

Pharmaceuticals: *What's Ahead?*

BUILD STRONG STATES

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Overview

What will we cover today?

- Impact of the ACA & Health Care Change
- What Is An Essential Health Benefits?
- Biosimilars: Role of the States
- The Generic Wars (Pay for Delay, Coupons, etc.)
- Medicare Part D & Dual Eligibles
- Drug Use, Misuse & Waste
- Medicaid AWP & EAC → AAC:
 - * A New Price Benchmark (?)
- Need for More R & D

Pharmaceutical Policy Issues (NCSL Resources & Issue Briefs)

- Brand & Generic Drug Use
- State Preferred Drug Lists
- Bulk Purchasing
- 340B Prices & Safety Net Agencies
- Rx Cost & Access
- Retail Generic Drug Pricing Issues
- State Pharm. Assistance Programs
- Rebates
- Drug Safety & Emergencies
- PPACA & Drugs
- Reimbursement for Rx Drugs (AAC)
- **Brand Drugs & Copay Coupons**
- **Medication Adherence**
- Academic Detailing
- Drug Error Prevention
- MTM & Drug Outcomes
- **Professional Practice Acts Updates**
- **Biosimilars & States Role**
- **Essential Health Benefit**
- Drug Return & Reuse
- **Drug Take-Backs & Waste**
- Drug Shortages

There Seem to Be More New Drug Issues than New Drugs

The ACA & Change In Health Care

Now We Know

It IS a LAW!

Public Law 111 - 148

***Patient Protection &
Affordable Care Act***

(PPACA; aka ACA)

March 2010

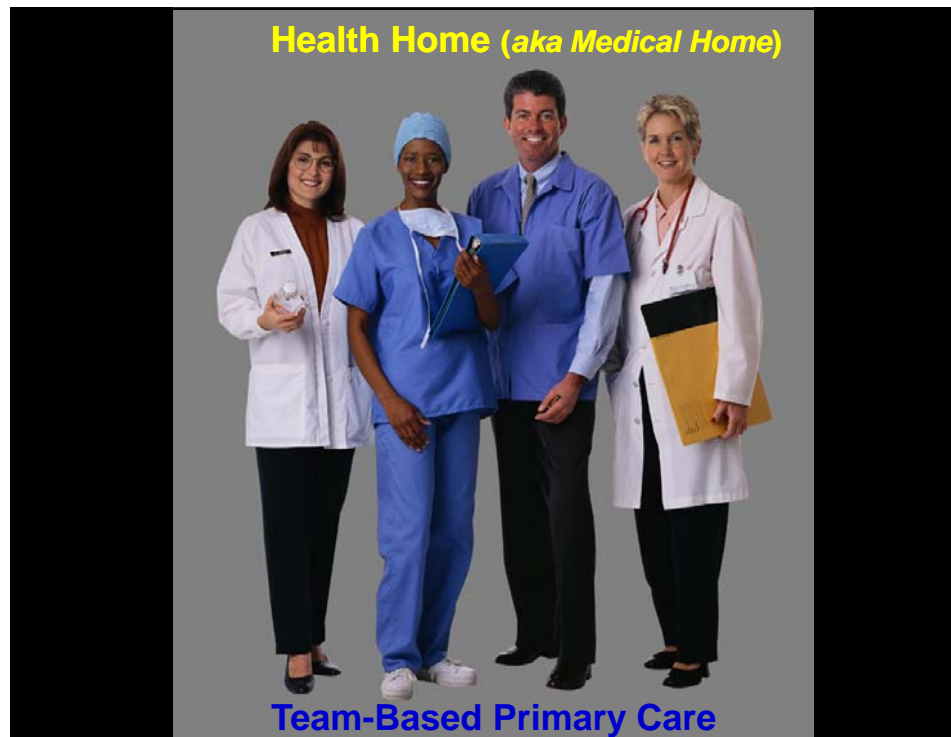
***State Implementation Efforts Were
Frozen or Paralyzed***

