Summary of the Quality of Care Provisions of Federal Health Care Reform Legislation

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

Health Care Plans Quality Reporting Requirements (Sec. 1002, 10101) The Secretary shall , by March 23, 2012, develop health care plan reporting requirements that include: initiatives to improve outcomes such as quality reporting, case management, care coordination and disease management; initiatives to prevent hospital readmissions through a comprehensive program for hospital discharge planning, and post discharge reinforcement by an appropriate health care professional; initiatives to improve patient safety and reduce medical errors; and initiatives on wellness and health promotion. Health plans are required to report annually to DHHS on whether plan benefits satisfy these quality elements.

Qualified Health Plans Hospital Contracts (Sec. 1311) Beginning January 1, 2015, qualified health plans in the state exchanges cannot contract with a hospital with more than 50 beds unless that hospital participates in a Patient Safety Organization as established under federal law, and has a comprehensive hospital discharge system. The Secretary may establish reasonable exceptions to these requirements.

Hospital Value-Based Purchasing (VBP) (Sec. 3001, 10335) *Budget neutral.*
The law establishes a VBP program to pay PPS hospitals for their actual performance on quality measures, rather than just the reporting of those measures, beginning in FY 2013. Certain hospitals are excluded, including those that do not have a sufficient number of patients within the related conditions. A demonstration project will be created for critical access hospitals (CAHs).

Measures will be selected from those used in the Medicare pay-for-reporting program, including measures for heart attack, heart failure, pneumonia and surgical care and HCAHPS. The VBP program cannot include readmission measures. The Secretary must include healthcare-associated infection measures and efficiency measures, including measures of Medicare-spending-per-beneficiary, which will be adjusted for differences in age, sex, race, severity of illness and other factors, as determined by the Secretary, in FY 2014 and beyond. Selected quality measures will need to be considered by a consensus-based organization, such as the National Quality Forum, although the Secretary will have discretion to implement other measures.

Funding for the program will be generated by reducing all Medicare inpatient PPS Medicare-severity DRG (MS-DRG) payments to participating hospitals using a phased-in approach. Payments will be reduced by 1 percent in FY 2013; 1.25 percent in FY 2014; 1.5 percent in FY 2015; 1.75 percent in FY 2016; and 2 percent in FY 2017 and beyond. The reduction will be applied to all MS-DRGs but will not affect disproportionate share, indirect medical education, low-volume adjustment or outlier payments. A hospital will be rewarded for quality improvement or quality attainment, whichever level is higher. A methodology for assessing hospital performance will be developed by the Secretary; a hospital that meets or exceeds the performance standards will be eligible to earn back the initially withheld money. A hospital's total composite performance score will be calculated and used to determine whether the hospital meets the overall performance standard. The payment adjustment will apply only to the relevant fiscal year, based on the prior year's performance, and will not be taken into account in calculating payments in future fiscal years. The program will be budget-neutral; that is, all of the money withheld to fund each year's incentive payments will be returned to hospitals. In order to track the progress of the VBP program, the Government

Accountability Organization (GAO) shall submit an interim report to Congress by October 1, 2015 and its final report by October 1, 2017. The Secretary shall submit a report to Congress by January 1, 2016.

Two demonstration projects will be created to test VBP models for CAHs and small hospitals that do not qualify, due to an insufficient number of qualifying cases, for the VBP program. These demonstration projects shall be implemented by March 23, 2012 and completed by March 23, 2015. The Secretary shall submit a report to Congress by September 23, 2016.

National Pilot Program on Payment Bundling (Sec. 3023, 10308)
The Secretary, beginning in 2013, must establish a national, voluntary five year pilot program on bundling in order to improve the coordination, quality and efficiency of health care services. If the Secretary, at any point after January 1, 2016, determines that expanding the pilot program does not reduce quality, but does reduce costs, or has improved quality and reduced spending, the Secretary can extend its duration and scope indefinitely. Entities comprised of groups of providers including a hospital, a physician group, a skilled-nursing facility (SNF) and a home health agency (HHA) may apply to participate in the pilot. In addition, the Secretary has the authority to waive Medicare statutory provisions as necessary to carry out the pilot program.

