Current Issues in Pharmacy

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SEAC Meeting

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Walgreens
AT THE CORNER OF HAPPY & HEALTHY®

Agenda

- Managing specialty pharmacy
  - Current landscape
  - Management challenges and opportunities
  - Lessons for actuaries
- The issue of adherence
  - How it's measured
  - What's the impact
  - Why we're talking about it

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The specialty landscape is changing

Headwinds

- Robust Pipeline/ Novel MOA
- Manufacturer Price
- Approval Pathways /Orphan Drugs
- 351 (k) pathway
- Accelerated approvals

- Ancillary Medication Cost Reduction
- Reduced Disease Impact Costs (hospitalizations, ER)
- Performance Guarantees
- Site Of Care and Channel Cost Disparity

- Emerging / Warehoused Populations
- Consensus Guidelines
- Pharma Market Pressure

- Patent Expirations
- Pharmacoeconomic Studies
- Market Landscape/ Competitive Pricing
- Biosimilars?

Tailwinds

References: 1. FDA Orphan Drug Act accessed at http://www.fda.gov/regulatoryinformation/legislation/federalfooddrugandcosmeticactfdcact/significantamendmentstothefdcact/orphandrugact/default.htm
2. Chughtai M, Chang J, Philips MI, et al. Benefits of the orphan drug act for rare disease treatments. *TUFTScope*. Spring, 2010.

Rare disease is a specialty subset accelerator

Orphan / Rare Disease

- Conditions that affect fewer than 200,000 patients[1]
- Estimated 15 to 20 million Americans affected[2]

Specialty Spend

Through 2018, there will be a 17 percent compound annual growth rate in U.S.[1]

Orphan Drugs Set to be 15.9% of Worldwide Prescription Sales by 2018[2]

Rare Disease

Prior to 1983 only 34 orphan products were marketed[3]

Between 1983 and 2009 the FDA approved 275 orphan drugs for 337 orphan indication[3]

There are an estimated 6,000 rare diseases currently recognized in the U.S. alone

2013-2018 CAGR

Orphan 5.67%

vs. Non-Orphan 3%

U.S. orphan market has resulted in 86 new approvals between 2000 and 2013[4]

•**References:**

•1. http://www.healthcarefinancenews.com/news/sensible-strategies-curb-cost-growth-specialty-drugs

•2. Hyde R. **Orphan Drug Pricing and Payer Management in the United States: Are We Approaching the Tipping Point. January/February 2010 Volume3 No1 American Health and Drug Benefits**

•3. Joshua P. Cohen and Abigail Felix. Are payers treating orphan drugs differently? Journal of Market Access & Health Policy 201.2; 23513. 4. http://www.fiercepharmamarketing.com/story/orphan-drug-approvals-are-prices-are-more/2014-07-16

Case Study: Pulmonary Arterial Hypertension

Population

- Prevalence of 109 per million for ages <65 and 451 per million for Medicare[1]
- High Comorbid Index[1]
- Average AWP Specialty Cost Per Month= $8,000[2]
- Based on data from the Registry to Evaluate Early And Long-term PAH disease management (REVEAL) of patients in the United States, there is an estimated five-year survival rate of 57% from diagnosis.

References:

•1.http://www.unboundmedicine.com/medline/citation/21793646/Prevalence_of_pulmonary_arterial_hypertension_and_chronic_thromboembolic_pulmonary_hypertension_in_the_United_States **2. Treatment patterns and resource utilization and costs among patients with pulmonary arterial hypertension in the United States** 2010, Vol. 13, No. 3 , Pages 393-402

Case Study: Pulmonary Arterial Hypertension

Pharmacy Coverage Differences

- Formulary / Preferred Product
- Staging/Population Burden
- Access vs. Adherence
- Medical/Pharmacy Benefit Cross Over

References:

•1.http://www.unboundmedicine.com/medline/citation/21793646/Prevalence_of_pulmonary_arterial_hypertension_and_chronic_thromboembolic_pulmonary_hypertension_in_the_United_States **2. Treatment patterns and resource utilization and costs among patients with pulmonary arterial hypertension in the United States** 2010, Vol. 13, No. 3 , Pages 393-402

Case Study: Pulmonary Arterial Hypertension

Critical Variables

- Patent Expiration / Generic
- Pipeline - Novel Agents/ Price Set
- Manufacturer Price Increases
- Ancillary Care
- Population/Disease Burden

References:

