QUALITY, OUTCOMES, & HEALTH INFORMATION TECHNOLOGY
(SECTION-BY-SECTION ANALYSIS)
(Information compiled from the Democratic Policy Committee (DPC) Report on The Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act. Available online at http://dpc.senate.gov/healthreformbill/healthbill96.pdf.)

Reporting requirements

Sec. 1001. Amendments to the Public Health Service Act.

Sec. 2717. Ensuring quality of care. Requires the Secretary to develop guidelines for use by health insurers to report information on initiatives and programs that improve health outcomes through the use of care coordination and chronic disease management, prevent hospital readmissions and improve patient safety, and promote wellness and health. As added by Section 10101, 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.

Subtitle G—Miscellaneous Provisions

Sec. 1561. Health information technology enrollment standards and protocols. Requires the development of standards and protocols to promote the interoperability of systems for enrollment of individuals in Federal and State health and human services programs. These standards shall allow for electronic data matching, and electronic documentation. The Secretary may require State or other entities to incorporate such standards as a condition of receiving Federal health information technology funds. (also included in Enrollment and Navigation)

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

Sec. 2701. Adult health quality measures. 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. The Secretary and the States will report on the development of and improvements to the quality measurement program on a regular basis.

Sec. 2702. Payment adjustment for health care-acquired conditions. Prohibits Medicaid payment for services related to a health care-acquired condition. 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. 2704. Demonstration project to evaluate integrated care around a hospitalization. Establishes a demonstration project, in up to eight States, to study the use of bundled payments for hospital and physicians services under Medicaid.

Sec. 2705. Medicaid global payment system demonstration project. Establishes a demonstration project, 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. Establishes a demonstration project 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 would share in those savings.

Sec. 2707. Medicaid emergency psychiatric demonstration project. Requires the Secretary of HHS to establish a three-year Medicaid demonstration project in up to eight States. Participating States would be required to reimburse certain institutions for mental disease (IMDs) 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.

TITLE III—IMPROVING THE QUALITY AND EFFICIENCY OF HEALTH CARE

Subtitle A—Transforming the Health Care Delivery System
Part I – Linking Payment to Quality Outcomes under the Medicare Program
Sec. 3001. Hospital value-based purchasing program. The proposal would establish a value-based purchasing program for hospitals starting in FY2013. Under this program, a percentage of hospital payment would be tied to hospital performance on quality measures related to common and high-cost conditions, such as cardiac, surgical and pneumonia care. Quality measures included in the program (and in all other quality programs in this title) will be developed and chosen with input from external stakeholders. Section 10335 clarifies that the hospital VBP program shall not include measures of hospital readmissions.

Sec. 3002. Improvements to the physician quality reporting initiative. Extends through 2014 payments under the PQRI program, which provide incentives to physicians who report quality data to Medicare. Creates appeals and feedback processes for participating professionals in PQRI. Establishes a participation pathway for physicians completing a qualified Maintenance of Certification program with their specialty board of medicine. Beginning in 2014, physicians who do not submit measures to PQRI will have their Medicare payments reduced. Section 10327 provides an additional 0.5 percent Medicare payment bonus to physicians who successfully report quality measures to CMS via the new Maintenance of Certification program and eliminates the MA Regional Plan Stabilization Fund.
Sec. 3003. Improvements to the physician feedback program. Expands Medicare’s physician resource use feedback program to provide for development of individualized reports by 2012. Reports will compare the per capita utilization of physicians (or groups of physicians) to other physicians who see similar patients. Reports will be risk-adjusted and standardized to take into account local health care costs.

Sec. 3004. Quality reporting for long-term care hospitals, inpatient rehabilitation hospitals, inpatient psychiatric hospitals and hospice programs. Establishes a path toward value-based purchasing for long-term care hospitals, inpatient rehabilitation facilities, and hospice providers by requiring the Secretary to implement quality measure reporting programs for these providers in FY2014. Providers under this section who do not successfully participate in the program would be subject to a reduction in their annual market basket update. Section 10322 also establishes a quality measure reporting program for inpatient psychiatric hospitals beginning FY2014.

