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Health Reform

Patient Protection and Affordable Care Act &
Health Care and Education Affordability Reconciliation Act

Key Provisions

Health Reform: Key Provisions

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OVERVIEW

Health Reform: Current Legislative Status

- **Patient Protection & Affordable Care Act**
  - The Senate passed the "Patient Protection and Affordable Care Act" (H.R. 3590) on December 24, 2009
  - The House passed the same bill on March 21, 2010
  - The President signed the bill into law on March 23, 2010
- **Health Care and Education Affordability Reconciliation Act**
  - The House passed the "Health Care and Education Affordability Reconciliation Act," meant to change several provisions in the base health reform bill, on March 21, 2010
  - The Senate passed the reconciliation bill on March 25, 2010, with revisions, and the House passed the revised bill on the same day
  - The President signed the reconciliation bill into law on March 30, 2010

**** This presentation reflects the Patient Protection & Affordable Care Act <u>as amended</u> by the Reconciliation Act.**

Health Reform: An Overview

COVERAGE →

- Insures 32 million uninsured by 2019
- Extends health insurance from 83 percent to 94 percent of Americans by 2019

COST →

- $938 billion, 2010-2019
- Second decade costs grow dramatically
- Deficit reduction of $124 billion

FINANCING →

- Reimbursement reductions for Medicare providers
- Excise taxes on high-value health plans
- Expansion of Medicare HI tax to non-payroll income
- Industry fees

Tools to Expand Coverage

High-Risk Pool	State Exchanges "American Health Benefit Exchange"	National Plan	Medicare	Medicaid/CHIP	Mandates
▪ Temporary high-risk pool for uninsured with pre-existing conditions ▪ Terminates in 2014 when Exchanges are established	▪ Each State required to establish an Exchange by 2014 ▪ Plans must be qualified health plans – criteria set by HHS Secretary ("Secretary") ▪ Allows interstate Exchanges with approval from the Secretary ▪ Individual and small group access offered in 2014; large group in 2017	▪ Office of Personnel Management (OPM) contracts with private insurers to offer at least two national health plans in each Exchange ▪ At least one plan must be non-profit ▪ Allows HHS to create a basic health program for low-income individuals not eligible for Medicaid	▪ Temporary reinsurance program for 55-64 aged ▪ Terminates in 2014 when Exchanges are established	▪ Effective 2014, expanded to 133% of federal poverty level (FPL) ▪ Requires Federal government to pay 100% of cost of newly-eligible individuals in 2014-2016; 95% in 2017; 94% in 2018;93% in 2019; and 90% in 2020 and thereafter ▪ Increased Federal matching assistance program (FMAP) for States; levels vary based on expanded coverage prior to reform ▪ CHIP matching rates increased	▪ Individual mandate begins 2013 ▪ Employer mandate begins 2014 for employers with over 50 employees

PRESCRIPTION DRUGS

Part D Coverage Gap, "Donut Hole"

- **Provides a one-time $250 coverage gap rebate in 2010**
  - Beneficiaries with annual income exceeding the Part B income thresholds exempt from subsidy
- **Effective after December 31, 2010, Part D plans may offer the first fill of a generic drug to enrollees with a reduced or no cost sharing.**
- **Manufacturer discount**
  - Requires manufacturers to contribute 50% of a brand drug's or biologic's negotiated price used by a non-subsidy eligible Part D beneficiary in the coverage gap beginning January 1, 2011
  - Discount is exempt from AMP calculation
  - Manufacturer discounts will count toward TrOOP
- **Coverage gap reduction** through change in benefit design
  - Reduces beneficiary coinsurance in gap for brands to 50% for 2011-2012; 47.5% for 2013-2014; 45% for 2015-2016; 40% for 2017; 35% for 2018; 30% for 2019; and 25% for 2020 and beyond – industry discount remains at 50%
  - Reduces beneficiary obligation in the Part D coverage gap for generics to 93% in 2011 and decreases by 7 percentage points each year until 2020, when it becomes and remains 25%
- **Model Agreement**
  - Secretary must establish a model agreement in consultation with manufacturers and allow for comment on such model agreement 180 days after enactment
  - Manufacturers required to enter into agreements 30 days after model agreement

Coverage Gap in Detail

Contribution of the beneficiary, pharmaceutical industry and federal government during the coverage gap; in percent

Years	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Beneficiary	100	50	50	47.5	47.5	45	45	40	35	30	25
Industry	0	50	50	50	50	50	50	50	50	50	50
Federal Government	0	0	0	2.5	2.5	5	5	10	15	20	25