•1.http://www.unboundmedicine.com/medline/citation/21793646/Prevalence_of_pulmonary_arterial_hypertension_and_chronic_thromboembolic_pulmonary_hypertension_in_the_United_States **2. Treatment patterns and resource utilization and costs among patients with pulmonary arterial hypertension in the United States** 2010, Vol. 13, No. 3 , Pages 393-402

Case Study: Hemophilia

Background and Population

- Hemophilia is a chronic and expensive condition, with antihemophilic medications accounting for 45%-93% of total health care costs, depending on severity and treatment regimen.
- Estimated 18,500 patients with hemophilia A and B in the United States[2]
- 1 in 5,000 male babies are born in the U.S. with hemophilia A each year[1]
- Approximately 12,500 hemophilia A patients utilize Factor VIII therapy[3]
- 28% mild, 19% moderate, 53% severe.

References:

•1. Hemophilia A (factor VIII deficiency). National Hemophilia Foundation Web site. Http://www.hemophilia.org/NHFWeb/MainPgs/MainNHF.aspx?menuid=180&contentid=45&rptname=bleeding 2. Summary report of UDC activity national patient demographics (hemophilia). Centers for Disease Control and Prevention Web site. 3.https://www2a.cdc.gov/ncbddd/htcweb/UDC_Report/UDC_view1.asp?para1=NATION&para2=DEMOH&para3=&ScreenWidth=1920&ScreenHeight=1200. 3. Summary report of UDC activity national treatment/clinical characteristics (hemophilia). Centers for Disease Control and Prevention Web site. 4.Smith PS. Levine PH. The benefits of comprehensive care of hemophilia: a five-year study of outcomes. *Am J Public Health*. 1984;74:616-617.

Case Study: Hemophilia

Coverage Drivers and Strategies

- Formulary / Preferred Product
- Medicaid Expansion
- Population Burden/Spend - Prevalence/ Spend Disparity in Medicaid vs. Commercial
- Care management vs. Drug Management
- StopLoss Reinsurance/ Risk Delegation/ Carve Out
- Medical benefit vs. Pharmacy benefit

References:

•1. Hemophilia A (factor VIII deficiency). National Hemophilia Foundation Web site. Http://www.hemophilia.org/NHFWeb/MainPgs/MainNHF.aspx?menuid=180&contentid=45&rptname=bleeding 2. Summary report of UDC activity national patient demographics (hemophilia). Centers for Disease Control and Prevention Web site. 3.https://www2a.cdc.gov/ncbddd/htcweb/UDC_Report/UDC_view1.asp?para1=NATION&para2=DEMOH&para3=&ScreenWidth=1920&ScreenHeight=1200. 3. Summary report of UDC activity national treatment/clinical characteristics (hemophilia). Centers for Disease Control and Prevention Web site. 4.Smith PS. Levine PH. The benefits of comprehensive care of hemophilia: a five-year study of outcomes. *Am J Public Health*. 1984;74:616-617.

Case Study: Hemophilia

Critical Variables

- New Long-Acting Products
- Performance Guarantees
- Manufacturer Price Increases
- Ancillary Care- Reduction in hospitalizations[4]
- Population/Disease Burden

References:

•1. Hemophilia A (factor VIII deficiency). National Hemophilia Foundation Web site. Http://www.hemophilia.org/NHFWeb/MainPgs/MainNHF.aspx?menuid=180&contentid=45&rptname=bleeding 2. Summary report of UDC activity national patient demographics (hemophilia). Centers for Disease Control and Prevention Web site. 3.https://www2a.cdc.gov/ncbddd/htcweb/UDC_Report/UDC_view1.asp?para1=NATION&para2=DEMOH&para3=&ScreenWidth=1920&ScreenHeight=1200. 3. Summary report of UDC activity national treatment/clinical characteristics (hemophilia). Centers for Disease Control and Prevention Web site. 4.Smith PS. Levine PH. The benefits of comprehensive care of hemophilia: a five-year study of outcomes. *Am J Public Health*. 1984;74:616-617.