Sec. 3005. Quality reporting for PPS-exempt cancer hospitals. Establishes a quality measure reporting program for PPS-exempt cancer hospitals beginning in FY2014. Providers under this section who do not successfully participate in the program would be subject to a reduction in their annual market basket update.

Sec. 3006. Plans for a value-based purchasing program for skilled nursing facilities and home health agencies. Directs the Secretary to submit a plan to Congress by FY2012 outlining how to effectively move these providers into a value-based purchasing payment system. As amended by Section 10301, requires the Secretary of HHS to develop a plan to reimburse Ambulatory Surgery Centers (ASCs) based on the quality and efficiency of care delivered in ASCs.

Sec. 3007. Value-based payment modifier under the physician fee schedule. Directs the Secretary of HHS to develop and implement a budget-neutral payment system that will adjust Medicare physician payments based on the quality and cost of the care they deliver. Quality and cost measures will be risk-adjusted and geographically standardized. The Secretary will phase-in the new payment system over a two-year period beginning in 2015.

Sec. 3008. Payment adjustment for conditions acquired in hospitals. Starting in FY2015, hospitals in the top 25th percentile of rates of hospital acquired conditions for certain high-cost and common conditions would be subject to a payment penalty under Medicare. This provision also requires the Secretary to submit a report to Congress by January 1, 2012 on the appropriateness of establishing a healthcare acquired condition policy related to other providers participating in Medicare, including nursing homes, inpatient rehabilitation facilities, long-term care hospitals, outpatient hospital departments, ambulatory surgical centers, and health clinics.

Part II – National Strategy to Improve Health Care Quality

Sec. 3011. National strategy. Requires the Secretary to establish and update annually a national strategy to improve the delivery of health care services, patient health outcomes, and population health. Establishes, not later than January 1, 2011, a Federal health care quality internet website. Section 10302 clarifies that the limitations on use of comparative
effectiveness data apply to the development of the National Strategy for Quality Improvement.

Sec. 3012. Interagency Working Group on Health Care Quality. Requires the President to convene an Interagency Working Group on Health Care Quality comprised of Federal agencies to collaborate on the development and dissemination of quality initiatives consistent with the national strategy.

Sec. 3013. Quality measure development. Authorizes $75 million over 5 years for the development of quality measures at AHRQ and the Centers for Medicare and Medicaid Services (CMS). Quality measures developed under this section will be consistent with the national strategy. As amended by Section 10303, requires the Secretary of HHS to develop and publicly report on patient outcomes measures.

Sec. 3014. Quality measurement. Provides $20 million to support the endorsement and use of endorsed quality and efficiency measures by the HHS Secretary for use in Medicare, reporting performance information to the public, and in health care programs.

Sec. 3015. Data Collection; Public Reporting. Requires the Secretary to collect and aggregate consistent data on quality and resource use measures from information systems used to support health care delivery to implement the public reporting of performance information. As amended by Section 10305, requires the Secretary of HHS to develop a plan for the collection and public reporting of quality measures.

Part III – Encouraging Development of New Patient Care Models

Sec. 3021. Establishment of Center for Medicare and Medicaid Innovation within CMS. Establishes within the Centers for Medicare and Medicaid Services (CMS) a Center for Medicare & Medicaid Innovation. The purpose of the Center will be to research, develop, test, and expand innovative payment and delivery arrangements to improve the quality and reduce the cost of care provided to patients in each program. Dedicated funding is provided to allow for testing of models that require benefits not currently covered by Medicare. Successful models can be expanded nationally. Section 10306 adds payment reform models to the list of projects for the Center to consider, including rural telehealth expansions and the development of a rapid learning network. Ensures that quality measures used by the Center are consistent with the quality framework within the underlying bill, and requires the Secretary to focus on models that both improve quality and reduce costs.