Medicaid Provisions

- **Base Rebate**
  - Percentage for innovator drugs raised to 23.1%
  - Clotting factors and exclusively pediatric drugs increased to 17.1%
  - All revenue resulting from increases in rebate percentage is transferred to federal government
  - Effective January 1, 2010 (can be retroactively applied)
- **Reformulations**
  - Treats new formulations of an existing single source drug as the original single source drug for purposes of determining the base Medicaid rebate
- **Rebate liability** cannot exceed 100 percent of the average manufacturer price of a drug or biological.
  - Effective for sales after December 31, 2009.
- **Managed Care Organizations**
  - Rebates extended to managed care organizations (MCOs)
  - Increased revenue is transferred to the states
  - Effective upon enactment
- **Federal Upper Payment Limit (FUL) (Payment to Pharmacies)**
  - Set at no less than 175% of the weighted average (determined on the basis of utilization) of the most recently reported monthly average manufacturer prices for pharmaceutically and therapeutically equivalent multiple source drug products that are available for purchase by retail community pharmacies on a nationwide basis
  - Secretary shall implement a smoothing process for average manufacturer prices similar to the process used under ASP

Medicaid Provisions (cont.)

- **Average Manufacturer Price (AMP) Definition**
  - AMP definition includes the average price paid by wholesalers for drugs distributed to retail community pharmacies and retail community pharmacies that purchase drugs directly from the manufacturer
  - Excludes customary prompt pay discounts extended to wholesalers
  - Includes bona fide service fees paid to wholesalers or retail community pharmacies, including (but not limited to) distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative services agreements and patient care programs (such as medication compliance programs, patient education programs)
  - Reimbursements by manufacturers for certain types of recalled, damaged/expired goods, are excluded
  - Payments received from and rebates or discounts provided to, PBMs, MCOs, HMOs, insurers, hospitals, clinics, mail order pharmacies, LTC providers, manufacturers, or any other entity that does not conduct business as a wholesaler or a retail community pharmacy are all excluded
- **Healthcare-Acquired Conditions (HACs)**
  - Secretary shall identify State practices that prohibit payment for HACs and, through regulations, incorporate practices determined appropriate for application to Medicaid
  - Regulations shall prohibit payments to States for amounts spent providing medical assistance for HACs
  - Provision effective July 1, 2011

Medicare 340B Drug Discount Program

- **Expands 'Covered 340B Entities'** to include free-standing children's hospitals, certain cancer hospitals, rural referral centers, sole community hospitals and critical access hospitals
  - Orphan drugs are excluded from the program only in regards to new covered entities
- **Strengthens manufacturer oversight** and compliance requirements
  - Secretary to establish system to verify the accuracy of ceiling prices calculated by manufacturers and charged to covered entities
  - Secretary to establish system to establish procedures for manufacturers to issue refunds to covered entities in case of overcharge
- **Establishes reasonable exceptions** related to drug unavailability, generic drugs, and inventory administration to the prohibition on obtaining covered outpatient drugs through a group purchasing organization or other group purchasing arrangements
- **Regulations.**
  - Secretary shall promulgate regulations 180 days after enactment to improve program integrity and oversight of expanded 340B programs, including imposition of civil monetary penalties
  - Secretary shall promulgate regulations to establish and implement an administrative process for the resolution of claims by covered entities that they have been overcharged for purchased drugs, and claims by manufacturers, including appropriate procedures for remedies and enforcement

Biosimilars: Pathway & Reimbursement

- **Biosimilar Pathway**
  - Provides a FDA pathway for biosimilars and interchangeable biosimilars
  - Provides requirements for applications and safety standards
  - Extends 12 years data exclusivity for reference products, 6 additional months for conducting pediatric studies
  - Requires new notification and exchange program for related patents
  - Secretary may, after opportunity for public comment, issue guidance with respect to the licensure of biosimilar products and such guidance may be general or class-specific
    - If class-specific guidance is issued, it must meet certain enumerated criteria
  - Secretary shall develop recommendations for user fees and review goals for biosimilars similar to PDUFA and MDUFMA
    - Recommendations to be implemented Oct. 1, 2012
  - Secretary shall develop recommendations for Congress regarding goals and plans for the process for review of biosimilar product applications
    - Secretary shall consult with others, such as committees of Congress, experts and industry
    - Development of recommendations no later than Oct. 1, 2010
    - Transmittal of recommendations no later than Jan. 15, 2012
- **Payment for Biosimilars**
  - Provides for separate billing codes for Part B biosimilar products
  - Reimbursement for biosimilar equals ASP of the biosimilar + 6% of the ASP of the reference product

Generic Drugs

- **Reduces beneficiary coinsurance** in the Part D coverage gap for generics to 93% in 2011 and decreases by 7 percentage points each year until 2020, when it becomes and remains 25%
- **Increase the Medicaid rebate** for generics from 11 percent to 13 percent of AMP beginning January 1, 2010 (can be applied retroactively)
- **Generic First Fill.** Effective after December 31, 2010, Part D plans may offer the first fill of a generic drug to enrollees with a reduced or no cost sharing.

