Rx Innovations and Challenges: Current Landscape

Presentation: NAMD Fall Conference
Presenter: Jerry Dubberly, Chief Medicaid Division

Date: 11/08/2011
Topics for Discussion

- Pharmacy Market
- Historical Tools
- Current Trends
  - Patent Expirations
  - Pipeline Drugs
  - Specialty Pharmacy Growth
  - Pharmacogenomics
U.S. Pharmacy Marketplace

• Statistics\(^1\)
  – Over 4 Billion prescriptions filled each year
  – 60,000 pharmacies
  – Annual industry revenues of $277 Billion

• Highly regulated

• Only 9% of drugs in Phase I clinical trials are ultimately approved\(^2\)

• Emerging technologies
Medicaid Pharmacy

- Annual Expenditures\(^3\)
  - Over $25 Billion
  - Offset by rebates - $15.7 Billion
- Drugs are 7% of all Medicaid healthcare payments prior to rebates\(^3\)
- Overall Rx spend trend low single digits
Traditional Management Tools

- Prior Authorization
- Step Therapy
- Quantity Level Limitations
- Preferred Drug List
- Supplemental Rebates
- Reimbursement Approaches
- Pharmacy Benefit Manager
- Audits
Current Trends
Patent Expiration

- Large number of drugs losing patent
- In 2010, 21 first-time generics
  - Individual prior year sales >$125 Million$^2$
- Record number of new generics over next 3 years
- Generics expected to account for >80% of prescription claims volume by end of 2013$^1$,$^2$
## Patent Expirations 2011

<table>
<thead>
<tr>
<th>Drug</th>
<th>Condition</th>
<th>2010 US Sales</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lipitor</td>
<td>Cholesterol</td>
<td>$5.239 B</td>
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<td>Zyprexa</td>
<td>Antipsychotic</td>
<td>$2.496 B</td>
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<tr>
<td>Levaquin</td>
<td>Antibiotic</td>
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<tr>
<td>Concerta</td>
<td>ADHD/ADD</td>
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<tr>
<td>Protonix</td>
<td>GERD</td>
<td>$690 M</td>
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## Patent Expirations 2012

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<tr>
<th>Drug</th>
<th>Condition</th>
<th>2010 US Sales</th>
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<tbody>
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<td>Plavix</td>
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<td>Seroquel</td>
<td>Antipsychotic</td>
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<tr>
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<tr>
<td>Enbrel</td>
<td>Arthritis</td>
<td>$3.304 B</td>
</tr>
</tbody>
</table>
Pipeline Drugs²

• Pipeline Volume
  – 3000 New drugs in clinical development
  – 1100 Drugs in Phase I
  – 600 Drugs in Phase II/III

• Cancer leads in count of drugs in development

• 2010 Brand drug inflation 9.4%
  – Blunted by first time generics

• Numerous “specialty drugs” in pipeline
Specialty Pharmacy

- Definition varies
- Large, complex, protein-based molecules or biologic products
- Require special handling or monitoring
- High cost
- Trends\(^3\)
  - Over next 3 years, 21% of Rx spend
  - By 2020, 40% Rx spend
Specialty Pharmacy

• Biologic/Protein-based Products
  – Highly complex manufacturing process
  – Typically produced using recombinant DNA technology
  – No FDA-approved “generic” process
  – Patient Protection and Affordable Care Act
    • Groundwork for “biosimilar” designation
  – Comparative Effectiveness Research and Evidence-Based Medicine approach still needed
  – >$91 Billion in worldwide sales in 2009
Pharmacogenomics

- **Pharmacogenomics** – study of how variations in the human genome affect the response to medications
- Intersection of pharmaceuticals and genetics
- Personalized drugs in hopes of greater efficacy and safety
- Require development of specialized diagnostic and prognostic genetic tests
Tips for Managing Rx Innovations and Challenges

• Prepare for patent expirations in advance
• Manage new blockbuster brands starting with traditional tools
• Demand clinical evidence and outcomes data
• Develop specialty pharmacy strategy
• Lobby for biosimilar process and criteria
• Ensure pharmacy is viewed within the medical continuum
References


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RX PAYMENT SOURCE 2006-2010

Summary of Third-Party Prescription Activity, 5-Year Trend

- 2010
- 2009
- 2008
- 2007
- 2006

- Non Third-Party
- Other Third-Party
- Medicare Part D
- Medicaid

Figure 15
NADAC – COMMUNITY PHARMACY PRINCIPLES

- Purchases generics at a cost of about 25 to 50% higher than large chains operations. This should be considered as reimbursement rates are determined.

