



Health Reform

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

Key Provisions

■ 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 (Pub L. No. 111-148)

■ 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 26, 2010 with minor technical amendments, to which the House concurred.
- The President signed the reconciliation bill into law on March 30, 2010

■ This presentation reflects the Patient Protection & Affordable Care Act as amended by the Reconciliation Act

COVERAGE →

- Insures 32 million uninsured
- 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 "Americans Health Benefit Exchange"	National Plan	Medicare	Medicaid/CHIP	Mandates
<ul style="list-style-type: none"> ▪ Temporary high-risk pool for uninsured with pre-existing conditions ▪ Terminates in 2014 when Exchanges are established 	<ul style="list-style-type: none"> ▪ 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 coverage offered in 2014; large group in 2017 	<ul style="list-style-type: none"> ▪ 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 plan 	<ul style="list-style-type: none"> ▪ Temporary reinsurance program for 55-64 aged ▪ Terminates in 2014 when Exchanges are established 	<ul style="list-style-type: none"> ▪ Effective 2014, expanded to 133% of federal poverty level (FPL) ▪ Federal matching rate for states to cover newly-eligible individuals ▪ CHIP matching rates increased 	<ul style="list-style-type: none"> ▪ Individual mandate begins 2013 ▪ Employer mandate begins 2014 for employers with over 50 employees

PRESCRIPTION DRUGS

- Closes the Part D Coverage Gap (Donut Hole)
- Increases the Medicaid Rebate, Revises Application of Medicaid Rebate to Reformulations, and Expands to Managed Care
- Expands the Medicare 340B Drug Discount Program to New Covered Entities
- Establishes a FDA Approval Pathway for Biosimilars
- Generic Drugs: Medicaid Rebate & Part D Coverage Gap
- Increases Medication Adherence through Part D Medication Therapy Management Programs
- Codifies the Current Part D Protected Classes
- Requires HHS Secretary Review of Drug Labeling

INDUSTRY TAXES & FEES

- Establishes an Industry Tax on Pharmaceuticals and Medical Devices
- Imposes an Annual Fee on Insurance Providers
- Creates Employer Mandates and Taxes on High-Cost Plans

PAYMENT REFORM

- Establishes a Non-Profit Corporation to Conduct Comparative Effective Research
- Establishes a Medicare & Medicaid Innovation Center within CMS
- Creates an Independent Payment Advisory Board (IPAB)
- Implements a National Pilot Program on Payment Bundling
- Excludes Medicare Advantage from Low-Income Subsidies
- Rewards Accountable Care Organizations for Quality of Care and Reducing Costs
- Extends Gainsharing Demonstration Project
- Encourages Development of Medical Homes

ADDITIONAL PROVISIONS

- Requires Increased Disclosure of Physician Payments
- Establishes Employer Wellness Based Programs
- Creates the Cures Acceleration Network at NIH
- Implements Insurance Reforms

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
- 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
 - Reduces beneficiary obligation 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%
- 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

- **Base Rebate**
 - Percentage for innovator drugs raised to 23.1%
 - Clotting factors and exclusively pediatric drugs increased to 17.1%
 - 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
 - Non-oral solid dose multi-source drugs are exempt
- **Managed Care Organizations**
 - Rebates extended to managed care organizations (MCOs)
 - Effective upon enactment
- **Federal Upper Payment Limit (FUL)**
 - 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 Manufacturing 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, rural referral centers, certain 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
- 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
- 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

■ 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 6% of ASP of reference product

Generic Drugs

- 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%
- Increase the Medicaid rebate for generics from 11 percent to 13 percent of AMP beginning January 1, 2010 (can be applied retroactively)

Medication Therapy Management

- 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
- MTMPs must include an annual medication review, possibly a medication action plan or other result, and necessary follow-up interventions
- PDPs required to assess medication use of at-risk beneficiaries every quarter
- Effective for plan year beginning 2 years after enactment

Part D Protected 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 for plan year 2011

Prescription Drug Labeling

- Not later than 1 year after the date of enactment, the Secretary shall submit to Congress a report on presentation of prescription drug benefit and risk information
 - 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
- Secretary shall promulgate regulations as necessary to implement such standardized formats
- Regulations must be promulgated not later than 3 years after the report

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 federal program sales
 - 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
- **Provides a new joint and several liability provision**
- **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

PAYMENT REFORM



Comparative Effectiveness Research

Non-Profit Institute

- Conducts/outsources research to compare the clinical effectiveness, risk and benefits of two or more medical treatments, services or items
- Scope includes: healthcare 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: identify priorities, carry out research agenda
- AHRQ & NIH are preferred research partners

Transparency/Patient Protections

- Meant to ensure that potential differences in outcomes among different subpopulations and different characteristics of treatment modalities are taken into account
- Precludes the Institute from mandating coverage, reimbursement or other policies for any public or private payer
- Establishes limitations to: 1) require the use of an iterative and transparent process when using the research in making coverage determinations; 2) allow stakeholders to provide information to inform the determination, review draft proposals and submit public comments on draft proposals; and 3) prohibit HHS from using the Institute's research as sole evidence in making a determination.

