POLICY IMPLICATIONS OF AFFORDABLE CARE ACT ON US MARKET ACCESS

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Objective

The Affordable Care Act (ACA) has introduced several major changes, which have had significant impact on pharmaceutical pricing, access and uptake in the United States. The objectives of this study were:

- Review all major new changes due to ACA and develop a target list of adjustments for budget impact model (BIM) for US payers.
- Assess likely impact of changes due to ACA on pricing and reimbursement.

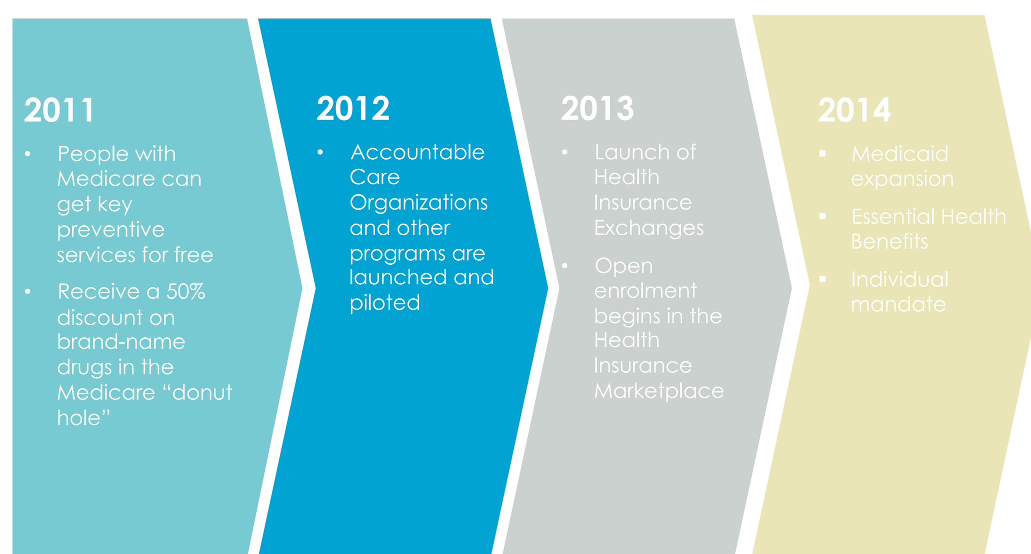
Methods

The new pricing, access and coverage changes impacting the pharmaceutical and devices products were reviewed using the bill for ACA (H. R. 3590), 2011-2013 policy publications, reports by Congressional Budget Office and Government Accountability Office, and the latest Centers for Medicare & Medicaid Services (CMS) guidelines for Essential Health Benefits (EHBs).

Primary discussions with US private payers and ex-CMS policy experts were conducted to understand key issues for medical products.

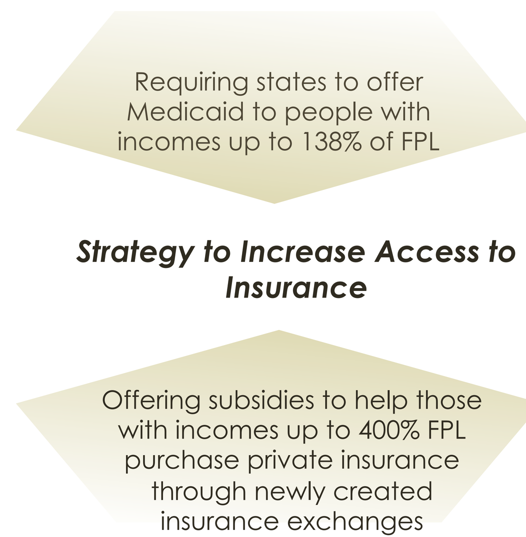
Background

- On March 23, 2010 the Affordable Care Act (ACA) was signed by the President of the United States as a law
- In 2012, The US Supreme Court upheld the ACA, while also allowing States to not participate in Medicaid expansion
- Since 2010, several provisions of the ACA have been put into practice and have potential to impact the access, pricing and uptake of various medical products and services

