preparation subjects. The program must replicate evidence-based effective programs, be medically-accurate and complete, and include activities to educate youth who are sexually active. The adulthood preparation subjects include healthy relationships, adolescent development, financial literacy, and healthy life skills. Funding is also available for innovative teen pregnancy prevention strategies, allotments to Indian tribes, and research.

Sec. 2954. Restoration of funding for abstinence education. Section 501 of the Social Security Act is amended to fund $50 million for the program through 2014.

Sec. 2955. Importance of having a health care power of attorney. Section 475(5)(H) of the Social Security Act is amended by inserting language including information about the importance of designating another individual to make health care treatment decisions on behalf of a child if the child becomes unable to participate in such decisions. An adolescent participating in this program must be provided with education about the importance of designating another individual to make health care treatment decisions.

Sec. 10212. Establishment of Pregnancy Assistance Fund. The Secretary will establish a Pregnancy Assistance Fund to award grants to States to assist pregnant and parenting teens and women. To be eligible for a grant, a State must submit an application to the Secretary, including a description of the purposes for which the grant is being requested and the designation of a state agency for receipt of funds. A State may use the grant money to make funding available to institutions of higher education to enable them to establish pregnant and parenting student services. Also, a State shall make funding available to eligible high schools and community service centers.

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. HHS will establish a value-based purchasing program under which hospitals will receive incentive payments for meeting certain performance standards related to discharges occurring on or after October 1, 2012. Initially, the program shall pertain to at least the following conditions:

acute myocardial infarction, heart failure, pneumonia, surgeries, and healthcare-associated infections. The program shall not apply to conditions treated upon readmission. HHS may extend the program to apply to additional conditions or procedures with at least 1 year's notice. The performance standards that hospitals can meet in order to receive incentive payments shall include both achievement and improvement standards and, beginning in 2014, efficiency measures such as "Medicare spending per beneficiary".

Under the program, if a hospital meets or exceeds performance standards, it will receive an increase in its base operating DRG payment for each applicable discharge occurring that year. However, beginning in 2013, each hospital's base operating DRG payment amount will be reduced annually (by 1.0% in 2013, 1.25% in 2014, 1.5% in 2015, 1.75% in 2016, and 2% thereafter), such that a hospital must meet or exceed the performance standards in order to maintain or increase actual DRG payment amounts per discharge from year to year.

A hospital shall have the right to appeal both the implementation of performance standards and the calculation of its performance score, but administrative and judicial review will be otherwise limited. In 2015 and 2017, the GAO will report to Congress on many aspects of the value-based purchasing program, including its impact on quality of care, program expenditures, and safety net and rural hospitals.

Beginning in 2012, HHS shall implement a 3-year demonstration program of value-based purchasing for critical access hospital inpatient services.

Sec. 3002. Improvements to the physician quality reporting system. Congress extended, through 2014, the Physician Quality Reporting System ("PQRS"), under which incentive payments are already made for certain physician services. Beginning in 2015, physicians who do not satisfactorily submit data on quality measures under PQRS will receive a fraction of the otherwise applicable fee schedule amounts (98.5% for 2015 and 98% for 2016 and thereafter). By January, 2012, HHS will develop a plan to ultimately integrate the PQRS with the meaningful use of electronic health records ("EHR").

Similarly, physicians who disclose the completion of a Maintenance of Certification Program ("MCP") will receive a 0.5% increase in applicable fee schedule amounts. An MCP includes license maintenance, education and self-assessment, a formal examination of specialty knowledge, and a practice assessment that includes a demonstration of the practice's use of evidence-based medicine, a survey of patient experience, and a response to any quality improvement intervention used to address any weaknesses identified in the initial practice assessment.

Sec. 3003. Improvements to the physician feedback program. Beginning in 2012, HHS shall provide reports to Medicare-enrolled physicians that compare the physician's pattern of resource use with other physicians' patterns of resource use. The reports shall account for differences in socioeconomic and demographic characteristics, ethnicity, and health status. The feedback program shall be coordinated with the value-based purchasing program for physicians' services (see below).

Sec. 3004 & 3005. Quality reporting for long-term care hospitals, inpatient rehabilitation hospitals, hospice programs, and PPS-exempt cancer hospitals. By October, 2012, HHS shall publish quality measures that long-term care ("LTC") hospitals, inpatient rehabilitation hospitals, hospice programs, and PPS-exempt cancer hospitals will be required to report to HHS. Beginning in 2014, any LTC hospital or inpatient rehab hospital that does not submit quality data shall suffer a 2% reduction in its discharge rates, although such reductions shall not be annually cumulative. Similarly, any hospice program that does not submit quality data shall suffer a 2% reduction in any increase to its market basket percentage, although such reductions shall not be annually cumulative. While PPS-exempt cancer hospitals will be obligated to report quality measures, failure to do so will not result in a reduction of payment.

Sec. 3006. Plans for a value-based purchasing program for skilled nursing facilities, home health agencies and other entities. HHS shall develop a plan to implement a value-based purchasing program for SNFs, HHAs, and ASCs. HHS shall report to Congress on these plans by January 1, 2011 (for ASCs) and by October 1, 2011 (for SNFs and HHAs). By January 1, 2016, HHS shall implement pilot programs for the implementation of value-based purchasing programs for psychiatric hospitals, LTC hospitals, rehabilitation hospitals, PPS-exempt cancer hospitals, and hospice programs. Such pilot programs may be extended after January 1, 2019 only if HHS determines, and the CMS Chief Actuary certifies, respectively, that such an extension would reduce Medicare spending.

Sec. 3007. Value-based payment modifier under the physician fee schedule. HHS shall establish and, beginning with 2015 but no later than 2017, implement a payment modifier that provides for differential payment to physicians based upon the quality of care furnished as compared to the cost of that care. To implement this program, HHS shall no later than January 1, 2012 establish both quality and cost measures, such as measures that reflect health outcomes, as risk-adjusted for geography and other risk factors, such as socioeconomic and demographic characteristics. Use of this modifier shall be coordinated with the physician feedback program (see above). Many aspects of this program shall not be subject to administrative or judicial review.

Sec. 3008. Payment adjustment for conditions acquired in hospitals. Beginning in 2015, if a hospital is in the top 25% of hospitals with the most hospital-acquired

conditions, that hospital shall thereafter only receive 99% of payments otherwise due. HHS shall publicize each hospital's experience with hospital-acquired conditions, but only after hospitals have had an opportunity to review and submit corrections to the proposed report. HHS shall study and, by January, 2012, report to Congress on the potential expansion of this policy to other facilities, such as LTC hospitals, inpatient rehabilitation facilities, SNFs, ASCs, and health clinics.

PART II – NATIONAL STRATEGY TO IMPROVE HEALTH CARE QUALITY

Sec. 3011. National strategy. By January 1, 2011, HHS shall establish a national strategy to improve the delivery of health care services, patient health outcomes, and population health, as well as prioritized action items to achieve that improvement. Action items will be considered prioritized if they have the greatest potential for improving outcomes, efficiency, and patient-centeredness for all; would operate in areas with the most potential for rapid improvement in the quality and efficiency of patient care; would address gaps in measures and data aggregation techniques; would improve Federal payment policy to emphasize quality and efficiency; would enhance the use of health care data; would address health care provided to patients with high-cost chronic diseases; would improve research and dissemination of best practices to improve safety and reduce errors, preventable admissions and readmissions; and would reduce health disparities across populations and geographic areas. HHS shall report annually on the implementation of the strategy.

Sec. 3012. Interagency working group on health care quality. The President shall convene an Interagency Working Group on Health Care Quality, which shall seek to achieve collaboration, cooperation and consultation across Federal departments and agencies with respect to implementing the priorities of the national strategy (see above); avoidance of duplication of efforts and resources; and alignment of quality efforts in the public and private sectors.

Sec. 3013. Quality measures development. HHS shall award grants, contracts or intergovernmental agreements for the purposes of developing and improving quality measures, which are defined to mean "standards for measuring the performance and improvement of population health or of health plans, providers of services, and other clinicians in the delivery of health care services." Such measures shall include physician-specific and hospital-specific measures, for acute and chronic diseases and primary and preventive care services. Each year from 2010 through 2014, HHS shall make $75,000,000 available for such grants, contracts, and agreements.

Sec. 3014. Quality measurement. Multi-stakeholder groups shall convene to provide input to HHS on the selection of quality and efficiency measures. These measures shall be used throughout the Medicare program (for purposes other than just payment), for reporting performance information to the public, and in health care programs. HHS shall use $20,0000 a year from 2010 through 2014 for these purposes.

Sec. 3015. Data collection; public reporting. With the goal of reporting performance information to the public, HHS shall collect and aggregate consistent data on quality measures and resource use measures. These collection and reporting efforts may be aligned with the requirements regarding the expansion of HIT systems, the interoperability of such systems, and related standards. HHS may award grants for this purpose.

PART III – ENCOURAGING DEVELOPMENT OF NEW PATIENT CARE MODELS

Sec. 3021. Establishment of Center for Medicare and Medicaid Innovation within CMS. Within CMS, Congress created a Center for Medicare and Medicaid Innovation ("CMI"). CMI shall test innovative payment and service delivery models to reduce program costs while preserving or enhancing quality of care. Congress identified certain models for CMI to test, including:

- patient-centered medical home models;
- models that transition primary care practices away from fee-for-service based reimbursement and toward either:
    - a comprehensive payment structure; or
    - a salary-based payment structure
- contracting directly with providers through either:
    - a risk-based, comprehensive payment structure; or
    - a salary-based payment structure
- varying payment to physicians who order advanced diagnostic imaging services on the basis of whether the physicians adheres to appropriateness criteria for ordering such services;
- paying providers who use patient decision-support tools;
- State testing and evaluation of all-payer payment reform;
- aligning payment incentives with nationally recognized, evidence-based guidelines of cancer care;
- eliminating gatekeeper models (for needed specialty services);
- establishing comprehensive payments to "Health Innovation Zones," which would consist of teaching hospitals, physicians, and other providers; and

- utilizing, in medically underserved and other certain areas, telehealth services for treating behavioral health issues, treating stroke, and for improving the capacity of non-medical and non-specialized medical providers.

Any test models shall be evaluated on the bases of the quality of care provided and the cost to the program. HHS shall report annually to the Congress on the models implemented. Congress has invested significant funds for CMI to achieve its goals: CMI shall be appropriated $5,000,000 for FY 2010, $10,000,000,000 for FY 2011 through 2019, and $10,000,000,000 for each ten-year period after that.

Sec. 3022. Medicare shared savings program. By January, 2012, HHS shall establish a shared savings program under which groups of providers (physicians, group practices, hospitals, and others) can work together through an "Accountable Care Organization" ("ACO") to manage and coordinate care for traditional (Part A and Part B) Medicare beneficiaries. Each ACO must be accountable for the quality, cost, and overall care provided to traditional Medicare beneficiaries, and participate in the program for at least three years. HHS will periodically measure each ACO based on quality of care measures, such as clinical processes and outcomes, patient and caregiver experiences, and utilization rates.

Providers participating in certain ACOs will continue to be paid based on the Medicare fee schedule, but ACOs that meet quality performance standards will be eligible to receive additional payments based on a share of the savings the ACO achieves for the Medicare program. Additional payments shall be made on the basis of the ACO's reduction in per-beneficiary expenditures, relative to the norm, and may be conditional upon demonstrable use of e-prescribing and EHR technologies.

ACOs that achieve program savings but do not meet quality performance standards will not be eligible to receive additional payments, and ACOs found to have avoided high-risk (high-cost) patients may be sanctioned.

In addition to the quality-of-care/shared savings hybrid model, other ACOs may be reimbursed on a partial capitation model, if such ACOs are highly integrated and are capable of bearing risk. To implement this model, HHS may give preference to ACOs that currently participate in similar arrangements with other third party payers.

Congress did not address how providers participating in an ACO may divide, amongst themselves, any additional payments received for achieving program savings or under a partial capitation model, or the degree to which inter-provider arrangements to divide such additional payments would implicate established federal health care fraud and abuse authorities, in particular the federal health care program anti-kickback statute and the Stark Law. Neither did Congress address whether any program participants

would be exempt from the federal prohibition on limiting care to beneficiaries, which has been interpreted to prohibit certain previous industry attempts at shared savings programs.

Sec. 3023. National Pilot Program On Payment Bundling. In order to improve the coordination, quality, and efficiency of health care services, HHS shall establish a five-year pilot program for making "bundled" payments to numerous providers for treating a beneficiary's episode of care provided around a hospitalization. Initially, the program will apply to ten specific conditions. Under this program, HHS will pay participating providers (*i.e.*, physicians, hospitals, SNFs, and HHAs) a bundled rate for treating the patient's entire episode of care, in lieu of making traditional Part A and Part B payments separately to such providers. The bundle rate would also cover the furnishing of services such as care coordination, medication reconciliation, discharge planning, and transitional care services.

The episode of care for which a bundled payment will be made will include the three days prior to admission, the length of the hospitalization, and the thirty days following the hospitalization. Providers who integrate for purposes of participating in this program may have the ability to bid on a bundled rate for each condition.

The quality of the care provided under this program shall be measured, evaluated, and reported to Congress. After January, 2016, HHS may expand the duration and scope of this program only if it and CMS' Chief Actuary determine and certify, respectively, that such an expansion would reduce Medicare spending.

Similar to the shared savings program (above), Congress did not address how integrated providers participating in a bundled payment pilot program may divide, amongst themselves, the bundled payments received, or the degree to which arrangement to divide such bundled payments would implicate federal health care fraud and abuse authorities such as the federal health care program anti-kickback statute and the Stark Law.

Sec. 3024. Independence at home demonstration program. By January, 2012, HHS shall establish a demonstration program to test whether payment incentives for teams of physicians and nurse practitioners can reduce program expenditures and improve health outcomes for certain chronically ill and dependent home-based patients. In particular, the incentives will seek to reduce preventable hospitalizations, ER visits, and hospital readmissions. Participating teams will create a budget of anticipated program expenditures relating to the care of their patients, and participating providers will receive an incentive payment if actual expenditures for services provided are less than anticipated expenditures.

Similar to the shared savings and bundled payment programs discussed above, Congress did not address whether Independence At Home program participants would be exempt from the federal prohibition on limiting care to beneficiaries, which has been interpreted to prohibit efforts that can result in limiting the nature or amount of health care services provided to beneficiaries, or other federal health care fraud and abuse authorities such as the anti-kickback statute.

Sec. 3025. Hospital readmissions reduction program. Beginning in 2012, HHS will establish a program designed to reduce hospital readmissions for the treatment of certain conditions. The program will compensate hospitals for treating patients who are readmitted to the hospital at a fraction of the typical DRG rate for such treatment. The percentage reductions will be specific to the hospital, based on its excess readmissions for the previous year, but will not go below 99% of the typical DRG rate in 2013, 98% of the typical DRG rate in 2014, and 97% of the typical DRG rate in 2015 and subsequent years. In 2015, the program shall be expanded to include readmissions for treatment of additional conditions. HHS will publicize all hospitals' readmission rates.

Sec. 3026. Community-based care transitions program. Beginning in 2011, HHS shall establish a program under which certain hospitals and community-based organizations can receive enhanced payments for furnishing improved care transition services to high-risk Medicare beneficiaries. Providers could demonstrate improvement in such services by initiating transition services not later than twenty-four hours prior to discharge, arranging follow-up services, providing information to patients and caregivers that can assist the identification of symptoms of deteriorating conditions, assisting provider-patient communications and self-management support, and conducting comprehensive medication review and management.

Sec. 3027. Extension of gainsharing demonstration. The gainsharing demonstration project established by the Deficit Reduction Act of 2005 has been extended to September 30, 2011, and funding for the project has been increased by $1,600,000 for FY 2010.

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. This section is repealed by Title X, Section 10310 of the Act.

Sec. 3102. Extension of the work geographic index floor and revisions to the practice expense geographic adjustment under the Medicare physician fee schedule. This provision extends a floor on geographic adjustments to the work portion of the fee schedule through 2010, with the effect of increasing practitioner fees in rural areas. With relation to the practice expense geographic adjustment, this section adds that the employee wage and rent portions of the index shall reflect ¾ of the difference between the relative costs of employee wages and rents in each of the different fee schedule areas and the national average for the year 2010, and ¾ of the difference for 2011. The Reconciliation Bill then changed "¾" to "½" with respect to 2010. Also prevents the practice expense portion of the geographic adjustment from being reduced below a certain amount in the event an area is negatively impacted by the amendment. Lastly, this provision requires the Secretary of HHS to analyze data that establishes distinctions in the costs of operating medical practices in different fee schedule areas in order to improve the methodology for calculating practice expense adjustments beginning in 2012.

Sec. 3103. Extension of exceptions process for Medicare therapy caps. This provision extends the process allowing exceptions to limitations on medically necessary therapy until December 31, 2010.

Sec. 3104. Extension of payment for technical component of certain physician pathology services. This provision extends a provision that directly reimburses qualified rural hospitals for certain clinical laboratory services through the end of 2010.

Sec. 3105. Extension of ambulance add-ons. This provision extends bonus payments made by Medicare for ground and air ambulance services in rural and other areas through the end of 2010. Title X, Section 10311 of the act requires the Secretary of HHS to implement the extension of the ambulance payment bonuses on January 1, 2010.

Sec. 3106. Extension of certain payment rules for long-term care hospital services and of moratorium on the establishment of certain hospitals and facilities. This provision extends Sections 114 (c) and (d) of the Medicare, Medicaid and SCHIP Extension Act of 2007 by two additional years, as amended by Title X, Section 10312 of the act.

