Summary of H.R. 6331:
The Medicare Improvements for Patients and Providers Act of 2008
As Passed by Congress July 15, 2008

Subtitle A: Beneficiary Improvements

Section 101: Improvements to Coverage of Preventive Services

- Adds Medicare coverage for preventive services that are:
  - Reasonable and necessary for the prevention or early detection of an illness or disability;
  - Recommended with a grade A or B by the US Preventive Services Task Force; and
  - Appropriate for individuals entitled to benefits under part A or enrolled under part B
- Makes changes to the initial "Welcome to Medicare" exam, including the addition of end-of-life planning and extending the eligibility for the exam from 6 months to 1 year after becoming eligible for Medicare Part B, and waiving the deductible

Section 102: Elimination of Discriminatory Copayment Rates for Medicare Outpatient Psychiatric Services

- Reduces beneficiary co-insurance requirements over a for mental health services over a 6 year period

Section 103: Prohibitions and Limitations on Certain Sales and Marketing Activities under Medicare Advantage Plans and Prescription Drug Plans

- Prohibits the following activities by MA and PD Plans:
  - Unsolicited direct contact of prospective enrollees, including door-to-door and outbound telemarketing
  - Cross selling of non-health related products
  - Meals, regardless of value
  - Sales and marketing activities for the enrollment of individuals in MA plans conducted
    - In health care settings (including pharmacies) except where conducted in common areas
    - Educational events
- Requires the Secretary to establish limitations on marketing of a MA or PD plan, co-branding of a network provider on MA plan membership and marketing materials, gifts and other promotional items (other than those of nominal value), compensation, and training and testing of brokers, agents and other third parties
- Requires PDPs and MA plans to comply with state licensing and appointment laws for agents and brokers

Section 104: Improvements to the Medigap Program

- Requires implementation of the National Association of Insurance Commissioners model law and regulations for Medicare supplement insurance (Medigap)

Part II: Low-Income Programs

Section 111: Extension of Qualifying Individual (QI) Program
- Extends the QI program from June 2008 to December2009
- Includes funding allocations for the states through December 2009

Section 112: Application of Full LIS Subsidy Assets Test under Medicare Savings Program
- Increases the asset allocation for the Medicare Savings Program to that of the Part D income-related full subsidy

Section 113: Eliminating Barriers to Enrollment
- Requires the Social Security Administration (SSA) to conduct outreach assistance for the Medicare Savings Program and the Low-Income Subsidy Program Applications, including:
  - Providing information on and applications for the low-income program, transmitting data for the initiation of benefits under the Medicare Savings Program, and information on completing an application for the Medicare Savings Program
  - Training personnel in explaining the programs and assistance in completing applications
  - Transmitting data to the State Medicaid agency
  - Coordinating outreach for both the Medicare Savings Program and the LIS program
- Includes funding for the reimbursement to the SSA for administrative costs
- Requires a GAO analysis and report on increasing participation in the Medicare Savings Program and the impact on States and the SSA
- Requires States to accept the data from the SSA regarding the Medicare Savings and the LIS programs and to take action in the same manner that the State would had the State received the information directly from the individual

Section 114: Elimination of Medicare Part D Late Enrollment Penalties Paid by Subsidy Eligible Individuals
- Prohibits an increase in monthly premiums for low-income subsidy eligible individuals due to late enrollment

Section 115: Eliminating Application of Estate Recovery
- Prohibits States from collecting or recovering from an individual's estate funds to cover the costs of providing low-income subsidy assistance to the individual

Section 116: Exemptions from Income and Resources for Determination of Eligibility for Low-Income Subsidy
- Excludes life insurance policies and in-kind support or maintenance from low-income subsidy determinations

Section 117: Judicial Review of Decisions of the Commissioner of Social Security under the Medicare Part D Low-Income Subsidy Program
- Allows for a court review of a denial by the SSA for low-income subsidy benefits

Section 118: Translation of Model Form

- Requires the Secretary to provide for the translation of the application for the Medicare Savings Program into at least the 10 languages (other than English) most often used by individuals

Section 119: Medicare Enrollment Assistance

- Provides grants to States for State health insurance assistance programs
- Provides grants to States for area agencies on aging and Native American programs carried out under the Older Americans Act of 1965. Funds may only be used for outreach to individuals who may be eligible for low-income assistance
- Provides grants to Aging and Disability Resource Centers for outreach to individuals regarding benefits available under Part D
- Requires the Assistant Secretary for Aging, in cooperation with related Federal agencies, to provide grants to qualified, experienced entities to:
    - Maintain and update web-based decision support tools designed to inform older Americans about the full range of benefits available under State and Federal programs
    - Utilize cost-effective strategies to find older individuals with the greatest economic need and inform them of available benefits
    - Develop and maintain a clearinghouse on best practices and most cost-effective methods for finding older individuals with the greatest economic need
    - Provide training and technical assistance on the most effective outreach, screening, and follow up strategies for State and Federal programs