Medication Therapy Management

- **MTMP**. Requires prescription drug plans (PDPs) to enroll target beneficiaries in medication therapy management programs (MTMPs), with an ability to opt-out, to increase medication adherence
  - Under current law, target beneficiaries have multiple chronic diseases, are taking multiple Part D drugs, and are likely to incur annual costs for covered Part D drugs that exceed a pre-determined level as specified by the Secretary
- **Annual & Quarterly Review.** MTMPs must include an annual medication review, possibly a medication action plan or other result, and necessary follow-up interventions for each beneficiary.
  - PDPs required to assess medication use of at-risk beneficiaries every quarter.
- **Effective Date.** Effective for plan year beginning 2 years after enactment

Part D Protected Classes

- **New Classes.** Provides HHS with authority to identify classes of clinical concern as defined by the Secretary through the promulgation of a regulation which includes a public notice and comment period.
- **Codifies the current 6 classes** – anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals and immunosuppressants for treatment of transplant rejection – requiring substantially all of these therapies to be covered.
- **Effective Date.** Effective for plan year 2011.

Prescription Drug Labeling – "Drug Facts Box"

- **Drug Facts Box Report.** Not later than 1 year after the date of enactment, requires the Secretary of HHS, through the Commissioner of FDA, to submit to Congress a report on presentation of prescription drug benefit and risk information.
  - The Secretary, acting through the FDA Commissioner, shall determine whether additional quantitative summaries of the benefits and risks of prescription drugs in a standardized format (such as table or drug facts box) to promotion labeling or print advertising of such drugs would improve healthcare decision making by clinicians, patients, and consumers.
  - In making such determination, the Secretary shall review all scientific evidence and research on decision making and social and cognitive psychology and consult with drug manufacturers, clinicians, patients and consumers, experts in health literacy, representatives of racial and ethnic minorities, and experts in women's and pediatric health.
- **Regulations.** Requires the Secretary to promulgate regulations as necessary to implement such standardized formats.
- **Effective Date.** Regulations must be promulgated not later than 3 years after the report.

Coverage of Preventive Services

- **Private Insurance**
  - Insurers must provide coverage for, and not impose any cost-sharing requirements for items or services that have a rating of 'A' or 'B' in the current recommendations of the U.S. Preventive Services Task Force (USPSTF); immunizations that have a recommendation from the Advisory Committee on Immunization Practices (ACIP) of the CDC; with respect to infants, children and adolescents, preventive care and screenings provided for in guidelines supported by the HRSA; and preventive care and screening for women as determined by HRSA.
  - Does not prohibit a plan or issuer from providing coverage for services in addition to those recommended by the USPSTF or from denying coverage for services that are not recommended by the USPSTF.
  - Effective six months after enactment, except for plans that existed as of date of enactment ("grandfathered plans").
- **Medicare:**
  - Medicare must provide coverage for, and not impose cost-sharing requirements for items or services rated 'A' or 'B' by the USPSTF.
  - Beginning Jan. 1, 2010, the Secretary may modify coverage of any preventive service to the extent consistent with USPSTF recommendations, as well as the services included in the initial physical examination, and may withdraw Medicare coverage for services not rated A, B, C, or I.
- **Expands Medicaid coverage of preventive services**
  - Effective Jan. 1, 2013, state option to cover and waive cost-sharing for any clinical preventive services that are assigned a grade of 'A' or 'B' by the USPSTF, and approved vaccines recommended by ACIP.
  - States who choose the option receive a 1% FMAP increase.