Sec. 3107. Extension of physician fee schedule mental health add-on. This provision extends the increased payment rate for psychiatric services of 5 percent through the end of 2010.

Sec. 3108. Permitting physician assistants to order post-hospital extended care services. This provision authorizes physician assistants to order skilled nursing care services in the Medicare program beginning in 2011.

Sec. 3109. Exemption of certain pharmacies from accreditation requirements. This provision allows DMEPOS supplier pharmacies with an average of less than 5 percent of revenues from Medicare DMEPOS billings over the past 3 years to be exempt from accreditation requirements until and if the Secretary of HHS decides to develop alternative accreditation requirements for these pharmacies.

Sec. 3110. Part B special enrollment period for disabled TRICARE beneficiaries. This provision creates a twelve-month special enrollment period for military retirees, their spouses (including widows/widowers) and dependent children, who are otherwise eligible for TRICARE and entitled to Medicare Part A based on disability or ESRD, but who have declined Part B. An individual is limited to being able to enroll during this special period to once during the individual's lifetime.

Sec. 3111. Payment for bone density tests. This provision restores payment for dual-energy x-ray absorptiometry ("DXA") services furnished during 2010 and 2011 to 70 percent of the Medicare rate paid in 2006. This provision further authorizes the Secretary to enter into an agreement with Institute of Medicine of the National Academies to conduct a study on the effects of the Medicare payment reductions for DXA and on beneficiary access to bone mass density tests.

Sec. 3112. Revision to the Medicare Improvement Fund. Eliminates the remaining funds in the Medicare Improvement Fund.

Sec. 3113. Treatment of certain complex diagnostic laboratory tests. This provision creates a demonstration program for 2 years beginning July 1, 2011 in order to test the impact of direct payments to laboratories for certain complex diagnostic laboratory tests including certain analyses of gene protein expression, topographic genotyping, and cancer chemotherapy sensitivity assays on Medicare quality and costs.

Sec. 3114. Improved access for certified nurse-midwife services. This provision increases the payment rate for certified nurse midwives after January 1, 2011 for covered services from 65 percent to 100 percent of the rate that would be paid were a physician performing a service to the full rate.

PART II - RURAL PROTECTIONS

Sec. 3121. Extension of outpatient hold harmless provision. This provision extends the existing outpatient hold harmless provision through the end of FY2010 and would allow Sole Community Hospitals with more than 100 beds to also be eligible to receive this adjustment through the end of FY2010.

Sec. 3122. Extension of Medicare reasonable costs payments for certain clinical diagnostic laboratory tests furnished to hospital patients in certain rural areas. This provision reinstates the policy included in the Medicare Modernization Act of 2003 (P.L. 108-173) that provides reasonable cost reimbursement for laboratory services provided by certain small rural hospitals from July 1, 2010 to July 1, 2011.

Sec. 3123. Extension of the Rural Community Hospital Demonstration Program. This provision extends the program for five years, as amended by Title X, Section 10313 of the act, expands eligible sites to additional States and to additional rural hospitals, and makes adjustments to payment levels provided within the demonstration program. Further, this section allows current rural community hospitals to continue in the demonstration project unless the hospital no longer wishes to participate.

Sec. 3124. Extension of the Medicare-dependent hospital (MDH) program. Extends the Medicare-dependent hospital program through October 1, 2012.

Sec. 3125. Temporary improvements to the Medicare inpatient hospital payment adjustment for low-volume hospitals. This provision expands the program providing a temporary adjustment to inpatient hospital payments for certain low-volume hospitals through FY2012. A temporary percentage increase will be afforded on a sliding scale depending on the amount of annual Part A enrollee discharges. A hospital with greater than 1,500 discharges will not qualify, and a hospital with under 200 discharges qualifies for 25%. This provision also modifies the eligibility requirements regarding distance from another facility. Also, as amended in Title X, Section 10314 of the act, the requirements regarding the number of eligible discharges are increased to 1,600 discharges.

Sec. 3126. Improvements to the demonstration project on community health integration models in certain rural counties. The Medicare Improvements for Patients and Providers Act ("MIPPA") authorized a demonstration project that will allow eligible rural entities to test new models for the delivery of health care services in rural areas. This provision expands the demonstration to allow additional counties to participate and also allows physicians to participate in the demonstration project.

Sec. 3127. MedPAC study on adequacy of Medicare payments for health care providers serving in rural areas. This provision would require MedPAC to review payment adequacy for rural health care providers serving the Medicare program, including an analysis of the rural payment adjustments included in this legislation, beneficiaries' access to care in rural communities, and quality of care.

Sec. 3128. Technical correction related to critical access hospital services. This provision clarifies that CAHs can continue to be eligible to receive 101 percent of reasonable costs for providing outpatient care regardless of eligible billing method the facility uses and for providing qualifying ambulance services.

Sec. 3129. Extension of and revisions to Medicare rural hospital flexibility program. This provision extends the Flex Grant program through 2012 and will allow Flex grant funding to be used to support rural hospitals' efforts to implement delivery system reform programs, such as value-based purchasing programs, accountable care organizations, bundling, and other delivery system reform programs.

PART III – IMPROVING PAYMENT ACCURACY

Sec. 3131. Payment adjustments for home health care – as amended by Title X. These sections require the Secretary to improve the accuracy of Medicare home health payments by, *inter alia*, adjusting these payments starting in 2014 based on an analysis of the mix of services, level of intensity, average cost, and other factors that the Secretary considers relevant. They also (a) increase the cap for outlier payments beginning in 2011 to 10 percent of estimated total Medicare payments, (b) reinstate and increase an add-on payment for rural home health providers from April 1, 2010 through 2015, and (c) require the Secretary to submit a report to Congress by March 1, 2014 on recommended payment reforms related to serving lower-income patients with varying severity of illness and improving access to care.

Sec. 3132. Hospice reform. This section requires the Secretary to begin by January 1, 2011 collecting data and information to enable the Secretary to revise, by regulation, the Medicare hospice payment system so as to improve payment accuracy by no earlier than October 1, 2013. It also imposes certain requirements as of January 1, 2011, on hospice providers relating to the 180-day recertification.

Sec. 3133. Improvement to Medicare DSH payments. These sections require the Secretary to update Medicare DSH payments to better account for anticipated lower uncompensated care costs. Starting October 1, 2014, Medicare DSH payments would be reduced to reflect lower uncompensated care costs relative to increases in the number of insured based on a highly technical formula with limitations on judicial review.

Sec. 3134. Misvalued codes under the physician fee schedule. This section requires the Secretary to periodically review fee schedule rates for physician services paid by Medicare, including services that have experienced high growth rates or substantial changes in practice expenses. The Section also requires the Secretary to adjust fees schedule rates that are found to be misvalued or inaccurate.

Sec. 3135. Modification of equipment utilization factor for advanced imaging services (as amended by the Reconciliation Act). These sections increase the practice expense units for imaging services from a presumed utilization rate of 50 percent to 75 percent for services provided on or after January 1, 2011. Also, for services on or after July 1, 2010, they adjust (a) the technical component discount on single session imaging studies on contiguous body parts and (b) the payment for multiple imaging procedures. They also require the Secretary to make publicly available an analysis of whether the cumulative reduction in expenditures from these adjustments is projected to exceed $3B from 2010 through 2019.

Sec. 3136. Revision of payment for power-driven wheelchairs. This section eliminates, as of January 1, 2011, the option for Medicare to purchase power-driven wheelchairs with a lump-sum payment at the time the chair is supplied. Medicare would continue to make the payments for power-driven chairs over a 13-month period while changing the methodology used to calculate those payments. The purchase option for complex rehabilitative power wheelchairs would be maintained.

Sec. 3137. Hospital wage index improvement – as amended by Title X. These sections extend reclassifications under §508 of the Medicare Modernization Act through September 30, 2010. They also require the Secretary to provide recommendations to Congress, by December 31, 2011, on ways to comprehensively reform the Medicare wage index system, while requiring the Secretary to use for FY 2010 the wage index rate published in the Federal Register on August 27, 2009.

Sec. 3138. Treatment of certain cancer hospitals. This section directs the Secretary to study whether existing cancer hospitals that are exempt from the inpatient prospective payment system have costs under the outpatient prospective payment system ("OPPS") that exceed costs of other hospitals, and to make an appropriate payment adjustment under OPPS based on that analysis for services provided on or after January 1, 2011.

Sec. 3139. Payment for biosimilar biological products. This section sets the add-on payment rate for biosimilar products reimbursement under Medicare Part B at 6 percent of the average sales price of the brand biological product.

Sec. 3140. Medicare hospice concurrent care demonstration program. This section directs the Secretary to establish a three-year demonstration program that would allow patients who are eligible for the Medicare hospice benefit also to receive all other Medicare covered services during the same period of time. The demonstration would be conducted in up to 15 hospice programs in both rural and urban areas and would evaluate the impact of the demonstration on patient care, quality of life, and spending in the Medicare program.

Sec. 3141. Application of budget neutrality on a national basis in the calculation of the Medicare hospital wage index floor. For discharges on or after October 1, 2010, this section requires the Secretary to apply the budget neutrality associated with the effect of the imputed rural and rural floor on a national, rather than state-specific, basis through a uniform, national adjustment to the area wage index.

Sec. 3142. HHS study on urban Medicare-dependent hospitals. This section requires the Secretary to conduct a study on the need for additional Medicare payments for certain urban Medicare-dependent hospitals paid under the inpatient prospective payment system and report the results to Congress within 9 months after enactment of the PPACA.

Sec. 3143. Protecting home health benefits. This section ensures that guaranteed Medicare home health benefits will not be reduced as a result of the enactment of the PPACA.

Subtitle C – Provisions Relating to Part C

Sec. 3201. Medicare Advantage Payment (repealed by Reconciliation Act and replaced with Sec. 1102 of Reconciliation Act. Medicare Advantage payments). This provision was added by the Reconciliation Act and repealed section 3201 of the Act. It freezes 2011 payments to Medicare Advantage or "MA" organizations at the 2010 amounts. Beginning for 2012, the provision establishes a new methodology for calculating the blended benchmark amount that is used in determining monthly payments to MA organizations. Benchmarks will vary from 95 percent of Medicare spending in high-cost areas to 115 percent of Medicare spending in low-cost areas. Changes will be phased-in over two, four or six years, depending on the level of payment reductions. Notwithstanding the foregoing, benchmarks will be increased by five percentage points in all areas for high-quality plans by 2014. Low enrollment and new MA plan are also eligible for quality bonuses.

The changes by the Reconciliation Act also extend CMS' authority to adjust risk scores under Medicare Advantage for observed differences in coding patterns relative to fee-for-service Medicare and phases up the adjustment to risk scores beginning in 2014. For

2014, the adjustment will be not less than the factor for 2010 plus 1.3 percent; for 2015 through 2018, not less than the previous year's adjustment factor plus 0.25 percent; and for 2019 and each subsequent year, not less than 5.7 percent. These adjustments to MA risk scores will apply until the Secretary implements risk adjustment using MA diagnostic, cost and use data.

The Reconciliation Act repeals the Comparative Cost Adjustment Program that was created by the Medicare Modernization Act of 2003 ("MMA").

Sec. 1103. Savings from limits on MA plan administrative costs (added by the Reconciliation Act). This provision, which is effective in 2014, requires Medicare Advantage plans to have a medical loss ratio of at least 85 percent. MA plans that fail to satisfy this minimum loss ratio requirement will be required to remit to the Secretary an amount equal to the plan's total revenue for the applicable contract year and the different between .85 and the plan's actual medical loss ratio. Plans that fail to meet the minimum medical loss ratio for three consecutive years shall not be allowed to enroll new beneficiaries for the second succeeding contract year. The Secretary is required to terminate the MA contracts of plans that fail to meet the minimum medical loss ratio for five consecutive years.

According to the House Report, Medicare Advantage plans claim to provide significant extra benefits, but neither the plans nor CMS quantify whether any of the revenue plans receive from the government is actually spent on enhanced benefits. In addition, MedPAC has reported that MA plans on average currently spend more than 13 percent of their Medicare payments on administrative costs and profits. The provision is intended to ensure that Medicare beneficiaries and taxpayers do not pay more than 15 cents per dollar for MA plans' administrative costs and profits.

Sec. 3202. Benefit protection and simplification (as amended by the Reconciliation Act). For plan years beginning on or after January 1, 2011, cost-sharing under MA plans for the following services may not exceed Part A and Part B cost-sharing amounts: (1) chemotherapy administration services, (2) renal dialysis services, (3) skilled nursing care, and (4) such other services that the Secretary determines appropriate including services that require a high level of predictability and transparency for beneficiaries.

The Reconciliation Act amends the rebate percentages that MA organizations must return to the enrollees and ties the rebate percentage to the MA plan's quality performance established under Section 1102. Currently, 75 percent of the difference between the MA plan bid and the applicable benchmark amount must be returned or rebated to MA plan enrollees in the form of premium reductions or additional benefits. The phase in of the new rebate percentages will commence with plan year 2012.

Sec. 3203. Application of coding intensity adjustment during MA payment transition – repealed by Reconciliation Act. For a discussion of the changes made by the Reconciliation Act, please see the summary of Section 1101 of Reconciliation Act above.

Sec. 3204. Simplification of annual beneficiary election periods. For 2011 and thereafter, MA enrollees may change their election during the first 45 days of the year only to return to fee-for-service Medicare. Such beneficiaries may also elect to enroll in a standalone Part D plan. The section also makes earlier the annual, coordinated election period under Medicare Advantage and Part D. Specifically, for 2012 and thereafter, the election period will be October 15th through December 7th, rather than November 15th through December 31st. This change will presumably give CMS and plans more time to process enrollment changes.

Sec. 3205. Extension for specialized MA plans for special needs individuals. The authority, which was set to expire this year, for MA special needs plans ("SNPs") is extended until 2014. The section makes a number of other changes to the SNP program. Effective for the 2011 plan year, the Secretary may apply the frailty payment adjustment currently applicable to the Program of All-Inclusive Care for the Elderly ("PACE") to dual-eligible SNPs that enroll frail populations. PACE is a capitated managed care benefit for the frail elderly. Only "fully-integrated dual-eligible SNPs will be eligible for the payment adjustment, meaning the SNPs must have capitated contracts with States for Medicaid benefits, including long-term care, and have similar average levels of frailty as the PACE program.

No later than 2013, the Secretary will transition MA enrollees who are enrolled in SNPs but are not "special needs individuals" to a non-SNP MA plan or to fee-for-service Medicare.

Effective for 2012, Medicare Advantage organizations that offer SNP plans must be approved by the National Committee for Quality Assurance ("NCQA").do not Requires HHS to transition beneficiaries enrolled in SNPs that do not meet statutory target definitions and requires dual-eligible SNPs to contract with State Medicaid programs beginning 2013.

Payments to SNPs for beneficiaries with chronic health conditions will improve effective 2011. Specifically, such plans shall receive a risk score that reflects the known underlying risk profile and chronic health status of similar individuals rather than the default risk score for new enrollees under Medicare Advantage.

Sec. 3206. Extension of reasonable cost contracts. Extends the period of time for which cost plans may operate in areas that have Medicare Advantage options until January 1, 2013.

Sec. 3207. Technical correction to MA private fee-for-service plans. Effective plan year 2011, the CMS service area waiver for employer group plans offered Medicare Advantage local coordinated care plans is extended to employers that contract directly with CMS as a Medicare Advantage private fee-for-service plan that had enrollment as of October 1, 2009.

Sec. 3208. Making senior housing facility demonstration permanent. This provision allows demonstration plans that serve residents in continuing care retirement communities to continue to operate as "Medicare Advantage senior housing facility plans" offerings under the MA program. Such plans will restrict enrollment of individuals under Medicare Advantage to individuals who reside in a continuing care retirement community; provide primary care services onsite and have an adequate ratio of accessible physicians to beneficiaries as determined by the Secretary; provide transportation services for beneficiaries to specialty providers outside of the facility; and have participated (as of December 31, 21 2009) in the demonstration project under which such a plan was offered for not less than 1 year. This provision applies to plan years beginning on or after January 1, 2010.

Sec. 3209. Authority to deny plan bids. This provision makes clear that the Secretary is not required to accept any or every bid that is submitted by a Medicare Advantage organization. In addition, Secretary may deny a bid if it proposes significant increases in cost-sharing or or decreases in benefits under the plan. This section also applies to bids under Part D. The provision applies to bids submitted for contract years on or after January 1, 2011,

Sec. 3210. Development of new standards for certain Medigap plans. The Secretary is required to request the NAIC to review and revise its standards for Medicare supplement plans "C" and "F" to include nominal cost sharing requirements in order to encourage the use of appropriate Part B physician services.

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

Sec. 3301. Medicare coverage gap discount program (as amended by the Reconciliation Act). Effective January 1, 2011, in order for a manufacturer's drug to be eligible for coverage under Part D, the manufacturer must— (1) participate in the new Medicare coverage gap discount program, (2) have entered into and have in effect an agreement with the Secretary as described in the Medicare coverage gap discount program, and (3) have entered into and have in effect, under terms and conditions specified by the Secretary, a contract with a third party with which the Secretary has entered into a contract to administer the program. Notwithstanding the foregoing, the

requirements of this section shall not apply to any drug for which the Secretary determines the availability of the drug is essential to the health of beneficiaries, or the Secretary determines that in the period of January 1, 2011 through December 31, 2011, there were "extenuating circumstances."