Subtitle B: Provisions Relating to Part A

Section 121: Expansion and Extension of the Medicare Rural Hospital Flexibility Program

- Extends the hospital flexibility program (FLEX) to 2010
- Provides for grants to States for the hospital FLEX program for increasing the delivery of mental health services for veterans in rural areas
- In awarding the grants the Secretary may take into account whether the State includes in its application regional approaches, networks, HIT, telehealth or telemedicine to deliver services. A network may include Federally qualified health centers, rural health clinics, home health agencies, community mental health centers, and other providers of mental health services, pharmacists, local government, and other providers deemed necessary to meet the needs of veterans.
- Requires coordination between the State and the hospital association, rural hospitals, providers of mental health services, or other appropriate stakeholders
- Provides grants to eligible critical access hospitals to assist them with transitioning to skilled nursing facilities and assisted living facilities

Section 122: Rebasing for Sole Community Hospitals

- Provides for a new base year for sole community hospitals

Section 123: Demonstration Project on Community Health Integration Models in Certain Rural Counties

- Establishes a 3-year demonstration project administered by HRSA's Office of Rural Health Policy and CMS which allows eligible entities to develop and test new models for the delivery of health care services in eligible countries for the purpose of improving access to acute care, extended care,

and other essential health care services for beneficiaries, including home health care services, hospice care, and rural health clinic services
- Requires that health care providers selected to participate be reimbursed at a rate that covers at least the reasonable costs of the provider in furnishing the services
- Requires coordination of the Medicare and Medicaid survey and certification processes across all health services categories
- Requires that health care providers in eligible counties and the Secretary work with the State to explore revised Medicaid reimbursement policies that improve access
- Requires the Secretary to identify regulatory requirements that may improve access to care
- Requires the identification of other essential health care services necessary to ensure access to a range of health care services and ways to ensure adequate funding for such services
- An eligible county is one with 6 or fewer residents per square mile
- Requires an interim report to Congress 2 years into the demonstration project and a final report 1 year after completion

Section 124: Extension of the Reclassification of Certain Hospitals
- Extends the MMA provision related to wage index reclassification for certain hospitals

Section 125: Revocation of Unique Deeming Authority of the Joint Commission
- Revokes the unique authority of the Joint Commission to deem hospitals as compliant with Medicare conditions of participation
- Allows for accreditation by a national accreditation body, which could be the Joint Commission

Subtitle C: Provisions Related to Part B

Part I: Physicians' Services

Section 131: Physician Payment, Efficiency, and Quality Improvements
- Blocks pending cuts to physician payments
- Provides for an update of 1.1% for physician payments in 2009
- Extends the physician quality reporting system to 2010
- Requires that measures used in quality reporting be selected from those endorsed by an approved consensus entity
- Requires input from "eligible professionals" regarding development, endorsement and selection of measures
- Includes a 1.5% incentive payment in 2007 and 2008 and 2.0% in 2009 and 2010
- Allows group practices to submit data on measures, using a statistical sampling model, that targets high-cost chronic conditions and preventive care
- Requires the Secretary to post on the CMS website the names of the professionals or group practices that satisfactorily submitted data on measures and that are successfully using e-prescribing
- Includes qualified audiologists as eligible professionals
- Requires the Secretary to establish a Physician Feedback Program that uses claims data to provide confidential feedback to physicians regarding their resource use in providing care
- Allows the Secretary to focus the feedback program on:

  - Physician specialties that account for a certain percentage of all spending for physician services
  - Physicians who treat conditions with a high cost or high volume
  - Physicians who use a high amount of resources
  - Physicians who treat a minimum number of individuals
- Requires a GAO Report on the feedback program
- Requires the Secretary to develop a plan to transition to value-based purchasing program for payment for covered professional services
- Requires a report to Congress on the transition plan