- Benchmark must be updated frequently.

- Benchmark must correspond to community retail pharmacy costs.

- Benchmark and dispensing fee must be considered together.

- Need to maintain incentives to dispense lower-cost generic drugs. Because generics are purchased in a commodity market, there are a wide range of manufacturer’s prices.

- A pharmacy cost of dispensing survey should be completed on an annual basis.

- States should consider implementing a dispensing fee incentive for those pharmacies that serve a significant number of Medicaid beneficiaries or where Medicaid claims make up a certain percentage of their total prescription volume.
PRINCIPLES DURING THE IMPLEMENTATION OF MANAGED CARE PROGRAMS

- Fair and reasonable pharmacy reimbursement must be implemented.
- Pharmacists should receive reimbursement in a timely manner.
- Collaborative patient management programs and MTM programs should be fostered.
- Co-payment protections should be implemented.
- Contracts between PBM, state and pharmacy should be transparent.
- Fair audit provisions should be incorporated into pharmacy contracts.
- Beneficiaries should not be unfairly coerced into utilizing mail order pharmacy.
Provisions to incorporate into state exchanges:

- PBM must comply with transparency requirements of PPACA.
- More stringent record keeping by a pharmacy than that required by State and Federal Law should not be required.
- During audits, there should be no recoupment of funds unless desire to commit fraud can be proven.
- Exchanges should keep accounting of all activities and annually report information to the Secretary, Governor, Insurance Commissioner, etc.
- Exchanges should comply with an existing “any willing provider” law.
- Health plans in the exchange should not require mail order pharmacy.
 ROLE IN PATIENT CARE & COST SAVINGS

- **University of Connecticut**: Educating future pharmacists on healthcare reform and a pharmacists role in The Medical Home (TMH).

- **Connecticut**: Pharmacy written into *New Models of Care* Grant received by state Medicaid.

- **Missouri**: Pharmacist/Physician teams reduced unnecessary healthcare utilization for Medicaid recipients. Estimated that the program reduced per capita annual program expenditures by $6,804 and has generated annual savings of **$2.4 million**.

- **North Carolina**: ChecKmeds helped seniors and low income residents gain access to and manage medications. The program reported a return on investment ratio of **$13.55 to $1.** Total Savings = **$13,211,470.00**

- **Iowa**: Physicians and pharmacists closely manage medication regimens of their most complex patients. Medicaid compensates providers for the additional care associated with drug therapy management. **Estimated Cost Saved: $4,255,416** / **Drug Product Costs Saved: $1,176,809**

- **Texas**: Recently received grant funding for MTM and disease management pilot.
CMS creates Plan ratings to indicate quality of Medicare plans (scale of 1 to 5 stars)

Stars determined through performance measures (17 for Part D) across four domains:

1. Drug plan customer service
2. Member complaints, problems accessing services, members choosing to leave plan
3. Member experience with drug plan
4. Drug pricing and patient safety (medication safety and adherence)

Pharmacy Quality Alliance (PQA) developed and maintains 5 of the current Part D measures related to adherence and safety
2008-11, 2 PQA-supported measures in Part D:

1. High-risk medications in the elderly: % of older patients (> 65 years) receiving medication considered high risk for adverse drug-related event
2. Appropriate treatment of HTN in diabetes: % of diabetes-hypertension patients with ACEI or ARB

New for 2012: medication adherence – proportion of days covered (PDC) measures for:

3. Blood pressure (ACEI/ARB)
4. Cholesterol (statins)
5. Diabetes (across 4 classes of oral diabetes meds)
Pharmacists are included as potential participants within ACOs.

CMS expects pharmacists to play a role in governing ACOs.

Beneficiaries will be prospectively assigned to ACOs.

Some ACOs will have access to upfront advance payments as start-up costs, which CMS will recoup later through generated savings.

