



Health Reform

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

**What happened, what's still
happening and where are we
headed?**

October 21, 2010

- **Overview**
- **Key Biopharmaceutical Provisions**
- **Health Insurance Reforms**
- **Delivery System Reforms**
- **Recent regulatory activities**

OVERVIEW



- **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.

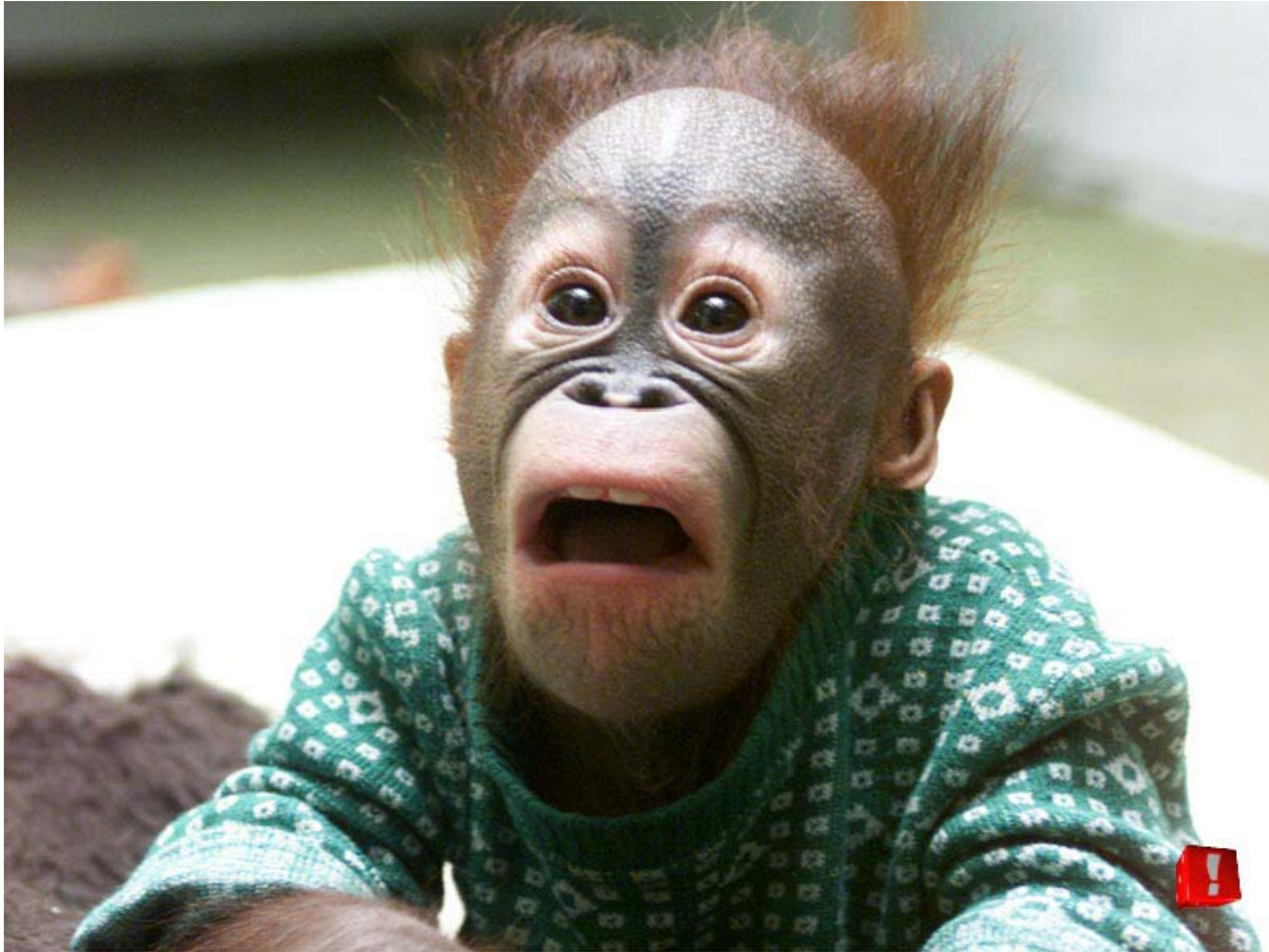
- **Further Legislation is likely**

- **Technicals bill**
- **Deficit Reduction**

- **Many regulations and guidance documents already released and many more to come.**

** This presentation reflects the Patient Protection & Affordable Care Act as amended by the Reconciliation Act and referred to by many as ACA, the Affordable Care Act.