Sec. 3022. Medicare shared savings program. Rewards Accountable Care Organizations (ACOs) that take responsibility for the costs and quality of care received by their patient panel over time. ACOs can include groups of health care providers (including physician groups, hospitals, nurse practitioners and physician assistants, and others). ACOs that meet quality-of-care targets and reduce the costs of their patients relative to a spending benchmark are rewarded with a share of the savings they achieve for the Medicare program. Section 10307 provides additional flexibility to the Secretary of HHS to implement innovative payment models for participating Accountable Care Organizations, including models currently used in the private sector.
Sec. 3023. National pilot program on payment bundling. Directs the Secretary to develop a national, voluntary pilot program encouraging hospitals, doctors, and post-acute care providers to improve patient care and achieve savings for the Medicare program through bundled payment models. Requires the Secretary to establish this program by January 1, 2013 for a period of five years. Before January 1, 2016, the Secretary is also required to submit a plan to Congress to expand the pilot program if doing so will improve patient care and reduce spending. Section 10308 provides the Secretary of HHS authority to expand the payment bundling pilot if it is found to improve quality and reduce costs. Also, directs the Secretary to test bundled payment arrangements involving continuing care hospitals within the bundling pilot program.

Sec. 3024. Independence at home demonstration program. Creates a new demonstration program for chronically ill Medicare beneficiaries to test a payment incentive and service delivery system that utilizes physician and nurse practitioner directed home-based primary care teams aimed at reducing expenditures and improving health outcomes. (also included in Long Term Care)

Sec. 3025. Hospital readmissions reduction program. Beginning in FY2012, this provision would adjust payments for hospitals paid under the inpatient prospective payment system based on the dollar value of each hospital’s percentage of potentially preventable Medicare readmissions for the three conditions with risk adjusted readmission measures that are currently endorsed by the National Quality Forum. Also, provides the Secretary authority to expand the policy to additional conditions in future years and directs the Secretary to calculate and make publicly available information on all patient hospital readmission rates for certain conditions. Section 10309 makes a technical correction to the hospital readmissions payment policy establishing in the underlying section.

Sec. 3026. Community-based care transitions program. Provides funding to hospitals and community-based entities that furnish evidence-based care transition services to Medicare beneficiaries at high risk for readmission. (also included in Long Term Care)

Sec. 3027. Extension of gainsharing demonstration. The Deficit Reduction Act of 2005 authorized a demonstration to evaluate arrangements between hospitals and physicians designed to improve the quality and efficiency of care provided to beneficiaries. This provision would extend the demonstration through September 30, 2011 and extend the date for the final report to Congress on the demonstration to September 30, 2012. It would also authorize an additional $1.6 million in FY2010 for carrying out the demonstration.

Subtitle B – Improving Medicare for Patients and Providers

Part I – Ensuring Beneficiary Access to Physician Care and Other Services

Sec. 3102. Extension of the work geographic index floor and revisions to the practice expense geographic adjustment under the Medicare physician fee schedule. Extends a floor on geographic adjustments to the work portion of the fee schedule through the end of 2010, with the effect of increasing practitioner fees in rural areas. Also provides immediate relief to areas negatively impacted by the geographic
adjustment for practice expenses, and requires the Secretary of HHS to improve the methodology for calculating practice expense adjustments beginning in 2012. As amended by Section 1108 of the Reconciliation Act, accelerates phase-in of Medicare physician practice expense adjustment for areas with below average practice expense payment rates. In 2010, the national blend would be increased from \( \frac{1}{4} \) to \( \frac{1}{2} \). (also included in Health Professional Workforce, and Safety Net)

**Sec. 3104. Extension of payment for technical component of certain physician pathology services.** 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.** Extends bonus payments made by Medicare for ground and air ambulance services in rural and other areas through the end of 2010. Section 10311 requires the Secretary of HHS to implement the extension of the ambulance payment bonuses on January 1, 2010.

**Sec. 3111. Payment for bone density tests.** 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. (also included in Prevention & Disparities)

**Sec. 3113. Treatment of certain complex diagnostic laboratory tests.** Creates a demonstration program to test the impact of direct payments for certain complex laboratory tests on Medicare quality and costs.

**Part III – Improving Payment Accuracy**

**Sec. 3136. Revision of payment for power-driven wheelchairs.** Eliminates 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 same payments for power-driven chairs over a 13-month period. Purchase option for complex rehabilitative power wheelchairs would be maintained.