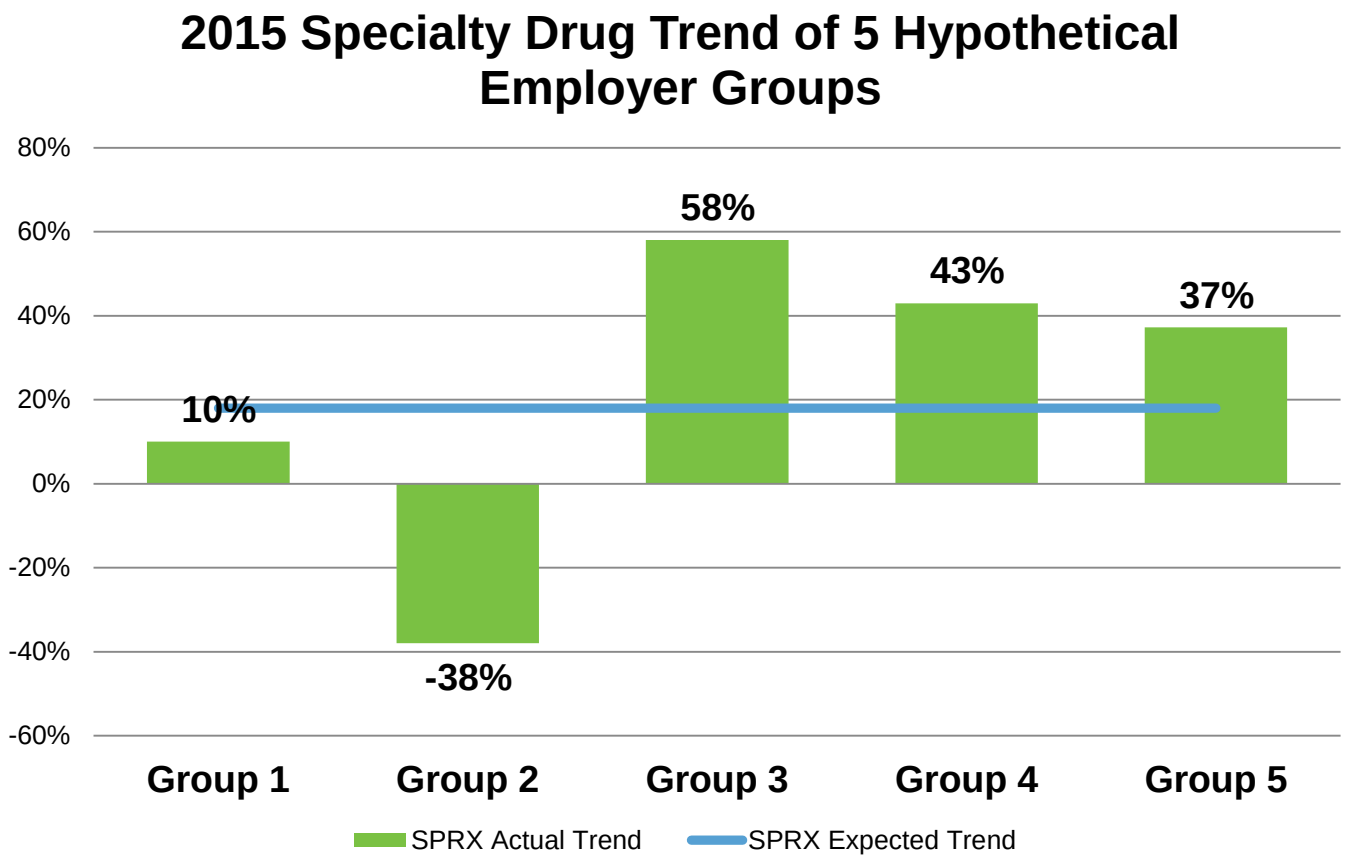
A “Simple” Story about 5 Hypothetical Employer Groups

- Assumptions for this presentation
  - Five employer groups are attempting to predict their specialty spend
  - Each employer group has 5,000 covered lives and has experienced no significant enrollment changes
  - They are all expecting a 2014 – 2015 SP trend of 18% based on information from advisors
  - Each plan had a 2014 Specialty pharmacy spend of $250 PMPY*
    - $1.25M incurred in 2014
    - Expecting $1.47 in 2015

**For illustrative purposes only. Commercial Specialty per member per year costs per Express Scripts Drug Trend Report was reported at $240.57 in 2013*

- One Year Later……

What Happened to the Expected 18% Trend?



Insight into Specialty Trend Drivers

- Annual specialty therapy can typically cost $30,000 per year or more.[1]
- Some therapies can cost >$300,000 per year.
- Pricing inflation is the only constant in every employer group's trend.
- Due to the low prevalence of specialty patients (~1-2% of a population), trend prediction can be challenging. [1]
- **Unlike traditional pharmacy, one specialty patient can impact trend.**
- Rare disease treatments can dramatically skew trend.
- Patients switching coverage between medical and pharmacy benefits can impact trend.
- One poorly managed specialty patient can dramatically negatively impact trend.