The Secretary is required to identify a patient assessment instrument that would determine the most clinically appropriate site for post-acute care for a given patient, and to develop episode-of-care and post-acute care quality measures. Participants will be required to submit data on the quality measures in each year of the program. To the extent practicable, the Secretary will specify that this submission occur through a qualified electronic health record. The law specifies that the episode-of-care quality measures will include measures of:

- Functional status improvement;
- Rates of avoidable hospital readmissions;
- Rates of discharge to the community;
- Rates of admission to an emergency room after a hospitalization;
- Incidence of healthcare-acquired infections;
- Efficiency measures;
- Measures of patient-centeredness of care;
- Measures of patient perception of care; and
- Other measures, including outcome measures, as determined by the Secretary.

The Secretary will select 10 conditions to be included in the pilot program, including:

- A mix of chronic and acute conditions;
- A mix of surgical and medical conditions;
- Conditions for which there is evidence of opportunity for providers to improve the quality of:
    - Care while reducing total expenditures;
    - Conditions with significant variation in readmissions and post-acute care spending;
    - Conditions with high volume or high post-acute care spending; and
    - Conditions that are deemed most amenable to bundling across a spectrum of care given current practice patterns.

The pilot program may cover inpatient and outpatient hospital services, physician services (both in the inpatient and outpatient settings), post-acute care services (IRFs, LTCHs, SNFs and HHAs), and other services that the Secretary determines appropriate. The episode of care will start three days prior to a qualifying hospital admission and end 30 days after the patient's discharge. However, the Secretary has the authority to use another timeframe if appropriate.

The law requires the Secretary to test alternative payment methodologies for the pilot program, which may include bundled payments or bids from participating entities. The payment methodology will include payment for applicable services and other services the Secretary deems appropriate, such as care coordination, medication reconciliation, discharge planning, transitional care services, and other patient-centered activities. The pilot also will include provisions to ensure that payment is made for post-acute care services that are furnished after the episode of care has ended. The law requires that the Secretary consult with representatives of small and rural hospitals, including CAHs, regarding their participation in the pilot program. The Secretary will be required to consider innovative methods of bundling, including how to address challenges due to low volume.

The law also requires the Secretary to test separately the continuing care hospital (CCH) model through a pilot. The episode is defined as a patient's stay in the CCH plus 30 days following discharge. A CCH is one that provides, under common management, the medical and rehabilitation services provided in IRFs, LTCHs and SNFs that are located in a hospital. The Secretary is required to conduct an independent evaluation of the pilot program and submit reports to Congress at two and three years after implementation. The reports will include an evaluation of the extent to which the pilot program has improved quality measures, health outcomes, beneficiary access to care and reduced spending.

Medicaid Demonstration on Bundled Payment (Sec. 2704)
The law requires the Secretary to establish a Medicaid bundled payment demonstration in up to eight states by January 1, 2012. The demonstration shall end on December 31, 2016 and must focus on an episode of care that includes a hospitalization and concurrent physician services. Each state may select episodes upon which to focus. States are required to submit a rationale for episode selection and monitor outcomes, costs, and quality associated with each episode. Hospitals participating in the demonstration must establish a robust discharge planning program. Payments will be adjusted for severity of illness and other beneficiary characteristics. No additional beneficiary cost sharing will be required. The Secretary may waive any provision of Medicare and Medicaid and Title X. The Secretary is required to submit a report to Congress on the demonstration by December 31, 2017.

Medicaid Global Payment System Demonstration Project (Sec. 2705)
The Secretary shall begin the Medicaid global payment demonstration by October 1, 2010 and end the demonstration by September 30, 2012, with a report to Congress on the demonstration due by October 1, 2013. States shall adjust payments made to eligible safety-net hospital systems or networks. Not more than five states are eligible to participate in the demonstration and budget neutrality is not required. The CMS Innovation Center is required to evaluate the demonstration.

Accountable Care Organizations (Shared Savings Program) (Sec. 3022, 10307) *Saves $4.9 billion over 10 years.*
Beginning January 1, 2012, groups of qualifying providers – such as physician group practice arrangements, networks of practices, hospital-physician joint ventures and hospitals employing physicians and other clinical professionals (physician assistants, nurse practitioners or clinical nurse specialists) – will have the opportunity to form Accountable Care Organizations **(**ACOs) and share in the cost savings they achieve for the Medicare program. To qualify as an ACO, an organization will have to meet several criteria. For example, it must:

- Agree to become accountable for the overall care of their Medicare fee-for-service beneficiaries;
- Agree to a minimum three-year participation per cycle;
- Have a formal legal structure enabling it to receive and distribute bonuses to participating providers;
- Provide information on the physicians participating in the ACO;
- Have a management and leadership structure in place;
- Define processes to promote evidence-based medicine and patient engagement, report on quality and cost measures and coordinate care; and
- Demonstrate that it meets any patient-centeredness criteria determined by the Secretary.