Section 132: Incentives for Electronic Prescribing

- Provides for incentive payments to prescribers who use e-prescribing:
  - 2% in 2009 and 2010
  - 1% in 2011 and 2012
  - .5% in 2013
- Exempts from the incentive payment those physicians who use e-prescribing for less than 10% of their covered prescriptions or if the prescriber does not submit a sufficient number of prescriptions under Part D (electronic or otherwise)
- Requires prescribers submit data using e-prescribing quality measures under the physician reporting system
- Requires prescribers to electronically submit a "sufficient" number of prescriptions under Part D
- Requires the use of e-prescribing systems that are in compliance with Part D e-prescribing standards
- Reduces payments to prescribers who do not successfully use e-prescribing systems by 2012
- Allows the Secretary to exempt an eligible professional from the payment reduction if compliance with e-prescribing would prove a "significant hardship", such as practice in a rural area without sufficient internet access
- "Eligible professional" means a physician, physical or occupational therapist or a qualified speech-language pathologist, physician assistant, nurse practitioner, or clinical nurse specialist, certified registered nurse anesthetist, certified nurse-midwife, clinical social worker, clinical psychologist, or registered dietitian or nutrition professional
- Requires GAO report on e-prescribing by September 1, 2012 that includes information on:
  - Percentage of eligible professionals suing e-prescribing systems, including a determination of whether 50% of less of eligible professionals are using e-prescribing systems
  - If less than 50%, recommendations for increasing the use of e-prescribing systems
  - Estimated saving to the Medicare program as result of e-prescribing
  - Reductions in avoidable medical errors as a result of e-prescribing
  - Extent to which privacy and security of personal health information is protected when prescription drug data is used for purposes other than direct clinical care
  - GAO recommendations

Section 133: Expanding Access to Primary Care Services

- Gives the Secretary authority to expand (in duration and scope) the Medicare Medical Home Demonstration Project if the projected is expected to improve quality of care without increasing spending and is expected to reduce spending without reducing quality of care

Section 134: Extension of Floor on Medicare Work Geographic Adjustment under the Medicare Physician Fee Schedule

- Extends the 1.0 geographic index (an index of the relative costs of goods and services that make up practice expenses) to 2010

Section 135: Imaging Provisions

- Requires accreditation of suppliers that provide the technical component of advanced diagnostic imaging services by 2012
- Diagnostic imaging services include:
    - Diagnostic magnetic resonance imaging, computed tomography, and nuclear medicine (including positron emission tomography)
    - Other diagnostic imaging services including x-ray, ultrasound, and fluoroscopy
- Lists factors that the Secretary must take into account when designating an accreditation organization
- Includes criteria for the accreditation organization to use in evaluating a supplier of services
- Establishes a demonstration project looking at the appropriateness of advanced diagnostic imaging services provided to Medicare beneficiaries
- Requires development of criteria for the clinical appropriateness of advanced diagnostic imaging with input from medical specialty societies and other stakeholders
- Outlines models by which the Secretary will collect data regarding physician compliance with the appropriateness criteria (point of service and point of order models)
- Requires comparison of the imaging services provided by physicians participating in the demonstration project and feedback reports to participating physicians
- Requires an evaluation by the Secretary of the demonstration project and a report to Congress
- Requires a GAO study (including an interim and final report) on the effect of accreditation

Section 136: Extension of Treatment of Certain Physician Pathology Services under Medicare

- Extends the provision regarding laboratory services that bill Medicare directly to 2009

Section 137: Accommodation of Physicians Ordered to Active Duty in the Armed Services

- Provides for special billing arrangements for physicians on active duty

Section 138: Adjustment for Medicare Mental Health Services

- Provides for a 5% increase in the fee schedule for psychiatric therapeutic procedures that are insight oriented, behavior modifying, supportive psychotherapy, or interactive psychotherapy

Section 139: Improvements for Medicare Anesthesia Teaching Programs

- Provides for 100% of the fee schedule for services performed by a teaching anesthesiologist
- Provides for adjustments to payments for teaching certified registered nurse anesthetists

Part II: Other Payment and Coverage Improvements

Section 141: Extension of Exceptions Process for Medicare Therapy Caps

- Provides for an extension of the exception to the cap on payments for therapy to December 31, 2009

Section 142: Extension of Payment Rule for Brachytherapy and Therapeutic Radiopharmaceuticals

- Extends the payment rule regarding brachytherapy and therapeutic radiopharmaceuticals to 2010

Section 143: Speech-Language Pathology Services

- Provides Medicare coverage for and a definition of "outpatient speech-language pathology services"

Section 144: Payment and Coverage Improvements for Patients with Chronic Obstructive Pulmonary Disease and Other Conditions

- Provides for Medicare coverage of cardiac rehabilitation and items and services furnished under an intensive cardiac rehabilitation program or pulmonary rehabilitation program
- An intensive cardiac rehabilitation program is a physician-supervised program that:
  - Positively affected the progression of heart disease
  - Reduced need for bypass surgery
  - Reduced need for percutaneous coronary interventions
  - And reduces 5 or more measures:
    - Low density lipoprotein
    - Triglycerides
    - Body mass index
    - Systolic blood pressure
    - Diastolic blood press
    - Need for cholesterol, blood pressure, and diabetes medications
- A pulmonary rehabilitation program is a physician-supervised program that includes services such as:
  - Physician-prescribed exercise
  - Education or training
  - Psychosocial assessment
  - Outcomes assessment
  - Other items and services
- Repeals provision requiring transfer of ownership of oxygen equipment to individuals after 36 months of renting