Reaction Post Passage of Health Legislation



COVERAGE →

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

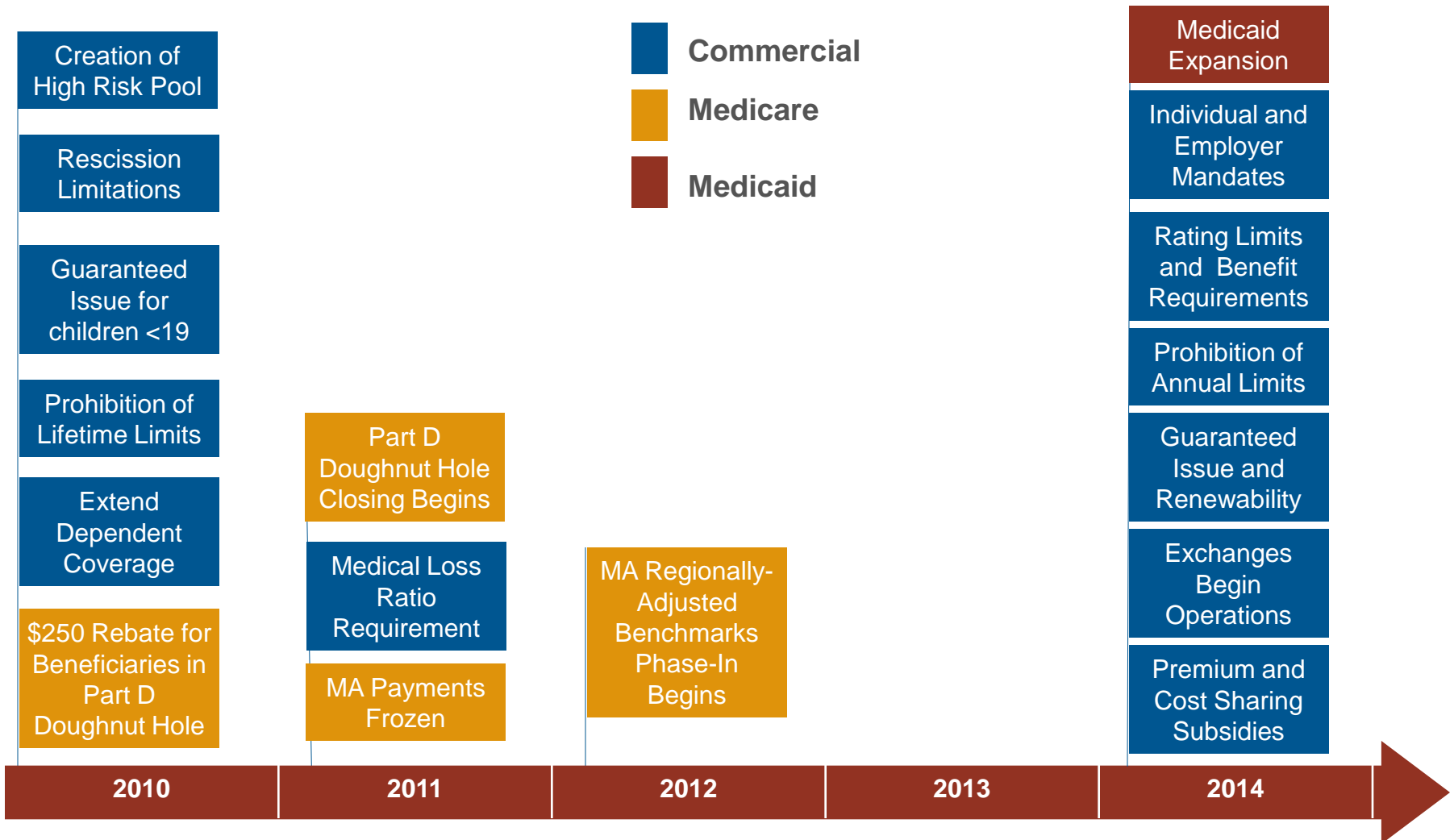
COST →

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

