Pharmacy Enterprise: Central to Health System Success

HFMA Conference
March 28, 2018

Michael Nnadi, Pharm.D., MHS, Sc.D. (hon)
Chief Pharmacy Officer
University of Louisville Medical Center | The James Brown Cancer Center
Objectives

- Health system concern
- Pharmacy story
- Pharmacy strategy
- 340B Program management
Objectives

- Health system concern
- Pharmacy story
- Pharmacy strategy
- 340B Program management
What’s keeping health system leaders up at night?

1. The speed of movement from volume to value and potential impacts
2. The cool-off as it relates to provider-sponsored health plans
3. Traditional M&A continues while nontraditional alliances grow more prevalent
4. Growth in ancillary systems and alliance efforts with best-in-class operators
5. The extent of risk being pushed to systems in each of core payer areas
   - Commercial, Medicare and Medicaid
6. A shrinking pool of acquisition candidates
7. The return to the basics of execution and business
8. The impact of the cost of pharmaceuticals and impact on healthcare costs
9. The competition with private equity for high-margin business
10. The pushing of procedures out of hospitals and the efforts to backfill
Pharmaceutical companies cite high cost of research as reason for price increases

- Pfizer raised list prices an avg. of 10.6% on 60 branded products; increases on 100 drugs
- 8 of their branded products increased 20%

- Amgen raised Enbrel (anti-inflammatory drug) by 10% (May), 8% (Sept), 8% (Dec)
- Drug cost is 4X launch price in 1990s
- $704 per week for typical dosing treatment for rheumatoid arthritis or $36,600/year
  - 10% increase to $148,000/yr
  - 76% higher than 2014 introduction

The price hikes for Enbrel and other drugs “seems to have increased in magnitude and frequency”,
Source: Christopher Raymond, Raymond James (analyst)
Objectives

- Health system concern
- Pharmacy story
- Pharmacy strategy
- 340B Program management
Pharmacy Story

- The pharmacy is often a sub-optimized asset in a health-system
- Usually viewed simply as a utility or cost center
- Add value and contribute substantially to revenue growth
- Represents both a revenue strategy as well as a cost containment opportunity
- Improved patient outcomes, and the creation of a competitive advantage
Pharmacy Story: Pharmacist Improve Access

- Residents in critical shortage areas are 1.7 times more likely to experience preventable hospitalization\(^1\)

- Pharmacists are a highly-trained, readily available workforce capable of rapidly expanding patient access to healthcare

- Pharmacist involvement in primary care has resulted in high satisfaction ratings from patients and providers alike\(^2\)

In medical homes, ACOs and hospitals, clinical pharmacists will play a key role

Pharmacy Story: Pharmacist Improve Quality

• Studies show that optimum medication use is demonstrated in only 4-21% of patients\(^1\)

• Greater pharmacist involvement leads to:
  ✓ Fewer rehospitalizations\(^2\)
  ✓ Lower healthcare costs\(^3\)
  ✓ Better adherence to evidence-based consensus guidelines\(^4\)
  ✓ Better outcomes\(^1-4\)

Pharmacy Story: Increasing Support for Pharmacist Involvement

• The *Wall Street Journal* notes that pharmacists are a useful and necessary resource on the primary care team\(^1\)

• The American Medical Association recognizes the important collaborative role pharmacists can fill\(^2\)

---

Decision making in Pharmacy is more critical or complex for these reasons………

- **Financial**
  - Intensifying margin
  - Transition to value-based care

- **Quality and Access**
  - Increasing quality, outcomes scrutiny
  - Rise in Health Care “Consumerism”
Financial: Intensifying Margin Pressure

• Steep increases in drug prices
• Continued growth in drug utilization
• Emerging retail and specialty growth opportunities

• Pharmacy response
  • Prioritize growth opportunities from specialty and retail
  • Right size pharmacy service portfolio, market footprint
  • Optimize operational efficiency
  • Pursue novel contracting arrangements with suppliers
Quality & Access: Increasing Quality, Outcomes Scrutiny

- Expansion of Medicare P4P programs (e.g., readmissions penalties)
- Increased reporting requirements from payers, regulators

Pharmacy Response
- Manage a growing list of regulatory and accreditation requirements
- Prioritize investments in pharmacy data and technology
- Advance quality and safety in an increasingly complex environment
Quality & Access: Rise in Health Care “Consumerism”

- Increasing importance of HCAHPS scores
- Increasing transparency on quality and price
- More alternative access points (e.g., retail pharmacies)

Pharmacy Response
  - Streamline pre-authorizations to ensure timely access
  - Address patient concerns about affordability
  - Enhance convenience, access to pharmacy services
  - Differentiate pharmacy program, establish a unique value proposition
Objectives

- Health system concern
- Pharmacy story
- Pharmacy strategy
- 340B Program management
Pharmacy Strategic Focus

“At the end of the day, your organization’s decision to optimize pharmacy has to be driven by pharmacy strategy. A strategic plan is a must”

Michael Nnadi
Market Forces: Why Grow Pharmacy?