INDUSTRY TAXES & FEES

Pharmaceutical Industry Excise Tax

- **Impact.** Establishes an aggregate annual fee to total $2.5 billion in 2011; $2.8 billion for 2012-2013; $3 billion for 2014-2016; $4 billion for 2017; $4.1 billion for 2018; and $2.8 billion for 2019 and thereafter
- **Determination**
  - Fee to be apportioned among those manufacturing or importing branded prescription drugs for sale in the U.S.
  - Based on prior year federal program sales under Medicare Part D, Medicare Part B, Medicaid, the VA, and TRICARE
  - Individual assessment for each calendar year is the total fee multiplied by the ratio of (1) the covered entity's branded prescription drug sales taken into account during the preceding calendar year to (2) the aggregate branded prescription drug sales of all covered entities taken into account during such preceding calendar year
  - Orphan drugs are exempt from calculation of sales
- **Calculation**
  - 0% of a covered entity's branded prescription drug sales for the preceding calendar year up to $5 million
  - 10% of sales between $5 million and $125 million
  - 40% of sales from $125 million to $225 million
  - 75% of sales from $225 million to $400 million
  - 100% of sales over $400 million
  - Fees collected are credited to the Medicare SMI trust fund
  - Fees are nondeductible for income tax purposes
- Secretary shall publish separate **guidance documents** to carry out the imposition of annual fees

Medical Device Tax & Insurer Fees

- **Medical Devices**
  - Imposes an excise tax on medical devices equal to 2.3 percent of the price of the device beginning in 2013
  - Assessed on all FDA approved devices except eyeglasses, contact lenses, hearing aids, and other devices that are sold to the general public at retail establishments
- **Insurance Provider Annual Fee**
  - Imposes an annual fee on any health insurance provider beginning in 2014
  - The aggregate annual fee for all providers would be $8 billion for 2014; $11.3 billion for 2015-2016; $13.9 billion for 2017; and $14.3 billion for 2018 and thereafter
  - Exempts voluntary employee benefit association and non-profits that receive more than 80 percent of gross revenues from government programs that target low-income, elderly, and disabled populations

Mandates and Taxes on Employers

- **Employer mandates.** Employers with more than 50 full-time employees can be assessed a penalty of $2000 per employee for not offering "affordable" coverage to their workers
- **High-Cost Employer-Sponsored Health Insurance ("Cadillac Plans")**
  - Imposes an excise tax on insurers if aggregate value of employer-sponsored health coverage for an employee exceeds a threshold amount
  - For 2018, the threshold amount would be $10,200 for individuals and $27,500 for families (indexed for inflation)
    - Increases the threshold for individuals who are retirees or work in certain high-risk fields
    - Allows adjustments for employers with significantly different age/gender employee compositions from the national workforce
  - Tax is equal to 40 percent of the aggregate value that exceeds the threshold amount
- **Retiree Drug Coverage Subsidy**
  - Effective 2013, the subsidy will be considered income and subject to taxation.

PAYMENT REFORM

CMS Innovation Center

- **Establishes a Medicare and Medicaid Innovation Center within CMS**
  - Center to test innovative payment and service delivery models to reduce program expenditures under Medicare, Medicaid, and CHIP while preserving or enhancing the quality of care furnished to individuals under such titles
  - Secretary may establish requirements for States and other participating entities to collect and report information that the Secretary determines necessary to monitor & evaluate models
  - Established no later than January 1, 2011
  - PHASE I testing where there are deficits in care, according to 16 specified care management and utilization efficiency characteristics and related to 7 factors
  - CMS is allowed to expand duration and scope of models or issue demonstrations if CMS determines that such expansion would reduce spending without reducing the quality of patient care
- **Funding**
  - Transfer from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund of $10 billion for FY11 – FY19
  - Funding remains until expended
- **Report to Congress**
  - Report due each year starting in 2012 on (1) the models tested (2) models chosen for expansion, (3) the results from evaluations, and (4) recommendations for legislative action to facilitate the development and expansion of successful payment models

Independent Payment Advisory Board (IPAB)

- **Overview.** Establishes 15-member IPAB tasked with presenting, beginning in 2014, the President and Congress with comprehensive proposals to reduce the per capita rate of growth in Medicare spending and to improve quality of care for Medicare beneficiaries.
  - Medicare spending defined as Medicare A, B and D net of premiums

- **Annual Proposals**. If the CMS Chief Actuary determines that the projected Medicare per capita growth rate exceeds the target growth rate for a year, the Board must make an annual recommendation by January 15, beginning in 2014, to reduce the projected Medicare growth rate.
  - Proposals may not reduce Medicare benefits or change eligibility, increase the Part B premium, raise taxes, or ration care.
  - Proposals submitted prior to Dec. 31, 2018 shall not include any recommendation that would reduce payment rates for providers, such as hospitals, already subject to productivity adjustments.
  - HHS is required to implement the Board's recommendations unless Congress enacts alternative measures (which can be considered on a fast track basis) that achieve the same level of savings.

- **Biennial Recommendations.** The Board is also tasked with making advisory recommendations to Congress and the President for non-Federal health care programs
  - Beginning in 2020, and biennially thereafter, the Board shall, if the CMS Actuary has made a determination that the projected growth rate of national health expenditures exceeds the Medicare growth rate, design its proposal to help reduce the growth rate in national health expenditures (in the private health care system) while maintaining or enhancing Medicare beneficiary access to quality care.