Finalized quality measures include measures related to vaccinations and medication reconciliation.
Many ACA programs focus on improving medication use; technology will be key to integrating pharmacies

Medical Home

Community Based Care Transition Program: Reduction in all hospital readmissions 20% by end of 2013. Focus on decreasing preventable complications during a transition from one care setting to another.
  + Lack of medication coordination/adherence

Federal Office for Dual Eligibles
  + Grants to better coordinate care, including drug therapy

Center for Medicare and Medicaid Innovation (CMMI)
  + Testing new models of MTM; Millions Hearts Initiative; Simplify my Meds
MEDICATION AND FINANCIAL WASTE ASSOCIATED WITH MAIL ORDER PHARMACY

“This is all for ONE patient that passed away and the family brought it into us to see if we could dispose of it for them. The patient was a Cystic Fibrosis patient that was dealing with Caremark Specialty mail order.”

$61,000
MAIL ORDER WASTE (CONT.)

Medicare Part D Patient
MAIL ORDER WASTE (CONT.)

Please visit the NCPA website for more mail-order waste testimony and pictures.

$2,500

$6,800

$17,000
The NY PSYCKES Program: Using Data to Drive Provider Improvements

Molly Finnerty, MD
New York State Office of Mental Health
New York State Psychiatric Institute/
Columbia University
Overview

- What is PSYCKES?
- PSYCKES projects
- Impact – quality and cost savings
What is PSYCKES?

- Secure, HIPAA-compliant portfolio of Web tools
  - PSYCKES – Medicaid (2008)
  - MyPSYCKES for consumers (2010)

- Developed by OMH to support quality improvement and clinical decision-making
  - Calculates performance on quality indicators at state/regional/agency/site levels
  - Provides treatment history across settings over time
  - MyPSYCKES allows consumers to enter data on treatment process, outcomes and goals

- Up to 5 yrs of data – all Medicaid service settings
Provider-Specific PSYCKES Homepage: QI Overview Screen

- Hospital/ER related measures
  - High utilization (4+/yr): BH, Medical, any cause
  - Readmission: 7 days, 30 days
  - Preventable admissions: Diabetes, Dehydration, Asthma

- High need ineffectively engaged

- Medication related indicator sets
  - Psychotropic polypharmacy (by class and over all)
  - Dose (by class of psychotropic)
  - Cardiometabolic (high/moderate risk AP + cardiometabolic condition)
  - Youth (“too many, too much, too young”)
QI Overview Screen:
Performance on measures with regional & state comparators
Drill Down on Indicator Set (e.g. 4+ Inpt/ER) to Individual Measures (e.g. BH, Medical, All)

### Quality Indicator Overview As Of 7/1/2011

**Agency:** Main Street Community Services

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<thead>
<tr>
<th>Indicator Type</th>
<th>Indicator</th>
<th>Population</th>
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![Graph showing indicator details]
Graph allows for rapid identification of utilization patterns, including medication adherence, outpatient and inpatient services.
# Medications: Psychotropics

Drug, dose, duration, start date, last pick up, prescriber

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
<th>Last Dose</th>
<th>Estimated Duration</th>
<th>First Day Picked Up</th>
<th>Last day Picked Up</th>
<th>Active in Past Month</th>
<th>Most Recent Prescriber</th>
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<td>1 Month(s)</td>
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<td>Geodon</td>
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<td>Seroquel Xr</td>
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<td>5/28/2011</td>
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<td>Clonazepam</td>
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<td>5/24/2011</td>
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<td>Shah Ketki Sharadkumar</td>
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## Regional and Provider Variation

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<th>Region</th>
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<td><strong>STATE</strong></td>
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<td>747</td>
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<td><strong>Hudson River</strong></td>
<td>9,255</td>
<td>2,695</td>
<td>29.12</td>
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<tr>
<td><strong>Long Island</strong></td>
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<td>1,003</td>
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<td><strong>New York City</strong></td>
<td>20,604</td>
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<tr>
<td><strong>Other Areas</strong></td>
<td>9,357</td>
<td>1,000</td>
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Recipient Search:
Find a client or group of clients at risk