[1] Walgreens data on file.

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Common measures of medication adherence

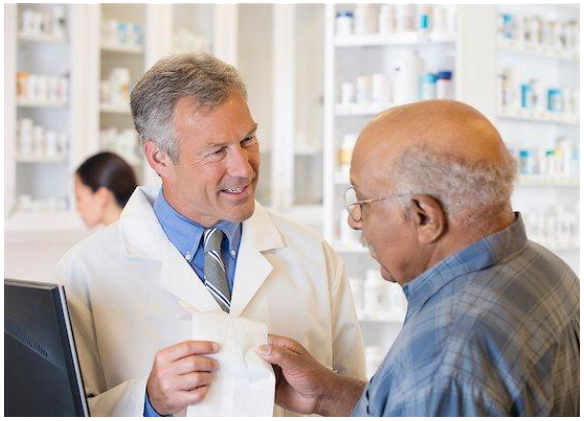
- **Medication possession ratio (MPR)** =
  - **Total days of supply** / **Total days in observation period**
- **Proportion of days covered (PDC)** =
  - **Total days covered** / **Total days in observation period**

•**1.** Nau DP. Proportion of days covered (PDC) as a preferred method of measuring medication adherence. http://www.pqaalliance.org/images/uploads/files/PQA%20PDC%20vs%20%20MPR.pdf. Accessed June 10, 2014. **2.** Leslie, RS. Calculating medication compliance, adherence, and persistence in administrative pharmacy claims databases. Paper presented at: SAS Global Forum; April 16-19, 2007; Orlando, FL.

Unmet needs of adherence

The Institute for Healthcare Improvement's "Triple Aim" focuses on three dimensions[1]

- **Improving patient satisfaction and quality of care**
- **Improving population health**
- **Reducing the cost of healthcare**



Medication nonadherence—the failure to take medication as prescribed—is an impediment to healthcare optimization[2]

- The Congressional Budget Office (CBO) estimates that a **1 percent increase in the number of prescriptions filled** by beneficiaries would cause Medicare's spending on medical services to fall by roughly **one-fifth of 1 percent**[3]

•**1.** Institute for Healthcare Improvement. The IHI Triple Aim. http://www.ihi.org/Engage/Initiatives/TripleAim/Pages/default.aspx. Accessed April 14, 2014. **2.** Nasseh K, Frazee SG, Visaria J, Viahiotis, Tian Y. Cost of medication nonadherence associated with diabetes, hypertension, and dyslipidemia. *Am J Pharm Benefits*. 2012;4(2):e41-e47. **3.** Congressional Budget Office. Offsetting effects of prescription drug use on Medicare's spending for medical services. www.cbo.gov/publication/43741. Published November 29, 2012. Accessed June 4, 2014.

Current clinical state of adherence

Medication nonadherence is common and costly

75 percent
fail to take **medications as directed**[1]

33 percent
of **prescriptions are never filled**[1]

Up to
60 percent
of the time, **patients with chronic conditions do not take their medication**[1]

- Approximately
- **125,000 deaths annually** are attributed to **nonadherence to medication therapy**[2]

Hospital readmissions

Adverse medication events (including patient nonadherence) are at the core of the readmission problem. This leads to treatment failures and wasted resources[3]

•**1.** Bosworth HB; National Consumers League. Medication adherence: making the case for increased awareness. http://www.scriptyourfuture.org/wp-content/themes/cons/m/Script_Your_Future_Briefing_Paper.pdf. Accessed September 17, 2014. **2.** American Hospital Association. Uncompensated Hospital Care Cost Fact Sheet. http://www.aha.org/content/13/1-2013-uncompensated-care-fs.pdf. Published January 2014. Accessed September 17, 2014 **3.** Institute for Safe Medication Practices. Reduce readmissions with pharmacy programs that focus on transitions from the hospital to the community. www.ismp.org/newsletters/acutecare/showarticle.aspx?id=36. Published November 15, 2012. Accessed June 1, 2014.