**Sec. 3137. Hospital wage index improvement.** Extends reclassifications under section 508 of the Medicare Modernization Act (P.L 108-173) through the end of FY2010. In addition, requires the Secretary to provide recommendations to Congress on ways to comprehensively reform the Medicare wage index system by December 31, 2011. Also directs the Secretary to restore the reclassification thresholds used to determine hospital reclassifications to the percentages used in FY2009, starting in FY2011 until the first fiscal year that is on or after the date the Secretary submits the report to Congress on reforming the wage index system. Section 10317 clarifies the Secretary may only use wage data of certain eligible hospitals in carrying out this provision if doing so does not result in lower wage index adjustments for affected facilities.
Sec. 3138. Treatment of certain cancer hospitals. 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.

Sec. 3139. Payment for biosimilar biological products. 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.

Subtitle F—Health Care Quality Improvements

Sec. 3501. Health care delivery system research; Quality improvement technical assistance. Builds on the Center for Quality Improvement and Patient Safety of the Agency for Healthcare Research and Quality (AHRQ) to support research, technical assistance and process implementation grants. Grants funded under this section will identify, develop, evaluate, disseminate, and provide training in innovative methodologies and strategies for quality improvement practices in the delivery of health care services.

Sec. 3502. Grants or contracts to establish community health teams to support the patient-centered medical home. Creates a program to establish and fund the development of community health teams to support the development of medical homes by increasing access to comprehensive, community based, coordinated care. Section 10321 clarifies that nurse practitioners and other primary care providers can participate in community care teams. 

Sec. 3503. Grants to implement medication management services in treatment of chronic disease. Creates a program to support medication management services by local health providers. Medication management services will help manage chronic disease, reduce medical errors, and improve patient adherence to therapies while reducing acute care costs and reducing hospital readmissions.

Sec. 3504. Design and implementation of regionalized systems for emergency care. 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. Requires the HHS Secretary to support emergency medicine research, including pediatric emergency medical research.

Sec. 3505. Trauma care centers and service availability. Reauthorizes and improves the trauma care program, providing grants administered by the HHS Secretary to States and trauma centers to strengthen the nation’s trauma system. Grants are targeted to assist trauma care centers in underserved areas susceptible to funding and workforce shortages.
Sec. 3506. Program to facilitate shared decisionmaking. Establishes a program at HHS for the development, testing, and disseminating of educational tools to help patients, caregivers, and authorized representatives understand their treatment options.

Sec. 3507. Presentation of prescription drug benefit and risk information. Requires the Food and Drug Administration (FDA) to evaluate and determine if the use of drug fact boxes which would clearly communicate drug risks and benefits and support clinician and patient decision making in advertising and other forms of communication for prescription medications is warranted.

Sec. 3508. Demonstration program to integrate quality improvement and patient safety training into clinical education of health professionals. Establishes a program at AHRQ to give grants to academic institutions to develop and implement academic curricula that integrate quality improvement and patient safety into health professionals’ clinical education.

Sec. 3509. Office of women’s health. Provides for women’s health offices at various Federal agencies to improve prevention, treatment, and research for women in health programs. (also included in Prevention & Disparities)

Sec. 3510. Patient navigator program. Reauthorizes demonstration programs to provide patient navigator services within communities to assist patients overcome barriers to health services. Program facilitates care by assisting individuals coordinate health services and provider referrals, assist community organizations in helping individuals receive better access to care, information on clinical trials, and conduct outreach to health disparity populations. (also included in Prevention & Disparities)

TITLE V—HEALTH CARE WORKFORCE

Subtitle G—Improving Access to Health Care Services

Sec. 5603. Reauthorization of Wakefield Emergency Medical Services for Children Program. Reauthorizes program to award grants to States and medical schools to support the improvement and expansion of emergency medical services for children needing trauma or critical care treatment. (also included in Safety Net)

Sec. 5605. Key national indicators. Establishes a Commission on Key National Indicators to conduct a comprehensive oversight of a newly established key national indicators system, with a required annual report to Congress.