FINANCING →

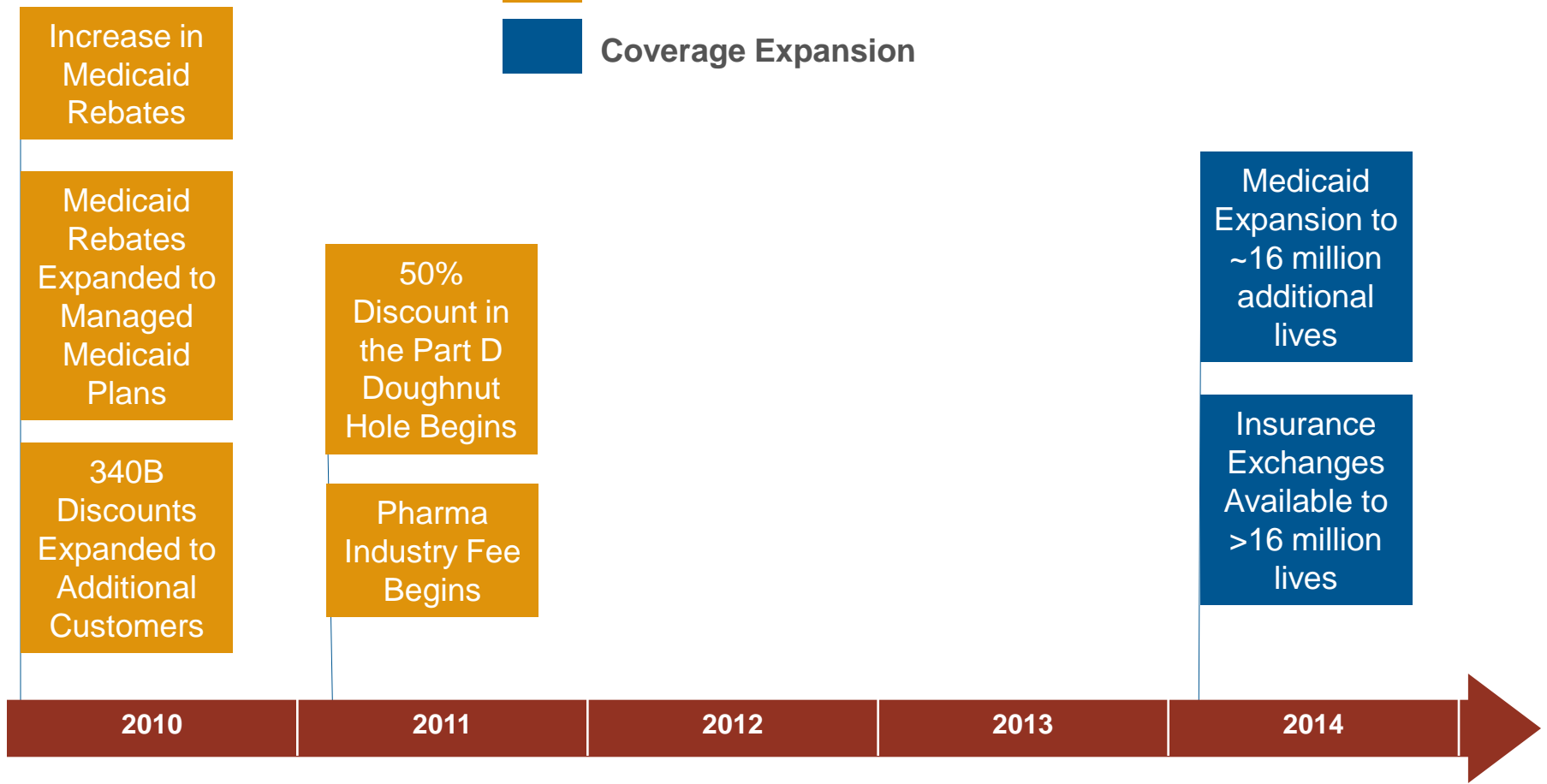
- Reimbursement reductions for Medicare providers
- Excise taxes on high-value health plans
- Expansion of Medicare HI tax to non-payroll income
- Industry fees