A new section is added to the Part D, that will be codified at 1860D–14A (42 U.S.C. § 1395w-114A), that provides for a Medicare coverage gap discount program to be established no later than January 1, 2011. Under the program, the Secretary will enter into agreements with manufacturers. The Secretary is required to develop a model agreement within 180 days of the Act's enactment.

Under these agreements, manufacturers are required to provide applicable beneficiaries access to discounted prices at the point-of-sale. The initial period of agreement is 18 months, and shall be automatically renewed for not less than 12 months unless terminated by either party. For purposes of this section, an applicable beneficiary is an individual enrolled in a Part D plan, is not enrolled in a qualified retiree prescription drug plan, is not entitled to a low-income subsidy under Part D, and who (i) has reached or exceeded the Part D coverage gap during the year and (ii) has not incurred costs equal to the annual out-of-pocket limit under Part D. Participating manufacturers must provide a 50 percent discount on applicable drugs provided to applicable beneficiaries while in the coverage gap or donut hole.

Sec. 3302. Improvement in determination of Medicare Part D low-income benchmark premium (as amended by the Reconciliation Act). This section provides that the determination of the low-income premium benchmark amount shall determined before the application of the monthly rebate for the plan and, if applicable, before the application of any quality increase for which the plan is eligible.

Sec. 3303. Voluntary de minimis policy for subsidy-eligible individuals under prescription drug plans and MA–PD plans. For premiums for months, and enrollments for plan years, beginning on or after January 1, 2011, the Secretary is required to permit a standalone prescription drug plan or an MA–PD plan to waive the monthly beneficiary premium for a subsidy eligible individual if the amount of such premium is "de minimis." If de minimis premium is waived, then subsidy eligible individuals enrolled in that plan will not be re-assigned to another drug plan based on the fact that the monthly beneficiary premium under the plan was greater than the low-income benchmark premium amount. The section also allows for auto-enrollment of a subsidy eligible individual who has failed to enroll in a Part D prescription drug plan or an MA–PD plan, into a Part D plan that has waived the de minimis premium for subsidy eligible individuals. If there is more than one such plan available, individual will be enrolled on a random basis among all such plans in the PDP region. Subsidy

eligible individuals retain the right to decline or change the plan they are assigned to through auto-enrollment.

Sec. 3304. Special rule for widows and widowers regarding eligibility for low-income assistance. Effective January 1, 2011, for widows or widowers whose spouse dies during the effective period of a low-income subsidy eligibility determination, the effective period of that determination will be extended for one year after the date on which the determination would otherwise cease to be effective.

Sec. 3305. Improved information for subsidy-eligible individuals reassigned to prescription drug plans and MA–PD plans. Beginning not later than January 1, 2011, the Secretary is required to provide the following to subsidy eligible individuals who have been re-assigned to a new Part D plan information: (1) 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 (2) a description of the individual's right to request a coverage determination, exception, or reconsideration, bring an appeal, or resolve a grievance. The information must be provided within 30 days of the reassignment.

Sec. 3306. Funding outreach and assistance for low-income programs. This section provides funding for outreach and education activities to State health Insurance Programs, the Administration on Aging, Aging Disability Resource Centers, and the National Benefits Outreach and Enrollment.

Sec. 3307. Improving formulary requirements for prescription drug plans and MA–PD plans with respect to certain categories or classes of drugs. This section gives the Secretary more authority in establishing formulary requirements under Part D effective for the 2011 plan year. Part D Plan Sponsors will be required to include all covered Part D drugs in the categories and classes for drugs of clinical concern as determined by the Secretary through rulemaking. However, the Secretary may, through rulemaking, establish an exceptions process by which Plan Sponsors may exclude or limit access to such drugs including through prior authorization or utilization management requirements.

Until the Secretary establishes the criteria for categories and classes of drugs of clinical concern,, the Act requires the mandates categories and classes: (1) anticonvulsants, (2) antidepressants, (3) antineoplastics, (4) antipsychotics; (5) antiretrovirals, and (6) immunosuppressants for the treatment of transplant rejection.

Sec. 3308. Reducing Part D premium subsidy for high-income beneficiaries. This section decreases the Part D premium subsidy for certain high-income Medicare beneficiaries effective after December 2010, i.e., individuals with incomes above the Part

B thresholds. The higher premium obligation will be paid by Social Security withholdings. In such withholdings are insufficient, then the Commissioner of Social Security is required to enter into agreements with the Secretary, the Director of OPM, and the Railroad Retirement Board, as necessary in order to allow other agencies to collect the amount.

Sec. 3309. Elimination of cost sharing for certain dual-eligible individuals. Under current law, the Part D cost-sharing requirement is eliminated for a beneficiary who is a full-benefit dual eligible individual and who is an institutionalized individual or couple. This section expands eligibility for cost-sharing elimination to include an individual or couple who would be institutionalized if the full-benefit dual eligible individual were not receiving services under a home or community-based waiver under Section 1115 or 1915 or state plan amendment, or services provided through enrollment in a Medicaid managed care plan. The effective date of this section will be determined by the Secretary, but shall not be earlier than January 1, 2012.

Sec. 3310. Reducing wasteful dispensing of outpatient prescription drugs in long-term care facilities under prescription drug plans and MA-PD plans. Part D Plan Sponsors will be require to utilize specific, uniform dispensing techniques applicable to dispensing covered Part D drugs to enrollees who reside in a long-term care facility in order to reduce waste associate with 30-day fills. The Secretary will determine such techniques, in consultation with relevant stakeholders, including representatives of nursing facilities, residents of nursing facilities, pharmacists, the pharmacy industry, Part and D Plan Sponsors).

Sec. 3311. Improved Medicare prescription drug plan and MA–PD plan complaint system. This section requires the Secretary to develop and maintain a complaint system, "that is widely known and easy to use," to collect information on Plan Sponsor complaints that are received by the Secretary (including HHS regional offices and contractors) through the date on which the complaint is resolved. The system must be able to report and initiate appropriate interventions and monitoring based on substantial complaints and guide quality improvement.

The Secretary is also required to develop a model electronic complaint that can be used for reporting plan complaints under the system established by the Secretary. The form will be "prominently displayed" on the front page of the *Medicare.gov* website and on the website of the Medicare Beneficiary Ombudsman.

Reports to Congress are due annually and must include an analysis of the number and types of complaints reported in the system, geographic variations in complaints, the timeliness of CMS or Plan Sponsor responses to such complaints, and the resolution of such complaints.

Sec. 3312. Uniform exceptions and appeals process for prescription drug plans and MA–PD plans. Despite the fact that the Plan Sponsors' appeal processes are already highly regulated by CMS, this section requires each Plan Sponsor to use a single, uniform exceptions and appeals process for coverage determinations. The process is to include, to extent the Secretary determines feasible, a single, uniform model form. In addition, Plan Sponsors must provide enrollees "instant access" to such process through a toll-free telephone number and Internet website. This section shall apply to exceptions and appeals effective January 1, 2012.

Sec. 3313. Office of the Inspector General studies and reports. This section requires the HHS Inspector General to conduct a study of the extent to which Plan Sponsors' formularies include drugs commonly used by full-benefit dual eligibles. Such reports are due no late than July 1 of each year starting with July 2011.

The Inspector General is also required to study the prices for covered Part D drugs and for outpatient drugs covered by Medicaid. The study is required to include: (1) a comparison, using the 200 most frequently drugs dispensed under Part D and Medicaid of the prices paid by Plan Sponsors and by State Medicaid plans; and (2) an assessment the financial impact on the Federal Government of any discrepancies in such prices, and the financial impact on Part D and Medicaid enrollees of any such discrepancies. For purposes of this study, the price of a covered drug includes any rebate or discount under the applicable program. The report is due by October 1, 2011 and shall include the Inspector General's recommendations for legislation and administrative action. In issuing the report, the Inspector General shall exclude information that the Inspector general determines is proprietary or is likely to negatively impact the ability of a Plan Sponsor or State Medicaid plan to negotiate prices.

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. Effective to costs incurred on or after January 1, 2011, drugs provided to beneficiaries by AIDS Drug Assistance Programs or the Indian Health Service shall count toward the Part D annual out-of-pocket threshold.

Sec. 3315. Immediate reduction in coverage gap for 2010 – repealed by the Reconciliation and replaced with 1101. Closing the Medicare Prescription Drug "Donut Hole." For an applicable beneficiary who, as of the last day of a calendar quarter in 2010, has incurred costs for covered Part D drugs so that the individual has exceeded the initial coverage gap, the Secretary shall make a one-time payment of $250 to such individual. For purposes of this section, an applicable beneficiary is an individual enrolled in a Part D plan, is not enrolled in a qualified retiree prescription drug plan, is entitled to a low-income subsidy under Part D, and is not subject to a

premium subsidy reduction under Part B. This Reconciliation Act expands on the manufacturers 50 percent discount on brand-name drugs, beginning in 2011 (discussed above), to close the donut hole with 75 percent discounts on brand-name and generic drugs by 2020.

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 – as amended by Title X. Market basket payment updates for various providers and Part B services will be reduced by a productivity adjustment equal to "the ten-year moving average of changes in annual economy-wide private non-farm business multi-factor productivity." The productivity adjustments effect inpatient acute hospitals, skilled nursing facilities, long-term care hospitals, inpatient rehabilitation facilities, home health agencies, psychiatric hospitals, hospice, dialysis, outpatient hospitals, ambulance services, ambulatory surgical center services, laboratory services, certain durable medical equipment, prosthetic devices, orthotics, and prosthetics, and other items. Section 3401, as amended by Section 10319, includes additional market basket payment updates of varying amounts for certain providers. The law permits the application of these adjustments to reduce the market basket increase to less than zero, which would permit payment rates to be reduced below the previous year's level. The implementation of the productivity adjustment is 2012 for most provider types. The implementation of the additional market basket adjustment varies by provider type.

Sec. 3402. Temporary adjustment to the calculation of Part B Premiums. For certain Medicare beneficiaries whose income exceeds the threshold amounts determined by the government, and thus receive reduced Part B premium subsidies, the threshold amount will be frozen at the 2010 level for the period January 1, 2011 through December 31, 2019.

Sec. 3403. Independent Medicare Advisory Board. This section establishes an independent, non-partisan advisory body whose purpose is to develop proposals to reduce the per capita growth rate in Medicare spending, including spending under Parts C and D. The Board's proposals may not include any recommendations to ration health care, raise revenues or Medicare beneficiary premiums, or increase Medicare beneficiary cost sharing amounts. In developing its proposals, the Board must give, to the extent feasible, priority to recommendations that extend the solvency of the Medicare program and include recommendations that improve the delivery and quality of health care services.

The Secretary is required to implement the Board's proposals in years in which Medicare spending growth is projected to be unsustainable, as determined by the CMS Chief Actuary, unless Congress passes alternative legislation. This section includes significant detail regarding the procedures Congress must take to consider the Board's proposals and move them through the legislative process, including limiting the amount of debate and amendments to the proposals.

Subtitle F – Health Care Quality Improvements

Sec. 3501. Health care delivery system research; quality improvement technical assistance. The section allows for the identification, development, evaluation, dissemination, and provision of training in innovative methodologies and strategies for quality improvements in the delivery of health care services that represent best practices. The new law also expands on the Center for Quality Improvement and Patient Safety of the Agency for Healthcare Research and Quality in order to support research, assess evidence and knowledge about what strategies and methodologies are most efficient, find ways to translate such information and assessments into practice, and process implementation grants, which will aid in the implementation of best practices. There are provisions that mandate the public availability of the research findings of the Center

Sec. 3502. Establishing community health teams to support the patient-centered medical home – as amended by Title X. This section creates a program that will establish and fund the development of community health teams through grants or contracts. The community health teams shall be community-based interdisciplinary, interprofessional teams to support primary care practices, including obstetrics and gynecology practices, within the hospital service areas served by eligible entities. Section 10321 makes it clear that "other primary care providers" besides physicians can participate in the community health teams.

Sec. 3503. Medication management services in treatment of chronic disease. A program is created to support, through grants or contracts, medication management services by local health providers. The services will include performing or obtaining necessary assessments of the health and functional states of each patient receiving such services, formulating a medication treatment plan for each patient based on therapeutic goals, and selecting, initiating, modifying, recommending changes to, or administering medication therapy. These services will help manage chronic disease, reduce medical errors, and improve patient adherence to treatment.

Sec. 3504. Design and implementation of regionalized systems for emergency care. This section provides funding to the Assistant Secretary for Preparedness and Response to support pilot projects that design, implement, and evaluate innovative models of

regionalized, comprehensive, and accountable emergency care and trauma systems. The Secretary shall award contracts or grants to eligible entities that propose new pilot projects that include certain objective elements, like the coordination with public health and safety services, emergency medical services, medical facilities, trauma centers, and other entities in a region. HHS is required to support emergency medicine research, including pediatric emergency medical research.

Sec. 3505. Trauma care centers and service availability. This section reauthorizes and improves the trauma care program, providing grants administered to by the Secretary to the States and trauma centers to strengthen the national trauma system. This section further promotes universal access to trauma care services provided by trauma centers and trauma-related physician specialties. The Act has certain minimum standards required of trauma centers in order to be recipients of grants. Underserved areas are given priority in terms of the distribution of grants.

Sec. 3506. Program to facilitate shared decisionmaking. An educational program is created to facilitate collaborative processes between patients, caregivers or authorized representatives, and others regarding understanding treatment as well as treatment options.

Sec. 3507. Presentation of prescription drug benefit and risk information. The FDA Commissioner shall evaluate and determine whether the use of quantitative summaries of the benefits and risks of prescription drugs, such as drug fact boxes, would assist in the clear communication of drug risks and benefits. The Secretary must submit to Congress, within one year after the Act's implementation, a report that provides the determination of the Secretary and the Secretary's reasoning and analysis.

Sec. 3508. Demonstration program to integrate quality improvement and patient safety training into clinical education of health professionals. A program is established at the Agency for Healthcare Research and Quality that will give grants to academic institutions to develop and implement academic curricula that integrate quality improvement and patient safety. The eligibility for the receipt of grants is spelled out in the Act. However eligibility factors include being or having a health professions school and collaborating in the development of curricula described in accordance with this section with an organization that accredits such school or institution.

Sec. 3509. Improving women's health. An Office of Women's Health is established within several federal agencies, including the Office of the Secretary of Health and Human Services and the Office of the Director of the Centers for Disease Control in order to improve women's health objectives, including prevention and treatment.

Sec. 3510. Patient navigator program. This section reauthorizes certain programs that provide patient navigator services within communities to assist patients in overcoming barriers to health services.

Sec. 3511. Authorization of appropriations. Except where otherwise provided in this subtitle (or an amendment hereto), funds necessary to carry out this subtitle (as amended) are authorized to be appropriated.

Sec. 3512. GAO study and report on causes of action -- as added by Section 10201 of Title X. The Comptroller General is required to study on whether implementation of provisions in the legislation would result in the establishment of new claims or causes of action. This study is to be concluded within two years of enactment of the Act.

Subtitle G – Protecting and Improving Guaranteed Medicare Benefits

Sec. 3601. Protecting and improving guaranteed Medicare benefits. Section 3601 provides that nothing in the Patient Protection and Affordable Care Act will result in a reduction of the benefits guaranteed to Medicare beneficiaries under Title 18. Any savings the Act generates will be used to extend the solvency of the Medicare program, reduce beneficiary premiums and cost-sharing amounts, and improve or expand benefits and access to Medicare providers.

Sec. 3602. No cuts in guaranteed benefits. Section 3602 prohibits the reduction or elimination of benefits guaranteed to enrollees in Medicare Advantage Plans.

TITLE IV
PREVENTION OF CHRONIC DISEASE AND IMPROVING PUBLIC HEALTH

- Subtitle A – Modernizing Disease Prevention and Public Health Systems
- Subtitle B – Increasing Access to Clinical Preventive Services
- Subtitle C – Creating Healthier Communities
- Subtitle D – Support for Prevention and Public Health Innovation
- Subtitle E – Miscellaneous Provisions

Subtitle A - Modernizing Disease Prevention and Public Health Systems

Sec, 4001. National prevention, health promotion and public health council. This section creates an inter-agency federal council to promote healthy policies and to establish a national prevention and health promotion strategy.

Sec. 4002. Prevention and public health fund. This section appropriates a fund to support initiatives and to establish a sustained national investment in prevention and public health.

Sec. 4003. Clinical and community prevention services. This section requires various task forces to coordinate and review the effectiveness of preventative services and provide recommendations for preventative interventions.

Sec. 4004. Education and outreach campaign regarding preventive benefits. This section requires the Secretary to convene a national public-private partnership to conduct a prevention and health promotion outreach and education campaign. Mandates the Secretary to develop and implement a plan for the dissemination of health promotion and disease prevention information to health care providers who participate in Federal programs.

Subtitle B - Increasing Access to Clinical Preventive Services

Sec. 4101. School-based health centers. This section authorizes a grant program to support the operation of school based health centers that provide preventative and primary health care services to medically underserved children and families.

Sec. 4102. Oral healthcare prevention activities. This section establishes a public education campaign focused on oral healthcare prevention and education.

Sec. 4103. Medicare coverage of annual wellness visit providing a personalized prevention plan. This section provides that Medicare will cover, with no co-payment or deductible, an annual wellness visit that includes a health risk assessment and personalized prevention plan.

Sec. 4104. Removal of barriers to preventive services in Medicare. This section waives coinsurance or deductible requirements for most preventative services in out-patient hospital settings, including colorectal cancer screening tests.