Section 145: Clinical Laboratory Tests

- Repeals the competitive bidding demonstration project for clinical laboratory services
- Reduces the payment update for clinical laboratory services by .5% each year 2009-2013

Section 146: Improved Access to Ambulance Services

- Extends the provision increasing payments for ground ambulance services to 2010
- Improves payment for rural area air ambulance services

Section 147: Extension and Expansion of the Medicare Hold Harmless Provision under the Prospective Payment System for Hospital Outpatient Department (HOPD) Services for Certain Hospitals

- Extends the hold harmless provision for certain hospitals to 2010, making sure that rural hospitals are paid at least 85% of what was received prior to the BBA
- Applies same provision to hospitals with fewer than 100 beds

Section 148: Clarification of Payment for Clinical Laboratory Tests Furnished by Critical Access Hospitals

- Treats critical access hospitals the same as skilled nursing facilities or clinics (including rural health clinic) for purposes of payment for clinical laboratory tests

Section 149: Adding Certain Entities as Originating Sites for Payment of Telehealth Services

- Adds hospital-based or critical access hospital-based renal dialysis centers, skilled nursing facilities, and community mental health centers to the list of originating sites for telehealth

Section 150: MedPAC Study and Report on Improving Chronic Care Demonstration Programs

- Requires a MedPAC Study on the feasibility and advisability of establishing a Medicare Chronic Care Practice Research Network to serve as a standing network of providers to test new models of care coordination and other care approaches for chronically ill beneficiaries
- Requires coordination with other care coordination and disease management programs including the Medicare Coordinated Care Demonstration Project
- Requires report to Congress by June 15, 2009

Section 151: Increase of FQHC Payment Limits

- Increases payments limits for Federally qualified health centers:
    - $5 increase in 2010
    - In subsequent years, limits are increased by the percentage increase in the MEI
- Requires a GAO study to determine whether the structure for payments for services furnished by FQHCs adequately reimburses for care furnished to beneficiaries. Requires the GAO to:
    - Use most current cost report data available
    - Examine effects of payment limits under Part B on FQHCs
    - Examine cost of furnishing services that were not originally covered services when the FQHC payment rate was established in 1991
- Requires GAO report to Congress on the structure and adequacy of the prospective payment methodology for FQHCs

Section 152: Kidney Disease Education and Awareness Provisions

- Requires the Secretary to establish pilot projects to:
    - Increase public and medical community awareness regarding chronic kidney disease, focusing on prevention
    - Increase screening for chronic kidney disease
    - Enhance surveillance systems to better assess the prevalence and incidence of chronic kidney disease
- The pilot project will take place in at least 3 states for 5 years, beginning January 1, 2009
- Requires GAO report within 12 months of completion
- Provides for Medicare coverage of kidney disease education services (up to 6 sessions), which are defined as:
    - Furnished to an individual with state IV chronic kidney disease and will require dialysis or kidney transplant
    - Furnished upon referral of managing physician

  - Designed to provide comprehensive information regarding management of co-morbidities, prevention of uremic complications, and options for renal replacement therapy
  - Designed to ensure that the individual has opportunity to actively participate in choice of therapy
  - Designed to be tailed to meet needs of individual
- Defines "qualified person" as physician or PA, NP, or clinical nurse specialist, or a provider of services located in a rural area
- Requires the Secretary to set standards for the content of educational information after consulting with physicians, other health professionals, health educators, professional organizations, accrediting organizations, kidney patient organizations, dialysis facilities, transplant centers, network organizations, and others. To the extent possible, the consultation should be with persons or entities that have not received funding from drug or biological manufacturers or dialysis facilities

<u>Section 153: Renal Dialysis Provisions</u>

- Provides for a 1% update for the composite rate component for services provided by renal dialysis centers in 2009 and 2010
- Requires the Secretary to develop an ESRD payment system under which a single payment is made (bundled payment)
- Renal dialysis services includes:
  - Items and services included in the composite rate for renal dialysis services
  - Erythropoiesis stimulating agents and any oral form of such agents for treatment of ESRD
  - Other drugs and biological furnished to individuals for treatment of ESRD
  - Diagnostic laboratory tests and other items and services furnished for treatment of ESRD
- Requires the Secretary to take into account the unique treatment needs of children and young adults in developing the payment system
- Requires a 4-year phase-in for the payment system after January 1, 2014
- Erythropoiesis stimulating agents and other drugs and biologicals shall be treated as prescribed and dispensed or administered and available only under Part D if they are:
  - Furnished for treatment of ESRD
  - Included as "renal dialysis services" for purposes of payment
- Requires performance standards and quality incentives for providers and renal dialysis facilities, or face a reduction in payment of up to 2%
- Requires the Secretary to public report on performance of facilities in meeting quality standards
- Requires providers to post certificates to indicate total performance score on quality standards
- Requires the Secretary to establish a website to list providers and their performance scores
- Requires GAO report on ESRD bundling system and quality initiative, including changes in utilization rates of drugs and biologicals