Some of the Reform Provisions Are Immediate....Most Start in 2014, however....



Pharma Industry's Financial Contributions Begin before the Coverage Expansion in 2014

Pharma Industry Contributions
Coverage Expansion



KEY BIOPHARMACEUTICAL PROVISIONS



Different Parts of Medicare-General

- Each Part is a different market requiring a different business plan and regulatory strategy
- Medicare Part A—Inpatient Setting
 - Prospective payment system based on diagnostic related groups
 - Created in 1982, funded by payroll tax
- Medicare Part B—Outpatient Setting
 - Covers physician services
 - Outpatient procedures
 - Diagnostic tests/procedures
 - “Incident to” drugs and biologicals
- Medicare Part C—Medicare Managed Care
 - At risk contracts with CMS to cover Medicare population for bucket of services based upon a fixed payment
- Medicare Part D—Prescription Drug Benefit
 - Administered by private sector

- In general, the cost of doing business in all markets increased.
 - However, more insured individuals.
- Modest impact to hospitals, physicians and other providers relying on prospective payment system.
- Pharmaceuticals, biologicals and devices--different story for each.
- Medicare Part D is prime example.
 - Requires manufacturers to contribute 50% of a brand drug's or biologic's negotiated price beginning January 1, 2011.

BRAND DRUGS: Percentage contribution of the beneficiary, pharmaceutical industry and federal government during the coverage gap

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
Fed Gov't	0	0	0	2.5	2.5	5	5	10	15	20	25

GENERIC DRUGS: Percentage contribution of the beneficiary, pharmaceutical industry and federal government during the coverage gap

Years	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Beneficiary	100	93	86	79	72	65	58	51	44	37	25
Fed Gov't	0	7	14	21	28	35	42	49	56	63	75

- Medicaid
 - Legislation changes rebate calculation, expands patient population and increased rebate liability.
- Expands entities that are eligible for reduced price (340B)
- Mandates new taxes:
 - Bio-pharmaceuticals: 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.
 - Devices: Beginning in 2013, imposes an excise tax on medical devices equal to 2.3% of the price of the device. Tax is payable by the device manufacturer but is deductible as a business expense by the device manufacturer.
 - Taxable Devices. Tax is assessed on all medical devices, as defined by the Federal Food Drug and Cosmetic Act, except eyeglasses, contact lenses, hearing aids, and other devices that are sold to the general public at retail establishments, as defined by the Secretary of the Treasury.

- Single-Payor health care system in the US.
- Federal government negotiation of Medicare Part D drug prices.
- A government-run public option plan that would have the authority to negotiate pharmaceutical prices.
- Legalized bulk importation of prescription drugs into the US from as many as 30 foreign countries.

HEALTH INSURANCE REFORMS



Immediate Insurance Reforms

Insurance Reform	Effective Date	Application to Grandfathered Plans
No lifetime limits on “essential health benefits.”	Plan years beginning on or after September 23, 2010.	Applicable.
Prohibition of preexisting condition exclusion or other discrimination based on health status for individuals under age 19.	Plan years beginning on or after September 23, 2010.	Applicable to grandfathered group health plans – not applicable to grandfathered individual plans.
Prohibition of cost-sharing for preventive services.	Plan years beginning on or after September 23, 2010.	Not applicable to grandfathered health plans.
Extension of dependent coverage through age 26.	Plan years beginning on or after September 23, 2010.	Applicable, except for grandfathered plans where the dependent is eligible for employment-based coverage.
Prohibition of rescissions.	Plan years beginning on or after September 23, 2010.	Applicable.