Sec. 4015. Evidence-based coverage of preventive services in Medicare. This section authorizes the Secretary to modify coverage of any Medicare-covered preventive service to be consistent with U.S. Preventive Services Task Force recommendations.

Sec. 4106. Improving access to preventive services for eligible adults in Medicaid. This section requires state Medicaid plans to offer adult beneficiaries a package of diagnostic, screening, preventative and rehabilitative services and certain adult immunizations without cost sharing.

Sec. 4107. Coverage of comprehensive tobacco cessation services for pregnant women in Medicaid. This section requires states to provide coverage to pregnant women in Medicaid for tobacco cessation services, including prescription drugs and counseling.

Sec. 4108. Incentives for prevention of chronic diseases in Medicaid. This section awards state grants to carry out initiatives providing incentives to Medicaid beneficiaries who participate in programs that assist in lowering cholesterol, blood pressure, weight or ceasing use of tobacco products.

Subtitle C - Creating Healthier Communities

Sec. 4201. Community transformation grants. This section provides competitive grants to implement programs that promote individual and community healthy lifestyles and prevent the incidence of chronic disease.

Sec. 4202. Health aging, living well; evaluation of community-based prevention and wellness programs for Medicare beneficiaries. This section establishes wellness programs for pre-Medicare beneficiaries between the ages of 55-64 to help evaluate and reduce chronic disease risk.

Sec. 4203. Removing barriers and improving access to wellness for individuals with disabilities. This section establishes standards for accessibility of medical diagnostic equipment to individuals with disabilities.

Sec. 4204. Immunizations. This section authorizes states to purchase adult vaccines under CDC contracts.

Sec. 4205. Nutrition labeling of standard menu items at chain restaurants. This section requires certain chain restaurants to disclose calories on its menu board and in written form.

Sec. 4206. Demonstration project concerning individualized wellness plan. This section provides at-risk populations with a risk-factor assessment and an individualized wellness plan.

Sec. 4207. Reasonable break time for nursing mothers. This section requires certain employers to provide a reasonable break time and a place for nursing mothers in the workplace.

Subtitle D - Support for Prevention and Public Health Innovation

Sec. 4301. Research on optimizing the delivery of public health services. This section provides funding for research in public health services and systems to examine best prevention practices.

Sec. 4302. Understanding health disparities; data collection and analysis. This section requires federal health programs to collect and analyze data on health disparities in the general public and in Medicaid and CHIP, and circulate those findings to federal agencies.

Sec. 4303. CDC and employer-based wellness programs. This section requires the CDC to evaluate best employer wellness practices and provide an educational campaign to promote the benefits of worksite health promotion.

Sec. 4304. Epidemiology-laboratory capacity grants. This section establishes a new CDC program to assist state and local public health agencies to improve information systems, improve surveillance for and responses to infectious disease, improve and develop outbreak control standards and coordinate reporting outbreaks.

Sec. 4305. Advancing research and treatment for pain care management. This section authorizes an Institute of Medicine Conference on Pain Care to evaluate the adequacy of pain assessment, treatment, and management; identify and address barriers to appropriate pain care; increase awareness; and report to Congress on findings and recommendations.

Sec. 4306. Funding for childhood obesity demonstration project. This section provides funding for a demonstration project to help reduce childhood obesity.

Subtitle E – Miscellaneous Provisions

Sec. 4402. Effectiveness of Federal health and wellness initiatives. This section mandates that the Secretary will conduct an evaluation of federal health and wellness initiatives for effectiveness.

TITLE V
HEALTH CARE WORKFORCE

Subtitle A – Purpose and Definitions

Sec. 5001. Purpose. The purpose of the title is to improve access to the delivery of health care services for all individuals, particularly low-income, underserved, uninsured, minority, health disparity, and rural populations by:

- Gathering and assessing comprehensive data to allow the health care workforce to meet the health care needs of individuals, including research on the supply, demand, distribution, diversity, and skills needs of the health care workforce;
- Increasing the supply of a qualified health care workforce to improve access to and the delivery of health care services for all individuals;
- Enhancing health care workforce education and training to improve access to and the delivery of health care services for all individuals; and
- Providing support to the existing health care workforce to improve access to and the delivery of health care services for all individuals.

Subtitle B – Innovations in the Health Care Workforce

Sec. 5101. National Health Care Workforce Commission. This section establishes a National Health Care Workforce Commission, the purpose of which is to determine whether the demand for health care workers is being met, identify barriers to improved coordination at all levels of government, and encourage innovation to address population needs. Specifically, the Commission is charged with creating an annual report making recommendations to Congress. This report shall include a review of the current and projected health care workforce supply and demand, the current and projected training and capacity levels, the needs of "special populations" (e.g., minorities, medically underserved populations, individuals with disabilities, etc.), and

any recommended changes to national loan repayment programs to ensure education financing is effective.

The Commission shall be established by September 30, 2010 and composed of 15 members appointed by the Comptroller General for three-year terms. Members must be nationally recognized for their expertise in health care labor market analysis, facility management, workforce education needs, and other related fields. The composition of the Commission is intended to provide a combination of professional perspectives and broad geographic representation by requiring at least one representative from several different groups (e.g., health care workforce, employers, third-party payers, consumers, labor unions, educational institutions, etc.). The majority of the Commission, however, may not be directly involved in health professions education or practice, and all members must disclose potential conflicts of interest.

The Commission seems intended to consolidate the efforts of several different agencies into a more efficient, unified body. Although not granted significant powers, the Commission is charged with what will become an enormously important task under the new health care law: ensuring that the millions of additional people who will now receive health insurance actually have access to health care professionals and other members of the health care workforce. This requires not only ensuring geographic availability, but anticipating the demand for health care workers in the future and making recommendations to ensure those needs are met.

Sec. 5102 & 5103. State health workforce development grants and assessment. This section recognizes that successfully developing the health care workforce will require active participation by the States. To that end, Congress has authorized for appropriation significant sums of money to encourage States to develop programs that will have both an immediate and substantial future effect on the availability of health care professionals and other members of the health care workforce. HHS, in consultation with the National Health Care Workforce Commission ("Commission") is charged with administering the grants, providing technical assistance, and reporting performance information to the Commission. The law requires that HHS conduct longitudinal studies regarding the effect of the grants awarded.

One grant available is a planning grant, which may not exceed $150,000 and may not last for more than one year. Only "State partnerships" are eligible for these grants, which are defined as State workforce investment boards with a membership composition similar to the Commission established under the previous section. The primary purposes of these awards are to help States develop programs that model projected health care workforce needs and encourage individuals to pursue courses of study that prepare them for postsecondary education in the health care field. States

receiving funds must match at least 15% of the grant. Eight million dollars authorized to be appropriated in 2010 for these grants.

Another grant available is an implementation grant. Once a State partnership has received a planning grant and fully completed all the associated requirements, HHS shall competitively award implementation grants to enable State partnerships to carry out the planned program. State partnerships seeking these grants must detail how they intend to administer the grant in a way that ensures development of the health care workforce, both geographically and numerically. Although there is no statutory maximum set for each grant, States must match at least 25% of the amount awarded. One hundred fifty million dollars is authorized to be appropriated for these grants in 2010.

Subtitle C – Increasing the Supply of the Health Care Workforce

Sec. 5201. Federally supported student loan funds. This section encourages medical school attendance by shortening payback periods, decreasing the interest rate increases for non-compliance, and by prohibiting the Secretary from considering parental financial information for independent students when assessing financial need.

Sec. 5202. Nursing student loan program. This section increases the available loan amounts for nursing students.

Sec. 5203. Health care workforce loan repayment programs. This section establishes an educational loan repayment program that will make interest and principal payments of $35,000 per year for up to three years. To qualify, individuals must specialize in pediatrics, or adolescent of child behavioral or mental health, and must work for at least two years in the shortage area or with a medically underserved population. The section authorizes for appropriation $50 million for each year from 2010-2014.

Sec. 5204. Public health workforce recruitment and retention program. This section creates a loan repayment program for public health workers in exchange for working at least three years (or longer) at a federal, state, local, or tribal public health agency. The worker must agree to relocate to an underserved area in exchange for an additional loan repayment amount, if necessary. The section authorizes for appropriation $195 million for 2010.

Sec. 5205. Allied health workforce recruitment and retention program. This section creates an Allied Health Loan Forgiveness Program to ensure an adequate supply of allied health workers at public health agencies. To qualify, individuals must provide health care to medically underserved populations, or to other patients located in health professional shortage areas or medically underserved areas.

Sec. 5206. Grants for States and local programs. This section awards grants to mid-career public and allied health professionals to receive additional training. To qualify, an individual must be employed in a public or allied health position at the Federal, State, tribal, or local level. The section authorizes for appropriation $60 million for 2010.

Sec. 5207. Funding for National Health Service Corps. This section increases the appropriations authorized, and extends the length of, the National Health Service Corps.

Sec. 5208. Nurse-managed health clinics. This section funds the development and operation of nurse-managed health clinics treating vulnerable or underserved populations. It authorizes for appropriation $50 million in 2010.

Sec. 5209-10. Elimination of cap on the Commissioned Corps, Establishing a Ready Reserve Corps. These sections eliminate the cap of 2800 Commissioned Corps members and allows the president to nominate additional members with the advice and consent of the Senate. A major purpose of the Commissioned Corps is to meet national public health needs during emergencies.

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 provide grants to support and develop primary care training programs to plan and operate an accredited professional training program; to provide need-based financial assistance; to develop a program for training physicians in family medicine, general internal medicine, and general pediatrics; to train physicians teaching in community-based settings; to develop a physician assistant education program; to provide training in new competencies, as recommended by the Advisory Committee on Training in Primary Care Medicine and Dentistry and the National Health Care Workforce Commission. The Secretary must give priority to qualified applicants that (among other things) propose a collaborative project between academic administrative units of primary care, propose innovative approaches to clinical teaching using models of primary care, have a record of training the greatest percentage of providers, and have a record of training individuals from underrepresented minority groups.

Sec. 5302. Training opportunities for direct care workers. The Secretary will award grants to eligible entities to provide new training opportunities for direct care workers who are employed in long-term care settings. An eligible entity must use the amounts awarded under a grant to provide assistance to eligible individuals to offset the cost of

tuition and required fees for enrollment in academic programs provided by such an entity.

Sec. 5303. Training in general, pediatric, and public health dentistry. The Secretary may make grants to, or enter into contracts with, a school of dentistry, public or nonprofit hospital, or a public or private nonprofit entity to participate in an approved professional dentistry training program; to provide financial assistance to students, residents, and practicing dentists to participate in training programs; to create a loan repayment program; to provide technical assistance to pediatric training programs; and to meet the costs of projects to establish, maintain, or improve dental faculty development programs in primary care.

Sec. 5304. Alternative dental health care providers demonstration project. The Secretary may award grants to fifteen eligible entities to enable those entities to establish a demonstration program to establish training programs to train, or to employ, alternative dental health care providers in order to increase access to dental health care services in rural and other underserved communities.

Sec. 5305. Geriatric education and training; career awards; comprehensive geriatric education. The Secretary shall awards grants or contracts to entities that operate a geriatric education center. Geriatric education centers must use these 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.

Sec. 5306. Mental and behavioral health education and training grants. The Secretary may award grants to eligible institutions of higher education to support the recruitment of students for, and education and clinical experience of the students in, programs of social work and graduate programs of psychology. Funds may also be awarded to accredited institutions of higher education that are establishing or expanding internships in child and adolescent mental health and state-licensed mental health nonprofit and for-profit organizations to enable such organizations to pay for programs for preservice or in-service training of paraprofessional child and adolescent mental health workers.

Sec. 5307. Cultural competency, prevention, and public health and individuals with disabilities training. This section amends Section 751 of the Public Health Service Act to award grants for the development, evaluation, and dissemination of research, demonstration projects, and model curricula for cultural competency, prevention, public health proficiency, reducing health disparities, and aptitude for working with individuals with disabilities training for use in health professions schools and continuing education programs.

Sec. 5308. Advanced nursing education grants. This section strengthens language for accredited Nurse Midwifery programs to receive advanced nurse education grants in Section 811 of the Public Health Service Act. Midwifery programs that are eligible for support under this section are educational programs that have as their objective the education of midwives and are accredited by the American College of Nurse-Midwives Accreditation Commission for Midwifery Education.

Sec. 5309. Nurse education, practice, and retention grants. The Secretary may award grants to, and enter into contracts with, eligible entities to enhance the nursing workforce by initiating and maintaining nurse retention programs.

Sec. 5310. Loan repayment and scholarship program. Faculty at nursing schools would be eligible for loan repayment and scholarship programs.

Sec. 5311. Nurse faculty loan program. The Secretary, acting through the Administrator of the Health Resources and Services Administration, may enter into an agreement with eligible individuals for the repayment of education loans to increase the number of qualified nursing faculty. Each agreement will require that the eligible individuals serve as a full-time member of the faculty of an accredited nursing school for a total period, in the aggregate, of at least four years within a six-year period.

Sec. 5312. Authorization of appropriations for parts B through D of title VIII. This section amends Section 871 of the Public Health Service Act to appropriate $338 million to fund Title VIII of the Public Health Service Act nursing programs.

Sec. 5313. Grants to promote the community health workforce. The Director of the Center for Disease Control and Prevention, in collaboration with the Secretary, shall award grants to states, public health departments, clinics, hospitals, Federally-qualified health centers, and other nonprofits to promote positive health behaviors and outcomes for populations in medically underserved communities through the use of community health workers. Community health workers will educate and provide outreach in a community setting regarding health problems prevalent in medically underserved communities; educate regarding effective strategies to promote positive health behaviors; educate regarding enrollment in health insurance; identify and enroll underserved populations to appropriate healthcare agencies and community-based programs; and educate regarding maternal health and prenatal care. The Secretary will give priority to applicants that propose to target certain geographic areas (e.g. areas with a high infant mortality rate), have experience with respect to providing services to underserved individuals, and have documented community activity and experience with community health workers. Section 10501 clarifies the definition and activities of community health workers.

Sec. 5314. Fellowship training in public health. The Secretary may carry out activities to address documented workforce shortages in State and local health departments in the critical areas of applied public health epidemiology and public health laboratory science and informatics and may expand the Epidemic Intelligence Service. The Secretary is also authorized to provide for the expansion of existing fellowship programs operated through the Centers for Disease Control and Prevention in a manner designed to alleviate the workforce shortages.

Sec. 5315. United States Public Health Sciences Track. This provision authorizes the establishment of a United States Public Health Services Track ("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. 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. Students will receive tuition remission and a stipend; they are accepted as Commission Corps officers in the U.S. Public Health Service with a two-year service commitment for each year of school covered.

Subtitle E – Supporting Existing Health Care Workforce

Sec. 5401. Centers of excellence. This section provides additional funding (authorizes for appropriation up to $50 million in 2010 alone) for the Centers of Excellence program (42 U.S.C. § 293), which is designed to increase health professional education for under-represented minority individuals.

Sec. 5402. Health professions training for diversity. This section increases available loan repayment and fellowship funding for disadvantaged students who agree to work in medically underserved areas as well as for faculty who serve at qualifying institutions.

Sec. 5403. Interdisciplinary, community-based linkages. This section authorizes funding to create health care workforce education programs and to continue supporting existing area health education centers. Eligible entities include schools of medicine or osteopathic medicine, or if none exist in the area, to schools of nursing. Qualifying entities must target individuals seeking careers in the health professions from urban and rural medically underserved communities, individuals in minority populations, or must otherwise emphasize an interdisciplinary approach to health care. The grants may be used for a large number of specific activities, provided these larger requirements are met. The minimum grant is $250,000 with a few exceptions; however, entities receiving federal funds must generally match between 25% and 50% of the award.

Sec. 5404. Workforce diversity grants. This section increases the permissible uses of nursing diversity grants to allow: "diploma or associate degree nurses to enter a bridge or degree completion program; student scholarships or stipends for accelerated nursing degree programs; pre-entry preparation; advanced education preparation; and retention activities."

Sec. 5405. Primary care extension program. This section establishes a Primary Care Extension Program to educate and provide technical assistance to primary care providers regarding evidence-based therapies, preventive medicine, health promotion, chronic disease management, and mental health, with the goal of encouraging providers to incorporate these methods into their practices. The Secretary shall award competitive grants to the States to establish Primary Care Extension Program State Hubs, which must include at a minimum the State health department, State-level entities administering Medicare and Medicaid, and at least one health professions school. These Hubs will be responsible for coordinating functions with quality improvement organizations and area health education centers as well as administering state-level Primary Care Extension Programs.

Subtitle F – Strengthening Primary Care and Other Workforce Improvements

Sec. 5501. Expanding access to primary care services and general surgery services. Primary care professionals will receive a ten percent payment increase for primary services performed between January 1, 2011 and January 1, 2016. Affected professionals include family practice and internal, geriatric, or pediatric physicians, nurse practitioners, clinical nurse specialists, and physician assistants for whom office, home health, and nursing facility visits comprised at least sixty percent of their allowed Medicare charges. These incentive payments are in addition to incentive payments some professionals receive for services performed in health professional shortage areas ("HPSAs").

General surgeons will receive a ten percent payment increase for major surgical procedures (identified by 10- or 90-day global service periods) performed in HPSAs between January 1, 2011 and January 1, 2016.