TITLE VI—TRANSPARENCY AND PROGRAM INTEGRITY

Subtitle A – Physician Ownership and Other Transparency
Sec. 6001. Limitation on Medicare exception to the prohibition on certain physician referrals for hospitals. Prohibits physician-owned hospitals that do not have a provider agreement prior to December 31, 2010, (as amended by Section 1106 of the Reconciliation Act) to participate in Medicare. Such hospitals that have a provider agreement prior to December 31, 2010, could continue to participate in Medicare under certain requirements addressing conflict of interest, bona fide investments, and patient safety issues, and expansion limitations. As amended by Section 1106 of the Reconciliation Act, provides a limited exception to the growth restrictions for grandfathered physician owned hospitals that treat the highest percentage of Medicaid patients in their county (and are not the sole hospital in a county).

Sec. 6002. Transparency reports and reporting of physician ownership or investment interests. Requires drug, device, biological and medical supply manufacturers to report transfers of value made to a physician, physician medical practice, a physician group practice, and/or a teaching hospital. Duplicative State or local laws would be preempted by Federal law, however, Federal preemption would not occur for State or 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. Adds an additional requirement to the Medicare in-office ancillary 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. Requires prescription drug manufacturers and distributors to report to the Secretary information pertaining to drug samples currently being collected internally, as required under the Federal Food, Drug and Cosmetic Act.

Sec. 6005. Pharmacy benefit managers transparency requirements. Requires a pharmacy benefit manager (PBM) or a health benefits plan that provides pharmacy benefits management services that contract with health plans under Medicare or the Exchange to report to the Secretary information regarding the generic dispensing rate: the rebates, discounts, or price concessions negotiated by the PBM and the payment difference between health plans and PBMs and the PBMs and pharmacies. All disclosed information would be confidential, except 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. Requires that skilled nursing facilities (SNFs) under Medicare and nursing facilities (NFs) under Medicaid make available on request by the Secretary, the Inspector General of the Department of Health and Human Services, the States, and the State long-term care ombudsman, information on ownership, including a description of the governing
body and organizational structure of the facility and information regarding additional
disclosable parties. (also included in Long Term Care)

**Sec. 6102. Accountability requirements for skilled nursing facilities and nursing facilities.** Requires SNFs and NFs to implement a compliance and ethics program to be followed by the facility’s employees and its agents within 36 months of enactment, and requires the Secretary to evaluate this program and report the results to Congress. (also included in Long Term Care)

**Sec. 6103. Nursing home compare Medicare website.** Requires the Secretary to publish the following information on the Nursing Home Compare Medicare website: standardized staffing data, links to State internet websites regarding State survey and certification programs, the model standardized complaint form, a summary of substantiated complaints, and the number of adjudicated instances of criminal violations by a facility or its employee. (also included in Long Term Care)

**Sec. 6104. Reporting of expenditures.** Requires the Secretary to modify cost reports for SNFs to require reporting of expenditures on wages and benefits for direct care staff, breaking out registered nurses, licensed professional nurses, certified nurse assistants, and other medical and therapy staff. (also included in Long Term Care)

**Part II – Targeting Enforcement**

**Sec. 6114. National demonstration projects on culture change and use of information technology in nursing homes.** Requires the Secretary to conduct two facility-based demonstration projects that would develop best practice models in two areas. The first would be designed to identify best practices in facilities that are involved in the “culture change” movement, including the development of resources where facilities may be able to access information in order to implement culture change. The second demonstration would focus on development of best practices in information technology that facilities are using to improve resident care. (also included in Quality, Outcomes & Health Information Technology)

**Subtitle D – Patient-Centered Outcomes Research**

**Sec. 6301. Patient-Centered Outcomes Research.** Establishes a private, nonprofit entity (the Patient-Centered Outcomes Research Institute) governed by a public-private sector board appointed by the Comptroller General to identify priorities for and provide for the conduct of comparative outcomes research. Requires the Institute to ensure that subpopulations are appropriately accounted for in research designs. Prohibits any findings to be construed as mandates on practice guidelines or coverage decisions and contains patient safeguards to protect against discriminatory coverage decisions by HHS based on age, disability, terminal illness, or an individual’s quality of life preference. Provides funding for the Institute and authorizes and provides funding for the Agency for Health Research and Quality to disseminate research findings of the Institute, as well as other government-funded research, to train researchers in comparative research methods and to build data capacity for comparative effectiveness research. Section 10602 clarifies publication rights of
researchers with respect to peer-reviewed journals and clarifies that findings published by
the Institute do not include practice guidelines, coverage, payment, or policy
recommendations. The provision also increases the number of physicians on the Board of
Governors from three to four.