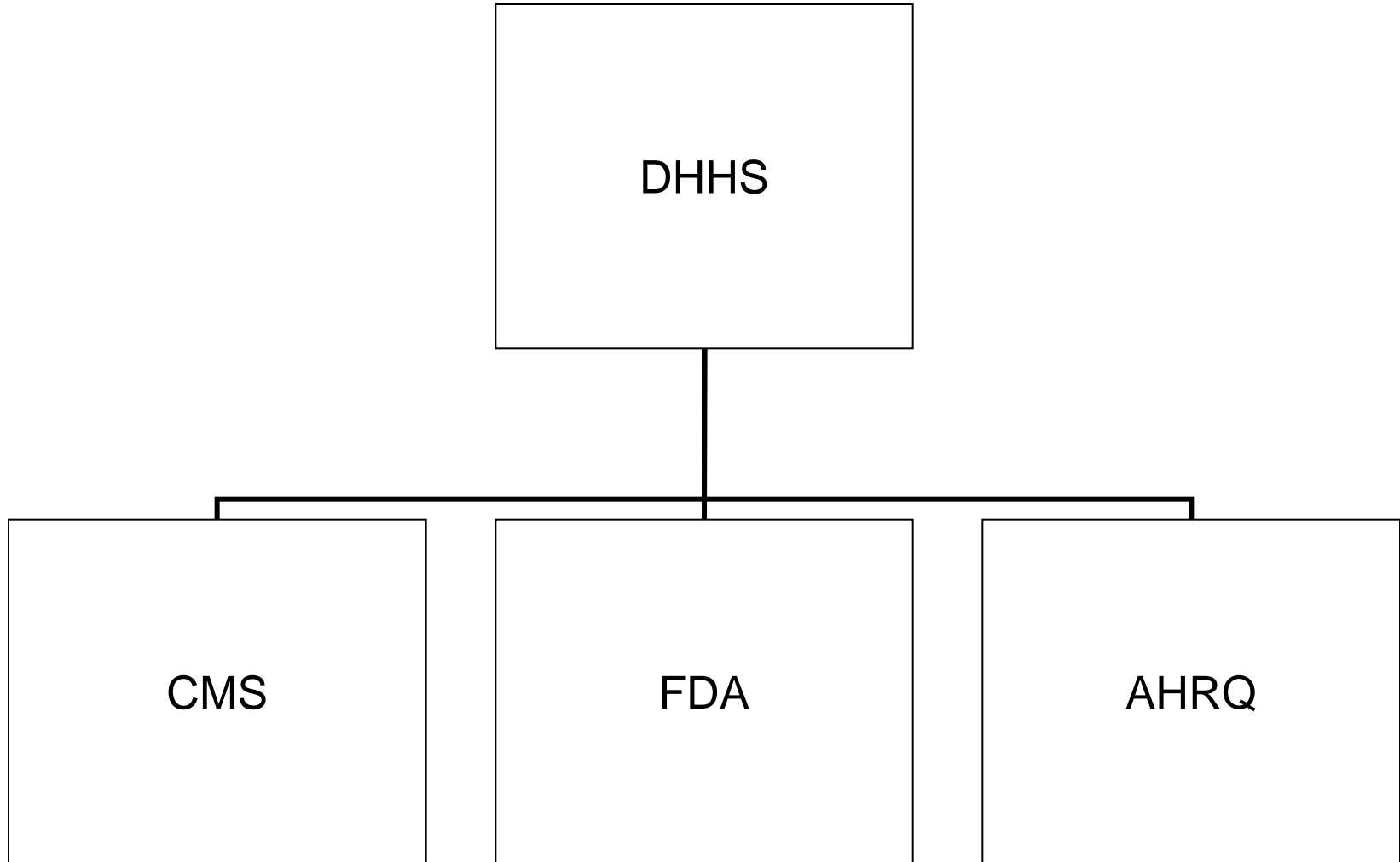
DELIVERY SYSTEM REFORMS



- Establishes **nonprofit corporation ('Institute')** to assist patients, clinicians, purchasers & policy makers in making health decisions.
 - 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.