Funding/Misc.

- \$600M/year: from mandatory appropriations, Medicare trust funds and health plan fee
- AHRQ Office of Communication and Knowledge Transfer designated as the key agency for the dissemination of Institute's research findings
- Terminates the Federal Coordinating Council for Comparative Effectiveness Research

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

- 15 Members Appointed by President, with advice and consent of Senate, to 6-year terms (HHS, CMS and HRSA included)
- Tasked with presenting Congress with comprehensive proposals to reduce the per capita rate of growth in Medicare spending (i.e., A, B and D net of premiums) and to improve quality of care for Medicare beneficiaries
- If Medicare per capita growth rate exceeds the target growth rate for a year, the Board must make recommendations to reduce the projected growth rate

Trigger & Methodology

- Board's "savings target" is the lesser of 1.5% of total Medicare spending (increasing gradually from 0.5% beginning in 2015 over a four-year period) or the excess identified by the CMS Actuary
- Board proposal to detail its recommendations to reduce Medicare spending by targeted amounts and a legislative proposal to accomplish such
- Proposals can not reduce Medicare benefits or change eligibility, increase the Part B premium, raise taxes, or ration care
- Proposals cannot consider institutional providers and physicians prior to December 31, 2019.

Review and Implementation

- Proposals must be submitted to the President by January 15 of each year and to Congress by March 1, beginning 2014
- HHS required to implement the Board's recommendations unless Congress enacts alternative measures that achieved the same level of savings
- Alternative provision would be considered on a fast-track basis by Congress

National Payment Bundling Pilot Program

- Secretary shall develop requirements for entities to participate in a national pilot program on payment bundling in Medicare
 - No date specified
- Secretary shall submit a plan, not later than January 1, 2016, for the implementation of the pilot program if the Secretary determines that the result will be to improve quality of patient care and reduce overall spending

Low Income Subsidies

- Requires Secretary to exclude Medicare Advantage rebates and bonus payments from the MA-PDP premium amount when calculating the regional LIS benchmarks
- Effective 2011
- For plan years beginning in 2011, LIS beneficiaries must be informed within 30 days of automatically reassignments to a new plan regarding formularies, coverage determination, and waiver/grievance processes

Accountable Care Organizations

- 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
- 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

Gainsharing Demonstration Project

- Extends the Medicare gainsharing demonstration project through 2014 to improve the quality and efficiency of care provided to beneficiaries
- 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
- 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

- 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
- 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
- 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

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

ADDITIONAL PROVISIONS

Physician Sunshine Payment Act
Employer Wellness Programs
Cures Acceleration Network
Private Insurance Reforms

Physician Payment Sunshine Act

- Requires disclosure of any drug, device, biological or medical supply, and any other category of information that the Secretary determines appropriate
- Preempts related state laws or regulations
- Reporting threshold: \$10 or annual \$100 aggregate
- 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
 - Samples, discounts, etc. are exempt
- 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
- 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
- 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)

- 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
- Meant to speed up specific research and development goals, coordinate and facilitate FDA review
- Tasked with identifying translational barriers to product development and submitting reports on each barrier

- **Six Months After Enactment:**

- Eliminates lifetime insurance caps
- Expands coverage to dependants
- Eliminates cost-sharing for preventive services that have a rating of ‘A’ or ‘B’ from the U.S. Preventive Services Task Force; immunizations that have a recommendation from the Advisory Committee on Immunization Practices of the CDC; and, with respect to infants, children, and adolescents, preventive care & screenings provided for in guidelines supported by HRSA
- Prohibits plan rescissions

- **Effective in 2014:**

- Eliminates annual insurance caps
 - “Restricted” annual caps permitted through 2014
- Prohibits discrimination based on health status
- Prohibits pre-existing condition exclusion in 2014
 - For enrollees in new plans under age 19, effective 6 months after enactment
- Allows insurers offering individual or small group plans to base premium rates only on: whether such plan or coverage covers an individual or family; age (3:1); tobacco use (1.5:1), and geographic area based on rating areas as defined by the State and reviewed by the Secretary

Timeline of Key Provisions