Sec. 5502. Medicare Federally qualified health center improvements. The Secretary will develop a prospective payment system ("PPS") for Federally qualified health centers ("FQHCs"). FQHCs are community-based organizations that provide comprehensive primary and preventive care services to persons regardless of their ability to pay. The PPS will be effective for cost reporting periods beginning on or after October 1, 2014 and will be designed to take into account the type, intensity, and duration of services provided by FQHCs. The estimated aggregate amount of

payments for the first year will be equal to the estimated amount of expenditures that would have been made in the absence of the PPS. Payments in the second year will be based on the first year's payments adjusted by the Medicare Expenditure Index ("MEI"). Payments for subsequent years will be based on the prior year's expenditures increased by the FQHC market basket update, if established by the Secretary, or the MEI.

Sec. 5503. Distribution of additional residency positions. Beginning July 1, 2011, the Secretary will redistribute residency positions that have been unfilled for the prior three reporting periods from the hospitals where they have been unfilled to hospitals that designate the majority of the new slots to training primary care physicians. The Secretary will consider the likelihood the hospital will be able to fill new slots and whether the hospital has an accredited rural training rack. The Secretary is further directed to give priority to hospitals with low resident-to-population ratios, hospitals in health professional shortage areas, and hospitals in rural areas.

Certain hospitals with unfilled residency positions for the last three cost reporting periods are exempt from the redistribution requirement, including hospitals with less than 250 acute care beds that are located in rural areas and hospitals that have specific plans for filling the unused slots.

Sec. 5504. Counting resident time in nonprovider settings. Teaching hospitals may begin counting time spent by medical residents providing patient care services in non-hospital settings, including physician offices, rural health clinics, and other ambulatory settings towards indirect medical education ("IME") and direct graduate medical education ("DGME") costs. Effective for cost reporting periods beginning on or after July 1, 2010, hospitals may receive increased IME and DGME payments if the hospital incurs the costs of the stipend and fringe benefits paid to the residents during the time the resident spends in the non-hospital setting. The law provides that these amendments may not be applied in a manner that requires reopening of any settled cost reports for which there is not a jurisdictionally proper appeal pending as of the date of enactment of the Act on the issue of IME or DGME costs.

Sec. 5505. Rules for counting resident time for didactic and scholarly activities and other activities. Teaching hospitals may begin counting time spent by medical interns and residents on educational activities, such as attending training conferences and seminars, towards the hospitals' IME and DGME costs. Hospitals may also count time spent by residents on vacation, sick leave, and other approved leave that does not prolong the total time the resident is participating in the residency program. The law provides that these amendments may not be applied in a manner that requires reopening of any settled cost reports for which there is not a jurisdictionally proper

appeal pending as of the date of enactment of the Act on the issue of IME or DGME costs.

Sec. 5506. Preservation of resident cap positions from closed hospitals. The Secretary will distribute medical residency slots that would otherwise be lost from hospitals that have closed within two years of the Act's enactment. In determining which hospitals will receive the redistributed slots, the Secretary will give priority to hospitals located in the same area, state, or region as the closed hospital.

Sec. 5507. Demonstration projects to address health professions workforce needs; extension of family-to-family health information centers. The Secretary, with the Secretary of Labor, will award grants for demonstration projects designed to provide supportive services, such as financial aid, child care, case management, and other services, to low-income individuals who have the opportunity to obtain education and training for health occupations that pay well and are expected to experience labor shortages or to be in high demand (such as nursing). Supportive services individuals receive under the program may not be taken into account for determining the individuals' eligibility for means-tested programs (such as Medicaid). The Secretary must award at least three grants to Indian tribes, tribal organizations, or tribal colleges or universities. This provision is effective immediately.

Within 18 months of enactment of the Act, the Secretary will award grants to a maximum of six states for demonstration projects that develop core training competencies and certification programs for personal or home care aides. Demonstration projects must be conducted for at least three years. Core training competencies must address the role of the aide, consumer rights, communication (including cultural and linguistic competence and sensitivity), training specific to an individual consumer's needs, and other areas.

Finally, funding for family-to-family information centers, organizations that help families with children with special health needs, is extended through year 2012.

Sec. 5508. Increasing teaching capacity. The Secretary will award grants to "teaching health centers" to expand and establish new accredited primary care residency programs. Teaching health centers include community based, ambulatory patient care centers. Entities eligible to apply for grants include . Funds may be used for costs associated with curriculum development; recruitment, training, and retention of residents and faculty; accreditation; faculty salaries during the development phase, and technical assistance.

Qualified teaching health centers that operate approved graduate medical residency training programs may receive payments for direct and indirect expenses associated

with sponsoring the training programs. The Act designates $230 million for funding such programs.

These provisions are effective upon enactment of the Act.

Sec. 5509. Graduate nurse education demonstration. The Secretary will establish a graduate nurse education demonstration program that will provide funding to up to five hospitals for the provision of qualified clinical training to advance practice nurses. "Qualified clinical training" includes training in the clinical skills necessary to provide primary care, preventative care, transitional care, chronic care management, and other services appropriate for individuals under Part A of the Medicare program and at least half of which are provided in a non-hospital community-based setting. This provision provides for the waiver of certain provisions of the United States Code necessary to implement the demonstration program, and provides for $50 million in funding for each of the fiscal years 2012 through 2015.

Subtitle G – Improving Access to Health Care Services

Subtitle G authorizes funding for new and preexisting Public Health Service programs.

Sec. 5601. Spending for federally qualified health centers (FQHCs). Under this section, specific monies are set aside to FQHCs. Under this section, community health centers are allowed to contract with outside entities to deliver primary health care services to persons who are eligible for free or reduced cost care.

Sec. 5602. Negotiated Rulemaking for development of methodology and criteria for designating medically underserved populations and health professions shortage areas. This section directs the Secretary to promulgate regulations establishing methods and criteria for designating "medically underserved populations" and "health professions shortage area." The Act prescribes the manner and schedule in which the Secretary must develop these regulations. The Secretary must appoint a rulemaking committee and "facilitator," must consult with key stakeholders, and must meet specific deadlines for a notice of proposed rulemaking, interim rule, and final rule.

Sec. 5603. Reauthorization of the Wakefield Emergency Medical Services for Children Program. This program is reauthorized and additional appropriations provided.

Sec. 5604. Co-locating primary and specialty care in community-based mental health settings. The Secretary, acting through the CMS Administrator, is required to award grants and cooperative agreements to eligible entities to establish demonstration projects for the provision of coordinated and integrated services to special populations through the co-location of primary and specialty care services in community-based

mental and behavioral health settings. "Special populations" refers to adults with mental illnesses who have co-occurring primary care conditions and chronic diseases.

To be eligible to receive a grant or cooperative agreement, an eligible entity (i.e., a qualified community mental health program) must submit an application to the Administrator at such time, in such manner, and accompanied by such information as the Administrator may require, including a description of partnerships, or other arrangements with local primary care providers, including community health centers, to provide services to special populations.

Sec. 5605. Key national indicators. This section establishes a Commission on Key National Indicators, with members to be appointed by Congress. The Commission's stated purpose is to oversee and coordinate with the National Academy of Sciences to develop a system of "Key National Indicators." The Act does not define "Key National Indicator," nor does it explain its purpose or function. There is no stated connection to health care. As best can be discerned from non-legislative sources, this provision appears to have evolved from a constituency concerned about defining parameters for the Government to measure how the nation is doing in areas deemed important to measure.

Subtitle H – General Provisions

Sec. 5701. Reports. This section requires the Secretary annually to report to Congress on activities carried out under this Title V.

TITLE VI
TRANSPARENCY AND PROGRAM INTEGRITY

- Subtitle A – Physician Ownership and Other Transparency
- Subtitle B – Nursing Home Transparency and Improvement
- Subtitle C – 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
- Subtitle E – Medicare, Medicaid and CHIP Program Integrity Provisions
- Subtitle F – Additional Medicaid Program Integrity Provisions
- Subtitle G – Additional Program Integrity Provisions
- Subtitle H – Elder Justice Act

Subtitle A – Physician Ownership and Other Transparency

Sec. 6001. Limitation on Medicare exception to the prohibition on certain physician referrals for hospitals. The physician self-referral (Stark) law "whole hospital" exception is amended to make it harder for physicians to refer to hospitals, including specialty hospitals, in which they have ownership or investment interests. The amendments prohibit physician-owned hospitals from billing Medicare for services provided by physician-owners who refer their patients to the hospital unless the hospital had physician ownership or investment, as well as a provider agreement with Medicare, effective on December 31, 2010. This change effectively creates an indefinite moratorium on physician ownership or investment in hospitals that do not currently have physician ownership or investment.

Those hospitals having physician investment or ownership and a provider agreement prior to December 31, 2010 can continue to participate in Medicare assuming certain requirements are met, including that the physician investment or ownership in the hospital is "*bona fide*." Included in the "*bona fide*" criteria is a requirement that the percentage of the total value of the ownership or investment interests held in the hospital, or in an entity whose assets include the hospital, by physician owners or investors in the aggregate cannot exceed such percentage as of the date of enactment. Effectively, this means that the *expansion* of current physician ownership or investment interests in hospitals is curtailed. The effect of this provision mandates that -- for future investment -- physicians can purchase shares *only* when those shares ultimately come from other selling physicians.

Furthermore, the physical expansion of any hospital with physician investors or owners -- in terms of operating rooms, procedure rooms, and beds -- is prohibited after the date of enactment unless an exception is granted by the Secretary. The Act also requires the hospital to publicize its physicians' ownership and investment interests on its website and in public advertising, and no hospital converted from an ambulatory surgery center after the date of enactment could satisfy the exception.

Sec. 6002. Transparency reports and reporting of physician ownership or investment interests. Beginning in 2013, drug, medical device, biological, and medical supply manufacturers must report to the Secretary transfers of value made to physicians, physician medical practices, physician group practices, and teaching hospitals. The information must include, among other things, the name of the covered recipient, the business address of the recipient, the amount of the payment or other transfer of value, and a description of the nature of the payment or other transfer of value. Furthermore, applicable manufacturers and group purchasing organizations must report information regarding any ownership or investment interest held by a physician (or immediate

family member of such physician) in the applicable manufacturer or applicable group purchasing organization.

Civil money penalties apply of not less than $1,000 but not more than $10,000 for noncompliance for each payment or other transfer of value or ownership or investment interest not reported as required. Total fines per annual submission may not exceed $150,000. The fines for knowing failures to report payments or transfers of value shall be not less than $10,000 but not more than $100,000 for each payment or other transfer of value or ownership or investment interest not reported. Total fines per annual submission may not exceed one million dollars. Federal preemption applies for duplicative state or local laws, however federal preemption does not occur for state and local laws that are beyond the scope of this section.

Sec. 6003. Disclosure requirements for in-office ancillary services exception to the prohibition on physician self-referral for certain imaging services. An additional requirement is added to the Medicare in-office ancillary services exception that requires the referring physician to inform the patient in writing that the individual may obtain the specified service from a person other than the referring physician, a physician who is a member of the same group practice as the referring physician, or an individual who is directly supervised by the physician or by another physician in the group practice.

Sec. 6004. Prescription drug sample transparency. Manufacturers and authorized distributors of record of applicable drugs shall submit to the Secretary a report regarding the identity and quantity of drug samples requested and the identity and quantity of drug samples distributed. The collection of this information is already required by the Food, Drug, and Cosmetic Act. The information shall be aggregated and submitted to the Secretary by the name, address, professional designation, and signature of the practitioner making the request (or of the individual making the request on behalf of the practitioner).

Sec. 6005. Pharmacy benefit managers transparency requirements. Any health benefits plan or entity that provides pharmacy benefits management services shall provide certain information to the Secretary, including: (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, by pharmacy type, that is paid by the health benefits plan or PBM; (2) the aggregate amount, and the type of rebates, discounts, or price concessions that the PBM negotiates that are attributable to patient utilization under the plan, including the concessions that are passed through to the plan sponsor; and (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.

The information disclosed by a health benefits plan or PBM under this section shall be confidential. However, the Secretary may disclose the information in a form that does not disclose the identity of a specific PBM, plan, or prices charged for drugs, for certain specific purposes.

Subtitle B—Nursing Home Transparency and Improvement

PART I—IMPROVING TRANSPARENCY OF INFORMATION

Sec. 6101. Required disclosure of ownership and additional disclosable parties information. Skilled nursing facilities are under Medicare and nursing facilities under Medicaid must make available to the Secretary, the HHS Inspector General, the States, and the state long-term care ombudsman, information related to ownership. The information shall include each member of the governing body of the facility, each person who is an office, director, member, partner, trustee, or managing employee of the facility, and other disclosable parties. Additional disclosable parties include persons or entities that exercise operational, financial, or managerial control over the facility or a part of the facility, persons or entities that lease or sublease real property to the facility or own an interest exceeding 5% of the total value of such real property, or persons or entities that provide management or other administrative services to the facility.

This section shall have no effect on existing reporting requirements, and it shall not reduce, diminish, or alter any other reporting requirement for a facility that is in effect as of the date of enactment.

Sec. 6102. Accountability requirements for skilled nursing facilities and nursing facilities. Skilled nursing facilities and nursing facilities must implement a compliance and ethics program to be followed by the facility's employees and agents within 36 months of enactment. The program must be effective in detecting criminal, civil, and administrative violations under this Act, and it must also promote quality of care. The Secretary , in accordance with the Inspector General of HHS, shall promulgate regulations for an effective compliance and ethics program for operating organizations, which may include a model program.

Sec. 6103. Nursing home compare Medicare website. The Secretary, as part of the information provided for comparison of nursing homes on the official internet website of the government for Medicare beneficiaries, must include, in a prominent place and on frequently-updated basis, the following information: standardized staffing data, links to state internet websites regarding state survey and certification programs, the

model standardized complaint form, and summary of substantiated complaints, and the number of adjudicated instances of criminal violations by a facility or its employee.

The Secretary must establish a process to review the accuracy, clarity of presentation, timeliness, and comprehensiveness of information reported on the website prior to the implementation of this section, which shall occur one year after the enactment of the Act. The Secretary must also ensure that, not later than one year after the date of enactment of this Act, that HHS develops and includes a consumer rights information page that contains links to descriptions of, and information with respect to, the documentation on nursing facilities that is available to the public, general information and tips on choosing nursing facilities, general information on consumer rights, the nursing facility survey process, and, on a state-specific basis, the services available through the state long-term care ombudsman for such State.

Sec. 6104. Reporting of expenditures. For cost reports submitted on or after the date that is two years after the enactment of this subsection, skilled nursing facilities shall separately report expenditures for wages and benefits for direct care staff. The report should break out, at a minimum, registered nurses, licensed professional nurses, certified nurse assistants, and other medical and therapy staff. The Secretary, in consultation with private sector accountants experienced with Medicare and Medicaid nursing facility cost reports, shall redesign the reports to meet the requirements of this section.

Sec. 6105. Standardized complaint form. The Secretary must develop a standardized complaint form for use by residents (or persons acting on the resident's behalf) in filing a complaint with a state survey and certification agency and a state long-term care ombudsman program with respect to a facility. Each state must make the standardized complaint form available upon request to a resident of a facility and any person acting on the resident's behalf.

States must establish a complaint resolution process in order to ensure that the legal representative of a resident of a facility or other responsible party is not denied access to such resident or otherwise retaliated against if they have complained about the quality of care provided by the facility or other issues. The complaint resolution process shall include procedures to assure accurate tracking of complaints received, procedures to determine the likely severity of a complaint, and deadlines for responding to the complaint.

Sec. 6106. Ensuring staffing accountability. Beginning two years after the date of enactment of this subsection, and after consulting with state long-term care ombudsman programs, consumer advocacy groups, and other groups, the Secretary must establish a program for facilities to report staffing information based on payroll and other verifiable and auditable data in a uniform format. The information submitted shall, among other things, specify the category of work a certified employee performs, include resident census data and information on resident case mix, include a regular reporting schedule, and include information on employee turnover and tenure.

Sec. 6107. GAO study and report on Five-Star Quality Rating System. The Government Accountability Office must conduct a study on the Five-Star Quality Rating System for nursing homes of the Centers for Medicare and Medicaid Services. The study must include an analysis of systems implementation and any potential improvements to the system.

PART II – TARGETING ENFORCEMENT

Sec. 6111. Civil money penalties. The Secretary may reduce the civil monetary penalty ("CMP") that would have been imposed by not more than 50 percent in cases where a facility self-reports and promptly corrects a deficiency within ten calendar days of the date of an imposition. The Secretary may not reduce the amount of a CMP if the Secretary had reduced a penalty imposed on the facility in the preceding year. Also, the Secretary may not reduce for a deficiency that resulted in a pattern of harm, immediately jeopardized the health or safety of a resident, or resulted in the death of a resident of the nursing facility. If a CMP is imposed, the Secretary must issue regulations that give the facility an opportunity to participate in informal dispute resolution. The CMP may be placed in an escrow account following completion of the CMP, or the date that is 90 days after the date of the imposition of the CMP, whichever is earlier. Where the facility successfully appeals the penalty, the CMP (plus interest) will be returned to the facility. Where the appeal is unsuccessful, some portion of the amounts collected may be used to support activities that benefit facility residents.

Sec. 6112. National independent monitor demonstration project. The Secretary will conduct a demonstration project to develop, test, and implement an independent monitor program, to oversee interstate and large intrastate chains of nursing facilities. The Secretary will select chains of nursing facilities to participate in the demonstration project from among those chains that submit an application to the Secretary. This project shall last for a two-year period, and it shall be implemented within one year of the Act's enactment. The Secretary, in consultation with the Inspector General of HHS, will evaluate the project.