- Dramatic changes in healthcare
- Potential for exponential financial and quality of care benefits
- Population Health
- Shortage of primary care physicians
- Increase in number and cost of specialty pharmaceuticals
Why Grow Pharmacy?

- Continuum of care now includes:
  - Clinics
  - Physician practices
  - Ambulatory centers
  - Nursing homes
  - Patient homes

- Follow patients through health-system footprint to enhance outcomes, improve safety, reduce readmissions, and reduce errors
  - 30-days of medicine at discharge through concierge pharmacy service
  - Support for chronically ill, high-risk patients through enrollment in
    - retail pharmacy
    - specialty pharmacy services
    - Infusion services
Growth Opportunities
Retail Pharmacy

• Growth in pharmacy driven by:
  • Ability to capture market share
  • Grow Volume
  • “Directed” employee benefit
  • Discharge medication fulfillment
  • Integrated patient experience with technological investments

• Benefits
  • Reduce 30 days readmission
  • Manage employee drug benefit
  • Leverage total drug spend in wholesaler contracts
Growth Opportunities
Retail Pharmacy

• Challenges/Headwinds
  • Narrow network of supply chain/therapy access

• 340B status; WAC versus GPO
Why Grow Infusion Program?

- Reimbursement for pharmaceutical products in the outpatient
- Improvements with early diagnosis of disease means that more patients will be needing infusion services
- New infusion drugs are in the pipeline
- Plans increasingly steer patient to less costly site of care
- Medical group is referral source
- Support population health
- Reducing admissions, readmissions, and length of stay
- Decompressing the ED
- Offering convenience to patients
Pharmacy & Population Health management

- Population Health mandate – to promote health and prevent disease

  Triple aim
  - Improve quality and the patient experience
  - Reduce costs
  - Improve the health of the population

- Pharmacy’s Role
  - Pharmacists are highly trained, capable of expanding patient access to healthcare
  - Pharmacist involvement leads to higher patient and provider satisfaction
  - Pharmacist involvement results in less medication related events and improved quality of care
Why is Specialty Pharmacy Critical?

• Growing at 20% per year

• Typical cost of $20K – over $100K per patient per year

• Current model fragments care for most complex patients

• Collaboration of physician thought leaders to create better patient outcomes
Why specialty pharmacy growth is critical

• Pipeline is dominated by significantly more expensive drugs aimed at smaller more targeted and complex patient populations:
  
  – “More than 400 Medicines in Development to Treat or Prevent Rare Diseases” – PhRMA
  – “More Than 900 Medicines and Vaccines in Clinical Testing Offer New Hope in the Fight Against Cancer” – PhRMA

• Health plans, hospitals and physicians are demanding more and better data to determine “real world” clinical and cost effectiveness beyond product launch
Specialty Pharmacy Spend

Spending in Billions (USD)

- $87.10 (2012)
- $192.20 (2016)
- $401.70 (2020)

121% increase from 2012 to 2016
109% increase from 2016 to 2020

At least 50%
Percentage of new medications considered specialty

New and Expensive Drugs need to be managed to maximize effectiveness and minimize serious problems

PWC Health Research Institute. Medical Cost Trend: Behind the Numbers 2016
Diplomat Clinical Services. Specialty Drug Approvals, 2016 Highlights & 2017 Projections
PWC Health Research Institute. Medical Cost Trend: Behind the Numbers 2015
Definition: There is no universal *specialty medication* definition.

- CMS definition - greater than $600/script
  - Most are over $2,000 per fill

- Accreditation definition –
  - usually require specialty handling, administration, unique inventory management,
  - a high level of patient monitoring,
  - more intense support than conventional therapies

- Specialty pharmaceuticals are the fastest growing segment of drug spend

- Small patient population (<2% of total population)
The 5 P’s of Specialty Pharmacy

- Patient
- Pharmacy
- Payer
- Pharma
- Providers
Patient Disease States

- Cardiology
  - Hyperlipidemia
- Infectious Diseases
  - HIV
  - Hepatitis
- Inflammatory Diseases
  - Crohn’s Disease
  - Psoriasis (PSO)
  - Psoriatic Arthritis (PSAO)
  - Rheumatologic diseases
- Hematology
  - Cancer
  - Hemophilia
- Medical Oncology
  - Cancer
- Neurology
  - Multiple Sclerosis
  - Movement Disorders
- Pulmonology
  - Cystic Fibrosis
  - Pulmonary Hypertension
- Transplant
  - Solid organ transplant
- Women’s Health
  - Infertility
Drug Spend by Disease State