**Sec. 6302. Federal coordinating council for comparative effectiveness research.** Upon date of enactment, this provision would sunset the Federal Coordinating Council created in the American Recovery and Reinvestment Act of 2010 (P.L. 111-5).

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**Subtitle E – Medicare, Medicaid, and CHIP Program Integrity Provisions**

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

Provider Screening. Requires that the Secretary, in consultation with the HHS Office of Inspector General (HHS OIG), establish procedures for screening providers and suppliers participating in Medicare, Medicaid, and CHIP. The Secretary would be required to determine the level of screening according to the risk of fraud, waste, and abuse with respect to each category of provider or supplier. At a minimum, all providers and suppliers would be subject to licensure checks. The Secretary would have the authority to impose additional screening measures based on risk, including fingerprinting, criminal background checks, multi-State data base inquiries, and random or unannounced site visits. An application fee of $200 for individual practitioners and $500 for institutional providers and suppliers would be imposed to cover the costs of screening each time they re-verify their enrollment (every five years). Section 10603 removes the enrollment fee for physicians.

Disclosure Requirements. Providers and suppliers enrolling or re-enrolling in Medicare, Medicaid, or CHIP would be subject to new disclosure requirements. Applicants would be required to disclose current or previous affiliations with any provider or supplier that has uncollected debt, has had their payments suspended, has been excluded from participating in a Federal health care program, or has had their billing privileges revoked. The Secretary would be authorized to deny enrollment in these programs if these affiliations pose an undue risk to a program.

Compliance Programs. By a date determined by the Secretary, certain providers and suppliers would be required to establish a compliance program. The requirements for the compliance program would be developed by the Secretary and the HHS OIG. (also included in Medicaid)

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

Integrated Data Repository. Requires CMS to include in the integrated data repository (IDR) claims and payment data from the following programs: 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).

Access to Data. The Secretary would be 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 identify fraud, waste, and abuse. The Committee Bill would grant the HHS OIG and the Department of Justice (DOJ) access to the IDR for the purposes of conducting law enforcement and oversight activities consistent with applicable privacy, security, and disclosure laws.
Overpayments. Requires that overpayments be reported and returned within 60 days from the date the overpayment was identified or by the date a corresponding cost report was due, whichever is later.

National Provider Identifier. Requires the Secretary to issue a regulation mandating that all Medicare, Medicaid, and CHIP providers include their NPI on enrollment applications.

Medicaid Management Information System. Authorizes the Secretary to withhold the Federal matching payment to States for medical assistance expenditures when the State does not report enrollee encounter data in a timely manner to the State’s Medicaid Management Information System (MMIS).

Permissive Exclusions. Subjects providers and suppliers to exclusion for providing false information on any application to enroll or participate in a Federal health care program.

Civil Monetary Penalties. Expands the use of Civil Monetary Penalties (CMPs) to excluded individuals who order or prescribe an item or service, make false statements on applications or contracts to participate in a Federal health care program, or who know of an overpayment and do not return the overpayment. Each violation would be subject to CMPs of up to $50,000.

Testimonial Subpoena Authority. The Secretary would be able to issue subpoenas and require the attendance and testimony of witnesses and the production of any other evidence that relates to matters under investigation or in question by the Secretary.

Surety Bonds. Requires that the Secretary take into account the volume of billing for a DME supplier or home health agency when determining the size of the surety bond. The Secretary would have the authority to impose this requirement on other providers and suppliers considered to be at risk by the Secretary.

Payment Suspensions. Authorizes the Secretary to suspend payments to a provider or supplier pending a fraud investigation. As amended by Section 1304 of the Reconciliation Act, allows a 90-day period of enhanced oversight and withholding of payment in cases where the HHS Secretary identifies a significant risk of fraud among DME suppliers.