To earn incentive payments, ACOs must meet certain quality thresholds. Reporting measures will be set by the Secretary and include: (1) clinical processes and outcomes; (2) patient and caregiver perspectives on care; and (3) utilization and costs. The ACO will then be able to share in any savings generated to the Medicare program at a rate determined by the Secretary. The Secretary will be required to set a minimum threshold of savings that would need to be achieved by the ACO before savings can be shared. Spending benchmarks will be based on total Medicare spending in the most recent three-year period for the beneficiaries that belong to the ACO, plus a dollar amount equal to the risk-adjusted average expenditure growth for beneficiaries nationally. The benchmark will be re-set at the end of the three-year period. In addition to shared savings, the Secretary also may implement a partial capitation payment with the ACO program. When accepting sites into the ACO program, the Secretary may give preference to those ACOs participating in similar arrangements with other payers and those ACOs that have participated previously in the CMS Physician Group Practice Demonstration. The Secretary may waive provisions contained in current statute and regulation (such as Civil Monetary Penalty) to allow hospitals and doctors to integrate clinically.

Community Health Teams for the Patient-Centered Medical Home (Sec. 3502, 10321)
The law provides grants to enter into contracts to establish community-based, interdisciplinary health teams that support primary care, including obstetrics and gynecology, within a hospital service area. The grants will provide capitated payments to primary care providers. State or state-designated entities and Indian tribes or tribal organizations are eligible for the grants. Grant applications must submit a plan for achieving long-term financial sustainability within three years and must include prevention initiatives. The primary care teams eligible for capitated payments may include medical specialists, nurses, pharmacists, nutritionists, dieticians, social workers, behavioral and mental health providers, doctors of chiropractic medicine, licensed complementary and alternative medicine practitioners, and physician assistants. Grant recipients must implement and maintain a health IT system and report quality measures.

Health Homes for Medicaid Enrollees with Chronic Conditions (Sec. 2703) *Saves $700 million over 10 years.*
The law requires the Secretary to award State Planning Grants to establish a Health Home Program for eligible enrollees by January 1, 2011. Eligible participants must have at least two chronic conditions, such as asthma, diabetes or mental health issues, and must select a designated provider to serve as a health home. States will provide payment for the health homes except for during the first eight fiscal year quarters in which the FMAP is at 90 percent. Payment is not limited to Per Member Per Month (PMPM) and states may propose alternative methods of payment. In addition to the methodology for payment, states also must include the following in the health home proposals:

- Requirement for hospitals to refer participants who seek emergency care to his/her health home provider;
- Plan for coordinating with the Substance Abuse and Mental Health Services Administration (SAMHSA);
- Methodology for tracking readmissions;
- Proposal for using health IT; and
- Report quality measures.

The Secretary is required to survey state participants by January 1, 2014 and submit a report to Congress by January 1, 2017. $25 million is available for payments to the health homes.

Hospital Readmissions (Sec. 3025) *Saves $7.1 billion over 10 years.*
Beginning in FY 2013, inpatient PPS hospitals with higher-than-expected readmissions rates will experience decreased Medicare payments for all Medicare discharges. Prior to March 23, 2012, the Secretary shall make available a program for eligible hospitals to improve their readmission rates through patient safety organizations. CAHs and post-acute care providers are exempt. Performance evaluation will be based on the 30-day readmission measures for heart attack, heart failure and pneumonia that are currently reported on *Hospital Compare*. The base inpatient payment for hospitals with *actual* readmission rates higher than their Medicare-calculated *expected* readmission rates will be reduced by an adjustment factor that is the greater of:

- A hospital-specific readmissions adjustment factor based on the number of readmitted patients in excess of the hospital's calculated expected readmission rate; or
- 0.99 in FY 2013; 0.98 in FY 2014; and 0.97 in FY 2015 and beyond.