## Trend Forecast for Key Specialty Therapy Classes

### 2016 - 2018

<table>
<thead>
<tr>
<th>Therapy Class</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inflammatory conditions</td>
<td>25.5%</td>
<td>25.5%</td>
<td>26.7%</td>
</tr>
<tr>
<td>Multiple sclerosis</td>
<td>11.2%</td>
<td>10.2%</td>
<td>7.2%</td>
</tr>
<tr>
<td>Oncology</td>
<td>21.1%</td>
<td>20.0%</td>
<td>20.0%</td>
</tr>
<tr>
<td>Hepatitis C</td>
<td>10.2%</td>
<td>8.1%</td>
<td>8.0%</td>
</tr>
<tr>
<td>HIV</td>
<td>17.7%</td>
<td>17.8%</td>
<td>18.9%</td>
</tr>
<tr>
<td>Growth deficiency</td>
<td>9.1%</td>
<td>9.1%</td>
<td>9.0%</td>
</tr>
<tr>
<td>Cystic fibrosis</td>
<td>58.2%</td>
<td>36.2%</td>
<td>28.8%</td>
</tr>
<tr>
<td>Pulmonary hypertension</td>
<td>16.6%</td>
<td>5.8%</td>
<td>5.9%</td>
</tr>
<tr>
<td>Hemophilia</td>
<td>17.3%</td>
<td>18.3%</td>
<td>22.4%</td>
</tr>
<tr>
<td>Sleep disorders</td>
<td>22.6%</td>
<td>21.5%</td>
<td>20.5%</td>
</tr>
<tr>
<td>Other specialty classes</td>
<td>6.7%</td>
<td>6.4%</td>
<td>6.4%</td>
</tr>
<tr>
<td><strong>Total Specialty</strong></td>
<td><strong>17.4%</strong></td>
<td><strong>16.8%</strong></td>
<td><strong>17.2%</strong></td>
</tr>
</tbody>
</table>

*Trend is forecast only for specialty medications billed through the pharmacy benefit.

Source: Express Scripts 2015 drug trend report
SP Health System Trends

Today’s Market

- Innovators: 2.5%
- Early Adopters: 13.5%
- Early Majority: 34%
- Late Majority: 34%
- Laggards: 16%

Source: Everett Rogers’ Diffusion of Innovations model.
Rational for Building Specialty Pharmacy

- Revenue
- Supply Chain Efficiency
- Improved Patient Health Outcomes
- Patient and Provider Experience

- ACO/Capitation Risk Avoidance
- Internal Retail Pharmacy Growth
- Continuity of Care
- Leverage

Becker's Hospital Review: Specialty Pharmacy: A Key to Organizational Success in Population Health Management
Clinical & Operational excellence and standardization will be key

- Automated dispensing cabinet (ADC)
- Medication storage designed with the end user in mind
- Reliable and predictable medication distribution
- Effective Pharmacy & Therapeutics Committee
  - Manage formulary
  - Manage cost
- Reduce drug waste
- Manage drug shortage
- Supply chain partnerships
MedStar Health, Novant Health and Sentara Healthcare have joined together through a formal relationship to aggregate their collective expenditures to approach the supplier community in a unified manner in order to create incremental economic advantage and to create additional value through other quality, cost and efficiency opportunities.*

* Board approved purpose of the company (December 2011)
Leaders share a compelling vision for a successful partnership.

- **Best pricing**: Enable MNS to maximize savings within each category of pharmacy spend.
- **Collaborative**: Work with MNS members and foster deeper connections within the MNS pharmacy network.
- **Strategic**: Build a longitudinal relationship focused on evolving pharmacy results over time.
- **Proactive**: Deliver data-driven pharmacy performance insights that advance value, practice and service.
- **Consultative**: Distill pharmacy insights into actionable recommendations and support success through shared learnings.
MNS Pharmacy Council offers a pathway to maximize member value through pricing and practice optimization.

**Current State: Key Areas of Focus**

01: Aggregation
- Pricing optimization through aggregation

02: Idea Exchange
- Clearinghouse for idea exchanges

03: Leading Practices
- Identification of “leading practices”

04: Networking
- Other networking opportunities

05: Enhancements
- Analytics, analytics, analytics
- 3-5 year strategic plan
- Enhanced MNS corporate support

**Needs for the Future**
Result

• More than $30M in three years
  • Distributor contract

• Other savings
  • Flu vaccine
  • Formulary standardization in key drugs
  • Single source contracts
  • Technology

• Relationships and collaboration enhanced
Objectives

- Health system concern
- Pharmacy story
- Pharmacy strategy
- 340B Program management
340B Program

- Bipartisan legislation passed in 1992
  - Required manufacturers to participate if they wanted Medicaid rebates
- Intent is for covered entities to stretch scarce federal resources as far as possible (patients, comprehensive services, etc)
What is Section 340B?

