



Potential Market and Pricing Effect of the Patient Protection and Affordable Health Care Act of 2010



Walt Addison Linscott, Esq.

Thompson Hine LLP

ATLANTA BRUSSELS CINCINNATI CLEVELAND COLUMBUS DAYTON NEW YORK WASHINGTON, D.C.

Market and Pricing Impact timeline

2010

1. Flat rate for single source and innovator multiple source outpatient prescription drugs increased to 23.1%, except for clotting factors and products that are FDA approved solely for pediatric indications increases to 17.1%. PPACA, The basic rebate for multi-source, non-innovator drugs increased to 13%.
 - Companies that have large Medicaid pickup will see a large bite into profit as the new law effectively pushes the base rebate up 8%. Deep commercial discounted products will not see feel the same bit because best pricing requirements already see a higher floor.
2. Authorize the Food and Drug Administration to approve generic versions of biologic drugs and grant biologics manufacturers 12 years of exclusive use before generics can be developed.
3. Impose a tax of 10% on the amount paid for indoor tanning services.



2011

- Award five-year demonstration grants to states to develop, implement, and evaluate alternatives to current tort litigations.
- Provide grants for up to five years to small employers that establish wellness programs.
- Require pharmaceutical manufacturers to provide a 50% discount on brand-name prescriptions filled in the Medicare Part D coverage gap beginning in 2011 and begin phasing-in federal subsidies for generic prescriptions filled in the Medicare Part D coverage gap.
- Exclude the costs for over-the-counter drugs not prescribed by a doctor from being reimbursed through an HRA or health FSA and from being reimbursed on a tax-free basis through an HSA or Archer Medical Savings Account.
- Impose new annual fees on the pharmaceutical manufacturing sector.

THOMPSON
HINE

2012

- Make Part D cost-sharing for full-benefit dual eligible beneficiaries receiving home and community-based care services equal to the cost-sharing for those who receive institutional care.
- Reduce rebates for Medicare Advantage plans.

THOMPSON
HINE

2013

- Create the Consumer Operated and Oriented Plan (CO-OP) program to foster the creation of non-profit, member-run health insurance companies in all 50 states and the District of Columbia to offer qualified health plans. (Appropriate \$6 billion to finance the program and award loans and grants to establish CO-OPs by July 1, 2013)
- Begin phasing-in federal subsidies for brand-name prescriptions filled in the Medicare Part D coverage gap (to 25% in 2020, in addition to the 50% manufacturer brand-name discount).
- Increase Medicaid payments for primary care services provided by primary care doctors for 2013 and 2014 with 100% federal funding.
- Impose an excise tax of 2.3% on the sale of any taxable medical device
- Eliminate the tax-deduction for employers who receive Medicare Part D retiree drug subsidy payments

THOMPSON
HINE

2014

- Require U.S. citizens and legal residents to have qualifying health coverage
- Implement penalty program for employers not offering health coverage (dependant on number of employees)
- Expand Medicaid to all non-Medicare eligible individuals under age 65 (children, pregnant women, parents, and adults without dependent children) with incomes up to 133% FPL based on modified adjusted gross income (MAGI)
- Permit employers to offer employees rewards of up to 30%, increasing to 50% if appropriate, of the cost of coverage for participating in a wellness program and meeting certain health-related standards
- Impose fees on the health insurance sector

THOMPSON
HINE

2015 and later

- Impose an excise tax on insurers of employer-sponsored health plans with aggregate values that exceed \$10,200 for individual coverage and \$27,500 for family coverage. (Effective January 1, 2018)

THOMPSON
HINE

Consumer interface points of possible change

- Medicare Part D plans are required to develop drug dispensing procedures for outpatient prescription drugs in long-term care facilities in an effort to eliminate waste in overprescribing.^[1] This may be a benefit to innovative drug manufacturers who develop product packaging that more easily allows compliance with the requirement.
- Manufacturers are required to report transfers of value made to a physician, physician medical practice, physician group practices, and teaching hospitals. These annual reports are made by manufacturers and specify the prescriber or entity that received the thing of value. The FDA will then within 90 days post the information on its website. Manufacturers can expect that FDA will issue regulations and guidance regarding these requirements. Because of the short period between the time the reports are due and the time they must be posted on the website it is likely FDA will require they are made electronically in a machine readable format.
- The Pharmaceutical Marketing Act requires that firms keep track of physician drug samples. The PPACA requires that firms will now report this sampling information to the FDA, with information identifying which prescribers received which samples. The information will be reported then on the FDA website.

THOMPSON
HINE