

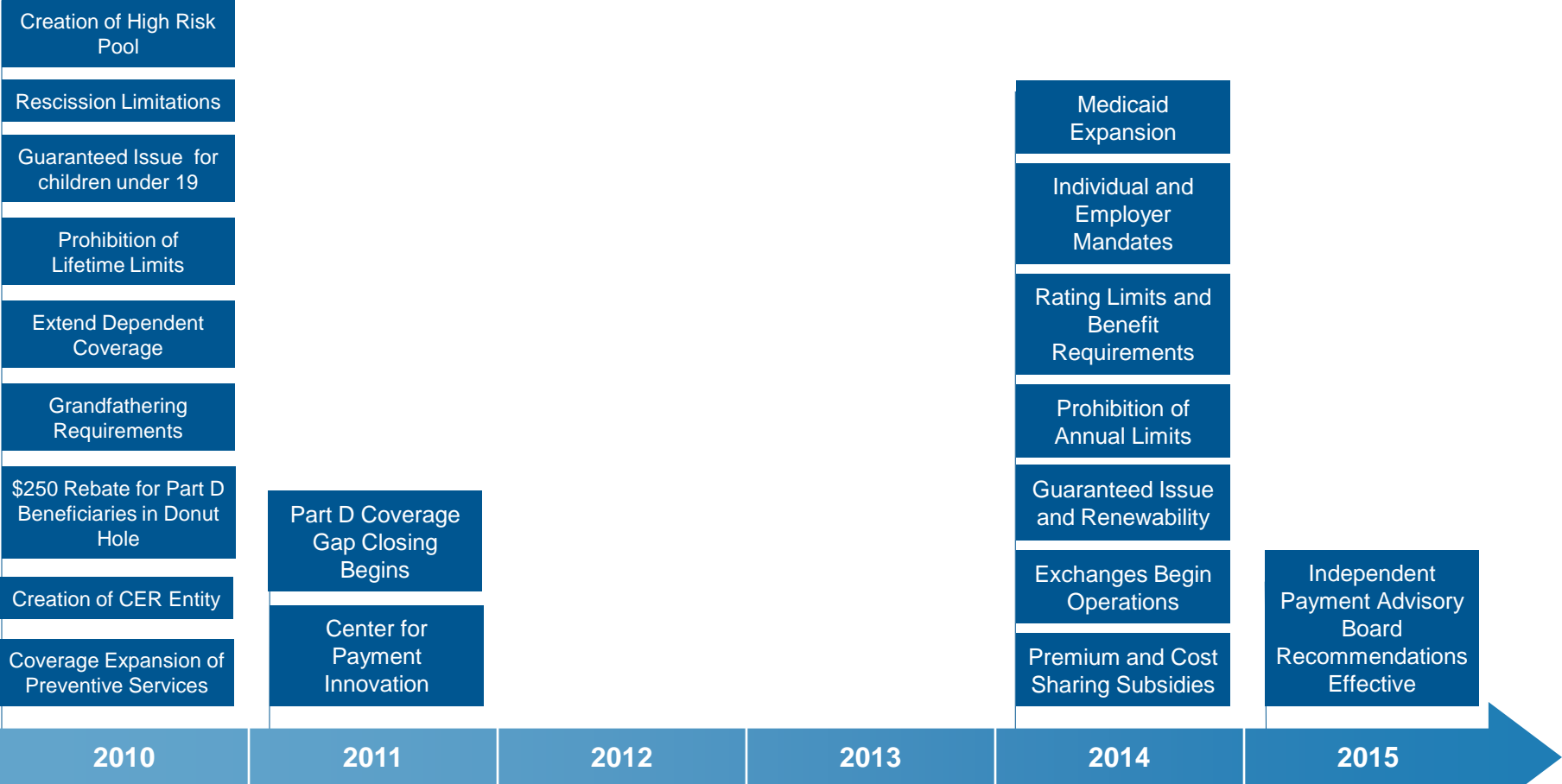


Key Healthcare Reform Provisions

Prepared for the National Health Council
April 1, 2010

Avalere Health LLC

Patients Will Experience Some Significant Changes Immediately



Key Health Reform Provisions: Insurance Market Reforms

- 1 Guaranteed Issue and Portability
- 2 Annual/Lifetime Limits
- 3 Rating Requirements and Limits
- 4 Grandfathering

Some Key Insurance Reform Provisions Occur in 2010

Provision	Details	Effective Date
Guaranteed Issue and Portability	<ul style="list-style-type: none"> ■ Prohibits pre-existing condition exclusions for children under 19 years old ■ Prohibits rescinding coverage, except in case of fraud 	6 months after enactment
	<ul style="list-style-type: none"> ■ Requires guarantee renewability ■ Requires all plans to issue coverage, regardless of pre-existing conditions 	January 1, 2014
Annual Limits	<ul style="list-style-type: none"> ■ Prohibits individual and group health plans from placing annual limits on the dollar value of coverage 	January 1, 2014
Lifetime Limits	<ul style="list-style-type: none"> ■ Prohibits individual and group health plans from placing lifetime limits on the dollar value of coverage 	6 months after enactment