But Now

**Time to Implement
the ACA**

Health Structure Change

- ◆ **Medical Home** (*Coordinated Team Care*)
- ◆ **Accountable Care Organizations** (ACOs)
 - *Accountable for improving health outcomes*
 - *Accountable for using resources efficiently*
- ◆ **Increased Need for Primary Care Providers**
- ◆ **Pay for Performance** (*Outcome*)
- ◆ **Electronic Health Information & Claims**



Accountable Care Organizations

Strategies for Success

CMS allows a wide range of strategies for ACOs:

- ◆ Use Primary Care Nurses
- ◆ Use Pharmacist as Case Managers
- ◆ Transition of Care Plans
- ◆ Guidance for Patients & Caregivers
- ◆ Predictive Modeling of Care
- ◆ Remote Monitoring
- ◆ Tele-Health

Update State Laws

What state laws need to be updated?

- **The Practice Acts of Health Professions**
 - *Most are remnants of laws written 75-150 years ago*
 - *Enable providers to practice up to level of education & license*
 - *Recognize New Forms of Primary Care Providers*
(Nurse Practitioners, Clinical Pharmacists)
 - *Authorize Collaborative Drug Therapy Agreements*

Practice Acts Need to Be Updated !

What Is An Essential Health Benefit?

Essential Health Benefits

- ◆ **Who defines?** (US DHHS & States)
- ◆ **May Be Up To State !**
- ◆ **Choosing a State Benchmark Plan**
 - *Largest Small Group Plan*
 - *State Employee Benefit Plan*
 - *Other*
- ◆ **Which Drug Classes Are Covered?**
- ◆ **How Many Drugs / Therapeutic Class?**
- ◆ **What About OTCs for Key Chronic Conditions?**

What About Biologicals & Biosimilars?

Biological & Specialty Drugs

What are other labels (aliases) for biological drugs?

Specialty Drugs

Biotech drugs

Biopharmaceuticals

Biologicals

Injectables

Large Molecule Agents

Biotech Drugs (>\$200,000 Annually)



The New Biotech Drugs

• Soliris	Alexion	\$ 409,500
• Elaprase	Shire	\$ 375,000
• Naglazyme	BioMarin	\$ 365,000
• Folutyn	Allos Therapeutics	\$ 360,000
• Cinryze	Viropharma	\$ 350,000
• Myozyme	Genzyme	\$ 300,000
• Arcalyst	Regeneron	\$ 250,000
• Fabrazyme	Genzyme	\$ 200,000
• Cerezyme	Genzyme	\$ 200,000

Will Biotech Drugs Bust the Bank? What is Their Value?

Mathew Herper, "The World's Most Expensive Drugs," Forbes, Feb 22, 2010,

Biologicals & Specialty

- ◆ 17% of Rx Drug Market in 2011 (\$47 bil.)
- ◆ Grew ~20% in 2011
- ◆ Limited Channels of Distribution
- ◆ 2/3 Flow through 3 Specialty Providers
 - *Express Scripts, CVS Caremark & Walgreens*
- ◆ 50% as Pharmacy Benefit &
- ◆ 50% as Medical Benefit

PPACA & BioSimilarars

- ◆ **PPACA Creates BioSimilar Process**
Biological Price Competition &
Innovation Act of 2009 (P.L. 111-148)
- ◆ **Conceptually Similar to Hatch-Waxman**
[Drug Price Competition &
Patent Term Restoration Act] (P.L. 111-148)
 - *12-year Exclusivity from License*
 - *Pediatric Exclusivity*
 - *1st Biosimilar Entrant Exclusivity*

BioSimilarars & State Role

- ◆ **PPACA Directs FDA to Establishes**
Biosimilar Process
- ◆ **FDA Will Define Reference Product &**
How to Demonstrate BioSimilarity
- ◆ **Role of FDA & States**
 - *FDA Regulates Biologicals & Drugs*
 - *States Regulate Professions & Practice*
 - *State Drug Product Selection Laws Need*
to be Updated to Cover BioSimilarars
 - *States May Reference FDA Biosimilarity Efforts*
 - *States May Allow Physician, Pharmacist &*
Patient Discretion