IPAB (cont.)

- **Consumer Advisory Council**
  - The Council, composed of 10 consumer representatives appointed by the Comptroller General, shall be established to advise the IPAB on the impact of Medicare payment policies on consumers, and shall be subject to the Federal Advisory Committee Act.
- **Funding**
  - Congress shall appropriate to the IPAB $15,000,000 for FY 2012.
  - For each subsequent fiscal year, the amount appropriated for the previous fiscal year increased by the annual percentage increase in the CPI for All Urban Consumers as of June of the previous year.
- **GAO Studies and Reports**
  - GAO is required to conduct a study on changes to payment policies, methodologies, and rates and coverage policies and methodologies under Medicare as a result of IPAB's recommendations, and not later than July 1, 2015, the Comptroller General shall submit a report to Congress.
- **Annual Public Report**
  - Not later than July 1, 2014, and annually thereafter, the Board shall produce a public report containing standardized information on system-wide health care costs, patient access to care, utilization, and quality of care that allows for comparison by region, types of services, types of providers, and both private payers and Medicare.

Medicare National Payment Bundling Pilot Program

- **Pilot program for integrated care** during an episode of care provided to a beneficiaries in Medicare parts A and B, around a hospitalization
- **Applicable services** include acute care inpatient services, physicians' services delivered in and out of an acute care hospital setting, outpatient hospital services (including emergency department services), post-acute care services, and other services determined by the Secretary
- **Quality measures** include functional status improvement, reducing rates of avoidable hospital readmissions, rates of discharge to the community, rates of admission to an emergency room after hospitalization, incidence of health care acquired infections, efficiency measures, measures of patient-centeredness of care and perception of care, and other measures determined by the Secretary
- **Effective Date.** 5-year program must begin no later than 2013, and the Secretary may extend the program for a period determined by the Secretary beginning in 2016
- **Reports.** Interim report due to Congress 2 years after implementation of the program; final report due 3 years after implementation of the program

Accountable Care Organizations

- **Medicare.** Beginning in 2012, 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
- **Medicaid.** Requires the Secretary of HHS to establish a Medicaid demonstration project to allow pediatric providers to be recognized as ACOs under Medicaid and to share in savings for services which are provided at a lower cost by the ACO from 2012 - 2016

Medicare Gainsharing Demonstration Project

- **Gainsharing Demonstration**. Extends the Medicare gainsharing demonstration project through 2014 to improve the quality and efficiency of care provided to beneficiaries
- **Purpose.** The gainsharing demonstration program is designed to test and evaluate new payment methodologies and financial arrangements between hospitals and physicians to improve the quality and efficiency of care provided to beneficiaries and to develop improved operational and financial hospital performance
- **Share of Savings.** Through the innovative hospital-physician financial agreements, physicians are rewarded with a share of the hospital savings achieved by the physician's delivery of more efficient and higher quality care

Medical Homes

- **Medical Homes.** Beginning in 2011, allows state Medicaid plans to provide medical homes for coordinating care for patients with chronic diseases, requires states to develop a payment methodology for the medical home model, and provides grants to states for medical home models
- **Grants.** Requires the Secretary to provide grants to eligible entities to establish community-based, interdisciplinary, interprofessional teams ("health teams") to support primary care practices which provide patient-centered medical homes
- **Reports.** Plans participating in a State Exchange must periodically report to the Exchange their activities related to improving quality, including medical home models,

Drug Coding & Reimbursement

- **Misvalued Codes.** Requires the HHS Secretary to review Medicare physician fee schedule payment rates to identify services as being potentially misvalued
- **Misvalued Codes.** Requires the Secretary to examine codes for services that have experienced recent high growth or substantial changes in practice expenses
- **Adjust Fee Schedules.** Provides increased authority to the Secretary to adjust fee schedule rates that are found to be misvalued or inaccurate
- **No Changes to ASP.** No changes to ASP payment methodology or rate for drug or biologics administered in a physician office setting
- **No Change to CAP.** No changes to competitive acquisition program (CAP)

Changes to Medicare Advantage Payments

- **Changes for 2011**:
  - *2011 county rates:* County rates for 2011 would be frozen at 2010 levels.
  - *2011 coding intensity adjustment:* The requirement for a coding intensity adjustment would be permanently extended, and for 2019 and subsequent years, the adjustment factor could be no less than 5.7%.
- **Changes for 2012 and future years**:
  - *Phase-in of modified benchmarks:* New payment rates would be phased in over 2 years (2012 – 2013) and would be determined by adjusting base payment amounts according to the assignment of counties to quartiles reflecting relative underlying county FFS costs.
  - *Quality adjustment:* Beginning in 2012, quality adjustments to base payment amounts would apply for 4 – 5 star plans and for other plans, at the Secretary's discretion, if they make "meaningful improvement" in their quality scores.
  - *Cap on rates:* New payment rates (with quality bonuses included) could not exceed rates that would have applied under current law.

