The Most Important Player in the Prescription Drug Market You Never Knew Existed

*How Pharmacy Benefit Managers Affect Drug Pricing and Access to Treatment*

*Wisconsin Rheumatology Association*
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Alliance for Safe Biologic Medicines – Chair
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What Is At Stake?

• Patient’s access to the correct drug as determined by the physician and patient based on **efficacy and safety and affordability.**

• **But instead we are faced with:**
  - Formulary restrictions – exclusionary preferred lists
  - Step-therapy
  - Non-medical switching
  - Higher cost sharing – higher drug prices
  - “Deductible Double Dipping”
  - *Prior Auths*
Who are the Players?

1. Drug Makers
2. 3rd Party Payers
3. Pharmacy Benefit Managers (PBMs)
4. Prescribers
5. Patients
How We Got Here...

• Digging into why there are step edits/non medical switching years ago – David Balto - PBMwatch.com

• Former insurance /PBM spoke at our SSAC - CSRO was shocked at what was going on, so decided to make PBMs a priority issue for 2017.

• Joined together with ACR and other patient and provider organizations to form an Alliance to address PBMs- ATAPadvocates.com
What is a PBM?

• Hired by Health Plans to manage prescription drug benefit programs and provide other services pursuant to negotiated contract.

• Act as intermediaries between Health Plans, Manufacturers, and Pharmacies.

• Develop formularies and determine patient access to drug therapies.

What is the role of PBMs?

• Initial purpose 1960s-1970s: purely administrative.
• 1990’s – Pharmaceutical cos. acquired PBMs – (Merck/Medco)

FTC said NO
PBMs Have Evolved

• As drug costs continued to rise, PBMs offered services that promised Health Plans less expensive drug programs and lower costs.

“UTILIZATION MANAGEMENT TOOLS”

• Now handle everything from negotiating prices with manufacturers to creating pharmacy networks to determining the formulary – Essentially what drugs our patients can take, where they can get them and how much they will pay (copay/coinsurance)

Who are the PBMs?

- **Express Scripts (ESI), CVS, and Optum Rx (United Health)** capture nearly 75% of PBM market share- 2 largest PBMs cover more than 170 million lives.

- In March 2015, UnitedHealth Group/Optum Rx (3rd largest PBM) acquired Catamaran (4th largest PBM), increasing the PBM market concentration.

- Competition – Transparency - good or bad?


Who are the PBMs?

PBM Market Share by Total Prescription Claims in 2015, *Forbes*

Who Regulates PBMs?

- Federal Trade Commission
- States – Board of Pharmacy – ERISA issues
- Federal
  - Congress
  - CMS

Removing ERISA’s Impediment to State Health Reform Erin C. Fuse Brown, J.D., M.P.H., and Ameet Sarpatwari, J.D., Ph.D. n engl j med 378;1 nejm.org January 4, 2018
Breaking Down the Drug/Money/Services Flow
The Drug Supply Chain

Drug Flow
Cash Flow

Manufacturer

Pharmacies
Patients
Wholesaler
Dispense Drug
Copay/Coinsurance

Drug Payment
Drug Shipment

*WAC (Wholesale Acquisition Cost): List price for a drug that manufacturers use to charge wholesalers; does not reflect discounts wholesalers may receive (i.e. for purchasing in bulk).
Drug Benefit Programs

- Cash Flow
- Services

Health Plans

PBM

Reimbursement + Admin Fee
Manage Drug Program

Drug Coverage
Premium

Patients

Pharmacies

Reimbursement + Disp Fee
Pharmacy Network
The Rebate System

- Drug Flow
- Services
- Cash Flow
- Rebate

**Manufacturer**

- Reimbursement + Admin Fee
- Manage Drug Program
- Share of Rebate

**Health Plans**

- Placement on Formulary

**PBM**

- Rebate (+ Fees)
PBM Claims

• PBMs claim to drive down drug costs by:
  ▫ Negotiating discounts for Health Plans and Patients.
  ▫ Designing formularies and negotiating/obtaining *rebates*.
  ▫ Increasing use of *their own* mail-order and specialty pharmacies.
  ▫ Offering more affordable pharmacy channels.
  ▫ Encouraging use of generics and affordable brands.
  ▫ *Managing* high-cost specialty medications.
PBM Realities

• Use position to negotiate contracts with Manufacturers/Health Plans/Pharmacies that often maximizes profits at expense of patients

• Sources of PBM Revenue/Profit:
  ▫ Spread Pricing
  ▫ **Manufacturer Rebates (specialty drugs)**
  ▫ Mail-Order Pharmacies/Specialty Pharmacies
  ▫ Administrative and Service Fees
  ▫ “Accumulator Adjustment Program” - *(New utilization management tool)*
Spread Pricing

- Spread Pricing: Difference between what PBM charges a Health Plan for a certain drug and what it reimburses a Pharmacy for dispensing it.

