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?

- **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?
Biotech Drugs
($>200,000 Annually)

The New Biotech Drugs

- Soliris
  - Alexion
  - $409,500
- Elaprase
  - Shire
  - $375,000
- Naglazyme
  - BioMarin
  - $365,000
- Folotyn
  - 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?


Biologics & 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 & BioSimilars

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

BioSimilars & 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 BioSimilars
  - 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*
* Society will determine size of the pie
* Performance of players will determine share of the pie

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?

◆ Rational Drug Use
  &

◆ Delivered Outcomes

Increased R & D Will Result in Improved Health Outcomes