Law Eliminates Medical Underwriting, Limits Rating Practices

Provision	Details	Effective Date
Rating Requirements/ Limits	<ul style="list-style-type: none">■ Requires modified community rating allowing insurers to vary premiums based only on:<ul style="list-style-type: none">» Geography» Family composition» Age, variation limited to 3:1» Tobacco use, variation limited to 1.5:1■ Rating requirements apply to individuals and groups size 1-100 (states may limit to less than 50 prior to 2016)<ul style="list-style-type: none">» Apply to larger groups if states allow into exchange■ Requirements in large group market apply only to fully-insured groups, not self-insured groups	January 1, 2014

¹Senate- Approved Patient Protection and Affordable Care Act plus H.R. 4872 as of 3/21/2010

Reconciliation Bill Expanded Rules for Grandfathered Plans

Provision	Details	Effective Date
Grandfathering	<ul style="list-style-type: none"> ■ Gives existing plans and plans covered through collective bargaining agreements “grandfathered” status 	Upon enactment
	<ul style="list-style-type: none"> ■ Applies the following provisions to grandfathered plans: <ul style="list-style-type: none"> » Limitations on waiting periods » Prohibition on rescissions » Extension of dependent coverage ■ Applies dependent coverage requirement on grandfathered group plans for individuals not eligible for employer-sponsored coverage 	Within 6 months of enactment
	<ul style="list-style-type: none"> ■ For grandfathered group plans, applies annual limit requirements 	6 months after enactment
	<ul style="list-style-type: none"> ■ For grandfathered group plans, prohibits pre-existing condition exclusions 	January 1, 2014

Key Health Reform Provisions: Coverage Expansions

- 1 Individual and Employer Mandates
- 2 Insurance Exchanges
- 3 Medicaid Expansions

Reconciliation Bill Raised Penalties to Strengthen Mandate

Provision	Details	Effective Date
Individual Mandate	<ul style="list-style-type: none"> ■ Sets penalties for noncompliance at the greater of: <ul style="list-style-type: none"> » 2014: \$95, 2015: \$325, 2016: \$695, indexed for subsequent years » 1.0% of household income in 2014, 2.0% in 2015, 2.5% in 2016 and beyond » Up to cost of lowest premium in area » Exempts individuals who cannot afford coverage, incarcerated individuals, individuals outside U.S., those with religious objections, and individuals with incomes below tax filing threshold 	December 31, 2013
Employer Mandate	<ul style="list-style-type: none"> ■ Sets penalties as follows: <ul style="list-style-type: none"> » For employers that offer coverage, fee will be lesser of \$3,000/employee receiving tax credit or \$2,000/full-time worker » For employers that do not offer coverage, fee will be \$2,000/full-time worker » For purposes of calculating total penalty, number of full-time employees is reduced by 30 	December 31, 2013

State Exchanges Create New Market in 2014

Provision	Details	Effective Date
Establishing State Exchanges	<ul style="list-style-type: none">Requires each state to establish an exchange for individual market and separately for small group market by 2014Allows states to form regional or interstate exchanges, subject to approval by Secretary	Required by 2014
Individual Eligibility	<ul style="list-style-type: none">Allows all legal U.S. residents (not incarcerated) to get coverage through exchange	Beginning 2014
Employer Eligibility	<ul style="list-style-type: none">Requires states to allow small businesses with up to 100 employees to purchase coverage through the small employer exchange<ul style="list-style-type: none">» States may allow employers with more than 100 employees into the state exchange in 2017» For plan years before January 1, 2016, a state may limit the small group market to 50 employees	Beginning 2014

Regulations Will Determine Benefit Flexibility in Exchanges

Provision	Details	Effective Date
Benefit Requirements	<ul style="list-style-type: none"> ▪ Ambulatory patient services ▪ Emergency services ▪ Hospitalization ▪ Mental health and substance abuse services ▪ Rehabilitative and habilitative services and devices ▪ Prescription drugs ▪ Laboratory services ▪ Preventive and wellness services and chronic disease management ▪ Maternity and newborn care ▪ Pediatric services 	2014
Benefit Tiers	<ul style="list-style-type: none"> ▪ Establishes four tiers of benefit packages, based on percent of healthcare costs covered: <ul style="list-style-type: none"> » Bronze: 60% » Silver: 70% » Gold: 80% » Platinum: 90% ▪ Requires all participating plans to offer at least the Silver and Gold plans ▪ Allows catastrophic coverage policies for individuals 30 or younger or those exempt from the individual mandate due to financial hardship 	2014