- Pharmacies typically have no idea what Health Plans are paying for a drug and Health Plans don't know how much Pharmacies are reimbursed for dispensing it.
Spread Pricing Example:

• Meridian Health contracted with ESI in 2008 to manage its drug benefit program.

• Meridian cross-referenced what ESI was billing for prescriptions against what ESI was reimbursing its pharmacies for the same drugs.

• Found that ESI was collecting a spread on almost every prescription, sometimes in excess of $60.
Accumulator Adjustment Program

Utilization Management Tool -
“Deductible Double Dipping”
- Co pays will need to be paid twice
- Once by the manufacturers coupon and once by the patient
- Signed affidavits

CVS Health admitted it would be “utilizing this tool” particularly for those patients with high deductibles
Specialty Manufacturer Rebates

PBMS CONTROL:

- **Formulary** - List of medications that will be covered by the PBM
- **Tiers** – levels within the formulary
- **Preferred drugs** – Step therapy, Non Medical Switching
- **Copay vs. Coinsurance**
- **Pharmacy choice** – gag contracts, claw backs, specialty pharmacies
Formulary Preferred Status

Why is there a yearly “fight” for this?

Benefits of exclusive positioning

• **STEP THERAPY** - Must step through 1-3 *preferred* drugs

• **NON MEDICAL SWITCHING** – changing a patient’s medication for non-medical reason
What Determines Preferred Placement?

- Efficacy?
- Safety?
- Lowest list price?

Guess again.....
THE REBATE STORY...
The Rebate System

• **Rebate**: A retroactive sum of money paid (per prescription filled) by a Manufacturer to a PBM in exchange for preferred placement on PBM formulary.
  - How does it work??

**SOURCES:**
How it works...

- Every year drug manufacturers compete in a bidding war to get a preferred place on the formularies of PBMs.
- The largest rebate bid (*chunk of money*) gets the preferred spot.
- Motivates PBMs to base drug utilization on rebates/fees (*aka profits*) rather than patient care * or reducing list price of drugs
  - *Efficacy and patient safety not as important in determining which drugs get preferred status as rebate amount.*
Rebate Bids

Pharmacy Benefit Manager
THE REBATE FORMULA

REBATE TOTAL = 

List Price x % Discount promised x # Scripts filled

1. List price of the drug
2. % Discount promised
3. # Scripts that are filled (Market share)

AN INCREASE IN ANY ONE OF THESE LEADS TO A BETTER CHANCE AT PREFERRED PLACEMENT
PBM’s Other Income Sources That are Tied to the List Price

- **Admin fees** - Manufacturers pay admin fees that average 3% to 5% of the list price value of a drug.
- **Price protection** - List price increases above the ceiling trigger additional rebate payments.
- **Specialty pharmacy** – fees are % of list price
Consequences of The Rebate System

- **Infringes** on Doctor – Patient relationship
  - Step Therapy – Fail first medications
  - **Non-Medical Switching**: Rebate contract can change within a year - Stable patients forced to change medications because of a more profitable contract with a different manufacturer.
- **Excludes** drugs that don’t offer a big enough “rebate” - deny co-pay cards, higher coinsurance

**Sources:**


Increasing Formulary Exclusions

Number of Products on PBM Formulary Exclusion Lists, 2012-2018

Note: Express Scripts did not publish exclusion lists for 2012 and 2013.
Source: Pembroke Consulting analysis of company reports
Published on Drug Channels (www.DrugChannels.net) on August 3, 2017.
Consequences of The Rebate System

• Incentivizes higher list prices?
  ▫ The higher the list price, the higher the rebate – increases the chances of getting on to the formulary.