Overall Affect on Physician Reimbursement

- **Medicare**:
  - No permanent or temporary fix to sustainable growth rate
  - Expanded financial incentives for quality outcomes and adoption of health information technology
  - Increased payments available for primary care physicians who provide preventative services
  - Transition away from fee for service model to bundle payments based on outcomes.
- **Medicaid:**
  - Similar to Medicare, incentives put in place to promote quality of care and coordination of care
- **Other:**
  - Beginning in fiscal year 2011, five year demonstration grants are available to states to develop, implement and evaluate alternatives to current tort litigations.

PBM Reporting Requirement

- **PBM shall report the following information to HHS**:
  - The percentage of all prescriptions that were provided through retail pharmacies compared to mail order pharmacies, and the percentage of prescriptions for which a generic drug was available and dispensed (generic dispensing rate), by pharmacy type that is paid by the health benefits plan or PBM under the contract.
  - The aggregate amount, and the type of rebates, discounts, or price concessions (excluding bona fide service fees, which include but are not limited to distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative services agreements and patient care programs (such as medication compliance programs and patient education programs that the PBM negotiates that are attributable to patient utilization under the plan, and the aggregate amount of the rebates, discounts, or price concessions that are passed through to the plan sponsor, and the total number of prescriptions that were dispensed.
  - The aggregate amount of the difference between the amount the health benefits plan pays the PBM and the amount that the PBM pays retail pharmacies, and mail order pharmacies, and the total number of prescriptions that were dispensed.
- **Confidentiality**
  - Information disclosed by the PBM is confidential and shall not be disclosed by the Secretary or by a plan receiving the information, except that the Secretary may disclose the information in a form which does not disclose the identity of a specific PBM, plan, or prices charged for drugs, under specified circumstances; for example, for review by the GAO and CBO.

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ADDITIONAL PROVISIONS

Comparative Effectiveness Research
Health Information Technology
Physician Payment Sunshine Act
Employer Wellness Programs
Cures Acceleration Network
Coverage of Clinical Trials
Improving the Quality of Care
Addressing Primary Care & Workforce Shortages
Private Insurance Reforms

Comparative Effectiveness Research

- Establishes **nonprofit corporation ('Institute')** to assist patients, clinicians, purchasers & policy makers in making health decisions
  - Terminates the Federal Coordinating Council for Comparative Effectiveness Research
  - Institute conducts research that would compare the clinical effectiveness, risk and benefits of two or more medical treatments, services or items
  - Defines treatment, services and items as: health care interventions, protocols for treatment, care management and delivery, procedures, medical devices, diagnostics tools, pharmaceuticals and any strategies or items used in the treatment, management and diagnosis of or prevention of illness or injury, in patients.
- **Duties of Institute**
  - Identify priorities, carry out research agenda, study the feasibility of conducting research in-house
  - Collect appropriate data from CMS, appoint advisory panels, support patient & consumer representatives, establish a methodology committee
  - Provide for a peer-review process, release research findings, coordinate research, and submit annual reports to the Congress, the President and the public
  - Includes preference in the contracting process for AHRQ & NIH, so long as research is authorized by governing statutes.
- **Funding**
  - Creates a Trust Fund to provide funding for the Institute
  - Amounts equal to $600M/year, which would come from mandatory appropriations, and a $2 per capita fee on Medicare trust fund and private insurers
  - Twenty percent of the funds in the Fund to go the Secretary to carry out this section the below Office of Communication; and of the 20%, 80% goes to AHRQ and 20% stays with the Secretary

CER (cont.)