The largest potential reduction for a hospital would be 1 percent in FY 2013; 2 percent in FY 2014; and 3 percent in FY 2015 and beyond. This reduction will apply to *all* Medicare discharges. Hospitals with a small number of applicable patient cases, as determined by the Secretary, will be excluded from the provision. Beginning in FY 2015, the Secretary is able to expand the list of conditions to include chronic obstructive pulmonary disorder and several cardiac and vascular surgical procedures, as well as any other condition or procedure the Secretary chooses. The Secretary is directed to seek endorsement from the NQF for all measures used to assess readmissions performance. However, the Secretary has the discretion to proceed without receiving endorsement. The Secretary is directed to calculate and report all-payer readmission rates for the conditions selected for the readmissions financial penalties program, based on all-payer data submitted by hospitals. No timeline is provided as to when this reporting should begin or when the all-payer data should be submitted.

Community-Based Care Transitions Program (Sec. 3026) *Spends $500 million over 10 years.*
Beginning in 2011, a five-year Medicare pilot program, the Community-Based Care Transitions Program, will be available to PPS hospitals identified by the Secretary as having high readmission rates, such as under the Hospital Readmissions Reduction Program (Section 3025). Hospitals serving medically underserved populations, small community hospitals and rural hospitals will be given priority for participation, as will hospitals participating in an eligible Administration on Aging program. Hospitals may elect to join the pilot program with community-based organizations or those that provide care transition services. Under the program, hospitals must engage in at least one evidence-based care transition intervention, such as conducting comprehensive medication review and management, targeted toward Medicare beneficiaries who are at high risk for a readmission or a poor transition from the hospital to their post-hospital site of care. The program will be funded for $500 million over five years; the Secretary may continue or expand the program if it reduces projected Medicare spending without reducing quality of care.

Center for Medicare and Medicaid Innovation (Sec. 3021, 10306) *Saves $1.3 billion over 10 years.*
The law requires the HHS Secretary to create a Center for Medicare and Medicaid Innovation (CMI) within CMS by January 1, 2011. The CMI is authorized to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing quality. In selecting such models, the Secretary may give preference to models that also improve the coordination, quality and efficiency of health care services furnished to beneficiaries, such as patient-centered medical homes and new continuing care hospitals that offer inpatient rehabilitation, long-term care, and home health or skilled nursing care after an inpatient stay. Many more models are listed in the law. Payment models will be evaluated based on the quality of care they incentivize, including patient-level outcomes and patient-centeredness, and the changes in Medicare spending they generate. The tested models will be exempt from budget neutrality and CMS will be able to terminate, modify or expand the scope or duration of the models. Beginning in 2012, and once every other year thereafter, the Secretary shall submit a report to Congress on the progress of the CMI. In selecting innovations to fund under the CMI, the Secretary has the authority to prioritize the following characteristics:

- Testing within certain geographic areas;
- Medically underserved areas and facilities of the Indian Health Service that focus on telehealth, behavioral health, stroke and non-medical providers;
- Programs that target beneficiaries with two or more chronic conditions; and
- Programs that link the public sector with private sector payers.

Independence at Home Demonstration Program (Sec. 3024)
This provision creates a Medicare demonstration program targeting physician and nurse practitioner directed home-based primary care teams. The teams are accountable for providing comprehensive, coordinated and continuous care to high need populations at home. The Secretary is required to begin the demonstration by January 1, 2012. The demonstration focuses on:

- Reducing preventable admissions;
- Preventing hospital readmissions;
- Reducing emergency room visits;
- Improving outcomes, commensurate with stage of chronic illness;
- Reducing cost of services; and
- Achieving beneficiary and caregiver satisfaction.

This demonstration requires a legal entity that is able to provide care as part of a team, including physicians, nurses, physician assistants, pharmacists and other social services staff. Each team must service a minimum of 200 beneficiaries during each year of the demonstration, use an electronic health record (EHR) system, and remote monitoring system, and report quality measures. The team must establish an estimated annual spending target, and may share savings in excess of 5 percent. A beneficiary with two or more chronic conditions who has had a non-elective hospital admission within the past 12 months, and has received acute or sub-acute rehabilitation services within the past 12 months is eligible to participate. The Secretary shall determine an appropriate method of ensuring beneficiaries have agreed to enroll in the demonstration. The total number of beneficiaries enrolled in the demonstration cannot exceed 10,000. An independent evaluation of the demonstration is required. $5 million is available for appropriations for FYs 2010-2014.