Sec. 6113. Notification of facility closure. The administrator of a facility must submit to the Secretary, the state long-term care ombudsman, residents of the facility, and legal representatives of such residents, written notification of an impending closure. The written notification should not be later than the date that is 60 days prior to the date of such closure and, if the Secretary has terminated the facility's participation, not later than the date the Secretary determines. The administrator must ensure the facility does not admit any new residents on or after the date written notification is submitted and must include a plan for the transfer and adequate relocation of the residents to a facility.

Sec. 6114. National demonstration projects on culture change and use of information technology in nursing homes. The Secretary is required to conduct two demonstration projects. One project is for the development of best practices in nursing facilities, including the development of resources for facilities to find and access funding in order to undertake cultural change. The other project is for the development of best practices in nursing facilities for the use of information technology to improve resident care. The demonstration projects will not exceed three years.

PART III—IMPROVING STAFF TRAINING

Sec. 6121. Dementia and abuse prevention training. Nursing facilities must include dementia and abuse prevention training as part of the preemployment initial training and, if the Secretary determines appropriate, as part of ongoing 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. The Secretary must establish a program to identify efficient, effective, and economical procedures for long-term care facilities or providers to conduct background checks on prospective direct patient access employees on a national basis. This nationwide program will be carried out under similar terms and conditions as the pilot program under section 307 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, including the prohibition on hiring abusive workers and the authorization of imposition of penalties.

Subtitle D—Patient-Centered Outcomes Research

Sec. 6301. Patient-Centered Outcomes Research. The Act establishes a nonprofit corporation, the Patient-Centered Outcomes Research Institute (the "Institute"). The purpose of the Institute is to assist patients, purchasers, and policy-makers in making

informed health decisions by advancing the quality and relevance of evidence concerning the manner in which diseases and other health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed through research and evidence synthesis. The Institute must ensure that subpopulations are appropriately accounted for in research designs. Findings published by the Institute do not include practice guidelines, coverage, payment, or policy recommendations. The number of physicians on the Board of Governors is four.

Sec. 6302. Federal coordinating counsel for comparative effectiveness research. The Federal Coordinating Council for Comparative Effectiveness Research established under section 804 of Division A of the American Recovery and Reinvestment Act of 2009 will terminate on the date of enactment of the Act.

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

Sec. 6401. Provider screening and other enrollment requirements under Medicare, Medicaid, and CHIP. The Secretary, in consultation with the Inspector General of the Department of HHS, 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. Such screening must include a licensure check. Also, the Secretary may determine, based on the risk of fraud, waste, and abuse, to include a criminal background check, fingerprinting, site visits, database checks, and any other appropriate screening. There will be an application fee of $200 for individual practitioners and $500 for institutional providers. Section 10603 removes the enrollment fee for physicians.

Providers and suppliers enrolling or reenrolling in Medicare, Medicaid, or CHIP are subject to new disclosure requirements. Applicants will be required to disclose affiliations with any provider or supplier that has had their payments suspended, uncollected debt, or their billing privileges revoked. The Secretary will determine a date by which certain providers and suppliers must establish a compliance program.

Sec. 6402. Enhanced Medicare and Medicaid program integrity provisions (as amended by the Reconciliation Act).

o **Integrated Data Repository**. CMS is required to include in the Integrated Data Repository, at a minimum, claims and payment data from Medicare (Parts A, B, C, and D), Medicaid, CHIP, health-related programs administered by the Departments of Veterans Affairs ("VA") and Defense ("DOD"), the Social Security Administration, and the Indian Health Service ("IHS"), making Medicare data the top priority.

o Access to Data and Data Sharing. The Secretary is required to enter into data-sharing agreements with the Commissioner of Social Security, the Secretaries of the VA and DOD, and the Director of the IHS to help identity fraud, waste, and abuse. The HHS-OIG and the Department of Justice are given access to Medicare, Medicaid, and CHIP claims and payment data for the purposes of conducting law enforcement and oversight activities consistent with applicable privacy, security, and disclosure laws. The HHS-OIG is also given broad authority to obtain information, including medical records, from "any individual (including a beneficiary provided all applicable privacy protections are followed) or entity" to validate Medicare and Medicaid claims.

o Administrative Penalty. The Secretary is required to impose an "appropriate administrative penalty commensurate with the offense or conspiracy" if an individual Medicare, Medicaid, or CHIP beneficiary knowingly participates in the offense or conspiracy.

o Overpayments. Medicare and Medicaid overpayments must be "reported and returned" within 60 days after they are "identified." This new requirement applies to providers, suppliers, Medicaid managed care organizations, Medicare Advantage organizations, and PDP sponsors, and requires the return of any "funds that a person receives or retains under [Medicare] or [Medicaid] to which the person, after "corresponding" reconciliation, is not entitled…." Because the obligation to report and return overpayments became effective upon enactment, overpayments that were "identified" on or before the effective date (March 23, 2010) must be reported and returned by May 22, 2010. The new law does not define, and thus leaves open for interpretation, the term "identified." Overpayments that are subject to a "reconciliation process" need not be reported and returned within 60 days, but must be reported and returned by the due date of the "corresponding" cost report. Note that under the new statute, merely returning the overpayment is not all that is required. The new statute, which is to be codified at 42 U.S.C. §1320a-7j(d), requires a person that has received an overpayment to:

- report and return the overpayment to the Secretary, the State, an intermediary, a carrier, or a contractor, as appropriate, at the correct address; and

- notify the Secretary, State, intermediary, carrier, or contractor to whom the overpayment was returned in writing of the reason for the overpayment.

Accordingly, reporting the reason for the overpayment is also required.

The new statute attempts to engraft provisions of the False Claims Act ("FCA") in ways that may cause confusion and litigation. It states that retention of an "identified" overpayment after the specified deadline "is an obligation" as that term is used in the FCA. One who knowingly and improperly avoids or decreases an "obligation" to the Government is liable under what is usually referred to as the reverse false claim section of the FCA,. But the FCA does not impose liability for failing to return an overpayment after a deadline for its return has passed. Liability is imposed only if the obligation to the Government is knowingly and improperly avoided. The words "improperly avoided" suggest that, unlike 6402(a), some level of bad intent is required under the FCA. The section 6402(a) provisions also provide that the words "knowing" and "knowingly" have the meaning given them in the FCA, but the words themselves do not appear in these provisions.

The failure to timely report and return overpayments can result in the imposition of civil monetary penalties and exclusion from the Medicare and Medicaid programs. *See* PPACA §§6402(d)(2), and 6502.

o **Civil Monetary Penalties**. Section 6402(d)(2) expands the use of Civil Monetary Penalties ("CMPs") to (a) excluded individuals who order or prescribe an item or service, (b) those who make false statements on applications or contracts to participate in a Federal health care program, or (c) those who know of an overpayment and do not report and return it, as required by law. Each violation would be subject to CMPs of up to $50,000 and potential exclusion.

o **Testimonial Subpoena Authority.** Section 6402 extends the Secretary's subpoena authority currently set forth at 42 U.S.C § 205 (d) and (e), to program exclusion investigations conducted under 42 U.S.C. § 1320a-7. The Secretary is authorized to delegate this testimonial subpoena authority to the OIG.

o **Kickback Violations are False Claims.** This provision dispels certain arguments that may have previously existed regarding whether and when a kickback violation results in a FCA violation. The kickback statute (42 U.S.C. § 1320-7b) will have a new paragraph (g), effective March 23, 2010, providing that "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the False Claims Act]." FCA violation normally requires that the claim be submitted with knowledge that it is false so there could be some uncertainty regarding establishment of that element.

o **Actual Knowledge Not Required to Violate Anti-Kickback Statute ("AKS").** Problematic, particularly for downstream contractors, Section 6402 further amends 42 U.S.C. § 1320a-7b to provide that a person need not have actual knowledge of the law's prohibitions in order to commit an AKS violation. Nor is specific intent to commit a

violation of the law required. This amendment, in effect, obliterates the specific intent requirement recognized in *U.S. v. Hanlester Network*, 51 F. 3rd 1390 (9th Cir. 1995).

o Suspension of Payments. Section 6402 allows for the suspension of Medicare and Medicaid payments to a provider or supplier if there is a "credible allegation of fraud" on the part of the supplier or provider. The Secretary is given the discretion to determine if there is "good cause" not to suspend payments.

o Surety Bonds. The existing surety bond requirements for durable medical equipment suppliers and home health agencies may now be based on the volume of the billing of the supplier or agency. This section further grants the Secretary the authority to impose surety bond requirements on other suppliers and providers based upon the level of risk the Secretary determines is involved with respect to the business of such supplier or provider.

o Health Care Fraud Control Spending Increase. Section 6402 provides for an appropriation of $10,000,000 for each fiscal year beginning in 2011 and continuing through fiscal year 2020. This automatic appropriation will be paid into the Health Care Fraud and Abuse Control Account. The Reconciliation bill adds an additional $250 million for fiscal years 2011 through 2016 to cover administrative and operations costs of the Health Care Fraud and Abuse Control Program as well as the Medicare Integrity Program. The Reconciliation Act provides for additional appropriations, beginning with $95,000,000 in 2011 and scaling downward through 2016.

o Medicare and Medicaid Integrity Programs. Entities contracting with the Medicare and Medicaid Integrity Programs must now submit annual performance statistics to the Secretary and the OIG. Such statistics must include "the number and amount of overpayments recovered, the number of fraud referrals, and the return on investment of such activities by the entity." The Secretary in turn, is required to conduct performance evaluations on each contracted entity no less than every three years and provide an annual report to Congress on the amount and effectiveness of the funds expended on these integrity programs.

Sec. 6403. Elimination of duplication between the Healthcare Integrity and Protection Data Bank and the National Practitioner Data Bank. The Secretary shall maintain a national health care fraud and abuse data collection program for reporting certain final adverse actions (not including settlements in which no findings of liability have been made) against health care providers, suppliers, or practitioners and shall furnish the information collected to the National Practitioner Data Bank ("NPDB"). The Secretary must also implement a transition process to cease operating the Healthcare Integrity and Protection Data Bank ("HIPDB") and must transfer all data collected to

the NPDB. The Secretary must ensure there are appropriate procedures to ensure that data collection and access to the HIPDB and NPDB are not disrupted.

Sec. 6404. Maximum period for submission of Medicare claims reduced to not more than 12 months. For services furnished on or after January 1, 2010, the maximum period of submission of Medicare claims would be reduced to not more than twelve months.

Sec. 6405. Physicians who order items or services required to be Medicare enrolled physicians or eligible professionals. Only those physicians "or other eligible professionals" enrolled in the Medicare program may, as of July 1, 2010, order DME or home health services. The Secretary is also given the authority to extend this requirement to other items or services, including Part D drugs. Section 10604 clarifies that only physicians enrolled in the Medicare program may order home health services under Medicare Part A and B.

Sec. 6406. Requirement for physicians to provide documentation on referrals to programs at high risk of waste and abuse. Beginning January 1, 2010, physicians and other suppliers and providers who order items of DME, home health services, or other items and services, to "provide access to documentation" relating to such orders. Failure to do so could result in disenrollment from the Medicare program, for up to a year, for the non-complying physician, supplier, or provider. Further, the OIG's permissive exclusion authority now extends to physicians, suppliers and providers who order DME, home health, and other items and services, who fail to provide access to the required documentation. This amendment is seemingly a win for DME suppliers in particular, who upon Medicare audit, often struggle to obtain supporting documentation from physicians to support the medical necessity of a DME product ordered by the physician. While the amendment requires physicians to maintain and provide such documentation to the government, it does not go so far as to obligate the physician to provide the requested documentation to the DME supplier under audit.

Sec. 6407. Face to face encounter with patient required before physicians may certify eligibility for home health services or durable medical equipment under Medicare – as amended by Title X. Before ordering an item of DME or certifying the need for home health services for a Medicare or Medicaid patient, physicians (and certain other allied health professionals) must now have a face to face encounter with the patient "within a reasonable timeframe" prior to the date of the order. What that time frame turns out to be will likely be determined through regulation or other guidance from CMS. The Secretary is also given the authority to extend this requirement to other items and services if it is determined that to do so would reduce the risk of fraud, waste, or abuse. Section 10605 of Title X clarifies that the face-to-face encounter required prior to

certification for home health services may be performed by a physician, nurse practitioner, clinical nurse specialist, certified nurse-midwife, or physician assistant.

Sec. 6408. Enhanced penalties. The penalties for engaging in conduct related to several different programs, including Medicare Advantage and Part D programs, have been enhanced significantly with this amendment. For example, MA or Part D plans that: enroll individuals without their consent, transfer individuals from one plan to another in order to earn a commission, fail to comply with marketing requirements, or employ or contract with an individual or entity that commits a violation, are now subject to sanctions and CMPs. Further, penalties for MA and Part D plans that misrepresent or falsify information would be increased up to three times the amount claimed by a plan or plan sponsor based on the misrepresentation or falsified information.

Penalties for all persons who fail to grant HHS OIG access to documents, for the purpose of audits, investigations, evaluations, or other statutory functions, in a timely manner, now include the imposition of CMPs of $15,000 per day. In addition, persons who knowingly make false statements in connection with any Federal health care program are now subject to CMPs of $50,000 for each violation.

Sec. 6409. Medicare self-referral disclosure protocol. Under the new Medicare self-referral disclosure protocol, HHS OIG, must establish, within six months of enactment of the law, a self-disclosure protocol for 'pure' Stark Law violations. The protocol will provide instruction on to whom self-disclosures will have to be made, as well as the implications that such self-disclosures will have on CIAs and CCAs. Moreover, the protocol must detail how HHS OIG will consider repayment in amounts less than claims made, based on: the nature and extent of the improper or illegal practice, the timeliness of the disclosure, and the cooperation offered by the disclosing entity.

Sec. 6410. Adjustments to the Medicare durable medical equipment, prosthetics, orthotics, and supplies competitive acquisition program. Simple adjustments were made to the DME Competitive Bidding provisions which will expand the number of areas to be included in the second round of the Competitive Bidding Program from 79 of the largest metropolitan statistical areas ("MSAs") to 100 of the largest MSAs. The Secretary is instructed to have competitively bid prices in place in all areas by 2016.

Sec. 6411. Expansion of the Recovery Audit Contractor (RAC) program. Due to the apparent success of the RAC program under traditional Medicare, Congress has expanded the RAC program into the areas of Medicaid, Medicare Advantage, and Part D. With regard to Medicaid, each State is required to enter into a contract(s) with a Recovery Audit Contractor(s) by December 31, 2010, "for the purpose of identifying underpayments and overpayments, and recouping overpayments under the State

Plan…". As regards MA and Part D Plans, the Secretary is required to enter into contracts with RAC contractors that will "ensure that each MA/Part D Plan has an anti-fraud plan in effect and to review the effectiveness of each such anti-fraud plan." The Secretary must submit an annual report to Congress concerning the effectiveness of these RAC programs.

Subtitle F—Additional Medicaid Program Integrity Provisions

Sec. 6501. Termination of provider participation under Medicaid if terminated under Medicare or other State plan. States are now required to terminate individuals or entities from their Medicaid programs if the individuals or entities have been terminated from Medicare or from another State Medicaid Program. Such terminations must occur beginning January 1, 2011, unless State legislation is required to effectuate this new requirement.

Sec. 6502. Medicaid exclusion from participation relating to certain ownership, control, and management affiliations. This section requires state Medicaid agencies to exclude individuals or entities from participating in Medicaid for a specified period of time if the individual or entity owns, controls, or manages an entity that: (1) has failed to repay overpayments (as defined by the Secretary) during the period, (2) is suspended, excluded, or terminated from participation in any Medicaid program during the period, or (3) is affiliated with an individual or entity that has been suspended, excluded, or terminated from Medicaid participation during the period.

Sec. 6503. Billing agents, clearinghouses, or other alternate payees required to register under Medicaid. All "agents, clearinghouses, or other alternate payees" that submit claims on behalf of health care providers, must register with the State and the Secretary in a form and manner specified by the Secretary.

Sec. 6504. Requirement to report expanded set of data elements under MMIS to detect fraud and abuse. This section requires States and Medicaid managed care organizations to submit data elements from the Medicaid Management Information System ("MMIS") that the Secretary determines to be necessary "for program integrity, program oversight, and administration."

Sec. 6505. Prohibition on payments to institutions or entities located outside of the United States. States are prohibited from providing any payments for items or services provided under a State plan to any financial institution or entity outside of the United States.

Sec. 6506. Overpayments. Under certain circumstances, States are granted additional time before adjustments to the Federal payments to the State are made. For example, when overpayments due to fraud on the part of an individual or entity are pending, State repayment of the Federal portion would not be due until 30 days after the date on which a final judgment is made. Similarly, States are given one year to repay overpayments when a final determination of the amount of the overpayment has not been determined due to an ongoing judicial or administrative process.

Sec. 6507. Mandatory State use of national correct coding initiative. Effective for claims filed on or after October 1, 2010, States are required to make their MMIS methodologies compatible with Medicare's National Correct Coding Initiative.

Sec. 6508. General effective date. Unless otherwise provided within a specific provision in the health reform legislation, States are required to implement all of the Medicaid Integrity provisions of Subtitle F by January 1, 2011. An exception is provided for those States whose State Plan require legislation to implement the changes required under Subtitle F.

Subtitle G—Additional Program Integrity Provisions

Sec. 6601. Prohibition on false statements and representations. No person, in connection with a plan or other arrangement that is a multiple employer welfare arrangement, shall make a false statement or representation of fact, knowing it to be false, in connection with the marketing or sale of such plan or arrangement concerning the following: the financial condition or solvency of the plan; the benefits provided by the plan; the regulatory status of the plan under any law governing collective bargaining or labor relations; and exemptions for state regulatory authority under the Act. Such individuals who provide false statements will be subject to criminal penalties.