- **Transparency/Patient Protections.**
 - Precludes the Institute from mandating coverage, reimbursement or other policies for any public or private payer.

Regulatory Activity Parallels Implementation



U. S. Food and Drug Administration (FDA)

“Safe and Effective”

- Mission to promote and protect the public health by helping safe and effective products reach the market in a timely way
- To monitor products for continued safety after they are approved for marketing
- To provide the public with accurate, science-based information needed to improve health

The Centers for Medicare & Medicaid Services (CMS)

“Reasonable and Necessary”

- Mission to ensure healthcare security for beneficiaries
- Administers the Medicare program
- Develops Medicare coverage and reimbursement policies for the Medicare program
- Works in partnership with States to administer the Medicaid program and the State Children’s Health Insurance Program (SCHIP)

Memorandum of Understanding

- A Memorandum of Understanding (MOU) between the FDA and CMS took effect on June 25, 2010.
- The purpose and goals as stated in the MOU are to:
 - Enhance information sharing efforts through more efficient and robust inter-agency activities;
 - Promote efficient utilization of tools and expertise for product analysis, validation and risk identification; and,
 - Build infrastructure and processes that meet the common needs for evaluating the safety, efficacy, utilization, coverage, payment and clinical benefit of drugs, biologicals and medical devices.

- September 16, 2010 the agencies opened a docket for public comment in response for their request for comments on:
 - “establishing a process for overlapping evaluations of premarket, FDA-regulated medical products when the product sponsor and both agencies agree to such parallel review.”

Agency Missions – Summary

- CMS and FDA have distinct statutory authorities.
- The MOU and Notice documents suggest an increasing overlap between the way in which CMS and FDA will regulate innovative products.
- The Notice contains statements that suggest a shift in mission to include a focus on quality, affordability, and comparative data.
 - “[t]hrough coordinated decisions regarding medical products, FDA and CMS can affect public health in critical ways: FDA in determining the safety and effectiveness of those products and CMS in providing beneficial coverage and appropriate payment . . . involving those products.”

Introduction of Cost Data into Pre and Post-Approval

- The Notice states that the agencies are considering introducing the concepts of cost into how they evaluate and give consideration to products in the pre-approval process.
 - “Both agencies believe that they should address the growing need to improve public health by speeding consumer access to and spurring the development of new affordable, reliable, safer and more effective medical products and services.”

Introduction of Comparative Data into Pre and Post-Approval

- The Notice suggests a possible future role for “comparative effectiveness”:
 - The agencies state in the Notice that currently “materials submitted by manufacturers to FDA may not adequately address the issues of importance to payers . . . and the incremental clinical utility of these products compared to currently available technologies.”
 - Further, the Notice states that the “NCD process includes evaluation of outcomes data, such as whether the product provides improved, equivalent, or complementary health outcomes in the Medicare population as compared to alternative treatments or diagnostics already covered by the program.”
- Uncertainty about if, and if so, how, the agencies will share data between FDA and CMS as a product is reviewed.

- Migration of specialty products to the pharmacy benefit
 - Use of pharmacy benefit tools on specialty products
 - Paying for adherence to clinical guidelines
- Increased role of the specialty pharmacy
 - More involved in data collection and demonstrating value proposition
- Development of unique shared risk arrangements
 - “money back guarantee”
- Does health information technology change anything?
 - If so, when?

Summary

- Regulatory:
 - The FDA is demanding more data to prove safety and efficacy.
 - CMS is starting to require data that new therapy works in the Medicare population.
- Costs of getting to market have increased and market is smaller.
- Partners are also now demanding more data as part of due diligence strategy.