Manufacturer

Copay Coupons

Mfg. Copay Coupons

- ◆ **New Phenomenon in Last 5 Year**
- ◆ **> 300 Drugs Have Copay Coupons**
(also use internet & web sites extensively)
- ◆ **Banned by Medicare as Kickbacks**
- ◆ **Used for Commercial & State Health Plans**
- ◆ **Invisible to Employer & Plan Sponsor**
(Except for impact on drug expenditures)
- ◆ **Cost Payers ~\$3.2 billion/Year in U.S.**
- ◆ **Banned for All in Massachusetts**

Drug Use Misuse & Waste

Drug Use & Waste

Medication Possession ≠ *Medication Adherence*

*5% to 25% of drugs dispensed are
never used & create
both abuse & pollution hazards !*

Pharmaceutical Waste

◆ Excess Drug Distribution Is a Problem

- *Unused medications in medicine cabinet*
- *Meds in medicine cabinet are sign of non-compliance*
- *Samples, duplicate Rxs, discontinued Rxs, expired meds*
- *Distributing more drugs (medication possession ratio) does not assure improved compliance, use & outcome*

◆ Estimates of Drug Waste Volume

- *Drug take-back programs with law enforcement*
- *Community collection points for drug waste*
- *Drug Take-back programs average 1 gallon / household*
- *Estimated 23 million pounds / year of drugs disposed*

Pharmaceutical Waste: Source of Water & Land Pollution



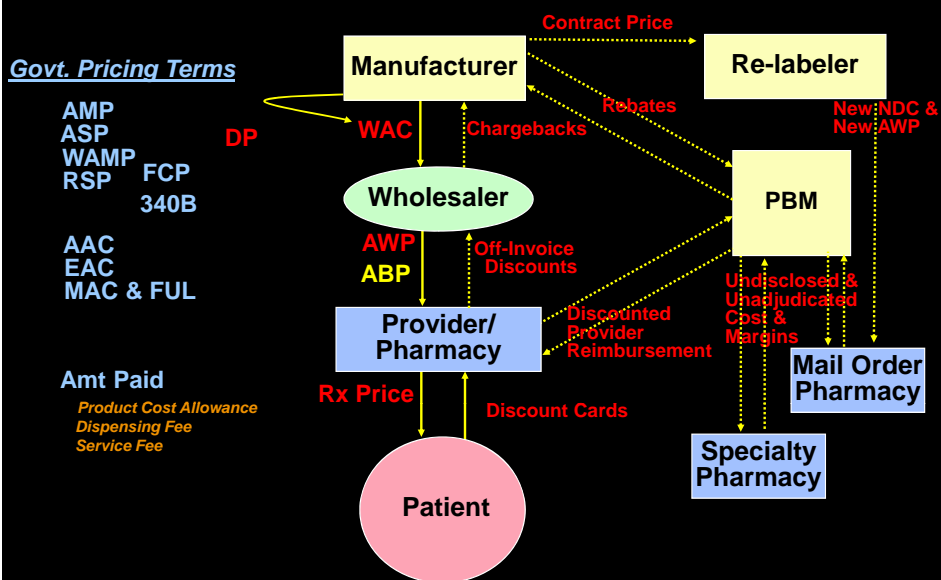
- *Medicines dumped in trash or flushed down toilet*
- *Detectable levels in water supply of some cities*

Economic Externalities

“Costs of production that are not borne by the producer but are dumped on society.”

Drug Firms Create Externalities

Distribution & Payment for Prescription Drugs



A Single Drug Has Many Prices?

AAC: A Good Benchmark?