<u>Section 154: Delay in and Reform of Medicare DMEPOS Competitive Acquisition Program</u>

- Delays implementation of the DMEPOS competitive acquisition program to 2011 and reduces the number of metropolitan statistical areas from 80 to 70
- For Round 1 of the competitive acquisition program:
  - Terminates contracts in existence prior to enactment

- Requires the Secretary to conduct competition for round 1 in 2009 with the same items and services, and the same area, except that Puerto Rico is exempted and negative pressure wound therapy items and services are excluded
- For Round 2 of the competitive acquisition program:
  - Includes metropolitan statistical areas that were selected by June 1, 2008
  - Allows the Secretary to subdivide metropolitan statistical areas with populations of at least 8,000,000 into separate areas for competitive acquisition purposes
- Excludes the following from subsequent rounds occurring before 2015:
  - Rural areas
  - Metropolitan statistical areas not selected under round 1 or 2 with population of less than 250,000
  - Areas with a low population density within a metropolitan statistical area that is otherwise selected
- Requires the OIG to assess the process used by CMS to conduct the competitive bidding program and subsequent pricing determinations
- Requires the Secretary to provide notice to the bidder within 45 days (for round 1) and 60 days (for subsequent rounds) after the covered document review date of any missing documents; the Secretary cannot reject the bid if the bidder provides the missing documents within 10 business days of notification
- Document review date is either 30 days before the final date for submission of bids or 30 days after the first date specified for submission of bids
- The document review process:
  - Applies only to timely submission of documents
  - Does not apply to any determination as to accuracy or completeness or whether the documents meet applicable requirements
  - Does not prevent the Secretary from rejecting a bid
  - Shall not be construed as permitting a bidder to change amounts or other information in a bid submission
- Covered documents are financial, tax or other document required as part of the bid submission in order to meet financial standards
- Excludes certain complex rehabilitative power wheelchairs and related accessories classified within group 3 or higher
- Provides for a covered item update in 2009 of 9.5% for items or services selected for competitive acquisition, including related accessories furnished with such items and services and diabetic supplies furnished through mail order, and for other items and services, the percentage increase in the consumer price index for all urban consumer for the 12-month period ending with June 2008
- For 2010-2013, the consumer price index for the 12-month period ending with June of the previous year
- For 2014, the consumer price index for the 12-month period ending June 2013 plus 2 % points for items included in the competitive acquisition program, or for other items and services, the consumer price index for the 12-month period ending with June 2013
- Requires that the methodology used be promulgated in regulation and requires the Secretary to take into consideration the costs of items and services compared to rates for items and services in the competitive acquisition areas
- Requires suppliers to submit evidence of accreditation as meeting applicable quality standards, except that the standards and accreditation requirement does not apply to professionals (physician,

physician assistant, nurse practitioner, or clinical nurse specialist, or certified registered nurse anesthetist, certified nurse-midwife, clinical social worker, clinical psychologist, or registered dietitian or nutrition professional) unless the Secretary determines that the standards are designed specifically to be applied to such professionals and allows the Secretary to exempt professionals and persons from standards and requirement if licensing, accreditation or other quality requirements apply

- Requires suppliers to disclose to the Secretary within 10 days of entering into a contract information on subcontracting relationships and whether each subcontractor meets accreditation requirements
- Requires suppliers to disclose any subsequent subcontracting relationships within 10 days
- Requires the establishment of a Competitive Acquisition Ombudsman within CMS to respond to complaints and inquiries
- Requires a GAO report within 1 year after the first day that payments are made and should include information on the following:
    - Beneficiary access, including impact on access by awarding contracts to bidders that are not physically present in area where they received a contract or had no previous experience providing the product category they were contracted to provide
    - Beneficiary satisfaction and cost savings
    - Costs to suppliers and recommendations to reduce costs without compromising quality or savings to the Medicare program
    - Impact of the program on small business suppliers
    - Analysis of the impact on utilization of different items and services paid within the same HCPCS code
    - Costs to CMS for administering the program
    - Impact on access, Medicare spending, and beneficiary spending of any difference in treatment for diabetic testing supplies depending on how such supplies are furnished
    - Other topics as determined appropriate
- Provides for delays in several other deadlines including:
    - Program advisory and oversight committee to December 31, 2011
    - Report from Secretary to July 1, 2011
    - IG report to July 1, 2011
- Requires the Secretary to evaluate existing HCPCS codes for negative pressure wound therapy to ensure accurate reporting and billing
- Exempts certain of-the-shelf orthotics from competitive acquisition if furnished by a physician or other practitioner (as defined by Secretary) to the physician's/practitioner's own patients or by a hospital to the hospital's own patients during admission or on discharge
- Exempts certain DME if furnished by a hospital to the hospital's own patients during admission or on discharge or by a physician to the physician's own patients
- Requires the Secretary to reject a bid for diabetic testing strips if the entity does not demonstrate that its bid covers at least 50% of all types of diabetic testing strip products
- Requires an IG study to determine the types of diabetic testing strip products
- Effective date is June 30, 2008