The economic cost of nonadherence

The total direct national cost of **nonadherence** for adults diagnosed with diabetes, hypertension, or dyslipidemia was **$105.8 billion**, or an average of **$453 per adult**, in 2010[1]

Diabetes
37.9 percent of patients are **nonadherent**[2]

Asthma
80.2 percent of pediatric patients and **53.8** percent of adult patients are **nonadherent**[2]

Hypertension
28.1 percent of patients are **nonadherent**[2]

Dyslipidemia
27.2 percent of patients are **nonadherent**[2]

Preventable hospital readmissions cost the U.S. healthcare system **$25 billion** annually[3]

•**1.** Nasseh K, Frazee SG, Visaria J, Viahiotis A, Tian Y. Cost of medication nonadherence associated with diabetes, hypertension, and dyslipidemia. *Am J Pharm Benefits*. 2012;4(2):e41-e47. **2.** Express Scripts. Drug trend report. http://lab.express-scripts.com/~/media/previous%20reports%20pdfs/drug%20trend%20report%202012.ashx. Updated October 2013. Accessed March 19, 2014. **3.** Pricewaterhouse Coopers' Health Research Institute. The price of excess: identifying waste in healthcare spending. http://www.pwc.com/us/en/healthcare/publications/the-price-of-excess.jhtml. Accessed April 29, 2014.

Improved adherence can impact your organization

Enhance clinical outcomes, patient satisfaction and quality of care

- Pharmacist counseling can significantly impact adherence and clinical outcomes[1-3]

Increase Medicare Advantage star quality ratings

- Star metrics adherence measures are triple weighted
- May impact bonus payments and improve competitiveness[4]

Reduce healthcare costs

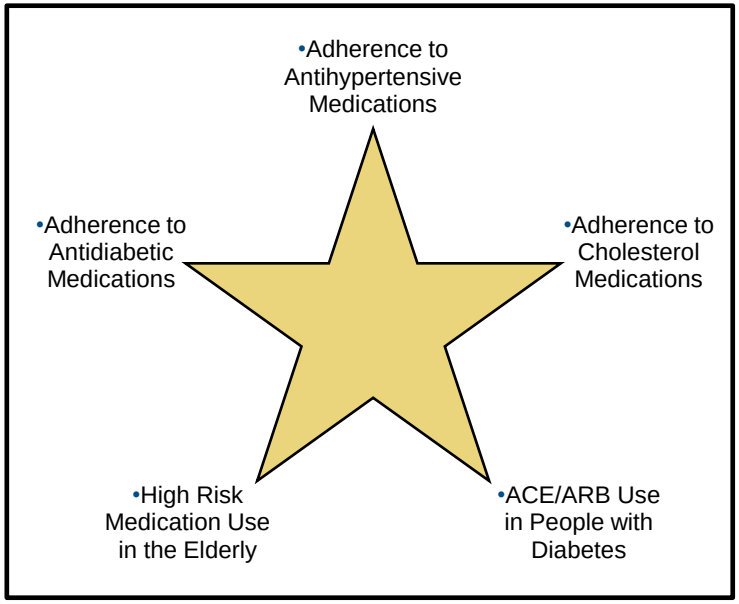
- Up to **19 percent** of discharged patients experienced an **adverse event after discharge**
  - **Two-thirds** were attributed to **medications**
  - **One-third** resulting in a hospital admission were related to **nonadherence**[5]

•**1.** Bluml BM, McKenney JM, Cziraky MJ. Pharmaceutical care services and results in project ImPACT: hyperlipidemia. *J Am Pharm Assoc (Wash)*. 2000;40(2):157-165. **2.** Bunting BA, Smith BH, Sutherland SE. The Asheville Project: clinical and economic outcomes of a community-based long-term medication therapy management program for hypertension and dyslipidemia. *J Am Pharm Assoc (2003).* 2008;48(1):23-31. **3.** Fera T, Bluml BM, Ellis WM. Diabetes Ten City Challenge: final economic and clinical results. *J Am Pharm Assoc (2003)*. 2009;49(3):383-391. **4.** Walgreen Co. Data on file; 2013. **5.** Bosworth HB; National Consumers League. Medication adherence: making the case for increased awareness. http://www.scriptyourfuture.org/wp-content/themes/cons/m/Script_Your_Future_Briefing_Paper.pdf. Accessed September 17, 2014.

Improved adherence can impact your organization

Increase Medicare Advantage star quality ratings

- Five heavily-weighted medication-related Star ratings
  - » *Account for ≥17% of a MA-PD's Star rating*
  - » *Account for ≥50% of a PDP's Star rating*
  - » *Star rating performance is relative*
    - *Must perform better than other plans to receive a high score*
- May impact bonus payments and improve competitiveness
  - » *Applicable for MA-PD plans*
  - » *Increase in overall Star rating can increase capitation*
  - » *High overall Star ratings lead to increases in enrollment*
    - *5-star plans are eligible to enroll year-round*
  - » *Improvement in quality measures can reduce medical cost*



Thank you!

Q&A (or O)