- What Is Starting Point on Invoice?
(AWP, WAC, other; Is it a list price?)
- Are There *Bona Fide* Fees?
- Are There Earned Discounts?
- Are There Other Discounts?
- Are There Off-Invoice Discounts?
- Are There Off-Invoice Rebates?
- Do All Wholesalers Invoice the Same?
- How Is Class of Trade Handled?
(Hospital, LTC, Home Health, HMO, 340B)

AWP = Ain't What's Paid
AAC = Ain't Actually Cost

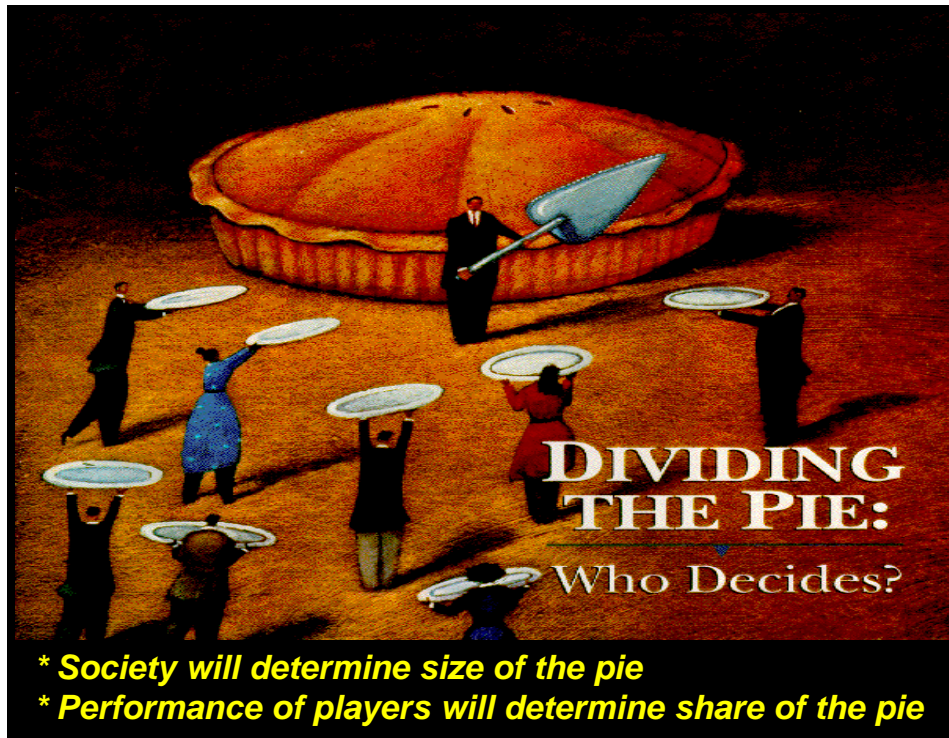
What Is the Future of Health Care ?





Summary

- ◆ **Drugs Are Essential to Health Care**
- ◆ **Drug-Related Problems Are Costly**
- ◆ **Manage Drug Use & Expend. Growth**
Specifically Target True Sources of Growth
- ◆ **Manage Drug Shortages**
- ◆ **New Drugs Must Deliver Better Value**
- ◆ **Med. Therapy Management Is Essential**
Improve Patient Health & Reduce Drug-Related Problems



Are Health Care Firms Too Big to Fail?

- * **Health Insurers**
- * **Hospitals & Health Systems**
- * **Drug Companies**
- * **PBMs**
- * **Pharmacy Chains**

*We Don't Know ?
What Happens If They Do ?*

Value of Drug Spending

Not All Increases in Drug Spending Are Beneficial !

◆ Increased Spending With Little Value

- *Increase in price for the same drug*
- *Switch to new patented dose form when generic enters*
- *Drug use when drug is ineffective for condition treated*
- *Possession of needed medication without compliance*

◆ Increased Spending With Greater Value

- *Coverage expansion with financial access to needed meds*
- *Use of effective med for previously untreated condition*
- *Targeted use of effective therapies based on evidence*
- *Appropriate use of more cost-effective med (even if high price)*
- *Continued use & compliance with needed & effective med*

Need for More R & D

We need more R & D ?

● **R**rational Drug Use

&

● **D**elivered Outcomes

*Increased R & D Will Result in
Improved Health Outcomes*

PRIME Institute

***Pharmaceutical
Research
In
Management &
Economics***



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