Subtitle D: Provisions Relating to Part C

<u>Section 161: Phase-Out of Indirect Medical Education (IME)</u>

- Adds a provision to phase-out payment adjustments to Medicare Advantage plans for indirect medical education beginning in 2010

Section 162: Revisions to Requirements for Medicare Advantage Private Fee-for-Service Plans
- Stating in plan year 2011, requires private fee-for-service plans to meet access standards by contracting with network providers

Section 163: Revisions to Quality Improvement Programs
- Amends quality improvement provision to requires private fee-for-service, regional, and MSA plans to have the same quality improvement program as other plans as of January 1, 2010

Section 164: Revisions Relating to Specialized Medicare Advantage Plans for Special Needs Individuals
- Extends to 2011 the provision granting authority to special needs plans to restrict enrollment to individuals who are within one or more classes of special needs individuals
- Prohibits the Secretary from designating other plans as specialized MA plans for special needs individuals for the period January 1, 2010 – December 31, 2010
- Adds requirements for institutional special needs plans regarding enrollment, including requiring a determination that an individual requires an institutional level of care by use of a State assessment tool and by an entity other than the special needs plan
- Adds requirements for dual special needs plans regarding enrollment, including a requirement that the plan provides each prospective enrollee with a comprehensive written statement describing benefits and cost-sharing protections, including those covered under the plan
- Adds requirements for severe or disabling chronic condition special needs plans
- Requires HHS to have sufficient staff and resources to address State inquiries regarding State-Federal coordination for special needs individuals
- Requires special needs plans to have an evidence-based model of care with appropriate networks of providers and specialists and to conduct initial and annual assessments of the individual, develop a plan including goals, objectives, and measurable goals, and use an interdisciplinary team to manage care
- Requires the Secretary to review MA plans for compliance with care management requirements
- Amends the definition of "severe or disabling chronic conditions specialized needs individual" to include those who have one or more co-morbid and medically complex chronic conditions that are substantially disabling or life threatening, have a high risk of hospitalization or other significant adverse health outcomes, and require specialized delivery system across domains of care
- Requires the Secretary to convene a panel of clinical advisory to determine the conditions that meet the definition of severe and disabling chronic conditions
- Requires special needs plans to provide for the collection, analysis, and reporting of data for quality improvement purposes

Section 165: Limitation on Out-of-Pocket Costs for Dual Eligibles and Qualified Medicare Beneficiaries Enrolled in a Specialized Medicare Advantage Plan for Special Needs Individuals
- Prohibits a special needs plan from imposing cost-sharing requirements full-benefit dual eligibles and qualified beneficiaries that exceed the amount permitted under Medicaid

Section 166: Adjustment to the Medicare Advantage Stabilization Fund

- Removes $1.79 billion from the MA Stabilization Fund

Section 167: Access to Medicare Reasonable Cost Contract Plans
- Extends the provision for reasonable cost contracts to 2010
- Revises requirements for cost contracts so that all such plans are not offered by the same MA organization
- Requires GAO study of cost contracts

Section 168: MedPAC Study and Report on Quality Measures
- Requires a MedPAC study on the collection and reporting of performance and patient experience measures and comparing the quality of care beneficiaries receive across MA plans and comparing the quality of care beneficiaries receive under MA plans and the original fee-for-service program

Section 169: MedPAC Study and Report on Medicare Advantage Payments
- Requires a MedPAC study on the correlation between:
    - Cost that MA organizations incur in providing coverage under original Medicare fee-for-service under Parts A and B and
    - County-level spending on the original Medicare fee-for-service program on a per capita basis
- Based on the study results, requires MedPAC to determine appropriate alternative payment approaches for MA plans