Sec. 6602. Clarifying definition. Title 18, section 24(a)(2) of the United States Code is amended to clarify that the definition of "federal health care offense" includes a violation of or a conspiracy to violate sections 411, 518, or 511 of the ERISA.

Sec. 6603. Development of model uniform report form. The NAIC will develop a standardized reporting form that private health insurance carriers may use to refer suspected instances of fraud and abuse to responsible State agencies. The NAIC will also develop standards for when private carriers should refer suspected instances of fraud and abuse.

Sec. 6604. Applicability of State law to combat fraud and abuse. The Department of Labor is authorized to adopt regulations that would impose State fraud and abuse prevention laws on individuals engaged in the business of providing health insurance through multiple-employer welfare arrangements, regardless of whether such laws would otherwise be preempted.

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. ERISA is amended to give the Department of Labor to issue *ex parte* cease and desist orders to temporary shut down a multiple-employer welfare plan's operations if it appears to the Department that the plan is engaging in fraudulent or hazardous conduct. The Department may also seize the assets of plans in hazardous financial condition. Plans subject to cease and desist orders may request a hearing, at which the plan has the burden of proof to demonstrate why the order should be set aside.

Sec. 6606. MEWA plan registration with Department of Labor. Multiple-employer welfare plans must file federal registration forms prior to beginning operations in a State, thus becoming subject to government verification that the plan is legitimate.

Sec. 6607. Permitting evidentiary privilege and confidential communications. The Department of Labor may establish an evidentiary privilege that would protect communications between State and Federal agencies responsible for investigating employer welfare benefit plans, including State insurance departments and attorneys general, the NAIC, and the U.S. Departments of Labor, Treasury, Justice, and Health and Human Services.

Subtitle H—Elder Justice Act

Sec. 6701. Short title of subtitle. The short title is the "Elder Justice Act of 2009."

Sec. 6702. Definitions. For purposes of the Elder Justice Act, this section defines the terms "abuse," "adult protective services," "caregiver," "direct care," "elder," "elder Justice," "eligible entity," "exploitation," "fiduciary," "grant," "guardianship," "Indian tribe," "law enforcement," "long-term care," "long-term care facility," "neglect," "nursing facility," "self-neglect," "serious bodily injury," "State legal assistance developer," and "State long-term care ombudsman."

Sec. 6703. Elder Justice. HHS, in consultation with the Departments of Labor and Justice, will establish several advisory bodies and grant programs designed to provide protections to residents of long term care facilities, including:

- Establishing an Elder Justice Coordinating Council comprised of representatives from DHHS, the Attorney General, and other applicable federal and state agencies, which will make recommendations to DHHS for coordinating the activities of the various agencies and legislative recommendations to Congress.

- Establishing an Advisory Board on Elder Abuse, Neglect and Exploitation, comprised of members of the public with relevant expertise, which will advise the Elder Justice Coordinating Council.

- Establishing forensic centers to assist in determining the occurrence of elder abuse and to research and distribute information on detection of and intervention in abuse cases.

- Establishing grant programs to:

  – Improve long-term care staffing, including training programs and increased compensation for long-term care employees.

  – Offset long-term care facilities' cost of adopting electronic health record technologies designed to improve patient safety and reduce complications resulting from medication errors.

  – Establish and enhance State adult protective services programs

  – Establish State and local demonstration programs to test training modules and methods for detecting elder abuse.

  – Improve the capacity of State long-term care ombudsmen to respond and resolve complaints regarding elder abuse and neglect, and establishing ombudsman training programs.

  – Design and implement State survey agency elder abuse and neglect complaint investigation systems.

- Establishing a National Training Institute for federal and State surveyors who investigate allegations of elder abuse in long-term care facilities that receive Medicare and Medicaid funds.

- Requiring long-term care facilities that receive federal funds to report to HHS and one or more local law enforcement agencies any reasonable suspicion that a crime has been committed against the facility's residents. Facilities

must report suspicions within twenty-four hours, or sooner in serious cases. Civil monetary penalties between $200,000-$300,000 and possible exclusion from participation in federal healthcare programs may be imposed on facilities who fail to make reports or who take retaliatory actions against employees who make reports.

- Requiring HHS to study and make recommendations to Congress regarding the establishment of a Nurse Aide Registry that would collect information regarding federal and State law violations by individuals included in the registry.

Subtitle I – Sense of the Senate Regarding Medical Malpractice

Sec. 6801. Sense of the Senate regarding medical malpractice. Encourages States to reform the medical malpractice litigation system in order to improve patient safety, reduce medical errors, increase the availability of prompt and fair resolution of disputes, and improve provider access to liability coverage, while maintaining individuals' rights to pursue claims in court. Encourages Congress to establish a State demonstration program to evaluate alternative resolutions of medical malpractice claims.

TITLE VII
IMPROVING ACCESS
TO INNOVATIVE MEDICAL THERAPIES

- Subtitle A – Biologics and Price Competition and innovation
- Subtitle B – More Affordable Medicines for Children and Underserved Communities

Subtitle A—Biologics Price Competition and Innovation

Sec. 7001. Short Title. The "Biologics Price Competition and Innovation Act of 2009."

Sec. 7002. Approval pathway for biosimilar biological products. This provision establishes a process under which the Secretary is required to create an approval pathway to license a biological product that is shown to be biosimilar to or interchangeable with a licensed biological product, commonly referred to as a reference product. The biosimilar regulatory pathway is based on the innovator's or "reference product's" prior FDA approval and determination of safety, purity and potency.

Biosimilar applications will be reviewed by the same FDA division as the reference product. To be approved, the application must satisfy two standards:

- *Biosimilar*-requires analytics demonstrating that product is "highly similar", preclinical, clinical (including immunogenicity, pharmacokinetics and pharmacodynamics) studies, any of which may be waived by the FDA; and

- *Interchangeability*--meeting above biosimilar requirement *and* (a)"expected to produce same clinical result …in any given patient"; and (b) risk of "safety or diminished efficacy of alternating or switching between use of the [biosimilar] and reference product is not greater than the risk of using the reference product" alone.

Other key features of the new law include the following:

- No biosimilar applicant can file sooner than 4 years after the reference product is first licensed (4.5 if pediatric request);
- 12 years of exclusivity for reference products from approval of the "first licensure";
- If FDA approves a biological product on the grounds that it is interchangeable to a reference product, HHS is prohibited from making a determination that a second or subsequent biological product is interchangeable to that same reference product until 1 year after the first commercial marketing of the first interchangeable product;
- Confidential document exchange and good faith negotiation between applicant and reference product patent owners before patent litigation;
- 180 day "Notice of Commercial Marketing" by biosimilar applicant to reference product owner prior to marketing;
- But unlike small molecule generics, there will be no "Orange Book" Listing

Sec. 7003. Savings. The Secretary of the Treasury is charged with determining for each fiscal year, in consultation with the Secretary, the amount of savings to the Federal Government as a result of the biosimilar approval provisions, and requires all savings to be used for deficit reduction.

While the pathway for the approval of biosimilar drugs creates an opportunity for potentially dramatic savings over existing branded bioproducts, the 12 year exclusivity period is longer than many generic manufacturers had sought.

Subtitle B—More Affordable Medicines for Children and Underserved Communities

Sec. 7101. Expanded participation in 340B program (as amended by the Reconciliation Act). In 1992, Congress established the 340B program to help health care providers serve low-income people. The law requires pharmaceutical manufacturers participating in the Medicaid program to provide discounts on covered outpatient drugs purchased by the types of community providers listed in the statute. This provision continues a pattern of extending 340B discounts to a wider range of entities, in this case, to certain children's hospitals, cancer hospitals, critical access and sole community hospitals, and rural referral centers, but only for outpatient drugs. The Act's expansion to include inpatient drugs was eliminated in the Reconciliation Act.

Sec. 7102. Improvements to 340B program integrity. This provision establishes new auditing, reporting, and other compliance requirements for the Secretary, and for pharmaceutical manufacturers and 340B covered entities.

Sec. 7103. GAO study to make recommendations on improving the 340B program. This provision requires the GAO to make recommendations to Congress within 18 months on improvements to the 340B program.

TITLE VIII

COMMUNITY LIVING ASSISTANCE SERVICES AND SUPPORTS (CLASS ACT)

Sec. 8002. Establishment of national voluntary insurance program for purchasing community living assistance services and support (CLASS program). This provision establishes a voluntary, self-funded public long-term care insurance program, to be known as the CLASS Independence Benefit Plan, for the purchase of community living assistance services and supports by individuals with functional limitations. The program defines who is eligible to participate, establishes a framework of benefits and enrollment and disenrollment standards, and requires the Secretary to develop at least 3 actuarially sound benefit plans as alternatives for consideration for designation by the Secretary as the CLASS Independence Benefit Plan under which eligible beneficiaries shall receive benefits. No taxpayer funds are permitted to be used for benefits.

TITLE IX

REVENUE PROVISIONS

Subtitle A – Revenue Offset Provisions

Sec. 9001. Excise Tax on High Cost Employer-Sponsored Health Coverage (as amended by the Reconciliation Act). Beginning in 2018, the new law imposes a 40 percent excise tax on health insurance companies and plan administrators for any health coverage plan with an annual premium that is greater than $10,200 for individual coverage and $27,500 for family coverage. An additional threshold amount of $1,650 for single coverage and $3,450 for family coverage applies for retired individuals age 55 and older and for plans that cover employees engaged in high risk professions or the repair or installation of electrical or telecommunications lines. Employees in high-risk professions include law enforcement officers, employees in fire protection activities, individuals who provide out-of-hospital emergency care, individuals whose primary work is longshore work, and individuals engaged in the construction, mining, agriculture, forestry and fishing industries. The tax only applies to the portion of the premium in excess of the threshold amount. The dollar thresholds are indexed to inflation.

The excise tax applies to self-insured plans and plans sold in the group market. Except for coverage eligible for deduction for self-employed individuals, the tax does not apply to plans sold in the individual market. Stand-alone dental and vision plans are excluded from the tax. Employers with age and gender demographics that result in higher premiums are allowed to value the coverage provided to employees using rates that would apply using a national risk pool.

In general, each employer is responsible for calculating the amount of excess benefit that is subject to the tax and the applicable share of excess benefit for each coverage provider. In the case of coverage available through a multi-employer plan, the plan sponsor is responsible for making the calculations and providing notice to the coverage provider.

If an employer or plan sponsor fails to properly calculate the excess benefit subject to the excise tax, it must pay a penalty that is equal to the excess amount plus an underpayment interest. A penalty does not apply to failures that are corrected within 30 days. There is no penalty imposed if the excise tax paid by a coverage provider is less than the amount due. The Secretary of the Department of Health and Human Services is authorized to waive part or all of a penalty if it would be excessive.

Sec. 9002. Inclusion of Cost of Employer-Sponsored Health Coverage on W-2. Employers must disclose the value of the benefit provided by the employer for each employee's health insurance coverage on the employee's annual Form W-2. This provision applies to taxable years beginning after December 31, 2010.

Sec. 9003. Distributions for Medicine Qualified Only if for Prescribed Drug or Insulin. The definition of qualified medical expenses for Health Savings Accounts ("HSAs"), Archer Medical Savings Accounts ("Archer MSAs"), Health Flexible Spending Arrangements ("Health FSAs"), and Health Reimbursement Arrangements is conformed to the definition used for the medical expense itemized deduction. This provision applies to amounts paid and expenses incurred in taxable years beginning after December 31, 2010.

Sec. 9004. Increase in additional tax on distributions from HSAs and Archer MSAs not used for qualified medical expenses. The additional tax imposed on withdrawals from HSAs prior to age 65 that are used for purposes other than qualified medical expenses is increased from 10 percent to 20 percent. The additional tax imposed on withdrawals from Archer MSAs that are not used for qualified medical expenses is increased from 15 percent to 20 percent. This tax applies to distributions made after December 31, 2010.

Sec. 9005. Limitations on Health Flexible Spending Arrangements under Cafeteria Plans – as amended by Title X and the Reconciliation Act. Beginning in taxable years after December 31, 2012, contributions to Health FSAs are limited to $2,500 per year. The $2,500 limit is adjusted for inflation for taxable years after December 31, 2013.

Sec. 9006. Expansion of Information Reporting Requirements. This provision amends the IRC to require businesses that pay more than $600 during the year to corporate and non-corporate providers of property and services file to an information report with each provider and with the IRS. This provision applies to payments made after December 31, 2011.

Sec. 9007. Additional requirements for charitable hospitals – as amended by Title X. Under the new law, nonprofit hospitals are required to conduct periodic community

needs assessments, establish a written financial assistance policy, implement a written emergency medical care policy, and meet certain billing and collection practices. As part of its financial assistance policy, a charitable hospital can charge for emergency or medically necessary care the amount that is generally billed to individuals who have insurance. Organizations that operate more than one charitable hospital facility must meet these requirements separately for each facility. A $50,000 excise tax will be imposed on charitable hospitals that fail to meet these requirements. Additionally, the Secretary of the Treasury must review the community benefit activities of charitable hospitals at least once every three years.

In general, these provisions go into effect in 2011. However, the excise tax applies to failures occurring after the date of enactment of this Act and the community health needs assessment requirement goes into effect in 2013.

Sec. 9008. Imposition of annual fee on branded prescription pharmaceutical manufacturers and importers – as amended by the Reconciliation Act. Beginning in 2011, an annual fee is imposed on pharmaceutical manufacturers and importers based on branded pharmaceutical sales. The fee is $2.5 billion in 2011; $2.8 billion in 2012 and 2013; $3 billion in the years 2014 through 2016; $4 billion in 2017; $4.1 billion in 2018; and $2.8 billion in 2019 and beyond. This non-deductible fee will be allocated across the industry according to the previous year's market share of branded prescription drug sales. The fee does not apply to companies with sales of branded pharmaceuticals of $5 million or less. Orphan drug sales are excluded from calculation of branded prescription drug sales. The Secretary of the Treasury will calculate the amount of each covered entity's fee.

Sec. 9009. Excise Tax on sale of medical devices. The IRC is amended to include a 2.3 percent excise tax on the sale of any taxable medical device by a manufacturer, producer or importer. Eyeglass, contact lenses, hearings aids, and any other device determined by the Secretary to be of a type which is generally purchased by the general public at retail for individual use are excluded from the tax. This new excise tax applies to sales beginning in 2013.

Sec. 9010. Imposition of annual fee on health insurance providers (as amended by the Reconciliation Act). Similar to the fee imposed on the pharmaceutical sector, the new law also imposes an annual fee on health insurance providers. Beginning in 2014, this non-deductible fee will be allocated across the industry according to market share of net premiums written. It will only apply to companies whose net premiums written are more than $25 million. A covered entity is required to report its health insurance premiums written to the Secretary of the Treasury, who is responsible for calculating each covered entity's fee.

The annual fee is $8 billion in 2014; $11.3 billion in 2015 and 2016; $13.9 billion in 2017; and $14.3 billion in 2018. Beginning in 2019, the annual fee will be the same as the preceding year increased by the rate of premium growth for the preceding year.

There are limited exemptions from the fee, including for certain non-profit insurers. For example, nonprofit insurance providers more than 80 percent of whose revenue is received from Social Security Act programs that target low income, elderly, or disabled populations are excluded. A penalty will be imposed for the understatement of a covered entity's net premiums written.

Sec. 9011. Study and report of effect on veterans health care. The Secretary of Veterans Affairs will review and report to Congress on the effect – if any – of the fees assessed on pharmaceutical manufacturers and importers and health insurance providers and the excise tax imposed on medical device manufacturers on the cost of medical care provided to veterans and veterans' access to medical devices and branded prescription drugs.

Sec. 9012. Elimination of the deduction for expenses allocable to Medicare Part D Subsidy – as amended by the Reconciliation Act. Beginning in 2013, the tax deduction for an amount equal to the subsidy for employers who maintain prescription drug plans for their Medicare Part D eligible retirees is eliminated.

Sec. 9013. Modification of itemized deduction for medical expenses. The adjusted gross income threshold for claiming itemized deductions for medical expenses is increased from 7.5 percent to 10 percent. This provision goes into effect in 2013; however, individuals age 65 and older will be able to continue to claim the itemized deduction for medical expenses at 7.5 percent of adjusted gross income through 2016.

Sec. 9014. Limitation on excessive remuneration paid by certain health insurance providers. If a health insurance provider derives at least 25 percent of its gross premium income from health insurance plans that offer minimum essential coverage, the deductibility of executive compensation under Section 162(m) of the IRC is limited to $500,000 per taxable year. This deduction limitation also applies to deferred compensation that exceeds $500,000. This provision applies to all officers, employees, directors, and other workers or service providers performing services for or on behalf of a covered health insurance provider.

From January 1, 2010 to December 31, 2012, a covered health insurance provider for the purposes of this section includes any employer that receives premiums from issuing health insurance coverage. Beginning on January 1, 2013, a covered health insurance provider includes a health insurance issuer that receives at least 25 percent of its gross premiums from providing health insurance plans with minimum essential

coverage.

Sec. 9015. Additional hospital insurance tax on high-income taxpayers. Beginning in 2013, the FICA and SECA tax rates increase to 0.9 percentage points for single taxpayers with income in excess of $200,000 and couples filing jointly with incomes in excess of $250,000.