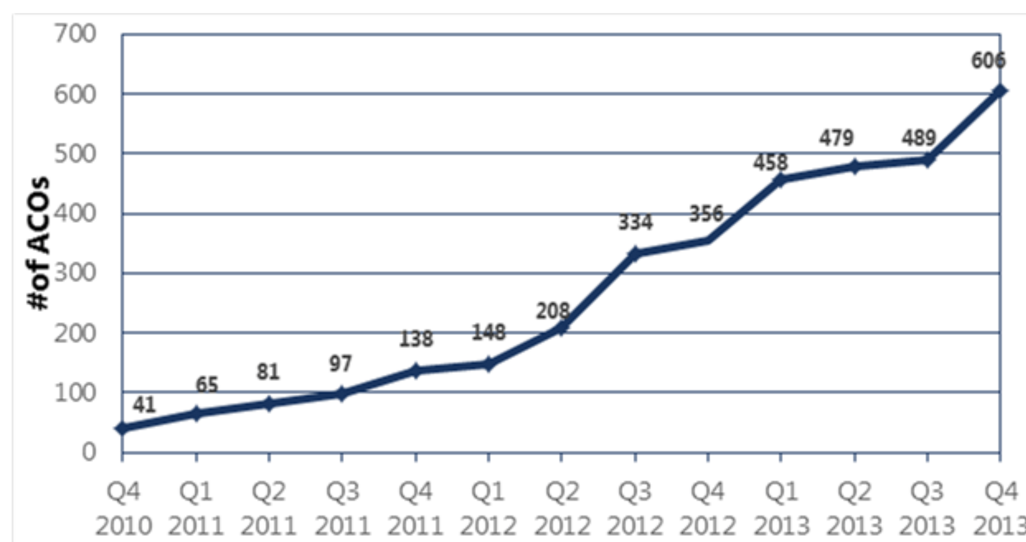


Increased Access

- The Congressional Budget Office (CBO) estimated that 32 million uninsured persons will take up coverage (CBO, 2010)
- Without reform, there would be 49.9 million nonelderly persons without health insurance (18.6 % of the nonelderly population), as opposed to 22.1 million uninsured with reform (8.3 %). (Urban Institute, 2010)

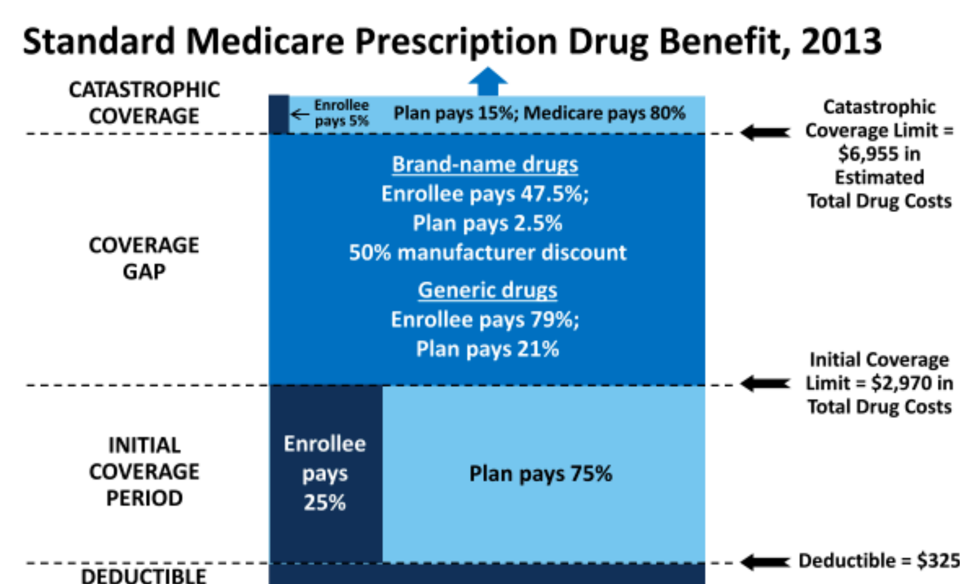


Current Status of ACOs



- On December 23, 2013, the Centers for Medicare and Medicaid Services announced 123 new Medicare Shared Savings Program (MSSP) Accountable Care Organizations (ACOs)
- The total number of Medicare ACOs ~366 (Health Affairs January 2014)