Reconciliation Bill Boosted Subsidies to Buy Via Exchanges

Provision	Details	Effective Date
Individual Subsidies	<ul style="list-style-type: none">■ Provides sliding-scale tax credits to limit premium spending as a percent of income as follows for the purchase of coverage through the exchange:<ul style="list-style-type: none">» Up to 133% FPL: 2.0%,» 133-150% FPL: 3.0-4.0%,» 150-200% FPL: 4.0-6.3%,» 200-250% FPL; 6.3-8.05%,» 250-300% FPL: 8.05-9.5%,» 300-400% FPL: 9.5%	2014

Other Key Health Reform Provisions

- 1 Delivery Reform
- 2 CER Institute
- 3 Follow-on Biologics
- 4 Prevention and Wellness

Delivery Reform

- CMS Center for Medicare and Medicaid Payment Innovation
 - » Test innovative payment and service delivery models
 - » \$5M for FY2010; \$10B over FY2011-2019; \$10B for every subsequent 10-FY period beginning in 2020
- Independent Payment Advisory Board
 - » Starting in 2015, the Board may propose changes to Medicare to limit spending growth
 - » May recommend changes to Part D to generate required savings
- Medicare Shared Savings (i.e., Accountable Care Organizations) Program
- State grants for patient-centered medical home and funds for Medicaid medical home models

The Role of a Proposed CER Entity and the Use of Findings

Senate Language (no change in Reconciliation)

Creation

- Non-profit, non-governmental Patient-Centered Outcomes Research (PCOR) Institute to set priorities and conduct CER

Placement

- Contract preference given to AHRQ and NIH

Funding

- Establishes PCOR Trust Fund
- FY2010 – 2012: appropriations of \$10M, \$50M, and \$150M respectively
- 2013: mix of public and private funding

Use of CER Findings

- CER findings cannot be construed as coverage/ payment recommendations, but can be used by HHS to inform coverage as long as process is transparent and iterative (does not define process)
- Prohibits use of quality-adjusted life year as threshold for establishing cost-effectiveness
- Allows HHS Secretary to set a co-pay differential based on effectiveness
- Establishes process to disseminate findings and archive government-funded CER for future research

Language clearly prohibits the use of CER findings as the sole determinant for coverage or reimbursement decisions.

Governance and Key Advisory Functions of PCOR

Senate Language

Governance

- GAO selects CER Board of Governors
 - » Includes a broad range of stakeholders: AHRQ, NIH join 19 others
 - » 3 representing patients and consumers;
 - » 2 must be “members representing the Federal Government or the States, including at least 1 member representing a Federal health program or agency”

Advisory Panels

- Expert advisory panels on Rare Diseases and one on expert panel on clinical trials
 - » Must include a patient representative

Patient and Consumer Representatives

- Institute must provide support and resources to help patient and consumer representatives effectively participate on the Board and expert advisory panels

Methodological Standards

- Methodology committee of AHRQ, NIH, and 15 GAO-appointed members set methodological standards 18 months after establishment

Dissemination

- Requires Institute to make research findings public within 90 days
- AHRQ Office of Communication and Knowledge Transfer (OCKT), in consultation with NIH, responsible for disseminating CER findings published by the Institute

Follow-on-Biologics: Twelve Year Innovator Exclusivity a Win for Manufacturers

Senate Language (no change in Reconciliation)

FOB Terminology

Biosimilar or interchangeable

FOB Application Process

FDA has authority to approve a biosimilar, then determine if it is interchangeable

Clinical Trials

Clinical studies to establish safety, purity, and potency are required; unless waived by FDA

Exclusivity for Innovator

12 years initial exclusivity for all reference products; 6 month extension possible for pediatric studies

Exclusivity for FOB

12 – 42 months for first interchangeable product

Coding and Payment

Interchangeable biologics will receive the same payment as the reference product; Biosimilar biologics will be paid at their own ASP +6 % of the reference product's ASP

Other

A non-interchangeable FOB is considered to have a new active ingredient; an interchangeable FOB is not considered to have a new active ingredient

Legislation Bolsters Access to Preventive Services and Increases Support for Wellness Program

Senate Language (no change in Reconciliation)

Coverage

- Expands Medicare and Medicaid coverage of preventive services to include annual wellness visits, waives most coinsurance requirements
- Authorizes the Secretary to modify or eliminate coverage of a preventive service currently covered if the modification is consistent with USPSTF recommendations

Wellness

- Allows employers to reduce premiums by up to 30% to reward employee participation in wellness programs
- Requires Secretary to establish a national public/private partnership to conduct a national prevention and health promotion outreach and education campaign
- Awards grants to entities that offer medication therapy management (MTM) services by licensed pharmacists

Funding

- Establishes a Prevention and Public Health Investment Fund to increase and sustain funding for prevention and wellness programs
 - » Authorizes \$5 billion total over FY 2010-2014 and \$2 billion annually for FY 2014 and beyond

Evidence Generation

- Expands & codifies mandate of AHRQ's USPSTF & CDC's Task Force on Community Preventive Services to examine the benefits, effectiveness, & cost* of community and clinical preventive services

*Reviewing cost effectiveness data is a new addition to scope of USPSTF and CDC's mandate