Recipient Last Name: [ ] Age Range: [Select Age Range] [ ]
Medicaid Id: [ ]
Prescriber Last Name: [ ]
Drug Name: [ ] Active Drug: [ ]
Psychotropic Drug Class:
- Antidepressant
- Antipsychotic
- Anxiolytic
- Mood Stabilizer
- Side-Effect Management
- Stimulant
- Withdrawal Management
Non-Psychotropic Drug Class:
- Analgesics and Anesthetics
- Anti-Infective Agents
- Anti-Obesity Agents
- Antidiabetic
- Antihyperlipidemic
- Antihypertensive
- Antineoplastic Agents
- Biologics
Mental Health Diagnosis:
- Adjustment Disorder
- Anxiety Disorder
- Attention Deficit Disorder
- Autism & Pervasive Developmental Disorder
- Bipolar Disorder
- Conduct Disorder
- Delusional Disorder
- Dissociative Disorder
Medical Diagnosis:
- Certain Conditions Originating in the Perinatal Period
- Complications of Pregnancy, Childbirth, and the Puerperium
- Congenital Anomalies
- Diabetes
- Diseases of Skin and Subcutaneous Tissue
- Diseases of the Blood and Blood-Forming Organs
- Diseases of the Circulatory System
- Diseases of the Digestive System

Search for Consented Recipients: [ ]
Export displayed rows to PDF/Excel [ ] Excel [ ]
De-Identify Data [ ]
Release: 4.2.7
PSYCKES Implementation

- State hospitals (2003): 27 hospitals
- Mental health clinics (2008): 340 clinics
- NYC Hospital affiliated clinics (2010): 25 clinics/ CDTs
- LGU pilot (2010): NYC, Erie
- ACT Transitions Project (2010): 27 teams
- MyPSYCKES pilot (2010): 2 clinics
- ER pilot (2011): 4 ERs
- Access for OMH and OASAS licensed hospitals and detox programs (2011)
  - Support goals of Phase I – Learning to use data
Traditional UR vs. Clinic-based QI

Traditional DUR:

- Communication outreach from unknown agent:
  - state/contract agent -> doctor

- QI Infrastructure:
  - No local QI infrastructure leveraged or built

- Accuracy of communication target: identification of doctor is often a challenge using Medicaid

- Intensity of outreach efforts:
  - Limited by capacity

- Impact
  - Low

Clinic-based Quality Collaborative and Automated UR

- Communication outreach is local:
  - Clinic point person (who accesses PSCYKES) -> doctor

- QI Infrastructure:
  - Reinforced by clinic and builds new capacity for providers to do CQI

- Accuracy of communication target:
  - Medicaid data is very accurate in identifying provider agency, and programs know who the doctor is

- Intensity of outreach efforts
  - All impacted enrollees, every month

- Impact
  - Higher
Impact
Impact of PSYCKES-CQI on Quality Measures (at 18 months)

- **Self Report QI Data:**
  - Nearly half of clinics have met 30% target

- **Medicaid data:**
  - Significant decreases in most of the indicators compared to clinics that were not eligible to participate

- **Fiscal impact**
  - Additional 41% cost savings over savings due to move to generics
Impact of PSYCKES CQI Initiative on the Statewide Prevalence of Quality Concerns in the Medicaid Mental Health Clinic Population: Longterm Antipsychotic Polypharmacy

NYC Participating, n=48
NYC NonParticipating, n=53
ROS Participating, n=62
ROS NonParticipating, n=54

Percent of Clients on Longterm Antipsychotic Polypharmacy among those on any Antipsychotic
Fiscal Impact

- Number of individuals receiving psychotropics is increasing
- Average annual per enrollee costs of psychotropics have been decreasing (e.g. due to medications coming off patent, etc.)
- Cost savings attributable to PSYCKES in year 1 of the project
  - $2.9M in savings attributed to the project (FY2009)
  - PSCYKES CQI generated approx. 40% in cost savings over general trends
MEDNET

- Accelerate the implementation of two types of comparative effectiveness findings in Medicaid mental health:
  - Effective and safe clinical practices related to pharmacological and psychosocial mental health treatment; and
  - Effective state policies, strategies, and organizational practices related to management of these treatments.

- California, Maine, Missouri, Oklahoma, Texas and Washington.