Sec. 9016. Modification to Section 833 treatment of certain health organizations. This provision modifies the IRC provisions providing special deductions for non-profit Blue Cross and Blue Shield ("BCBS") organizations and certain other qualifying non-profit plans. Specifically, the provision adds a requirement to have a medical loss ratio of 85 percent or higher in order to benefit from the deductions included in Section 833. This provision applies to tax years beginning on January 1, 2010.

Sec. 9017. Excise tax on indoor tanning services (as amended by the Reconciliation Act). The new law imposes a 10 percent tax on the amount paid for indoor tanning services, whether the services are paid for by health insurance or otherwise. Indoor tanning services are services that use an electronic product with one of more ultraviolet lamps to induce skin tanning. Phototherapy services performed by a licensed medical professional are excluded from the tax. The tax is imposed on the individual on whom the service is performed and applies to services beginning on July 1, 2010.

Subtitle B – Other Provisions

Sec. 9021. Exclusion of health benefits provided by Indian tribal governments. This section, which is effective following enactment of the PPACA, excludes the value of a qualified Indian health care benefit from gross income.

Sec. 9022. Establishment of simple cafeteria plans for small businesses. This provision establishes simple cafeteria plans for small businesses under the IRC. An employer is eligible under this section if it employed an average of 100 or fewer employees on business days during either of the two preceding years. Certain eligible employers may continue to participate under this section as they grow, up to an average of 200 employees. This provision goes into effect on January 1, 2011.

Sec. 9023. Qualifying therapeutic discovery project credit. The IRC is amended with the establishment of a tax credit for qualifying therapeutic discovery projects. Under this new provision, up to 50 percent of the qualified investments in projects designed to develop new therapies to prevent, diagnose, and treat acute and chronic diseases is eligible for the tax credit. The tax credit is available for two years and applies to

amounts paid or incurred beginning on January 1, 2009. It is subject to a cap of $1 billion.

Sec. 10908. Exclusion for assistance provided to participants provided to student loan repayment programs for certain health professionals. Under this provision, payments made under the National Health Service Corps loan repayment program and any State loan repayment or loan forgiveness program that is intended to provide for the increased availability of health care services in underserved or health professional shortage areas are exempted from an individual's grow income. This provision applies to amounts received by an individual in taxable years beginning after December 31, 2008.

Sec. 10909. Expansion of adoption tax credit and adoption assistance programs. The IRC is amended to increase the adoption tax credit and adoption assistance exclusion to $13,170, extend the tax credit through 2011 and make the tax credit refundable. This provision applies to taxable years beginning after December 31, 2009.

TITLE X

STRENGTHENING QUALITY, AFFORDABLE HEALTH CARE FOR ALL AMERICANS

The following is a summary of notable changes made by Title X of the Act that are not discussed in the summary of the first nine titles of the Act.

- Subtitle A – Provisions Relating to Title I
- Subtitle C – Provisions Relating to Title III
- Subtitle D – Provisions Relating to Title IV
- Subtitle F – Provisions Relating to Title VI

Subtitle A – Provisions Relating to Title I

Sec. 10104. Amendments to Subtitle D. Section 10104(j) of the Act amends the "public disclosure" and "original source" provisions in 31 U.S.C. § 3730(e) of the FCA. The FCA currently deprives courts of jurisdiction over FCA actions brought by whistleblowers that are based upon the public disclosure of allegations or transactions in certain settings. The jurisdictional bar is not applicable to whistleblowers who are original sources.

Section 10104(j) strikes the jurisdictional bar language but directs that courts dismiss whistleblower actions or claims "unless opposed by the Government, if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed". But the types of public disclosures that would require dismissal have been expressly limited to "Federal" hearings, reports, audits or investigations. Disclosure in comparable state proceedings would not require dismissal.

The new language precluding dismissal in the face of Government opposition may be intended to ensure the viability of not only actions "brought by the Attorney General", but also those cases brought by whistleblowers where the Government has decided to intervene. But it also provides the additional option to the Government of permitting it to prevent the dismissal of even those whistleblower cases in which it has declined to intervene. And it appears that a simple statement of opposition by the Government will be sufficient to deprive the court of its ability to dismiss the case; the law does not set a standard for consideration of the opposition.

Under the existing statute, cases subject to dismissal were those that were "based upon" public disclosures; now it is those that have "substantially the same allegations" as the disclosures. This would seem to eliminate the need to show a causal connection between a suit and a public disclosures; a substantial similarity between the two may be sufficient to warrant dismissal.

The new law retains the "original source" exception to public disclosure dismissals, but it alters its definition. An original source is now someone who either voluntarily discloses to the Government the information on which allegations in a FCA suit are based before that information has been publicly disclosed, or who has knowledge that is independent of and that "materially adds" to the publicly disclosed allegations, and has voluntarily disclosed it to the Government before filing suit.

The original source need no longer have direct knowledge of the information publicly disclosed but that knowledge must still be independent of the public disclosure. The new law does not explain or define what is meant by the new requirement that the

original source's knowledge materially add to the publicly disclosed allegations. It is likely that that requirement will be the subject of a considerable amount of litigation.

Sec. 10108. Free choice vouchers. Section 10108, which was added by Title X, requires an employer that pays a portion of the cost of coverage through an employer-sponsored plan, to also provide a free choice voucher to certain qualified low-income employees. The qualified employee could then use the voucher to purchase alternative coverage through a national exchange established by the States.

The voucher would be equivalent to the monthly portion of the cost of coverage that the employer would have otherwise paid if the employee was covered under the employer's plan. The employer must pay that amount directly to the national exchange and is deductible by the employer. The employee would receive any amount of the voucher that exceeds the cost of the exchange coverage.

The amendment applies to vouchers provided after January 1, 2014.

Sec. 10109. Development of standards for financial and administrative transactions. Section 10109, which was added by Title X, provides that the Secretary solicit input relating to the creation of uniform standards for various health care transactions, including forms for enrollment of healthcare providers by health plans, financial audits, or methodologies used by health plans to establish claim edits. The Secretary would also task a committee to receive input regarding the cross-walk between the Ninth and Tenth Revisions of the International Classification of Diseases and make recommendations about appropriate revisions to the crosswalk.

Subtitle C – Provisions Relating to Title III

Sec. 10323. Medicare coverage for individuals exposed to environmental health hazards. Certain individuals determined to be exposed to environmental health hazards as a result of a public health determination under CERCLA will be eligible for Medicare Part A and Part B benefits and medical screening services. HHS shall also establish a program under which competitive grants will be awarded to certain entities for the purposes of (i) screening certain individuals at-risk for environmental health conditions and present in a geographic area subject to an emergency declaration under CERCLA, and (ii) developing and disseminating public information and education about the availability of such screening and the detection, prevention and treatment of such conditions.

In addition, HHS must establish a pilot program to furnish comprehensive, coordinated, cost-effective care to certain individuals living in or around Libby, Montana who are affected by the presence of asbestos fibers at the defunct W.R. Grace & Co. mine.

Sec. 10324. Protections for frontier states. Beginning in October 1, 2010, inpatient and outpatient services provided by hospitals located in a frontier state, (*i.e.*, a State wherein 50% of the counties have a population per square mile of less than 6), shall be subject to an area wage index floor. Similarly, on January 1, 2011, the practice expense index component of payment for physician services in such States shall also be subject to a floor. Currently, hospitals and physicians qualify for these floors if they are located in Montana, North Dakota, South Dakota, Utah, or Wyoming.

Sec. 10325. Revision to skilled nursing facility prospective payment system. Congress delayed by a year, until October 1, 2011, the implementation of the SNF RUGS-IV payment system.

Sec. 10328. Improvement in Part D Medication Management (MTM) Programs. The Act expands on the MTM requirements for Plan Sponsors that CMS has been adding through the Call Letters. For plan years beginning on or after two years following the date of the Act's enactment, Plan Sponsors shall offer medication therapy management services to targeted beneficiaries described that include, at a minimum, the following to increase adherence to prescription medications or other goals deemed necessary by the Secretary: (i) An annual comprehensive medication review furnished person-to-person or using telehealth technologies by a licensed pharmacist or other qualified provider. The comprehensive medication review shall include a review of the individual's medications and may result in the creation of a recommended medication action plan or other actions in consultation with the individual and with input from the prescriber to the extent necessary and practicable; and shall include providing the individual with a written or printed summary of the results of the review. The Secretary, in consultation with relevant stakeholders, is required to develop a standardized format for the action plan and the summary.

Plan Sponsors are required to have in place a process to assess, at least on a quarterly basis, the medication use of individuals who are at risk but not enrolled in the medication therapy management program, including individuals who have experienced a transition in care, if the Plan Sponsor has access to that information.

Plan Sponsor are required to have in place a process to automatically enroll targeted beneficiaries in the medication therapy management program, and permit such beneficiaries to opt out of enrollment in such program.

This section is not intended to limit the Secretary's authority to modify or broaden requirements for a medication therapy management program under Part D or to study new models for medication therapy management through the Center for Medicare and Medicaid Innovation.

Sec. 10329. Developing methodology to assess health plan value. HHS shall, in concert with various stakeholders, develop a methodology to measure health plan value and report to Congress concerning that methodology by September 23, 2011. The methodology of measuring health plan value shall consider the overall cost to plan enrollees, the quality of care provided under the plan, the efficiency of the plan in providing care, and the relative risk of the plan's enrollees as compared to other plans.

Sec. 10330. Modernizing computer and data systems of the CMS to support improvements in care delivery. By December 23, 2010, HHS shall develop a plan and a detailed budget for modernizing CMS' computer and data systems.

Sec. 10331. Public reporting of performance information. By January 1, 2011, HHS shall develop a Physician Compare Internet website with information on Medicare-enrolled physicians and other professionals who participate in the PQRI program. By January 1, 2013, HHS shall make publicly available, through that website, comparative information on Medicare-enrolled physicians' performance. To the extent "scientifically sound" and practicable, information to be made publicly available shall include PQRI measures; assessments of patient health outcomes; functional status of patients; assessments of the continuity of care, coordination of care, and care transitions; assessments of efficiency; assessments of patient experience and patient, caregiver, and family engagement; and assessments of the safety, effectiveness and timeliness of care. Prior to such publication, physicians will have reasonable opportunities to review the information.

By January 1, 2008, HHS may establish a demonstration program wherein Medicare beneficiaries are provided financial incentives to utilize high quality physicians, as determined by the factors listed above.

Sec. 10332. Availability of Medicare data for performance measurement. By January 1, 2012, HHS shall make available to both public and private entities standardized extracts of the Part A, Part B and Part D claims data that HHS uses to evaluate the performance of providers and suppliers, to the extent the entities to which the data will provided (i) are qualified to use claims data to evaluate provider and supplier performance on measures of quality, efficiency, effectiveness, and resource use; (ii) agree to pay a fee equal to the cost of making such data available; (iii) agree to describe to HHS the methodologies by which the entity will use the data to evaluate provider and supplier performance; (iv) agree to include information on provider and

supplier performance evaluation only in reports that include an understandable description of the measures and methods by which performance was measured and that are made available, confidentially and prior to publication, to providers and suppliers for purposes of appeal and correction; and (v) agree to make the data available to providers and suppliers upon their request. Data released to an entity shall not be subject to discovery or admission as evidence in a judicial or administrative proceeding, without the provider's or supplier's consent.

Sec. 10333. Community-based collaborative care networks. HHS shall award grants to community-based collaborative care networks that seek to assist low-income individuals to access and appropriately use health services, to enroll in health coverage programs, and to obtain a regular primary care provider or medical home; to provide case and care management; to perform health outreach using neighborhood health workers; to provide transportation; to expand after-hours or urgent care services, including through telehealth services; or to provide direct patient care services. Such networks must include a hospital and all Federally qualified health centers in the community.

Sec. 10334 Minority health. Congress has created, within HHS, an Office of Minority Health that shall report directly to the Secretary and seek to improve minority health, to improve the quality of health care that minorities receive, and to eliminate racial and ethnic disparities. Congress also established a network of Offices of Minority Health within the CDC, the HRSA, the SAMHSA, the AHRQ, the FDA, and the CMS. Within a year, HHS must report to the Congress on the steps it has taken to implement these offices and the activities such offices have taken.

Sec. 10336 GAO study and report on Medicare beneficiary access to high-quality dialysis services. The Comptroller General must conduct a study on the ESRD PPS' impact on Medicare ESRD beneficiaries' access to high-quality dialysis services (including specified oral drugs). The Comptroller General must report to Congress on this study no later than March 23, 2011, as well as on recommendations for further legislative and/or administration actions.

Subtitle D – Provisions Relating to Title IV

Section 10407. Better diabetes care. This section provides for various programs relating to the study and report of diabetes care costs and prevalence.

Section 10408. Grants for small businesses to provide comprehensive workplace wellness programs. This appropriates funds to provide employees of small businesses access to workplace wellness programs.

Section 10409. Cures acceleration network. This section awards various grants to help develop cures and treatments of diseases.

Section 10410. Centers of excellence for depression. This section awards grants to help treat depressive disorders.

Section 10411. Programs relating to congenital heart disease. This section establishes initiatives for the research and surveillance of congenital heart disease

Section 10412: Automated defibrillation in Adam's Memory Act. This section reauthorizes public access defibrillation programs.

Section 10413. Young women's breast health awareness and support of young women diagnosed with breast cancer. This section develops a national education campaign about breast health and cancer.

Subtitle F – Provisions Relating to Title VI

Sec. 10606. Health care fraud enforcement. This Section enhances the U.S. Sentencing Guidelines for persons convicted of Federal health care fraud offenses by:

- equating the aggregate dollar amount of fraudulent bills to the "intended loss" for sentencing purposes. (This eliminates any argument that the government's "loss" might be mitigated by, for example, the value of services provided.)

- for sentence enhancement purposes, adjusting the weight of the "level increases" by 20-50% for health care offenses involving "losses" greater than $1 million – a frequent occurrence in health care fraud cases.

- urging the Federal Sentencing Commission to take additional steps as appropriate to emphasize the serious nature of health care fraud offenses.

Subsection (b) establishes that proving the intent element in the health care fraud statute ("whoever knowingly….") does not require that there be proof that the defendant intended to "violate the statute itself," only that there has been a general intent to knowingly violate "the law." This change is consistent with changes made elsewhere to the "intent" element in the federal anti-kickback statute, and wipes out the 9th Circuit holding in the *Hanlester* case, which stood apart from other Circuits and held that proof of intent to violate the specific law was required.

Subsection (c) provides broader subpoena authority to the Attorney General or, at the Attorney General's direction, any officer or employee of the department to issue subpoenas to any institution that is the subject of an investigation to determine "whether there are conditions which deprive persons residing or confined to the institution of any rights or privileges under the constitution or federal law. The subsection protects against the use of subpoenaed materials for any other purpose and requires redaction if necessary to protect against personal identification. This expansion of the AG's subpoena power signals the interest of the government in investigating and prosecuting cases where patient care may be of substandard quality.

Sec. 10607. State demonstration programs to evaluate alternatives to current medical tort litigation. This section establishes funding for state demonstration projects to evaluate alternatives to current medical tort litigation procedures. Any demonstration project must provide patients with the opportunity to opt out of the alternative process and utilize that State's existing litigation system if the patient so chooses. MedPac and MACPAC are to conduct independent reviews of the various state alternatives to determine their impact on Medicare and Medicaid.

Section 10608. Extension of medical malpractice coverage to free clinics. This section adds "free clinics" to the entities protected from liability under the Federal Torts Claims Act.

Certain Revenue Provisions of the Reconciliation Act

TITLE I
COVERAGE, MEDICARE, MEDICAID AND REVENUES

Subtitle E – Provisions Relating to Revenue

NOTE: The sections below are those revenue provisions of the Reconciliation Act that did not amend related provisions of PPACA.

Sec. 1402. Unearned income Medicare contribution. Under this section of the Reconciliation Act, net investment income is included as part of the taxable income base and is subject to a 3.8 percent Medicare tax. The Medicare tax on net investment income applies to modified adjusted gross income of $250,000 or more in the case of a joint return or $200,000 or more in the case of a single return. Net investment income includes interest, dividends, annuities, royalties, rents, gross income from a trade or business involving passive activities, and net gain from disposition of a property (other than property held in a trade or business). There

are exceptions in place for certain active interests in partnerships and S corporations and distributions from qualified plans. These provisions apply to tax years beginning on January 1, 2013.

Sec. 1408. Elimination of unintended application of cellulosic biofuel producer credit. This provision limits the cellulosic biofuel producer tax credit to processed fuels (i.e. fuels that can be used in a car engine or in a home heating application). This is an effort to prevent some taxpayers from attempting to claim this tax credit for unprocessed fuels. This provision applies to fuels sold or used beginning on January 1, 2010.

Sec. 1409. Codification of economic substantive doctrine and penalties. This section of the Reconciliation Act clarifies the application of the economic substance doctrine, a common law doctrine under which certain tax benefits are not allowed if the transaction does not have economic substance or lacks a business purpose. The economic substance doctrine will only apply if a transaction changes a taxpayer's economic position in a meaningful way and that taxpayer has a substantial purpose, apart from Federal income tax effects, for entering into the transaction. The provision also imposes a penalty on understatements attributable to transactions lacking economic substance. This codification applies to transactions entered into after the date of enactment of the Act.

Sec. 1410. Time for payment of corporate estimated taxes. This section includes a 15.75 percent increase to the amount in Section (202)(b)(1) of the Corporate Estimated Tax Shift Act of 2009 in effect on the date of enactment of this Act.

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