- **Board of Governors**
  - The Institute's board shall consist of the Director of the AHRQ, NIH and 19 other members appointed not later than six months after enactment by the Comptroller General. These 19 members shall consist of: 3 members representing patients and health care consumers, 7 members representing physicians and providers, 3 members representing private payers, 3 members representing pharmaceutical, device and diagnostic manufacturers, and 2 members representing the Federal Government or the States.
- **Transparency/Patient Protections**
  - Ensures that research is designed to take into account potential differences in outcomes among different subpopulations
    and different characteristics of treatment modalities
  - Precludes the Institute from mandating coverage, reimbursement or other polices for any public or private payer
  - Ensures that none of the reports or findings are construed as mandates, guidelines, or policy recommendations
  - Establishes limitations around the use of the Institute's research findings which include: 1) requiring the Secretary to use an iterative and transparent process when using the research in making coverage determinations; 2) allows stakeholders to provide information to inform the determination, review draft proposals and submit public comments on draft proposals; and 3) prohibits Secretary from using the Institute's research as sole evidence in making a determination.

Health Information Technology

- **Build on ARRA.** The new rules build on the $19 billion in funding for health information technology and HITECH Act, as well as HIPAA, but are substantially different
  - Accelerate HHS adoption of uniform operating rules for electronic administrative transactions between providers and plans
  - Support the current private, voluntary effort underway and supported by Merck and other companies to eliminate administrative paper in the health care
- **Regulations.** Requires the Secretary to adopt and promulgate rules for electronic administrative health insurance transactions.
  - Rules for health plan eligibility, coverage and claim status by 2011 and implemented by plans by 2013
  - Rules for remittance and electronic fund transfer by 2012 and implemented by plans by 2013
  - Plans implement operating rules for enrollment, payment and other administrative activities by 2016
- **HIT Committee.** The Secretary is required to establish a committee to conduct hearings to evaluate and review the adopted standards and operating rules.
- **Penalty Fees.** By April 1, 2014, the Secretary must assess a penalty fee against a health plan that has failed to meet these requirements
  - The penalty fee is $1 per covered life, for each day that a plan is not in compliance

Physician Payments Sunshine Act

- **Industry Reports.** Requires disclosure of manufacturer payments or other transfers of value provided to physicians and teaching hospitals.
  - Reporting threshold: $10 or annual $100 aggregate
- **Preemption.** Preempts only state laws/ regulations that require reporting of the same information.
- **Payment reporting**
  - Annual reporting beginning March 31, 2013
  - Starting September 30, 2012 and on June 30 of subsequent years, submitted information to be available on an Internet website
  - HHS OIG to issue a report on effect and HHS to issue an annual report starting in 2013
  - Delayed reporting for clinical trials
  - Includes a number of exemptions to reporting requirements, including samples, discounts, rebates, etc.
- **Penalties**
  - Manufacturers or group purchasing organizations subject to a civil money penalty of $1K-$10K for each unreported payment/transfer; total to not exceed $150K for any annual submission
  - Knowing failure increases fines to $10K-$100K and maximum is the greater of $1 million or 0.1% of annual revenues of manufacturer

Employer Based Wellness Programs

- **Codifies HIPAA non-discrimination regulations** to allow rewards to be provided to employees for participation in or for meeting certain health standards related to a wellness program
  - Allows the award for participating in a wellness program to include insurance premium discounts, rebates or waiver of cost-sharing
- **HIPAA Compliance.** Provides that wellness programs that provide rewards based on an individual satisfying a standard that is related to a health factor do not violate the HIPAA non-discrimination rules if certain requirements are met
  - Caps reward at 30% of the employee-only coverage under the plan, but provides protections for plan participants that cannot meet the applicable standard due to a medical condition or because it is medically inadvisable to do so
  - Provides Secretaries of HHS, Labor and Treasury discretion to increase the reward to 50% if they deem it is appropriate
- **Demonstration Project.** Establishes 10-state demonstration project to begin not later than July 1, 2014 whereby states would receive grants to support wellness programs
  - Provides discretion to Secretaries to expand the demonstration project July 1, 2017
  - Regulations may be promulgated
  - Report to Congress on the program due within 3 years of the Act's promulgation.

Cures Acceleration Network (CAN)

- **CAN.** Creates the Cures Acceleration Network (CAN) within the Office of the Director of NIH to follow recommendations of the new CAN Review Board and award grants to accelerate high need cures
- **FDA Collaboration.** Meant to speed up specific research and development goals, coordinate and facilitate FDA review
- **Translation Research.** Tasked with identifying translational barriers to product development and submitting reports on each barrier
- **Eligible Entity.** An eligible entity can be a public or private entity, which may include a private or public research institution, an institution of higher education, a medical center, a biotechnology company, a pharmaceutical company, a disease advocacy organization, a patient advocacy organization, or an academic research institution.