Subtitle E: Provisions Relating to Part D

Part I: Improving Pharmacy Access

Section 171: Prompt Payment by Prescription Drug Plans and MA-PD Plans under Part D
- Requires PDPs and MA-PDs to transmit payment to pharmacies for all clean claims within 14 calendar days for electronic claims and 30 days for claims submitted otherwise
- A "clean claim" is defined as a claim that has no defect or impropriety that prevents timely payment from being made
- For an electronic claim, the date considered as received is the date the claim is transmitted and for claims submitted otherwise, the date considered is the 5th day after the postmark date of the claim or date specified in the time stamp of the transaction
- If the payment is not transmitted with the applicable timeframe, the PDP or MA-PD will pay interest to the pharmacy, unless the Secretary determines that there are exigent circumstances
- A claim is deemed clean if the PDP does not provide the pharmacy notice of any deficiency within 10 days for an electronic claim and within 15 days for claims transmitted otherwise
- The PDP must provide notice within the timeframe above and specify all defects and improprieties, including the additional information needed to process the claim
- A claim is considered to be a clean claim 10 days after submission of additional information
- If the PDP does not pay or contest the claim within the applicable number of days, the claim is considered to be a clean claim and to be paid
- A payment is considered to have been made:
    - For electronic claims, on the date the payment is transferred

- For other claims, the date the payment is submitted to the US Postal Service or common carrier
- Requires a PDP to pay all clean claims submitted electronically via electronic transfer of funds if so requested by the pharmacy or has so previously requested
- Includes protections for pharmacies including anti-retaliation against an individual or provider for exercising a right of action under this section
- A determination of a clean claim does not constitute eligibility for payment
- Effective date: January 1, 2010

Section 172: Submission of Claims by Pharmacies Located in or Contracting with Long-Term Care Facilities

- Requires pharmacies that are located in or have a contract with a long-term care facility to submit claims in not less than 30 days, but not more than 90 days
- Effective date: January 1, 2010

Section 173: Regular Update of Prescription Drug Pricing Standard

- Requires PDPs that use a standard for reimbursement for pharmacies based on the cost of a drug to provide an update at least once every 7 days, beginning January 1 of each year
- Effective date: January1, 2009

Part II: Other Provisions

Section 175: Inclusion of Barbiturates and Benzodiazepines as Covered Part D Drugs

- Permits coverage of barbiturates for treatment of epilepsy, cancer, or chronic mental health disorder and benzodiazepines as of January 1, 2013

Section 176: Formulary Requirements with Respect to Certain Categories or Classes of Drugs

- Requires PDPs to include all covered Part D drugs in categories and classes which are identified by the Secretary
- The Secretary shall identify categories and classes of drugs if the following criteria are met:
  - Restricted access to drugs in the category or class would have major or life threatening clinical consequences for individuals who have a disease or disorder treated by the drugs in such category or class
  - There is significant clinical need for such individuals to have access to multiple drugs within a category or class due to unique chemical actions and pharmacological effects of the drugs within the category or class, such as drugs used in the treatment of cancer
- The Secretary may establish an exceptions process permitting a PDP to exclude a particular covered drug from its formulary. The exceptions process shall:
  - Ensure that any exception is based on scientific evidence and medical standards
  - Include public notice and comment period

Subtitle F: Other Provisions

Section 181: Use of Part D Data

- Amends provisions related to the use of Part D data to include improving public health through research on utilization, safety, effectiveness, quality and efficiency of health care and requires that

data be made available to Congressional support agencies for purposes of Congressional oversight, monitoring, making recommendations, and analysis

Section 182: Revision of Definition of Medically Accepted Indication for Drugs

- Revises the definition of "medically accepted indication for drugs" to include covered part D drugs used in anticancer chemotherapeutic regimen

Section 183: Contract with a Consensus-Based Entity Regarding Performance Measurement

- Provides for the Secretary to contract with a consensus-based organization (such as the National Quality Forum) to synthesize evidence and convene key stakeholders to make recommendation on an integrated national strategy and priorities for health care performance measurement in all applicable settings
- Priority is to be given to measures:
    - That address health care provided to patients with prevalent, high-cost chronic diseases
    - With the greatest potential for improving the quality, efficiency, and patient-centeredness of health care
    - That may be implemented rapidly due to existing evidence, standards of care, or other reasons, and
- Take into account measures that:
    - May assist consumers and patients in making informed health care decisions
    - Address health disparities across groups and areas
    - Address the continuum of care, including services furnished by multiple providers or practitioners across multiple settings
- The organization shall endorse standardized health care performance measures using an endorsement process that:
    - Is evidence based, reliable, valid, verifiable, relevant to enhanced health outcomes, actionable at the caregiver level, feasible to collect and report, and responsive to variations in patient care, such as health status, language capabilities, race or ethnicity, and income level
    - Is consistent across types of health care providers, including physicians and hospitals
- Requires the consensus organization to establish a process to update the measures
- Requires the consensus organization to promote development of electronic health records
- Requires annual report to Congress on implementation, recommendations, and performance
- The consensus organization must meet certain criteria, including:
    - A nonprofit entity
    - Have a board comprised of representatives of health plans and providers/practitioners or groups representing plans, providers, practitioners
    - Health care consumers or their representatives
    - Representatives of purchasers and employers or their representatives
- The membership of the organization must have experience with:
    - Urban health care issues
    - Safety net health care issue
    - Rural and frontier health care issues
    - Health care quality and safety issues