Epidemiology-Laboratory Capacity Grants (Sec.4304)
The Secretary, acting through the CDC director, will establish an Epidemiology and Laboratory Capacity Grant Program to award grants to state and local health departments and, at the director's discretion, to academic centers, to assist public health agencies in improving surveillance and response to infectious diseases. The law authorizes $190 million for each of fiscal years 2010 to 2013 for these grants, of which at least $95 million per year would be for epidemiology, $60 million per year for information management and $32 million per year for laboratory capacity.

National Quality Strategy (Sections 3011-3015, 10302-10305) *Spends $100 million over 10 years.*
The law calls for the Secretary to establish a national quality improvement strategy that includes priorities that have the greatest potential to improve patient outcomes, patient-centeredness and efficiency. These priorities are to apply to all patients, including children and vulnerable populations. In setting the priorities, the Secretary is mandated to take into consideration recommendations submitted by the National Priority Partners that have been convened by the NQF. The Secretary also must develop a comprehensive strategic plan to achieve priority improvements and coordinating activities among HHS agencies and with the state Medicaid programs to help achieve these goals. The national strategy will be updated every three years at most, with the first report due to Congress by January 1, 2011. The selected priorities would become the basis for further work to develop and implement measures to foster improvement and public reporting, including public reporting on hospital quality on *Hospital Compare*. In selecting the measures to use in public reporting and hospital payment under value-based purchasing, the Secretary must choose measures that have been considered by a consensus based organization, such as the NQF, and are recommended by a multi-stakeholder group, such as the Hospital Quality Alliance. The law also requires the Secretary to:

- Develop not less than 10 acute/chronic outcome measures (targeting the five most prevalent in each category) by March 23, 2012 (no later than 24 months after enactment);
- Develop not less than 10 primary/preventive outcome measures (targeting healthy children, chronically ill adults or infirm elderly) by March 23, 2013;
- Develop and update (not less than every three years) provider-level outcome measures for hospitals and physicians, as well as other providers that address:
    (a) risk adjustment;
    (b) accountability;
    (c) sample size; and
    (d) the full scope of services that comprise a cycle of care;
- Select efficiency measures; and

- Establish and implement an overall strategic framework to carry out the public reporting of performance information.

Payment Adjustment for Hospital Acquired Conditions (Sec. 3008) *Saves $1.4 billion over 10 years.*
The provision applies a financial penalty to hospitals with high risk-adjusted rates of the hospital-acquired conditions identified by CMS for use in the inpatient PPS hospital-acquired conditions policy, or any other condition selected by the Secretary. Prior to implementation, the Secretary shall submit a report to Congress (January 1, 2012) on the state of the current Hospital-Acquired Conditions Program and possible expansion of the program to other facilities, such as LTCHs, IRFs, SNFs, ASCs and hospital outpatient departments. Beginning in FY 2015, hospitals in the top quartile of national hospital-acquired condition rates will receive 99 percent of their otherwise applicable Medicare payments for all discharges. The Secretary is required to develop and use a risk-adjustment methodology when calculating the hospital-acquired condition rates. Prior to FY 2015, the Secretary will calculate and share confidentially with hospitals their hospital-acquired condition rates. The Secretary will report hospital-specific hospital-acquired conditions information on the *Hospital Compare* Web site, after allowing hospitals to review the information and to submit corrections.

Pilot Testing VBP for Certain Medicare Providers (Sec. 10326)
The law requires the Secretary, by January 1, 2016, to conduct VBP pilot programs for psychiatric hospitals and units, LTCHs, IRFs, PPS-exempt cancer hospitals and hospice programs. Further, no earlier than January 1, 2018, the Secretary may expand the duration and scope of these VBP pilot programs based on whether Medicare spending is reduced, quality is maintained or increased, and coverage or beneficiary benefits are not limited or denied.

VBP for Physicians (Sec. 3007) *Budget Neutral.*
The law institutes a budget-neutral VBP adjustment to the physician fee schedule by directing the Secretary to evaluate physicians' quality of care compared to cost and apply a payment modifier under the physician fee schedule based on the evaluation. The Secretary is required to publish specific measures of quality and cost by January 1, 2012. The implementation of the modifier will begin during the 2013 rulemaking process and an initial performance period will begin in 2014. The payment change will be implemented beginning in 2015 for specific physicians and groups of physicians, as determined by the Secretary, and will expand to all physicians and groups of physicians in 2017, including other eligible health care practitioners, as determined by the Secretary.