Health Care Fraud and Abuse Control Account. As amended by Section 1301 of the Reconciliation Act, increases Health Care Fraud and Abuse Control (HCFAC) funding by $350 million over the next decade. The provision would also permanently apply the CPI-U adjustment to HCFAC and Medicare Integrity Program (MIP) funding.

Medicare and Medicaid Integrity Programs. Requires Medicare and Medicaid Integrity Program contractors to provide the Secretary and the HHS OIG with performance statistics, including the number and amount of overpayments recovered, the number of fraud referrals, and the return on investment for such activities. (also included in Medicaid)

Subtitle I – Sense of the Senate Regarding Medical Malpractice

Sec. 6801. Sense of the Senate regarding medical malpractice. Expresses the sense of the Senate that health reform presents an opportunity to address issues related to medical malpractice and medical liability insurance, states should be encouraged to develop and test alternative models to the existing civil litigation system, and Congress should consider state demonstration projects to evaluate such alternatives.

Title VII – IMPROVING ACCESS TO INNOVATIVE MEDICAL THERAPIES

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.** Establishes a process under which the Secretary is required 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. Prohibits the approval of an application as either biosimilar or interchangeable until 12 years from the date on which the reference product is first approved. If FDA approves a biological product on the grounds that it is interchangeable to a reference product, HHS is prohibited from making a determination that a second or subsequent biological product is interchangeable to that same reference product until 1 year after the first commercial marketing of the first interchangeable product. Authorizes HHS to issue guidance with respect to the licensure of biological products under this new pathway, and it includes provisions governing patent infringement concerns such as the exchange of information, good faith negotiations, and initiation infringement actions. Applies certain provisions of the Food, Drug, and Cosmetic Act to this subtitle with respect to pediatric studies of biological products. Requires HHS to develop recommendations for Congress with respect to the goals for the process for the review of biosimilar biological product applications for the first five fiscal years after FY 2012.

**TITLE X—STRENGTHENING QUALITY, AFFORDABLE HEALTH CARE FOR ALL AMERICANS**

**Subtitle A – Provisions Relating to Title I**

**Sec. 10109. Development of standards for financial and administrative transactions.** Requires the Secretary to consult stakeholders and the National Committee on Vital and Health Statistics and the Health Information Technology Standards and Policy Committees to identify opportunities to create uniform standards for financial and administrative health care transactions, not already named under HIPAA, that would improve the operation of the health system and reduce costs.

**Subtitle C – Provisions Related to Title III**

**Sec. 10324. Protections for frontier states.** Starting in fiscal year 2011, establishes hospital wage index and geographic practice expense floors for hospitals and physicians located in states in which at least 50 percent of the counties in the state are frontier.

**Sec. 10326. Pilot testing pay-for-performance programs for certain Medicare providers.** Provides the Secretary of HHS the authority to test value-based purchasing programs for inpatient rehabilitation facilities, inpatient psychiatric hospitals, long-term care hospitals, certain cancer hospitals and hospice providers by no later than January 1, 2016.
Sec. 10335. Technical correction to hospital value-based purchasing (VBP) program. Clarifies that the hospital VBP program shall not include measures of hospital readmissions.

Sec. 10336. GAO study and report on Medicare beneficiary access to high-quality dialysis services. Directs the Comptroller General to submit to Congress, within one year of enactment, a study on the impact on Medicare beneficiary access to high-quality dialysis services of the end stage renal disease prospective payment system.

Subtitle D—Provisions Relating to Title IV

Sec. 10409. Cures Acceleration Network. Authorizes the Cures Acceleration Network, within the National Institutes of Health (NIH), to award grants and contracts to develop cures and treatments of diseases. Grants will be awarded to accelerate the development of medical products and behavioral therapies. The network shall work with the Food and Drug Administration (FDA) to streamline protocols assuring compliance with regulations and standards that meet regulatory requirements at all stages of manufacturing, review, approval, and safety surveillance. (also included in Prevention & Disparities)