- The organization must conduct its business in an open and transparent manner and provide for public comment and must have at least 4years experience in establishing national consensus standards. Membership fees should not pose a barrier to participation
- Requires GAO study on the performance of the consensus entity and costs incurred

Section 184: Cost-Sharing for Clinical Trials

- Authorizes the Secretary to develop alternative methods of payment for items and services provided under clinical trials and comparative effectiveness studies

Section 185: Addressing Health Care Disparities

- Requires the Secretary to evaluate approaches for collecting data on disparities in health care services and performance on the basis of race, ethnicity, and gender. The Secretary must take into account the following objectives:
    - Protecting patient privacy
    - Minimizing administrative burdens on providers and plans
    - Improving the Medicare program data on race, ethnicity, and gender
- Requires report to Congress identifying approaches and recommendations on most effective strategies and implementation within 24 months after enactment

Section 186: Demonstration to Improve Care to Previously Uninsured

- Requires the Secretary to establish a 2-year demonstration project to determine the greatest needs and most effective methods of outreach to beneficiaries who were previously uninsured
- There shall be at least 10 sites that include state health insurance assistance programs, community health centers, community-based organizations, community health workers, and other service providers under parts A, B, and C
- Requires report to Congress within one year of completion on effectiveness of outreach, and the effect of outreach on beneficiary access to care, utilization, efficiency and cost effectiveness of health care delivery, patient satisfaction, and select health outcomes

Section 187: Office of the Inspector General Report on Compliance with and Enforcement of National Standards on Culturally and Linguistically Appropriate Services (CLAS) in Medicare

- Requires IG report on the extent to which providers are complying with the Office of Civil Rights' guidance on discrimination affecting limited English proficient persons and the Office of Minority Health's CLAS standards
- The report should include recommendations for improving compliance with and enforcement of CLAS standards

Section 188: Medicare Improvement Funding

- Establishes a "Medicare Improvement Fund" to make improvements under the original fee-for-service program

Section 189: Inclusion of Medicare Providers and Suppliers in Federal Payment Levy and Administrative Offset Program

- Requires that CMS participate in the Federal Payment Levy Program (FPLP) and ensure that:
    - 50% of all Parts A and B payments are processed through the FPLP within 1 year of enactment

  - 75% of all Parts A and B payments are processed through FPLP within 2 years
  - All payments are processed through FPLP by September 30, 2011

Title II: Medicaid

Section 201: Extension of Transitional Medical Assistance (TMA) and Abstinence Education Program

- Extends TMA and abstinence education program through June 30, 2009

Section 202: Medicaid DSH Extension

- Extends the DSH allotment for Tennessee and Hawaii through December 31, 2009

Section 203: Pharmacy Reimbursement under Medicaid

- Delays the payment limit for multiple source drugs until September 30, 2009
- Prohibits the Secretary from taking action prior to October 1, 2009 to finalize, implement, or enforce the upper limit established in regulations published July 17, 2007
- Prohibits the Secretary from publishing AMP data prior to October 1, 2009

Section 204: Review of Administrative Claim Determinations

- Allows States to request and receive a reconsideration of any disallowance of Federal payment for any item or service, provided that the request is made within 60 days
- Allows States to appeal a disallowance to the Departmental Appeals Board
- Allows States to obtain a judicial review of the Appeals Board decision

Section 205: County Medicaid Health Insuring Organizations

- Increases the percent of Medicaid recipients who may participate in county Medicaid health insuring organizations and expands the list of authorized counties

Title III: Miscellaneous

Section 301: Extension of TANF Supplemental Grants

- Extends the TANF grants through fiscal year 2009

Section 302: 70 Percent Federal Matching for Foster Care and Adoption Assistance for the District of Columbia

- Provides 70% Federal matching for the District of Columbia for foster care and adoption assistance

Section 303: Extension of Special Diabetes Grant Programs

- Extends the special diabetes grant program for type I diabetes to 2011
- Extends the special diabetes grant program for Indians to 2011
- Requires a report on the grant program by January 1, 2011

Section 304: IOM Reports on Best Practices for Conducting Systematic Reviews of Clinical Effectiveness Research and for Developing Clinical Protocols

- Requires an IOM study to identify methodological standards for conducting systematic reviews of clinical effectiveness research on health and health care to ensure that organizations conducting reviews have information on methods that are objective, scientifically valid, and consistent
- Requires participation by stakeholders with expertise in conducting clinical effectiveness research

- Requires an IOM study on the best methods used in developing clinical practice guidelines to ensure organizations have information on approaches that are objective, scientifically valid, and consistent
- Requires participation by stakeholders that have expertise in making clinical recommendations