Improvements to the Physician Quality Reporting System (Sec. 3002, 10327) *Spends $300 million and saves $200 million over 10 years.*
The law extends the physician quality reporting initiative (PQRI) through 2014 and establishes a mandatory physician quality reporting program beginning in 2015. The law modifies the PQRI program to:

- Allow eligible professionals to receive incentive payments if they participate in a qualified Maintenance of Certification (MOC) program by submitting quality measures into a registry or through an alternative form and manner determined by the Secretary;
- Define a qualified MOC as a program that requires physicians to comply with the following:
    - Maintenance of a valid, unrestricted medical license;
    - Participation in continuing education;
    - Passing a formalized secure examination;

  - Having the following practice assessment procedures in place:
  - Use of evidence-based medicine;
  - Surveying of patient experience of care; and
  - A quality improvement process to address practice weaknesses.
- Establish an appeals process for providers who participated in the program but did not qualify for incentive payments by January 1, 2011;
- Require CMS to provide more timely feedback to providers on their performance;
- Extend the PQRI incentive program beyond 2010; and
- Develop a plan for integrating quality reporting with the meaningful use of electronic health records by January 1, 2012.

Eligible professionals (physicians, nurse practitioners, physician assistants, clinical psychologists, physical and occupational therapists, and speech-language pathologists and audiologists) who successfully report in 2010 will receive a 1.0 percent bonus payment in 2011 and a 0.5 percent bonus payment in 2012 through 2014. Eligible professionals who elect not to participate will be penalized 1.5 percent of their Medicare payment in 2015 and two percent of their payment in 2016 and beyond.

Improvements to the Physician Feedback Program (Sec. 3003) *Budget Neutral.*
The law requires the Secretary, beginning in 2012, to provide feedback reports to physicians that compare their resource use with that of other physicians or groups of physicians. It also requires the Secretary to develop an episode grouper by January 1, 2012. The grouper will combine separate but clinically-related services into an episode of care for which a physician is accountable. The Secretary will make the methodology available to the public and seek endorsement from the consensus based organization with which it has a contract, such as the NQF. The feedback program will be coordinated with the value-based payment modifier.

Public Reporting of Performance Information (Sec. 10331)
The law requires the Secretary to develop a *Physician Compare* Internet Web site for physicians and other professionals participating in the PQRI program by January 1, 2011. Beginning January 1, 2013, the Secretary shall publicly report physician performance measures regarding the following:

- PQRI measures;
- Assessment of beneficiary outcomes and functional status;
- Care coordination;
- Episodes of care;
- Risk-adjusted resource use;
- Patient experience of care; and
- Safety and effectiveness.

In addition, the Secretary shall:

- Make data available to the public, including risk-adjustment mechanisms;
- Provide opportunity for reasonable review of the data;
- Capture robust and accurate portrayal of a physician's performance;
- Include all-payer data;

- Appropriately attribute care;
- Provide timely statistical performance feedback;
- Publicly report only valid, reliable and accurate data; and
- Attain feedback from stakeholders.

The Secretary shall report to Congress on the progress of *Physician Compare* by January 1, 2015. The Secretary may establish a demonstration program to provide financial incentives to Medicare beneficiaries who are furnished services by high-quality physicians no earlier than January 1, 2019.

Patient Safety Research Center (Sec. 3501)
The law establishes a Center for Quality Improvement and Patient Safety within AHRQ that will conduct research to identify best practices for quality improvement and health care system redesign processes that improve patient safety, promote the successful adoption of such best practices, and build capacity at the state and community levels to lead quality and safety efforts. The center will award technical assistance grants to entities to assist providers in adopting the best practices identified through the center's research. Grantees must coordinate with HIT regional extension centers of the Office of the National Coordinator for Health Information Technology.