• Section 340B of the Public Health Service Act.

• Requires manufacturers participating in the Medicaid program to also provide discounts on covered outpatient drugs purchased by specific “covered entities”.

• The “covered entities” are safety-net hospitals and other entities serving the uninsured or vulnerable patient groups.
Operation of 340B Program

• Prices average 54% below AWP and 24% lower than GPO prices.

• Administered by Health Resources Services Administration / Office Pharmacy Affairs (HRSA/OPA)
Program Pillars

• Patient must be an outpatient of the covered entity
  • Medical record; must maintain care

• Prescribing provider must be employed by, have a contractual relationship with, or other arrangement with the covered entity
DSH Hospital Eligibility Criteria

- Owned or operated by state or local government.
- Granted governmental powers by state or local government.
- Private, non-profit with contract with state or local government to serve indigent.
- Medicare DSH adjustment of 11.75% or greater.
340B Restrictions – Anti-Diversion

• Drugs purchased under 340B may not be resold or transferred to anyone other than a patient of the facility.

• Penalty for violation is forfeiture of discounts and possible disqualification from the program.

• Manufacturers and the government (OPA) have the right to audit records to prevent diversion.
HRSA 340B Program Audits

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Healthcare Providers Audited</th>
</tr>
</thead>
<tbody>
<tr>
<td>FY 2013</td>
<td>94</td>
</tr>
<tr>
<td>FY 2014</td>
<td>99</td>
</tr>
<tr>
<td>FY 2015, 2016, 2017</td>
<td>200+</td>
</tr>
</tbody>
</table>
### Specific Hospital Audit Findings

<table>
<thead>
<tr>
<th></th>
<th>FY 12</th>
<th>FY 13</th>
<th>FY 14</th>
<th>FY 15</th>
<th>FY16*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Diversion</strong></td>
<td>33%</td>
<td>58%</td>
<td>61%</td>
<td>53%</td>
<td>51%</td>
</tr>
<tr>
<td><strong>Duplicate Discount</strong></td>
<td>30%</td>
<td>21%</td>
<td>23%</td>
<td>23%</td>
<td>19%</td>
</tr>
<tr>
<td><strong>Inaccurate Database</strong></td>
<td>24%</td>
<td>50%</td>
<td>48%</td>
<td>43%</td>
<td>34%</td>
</tr>
<tr>
<td><strong>Contract Pharmacy</strong></td>
<td>4%</td>
<td>5%</td>
<td>3%</td>
<td>2%</td>
<td></td>
</tr>
<tr>
<td><strong>Oversight</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>GPO Exclusion</strong></td>
<td>1%</td>
<td>11%</td>
<td>11%</td>
<td>6%</td>
<td></td>
</tr>
<tr>
<td><strong>Unauditable Records</strong></td>
<td>1%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Non-Reimbursable Site</strong></td>
<td>1%</td>
<td>1%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>DSH Adjustment %</strong></td>
<td>1%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Orphan Drug</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2%</td>
</tr>
</tbody>
</table>

*not all results are available yet*
340B CMS Billing

New CMS Billing Rules for January 2018
Medicare’s payment policy for 340B-acquired drugs provided by a hospital outpatient department

• Beginning January 1, 2018, Medicare pays an adjusted amount of the average sales price (ASP) minus 22.5 percent for certain drugs or biologicals.

• Medicare will continue to pay for separately payable drugs that were not acquired through the 340B Program at ASP+6 percent.

• For CY 2018, CMS designated rural sole community hospitals (SCHs), children’s hospitals, and PPS-exempt cancer hospitals are excepted from the 340B payment adjustment.
Modifiers CMS establish to report 340B-acquired drugs

- CMS established two Healthcare Common Procedure Coding System (HCPCS) Level II modifiers to identify 340B-acquired drugs:
  - Modifier “JG” Drug or biological acquired with 340B drug pricing program discount.
  - Modifier “TB” reported for informational purposes.

- When applicable, providers are required to report either modifier “JG” or “TB” on OPPS claims. Though modifier “TB” is an informational modifier, reporting is mandatory for applicable providers.

- Critical Access hospitals and hospitals paid under the Maryland waiver are excluded from the OPPS and are not subject to the payment policy change.

- Each separately payable, non-pass through 340B-acquired drug should be billed on a separate claim line with the appropriate 340B modifier. The use of modifier “JG” will trigger a drug payment rate of ASP minus 22.5 percent. The use of modifier “TB” will have no effect on the drug payment rate.