Current Status of Part D Discounts



Types of Rebates for Medicaid

Discount	Description
23.1%	**Innovator Drugs** The greater of 23.1 % of the Average Manufacturer Price (AMP) per unit or the difference between the AMP and the best price per unit and adjusted by the Consumer Price Index-Urban (CPI-U) based on launch date and current quarter AMP.
17.1%	**Blood Clotting Factors** – the greater of 17.1 % of the AMP per unit or the difference between the AMP and the best price per unit and adjusted by the CPI-U based on launch date and current quarter AMP.
17.1%	**Drugs Approved by FDA Exclusively for Pediatric Indications** – the larger of 17.1 % of the AMP per unit or the difference between the AMP and the best price per unit and adjusted by the CPI-U based on launch date and current quarter AMP
New Formula	**Line Extensions –** For a drug that is a new formulation (line extension) of a brand name drug that is an oral solid dosage form
13%	**Non-innovator Drugs** – 13 % of the AMP per unit.

Cost Sharing & Deductibles

Annual Deductible and Out-of-Pocket Maximums after Implementation of Affordable Care Act Coverage Provisions.*		
Insurance Coverage Vehicle	Annual Deductible/ Out-of-Pocket Maximum for a Family $	Annual Deductible/Out-of-Pocket Maximum as a Percentage of Income for a Family of Four with Income at 200% of the Poverty Level
Grandfathered	None/None	NA
Individual nongroup and small-group market (non-grandfathered), including small-business exchanges	4,000/12,700	8/27
Individual exchanges, by income category		
100 to 199% of poverty level	4,233/4,233	NA
200 to 299% of poverty level	6,350/6,350	13/13
300 to 399% of poverty level	8,467/8,467	NA
400% of poverty level or higher	12,700/12,700	NA
Self-insured or larger-group market (non-grandfathered)	12,700/12,700	27/27

Essential Health Benefits

- The benchmark plans for top five states provide coverage of 4215 drugs belonging to 158 classes as defined by USP .
- While four states FL, IL, NY and TX had similar number of covered drugs (Median of 892 drugs), CA had significantly lower number of covered drugs, 28% less than other four states.
- On average, 10% of the drugs were in the class called "No USP Class", highlighting the limitation of CMS designated USP classification system for the new plans.
- In CA, FL, IL, NY and TX there were 18, 7, 8, 11 and 8 classes, respectively for which only 1 was covered.
- For CA, top 8 classes were identified for which patients had 75% lower choice than other states, these include indications such as Anti-Diabetics and Pain medications.

Summary

Topic	Implications
Increased Access	As of 01/2014 health insurance access has improved for a significantly smaller population than expected. States have opted out of Medicaid expansion and majority of signups for with new exchanges are previously insured patients
Part D Discounts	Phase out of donut hole is on-going as planned. As of 2014, beneficiaries are paying 47% of donut hole cost
Capped Deductibles	Capping of deductibles can potentially decrease patient share of the cost (especially for high cost specialty products)
ACOs	ACO rollout has been slower than expected. As of 01/2014 ~18million lives were covered under ACO programs (less than 7% of total population)
Medicaid Discounts	As per ACA drug manufactures have to provide discounts to Medicaid programs. CMS is now publishing NADAC files
Essential Health Benefits	As of 2014 plans are required to offer at least the coverage as per the EHB benchmark in each State. Significant variations exists in benchmark plans for pharmaceuticals

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Awarded Two Platinum and One Bronze Medal by AMCP

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