Medication Management Services in the Treatment of Chronic Diseases (Sec. 3503)
The Secretary shall create the Medication Management Program by May 1, 2010. The Patient Safety Research Center shall administer grants or contracts for services provided by licensed pharmacists to treat chronic diseases. Beneficiaries who have two or more chronic diseases, take any high-risk medications, take four or more prescribed medications, or who have undergone a transition of care recently are eligible to participate. One goal is to improve patient adherence to therapies while reducing acute care costs and hospital readmissions. Further, grant recipients must coordinate with local community health teams. The grant recipients are responsible for the following functions:

- Health and functional status assessments;
- Formulating medication treatment plans;
- Initiating and modifying medication therapy;
- Monitoring for medication safety and effectiveness; and
- Comprehensive medication review.

Adult Health Medicaid Quality Measures (Sec. 2701) *Spends $300 million over 10 years.*
This provision directs the Secretary, in consultation with the states, to develop an initial set of health care quality measures specific to adults who are eligible for Medicaid. By January 1, 2011, the Secretary shall identify, for comment, a recommended core set of adult health quality measures for Medicaid eligible adults and by January 1, 2012, the Secretary shall publish the final set of measures. The section establishes the Medicaid Quality Measurement Program (no later than January 1, 2013), which will expand upon existing quality measures, identify gaps in current quality measurement, and establish priorities for the development and advancement of quality measures and consult with relevant stakeholders. The Secretary, along with states, will report regularly to Congress on the progress made in identifying quality measures and implementing them in each state's Medicaid program. The initial report to Congress on adult and children's quality measures is due January 1, 2014, and every three years thereafter.

By September 30, 2014 (and annually thereafter), the Secretary shall collect, analyze and make publicly available the information reported by states. By January 1, 2015, the Secretary shall publish changes to the recommended core measure set. States will receive grant funding to support the development and reporting of quality measures. This provision adds a Treasury appropriation of $60 million for each of FYs 2010-2014; the funds will remain available until expended.

Medicaid Non-payment for Health Care-acquired Conditions (Sec. 2702)
The law prohibits federal payments to states for Medicaid services related to health care-acquired conditions, effective July 1, 2011. The Secretary will identify conditions consistent with Medicare, but will not be limited to conditions acquired in hospitals, and will take into account the differences between the Medicare and Medicaid programs. The Secretary will consider existing state policies that limit payment for health care acquired-conditions. State Medicaid programs must adopt policies that will not result in higher payments to hospitals should a patient have a health care-acquired condition during the hospital stay (similar to the Medicare hospital-acquired conditions policy).

Comparative Effectiveness Research and Evidence-Based Medicine (Sec. 6301-6302, as amended by Sec. 10602) *Spends $2.5 billion and saves $0.3 billion over 10 years.*
The law creates an independent Patient-Centered Outcomes Research Institute that is neither an agency nor an establishment of the U.S. Government. The tax-exempt institute will conduct comparative *clinical* effectiveness research to evaluate the clinical effectiveness, risks and benefits of two or more medical treatments, services and items, including health care interventions, protocols for treatment, care management and delivery, procedures, medical devices, diagnostic tools, pharmaceuticals and integrative health practices. The institute will assist patients, clinicians, purchasers and policymakers in making informed health decisions by advancing the evidence by which diseases and other health conditions can effectively and appropriately be prevented, diagnosed, treated and managed. Specifically, the institute will:

- Identify research priorities and establish a research project agenda;
- Carry out the research project agenda, including managing contracts, reviewing and updating evidence, and taking into account potential differences;
- Collect data from CMS and other federal, state or private entities;
- Appoint expert advisory panels, especially for clinical trials and rare diseases;
- Support patient and consumer representatives;
- Establish a 15-member methodology committee, which would include the directors of the AHRQ and NIH;
- Provide for a peer-review process for primary research;
- Release research findings;
- Adopt the national priorities, the research project agenda, the methodological standards, and other processes and protocols; and
- Submit annual reports to the Congress, the President and the public.

The institute's 19-member board will consist of patients and health care consumers, physicians and providers – including one hospital representative – private payers, pharmaceutical, device and diagnostic manufacturers, members representing state or federal government and others. It also will include the directors of AHRQ and NIH, or their respective designees. Board members will be appointed by the Comptroller General of the United States to hold six-year terms, serving a maximum of two terms.

The institute will review existing research and conduct new research. It will have access to data from federal, state and private entities, including data from clinical databases and registries. It may enter into contracts with federal agencies and private entities. Its research will be prioritized based on disease incidence and prevalence, evidence gaps in terms of clinical outcomes, practice variations and health disparities, the potential to improve health and quality of care, and expenditures associated with a health care treatment strategy or condition, among others. The research will be designed to take into account differences among subpopulations and in treatment modalities.