Coverage for Individuals Participating in Clinical Trials

- **Routine Patient Costs.** Requires group and individual plans to cover routine patient costs of qualified individuals who participate in clinical trials.
  - Excludes costs for the investigational item, device or service itself; items and services that are provided solely to satisfy data collection and analysis needs and that are not use in the direct clinical management of the patient; and a service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis.
- **No Discrimination.** Prohibits discrimination against an individual based on his/her participation in the trials.
- **"Qualified individual"** means a participant or beneficiary in a health plan or with coverage who is eligible to participate in an approved clinical trial with respect to treatment of cancer or other life-threatening disease or condition; and either
  - (A) the referring health care professional is a participating provider and has concluded the individual's participation would be appropriate; or
  - (B) the participant or beneficiary provides medical and scientific information establishing that his or her participation in such trial would be appropriate based on his or her condition.
- Requirement does not apply to services outside of the plan's health care provider network unless those services are otherwise provided under the plan.
- **"Approved clinical trial"** means a phase I, II, III, or IV clinical trial that is conducted in relation to the prevention, detection, or treatment of cancer or other life-threatening disease or condition and funded by one of the entities enumerated in the provision, including, e.g. NIH, CDC, AHRQ, CMS, or a cooperative group or center of any of the above.

Improving the Quality of Care

- **Prevention.** Establishes the Prevention, Health Promotion, and Public Health Council established within HHS to provide coordination and leadership among all Federal agencies with respect to prevention, wellness, and health promotion practices.
- **Public Health.** Beginning in FY2010, establishes the Prevention & Public Health Fund to expand and sustain national investment in prevention and public health programs.
- **National Quality Strategy.** By Jan. 1, 2011, requires HHS to develop the National Strategy on Health Care Quality to improve the delivery of health care services, patient health outcomes, and population health. Pursuant to the National Quality Strategy, authorizes $75M over 5 years for AHRQ and CMS to develop quality measures.
- **Quality Measures.** In addition to the National Quality Strategy:
  - Authorizes $20M for AHRQ (FY2010-2014) to identify, develop, evaluate, disseminate, and provide training in innovative methodologies and strategies for quality improvement practices in the delivery of health cares services.
  - Requires HHS to develop and publicly report on patient outcome measures and adult health care quality measures by Jan. 1, 2012.
- **Minority Health.** Codifies the Office of Minority Health within the Office of the Secretary of HHS and creates new Offices of Minority Health within HHS agencies, such as CDC, SAMSHA, HRSA, AHRQ, CMS, NIH, and FDA.

Addressing Primary Care & Workforce Shortages

- **National Health Care Workforce Commission**. Establishes a 15-member, national commission tasked with reviewing health care workforce and projected workforce needs.
- **Primary Care.** Creates a Primary Care Extension Program and a grant program to states through AHRQ to educate and provide technical assistance to primary care providers about evidence based therapies, preventive medicine, health promotion, chronic disease management, and mental health.
- **Workforce Grant Programs.** Establishes at HRSA the Rural Physician Training Grants program, the Preventive Medicine and Public Health Training Grant Program, and a grant program to support nurse-managed health clinics.

Private Insurance Reforms

Amends the ERISA, PHSA, and Internal Revenue Code to enact the following reforms:

Six Months After Enactment IN ALL PLANS:

- Lifetime insurance caps eliminated
- Coverage extended to a beneficiary's dependents under age 26 (unless the child is eligible for employer-based coverage) Insurers prohibited from excluding coverage of pre-existing conditions for enrollees under age 19
- Prohibits rescission of a plan or coverage once an enrollee is covered, except in the case of fraud

January 1, 2014:

- Annual limits eliminated ("restricted" annual limits permitted through 2014, to be defined by the Secretary), except for existing ("grandfathered") individual plans
- Prohibits an insurer from establishing eligibility rules for enrollment based on health status-related factors, except for existing ("grandfathered") plans
- Insurers offering individual or small group plans in a State must accept every employer and individual that applies for coverage in the State, and must offer coverage on a guaranteed renewability basis, except for existing ("grandfathered") plans
- An insurer that offers coverage in the individual or small group market must include the "essential health benefits package", to be defined by the Secretary
  - January 1, 2014 for plans offered in the Exchange
  - January 1, 2014 for plans offered outside the Exchange, except for existing ("grandfathered") plans
  - Large group plans are exempt until they are offered through a State Exchange, which may begin in 2017
- Insurers prohibited from excluding coverage of pre-existing conditions for enrollees over age 19 in all plans

***Grandfathered Plans**: A group health plan or health insurance coverage in which an individual was enrolled on the date of enactment, regardless of whether the individual renews such coverage after such date of enactment. Enrollment of family members and new employees in grandfathered plans does not affect the exemption from insurance reforms, i.e. such plans remain exempt. (See Sec. 1251)*

Timeline of Key Provisions