The law also creates an Office of Communication and Knowledge Transfer at AHRQ, in consultation with NIH, to broadly disseminate research findings. All research will be conducted under a set of requirements to ensure transparency, public input, adherence to ethical standards, and disclosure of any conflicts of interest. The law establishes several limitations around the use of the institute's comparative effectiveness research findings:

- The institute may not mandate coverage, reimbursement or other policies for any public or private payer, and none of its reports or research findings should be construed as mandates, practice guidelines or policy recommendations;
- The Secretary is prohibited from making coverage determinations based solely on the institute's research or findings, but can use the evidence for coverage determinations if it includes an iterative and transparent process with public comment and consideration of the effect on subpopulations;
- The Secretary is prohibited from determining coverage or reimbursement that would lower the value of extending the life of an elderly, disabled or terminally ill individual over that of an individual who is younger and healthier; and
- The institute is prohibited from developing a "dollars per quality-adjusted life year" (or similar measure) to determine what health care services or treatments are cost-effective or recommended. And it would be prohibited from using such a measure as a threshold to determine coverage, reimbursement or incentive programs.

The law creates a Patient-Centered Outcomes Research Trust Fund (PCORTC) to fund the institute and its activities. The PCORTC is financed in a public/private manner using general funds from the U.S. Treasury, an assessment per Medicare beneficiary, and a fee for insured and self-insured health plans. The fee on health plans would be based on an amount per number of lives covered by the plan and would sunset after FY 2019. The Federal Coordinating Council created under the *American Recovery and Reinvestment Act of 2009* was terminated as of March 23, 2010.

<u>Program to Establish Shared Decision Making</u> (Sec. 3506)
The purpose of this program is to facilitate collaborative processes between patients, caregivers and clinicians in decision making; to provide information about their treatment options, including the advantages and disadvantages among options; and to facilitate incorporation of patient preferences and values into the medical plan. The Secretary shall coordinate with CDC and NIH to establish a program to award grants or contracts to develop, update and produce patient decision aids, test such aids and educate providers on the use of such aids. The Secretary shall contract with NQF to identify and develop standards for patient decision aids and endorse such aids. Further, the Secretary shall fund grants in order to provide technical assistance to care givers.

Presentation of Prescription Drug Benefit and Risk Information (Sec. 3507)
The Secretary shall coordinate with the FDA to determine if the addition of quantitative summaries of the benefits and risks of prescription drugs in a standardized format (drug fact boxes) to promotional labeling or print advertising improves health care decision making by clinicians, patients, and consumers. The Secretary shall consult with drug manufacturers, clinicians, patients, consumers, experts in health literacy, representatives of racial and ethnic minorities, and experts in women's and pediatric health in assessing the summaries. The Secretary shall submit a report to Congress on the summaries by March 23, 2011 and issue any necessary regulations by March 23, 2014.

Primary Care Extension Program (Sec. 5405)
The law creates a Primary Care Extension Program to educate and provide technical assistance to primary care providers about evidence-based therapies, preventive medicine, health promotion, chronic disease management and mental health. AHRQ will award planning and program grants to state hubs, including at least one health professions school.

Demonstration Program to Integrate Quality Improvement and Patient Safety Training Into Clinical Education of Health Professionals. (Sec. 3508)
The Secretary, through AHRQ, may award grants to academic institutions to develop and implement an academic curriculum that integrates quality improvement and patient safety into the clinical education of health professionals. Selected participants must match funds at a rate not less than $1 for each $5 of federal funds. The Secretary shall submit a report to Congress on the demonstration program by March 23, 2012 and annually thereafter. The following programs are eligible for the grants:

- Health professions schools;
- Schools of public health;
- Schools of social work;
- Schools of nursing;
- Schools of pharmacy;
- Institutions with a graduate medical education program; and
- Schools of health care administration.

Patient Navigator Program (Sec. 3510)
The Secretary will collaborate with HRSA to award grants (not to exceed four years) to programs for patient navigators to coordinate health care services and to assist patients in overcoming barriers to health care services, coordinate provider referrals, provide information on clinical trials, and conduct outreach to health disparity populations. The applications shall define minimum core proficiencies for patient navigators. This provision includes an appropriation of $3,500,000 for FY 2010.