• Harder for Biosimilars and new medications to get on to formulary (stifles innovation?)

• Patient cost-sharing obligations are based off list price, not rebated price, which forces patients to pay inflated out-of-pocket amount. This includes Medicare Part D beneficiaries. (average rebate now close to 50%)

Traditional drugs rebate pass-through

PBM Rebate Arrangements for Traditional Medications in Employer-Sponsored Plans, by Employer Size, 2014 vs. 2017

- **100% of rebates**
- **Percentage share of rebates**
- **Flat guaranteed amount per script**

**Smaller employers**

<table>
<thead>
<tr>
<th></th>
<th>2014</th>
<th>2017</th>
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</thead>
<tbody>
<tr>
<td>100% of rebates</td>
<td>35%</td>
<td>29%</td>
</tr>
<tr>
<td>Flat guaranteed amount per script</td>
<td>35%</td>
<td>42%</td>
</tr>
<tr>
<td>Percentage share of rebates</td>
<td>30%</td>
<td>29%</td>
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</table>

**Larger employers**

<table>
<thead>
<tr>
<th></th>
<th>2014</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>100% of rebates</td>
<td>44%</td>
<td>33%</td>
</tr>
<tr>
<td>Flat guaranteed amount per script</td>
<td>32%</td>
<td>53%</td>
</tr>
<tr>
<td>Percentage share of rebates</td>
<td>14%</td>
<td>24%</td>
</tr>
</tbody>
</table>

Smaller employers = 5,000 or fewer covered lives; Larger employers = more than 5,000 covered lives. Number of covered lives includes employees and dependents. Source: Drug Channels Institute analysis of Trends in Drug Benefit Design, PBMs, various years. Data include only responding firms that receive rebates. 2014 figures recomputed to exclude those who were not sure about their company’s rebate arrangements.

Published on Drug Channels (www.DrugChannels.net) on January 17, 2018.
Largest source of PBM Gross Profits

Share of PBM Gross Profits By Source - 2002-16

Phase 1

Phase 2

Phase 3

Source: Abrams papers on Medco to 2007, guestimates thereafter
WE WANTS IT. WE NEEDS IT. MUST HAVE THE REBATESSS.
How much money is paid in rebates?


WHERE DO THE SAVINGS GO?

• Huge Lack of Transparency –
  ▫ Hides Practices by PBMs – designed to increase profits?
  ▫ Hides where the money comes from and where it goes

“Show me the Money”
• Lower premiums?
• Lower co-pays / coinsurance amounts?
• Lower list prices of medications?

Hmmmmmm......
Profit in Millions for the “Big Two”

2017 Express Scripts Profits


- That is nearly $3.5 billion based on profits as percent of revenue – that doubles to nearly $7 billion if you look at profits as percent of assets.

- *Express Scripts is #22 on Fortune 500 list*
# Drug Channels Companies in the 2017 *Fortune* 500 List

<table>
<thead>
<tr>
<th>Company (stock symbol)</th>
<th>2017 Fortune 500 Rank</th>
<th>Revenues ($B)</th>
<th>Revenues, % vs. 2015</th>
<th>Market Value (as of 3/31/17)</th>
<th>Revenue per Employee ($M)</th>
<th>Profit as % of Revenues</th>
<th>Profit as % of Assets</th>
<th>Annualized Return to Investors (2006-2016)</th>
<th>Total Return to Investors (2016)</th>
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</thead>
<tbody>
<tr>
<td>McKesson (MCK)</td>
<td>5</td>
<td>$192.5</td>
<td>6.2%</td>
<td>$31.4</td>
<td>$2.8</td>
<td>1.2%</td>
<td>4.6%</td>
<td>11.6%</td>
<td>-28.3%</td>
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<td>CVS Health (CVS)</td>
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<td>$177.5</td>
<td>15.8%</td>
<td>$81.3</td>
<td>$0.9</td>
<td>3.0%</td>
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<td>AmerisourceBergen (ABC)</td>
<td>11</td>
<td>$146.9</td>
<td>8.0%</td>
<td>$19.2</td>
<td>$7.9</td>
<td>1.0%</td>
<td>4.2%</td>
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<td>Walgreens Boots Alliance (WBA)</td>
<td>17</td>
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<td>$89.6</td>
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<td>3.6%</td>
<td>5.7%</td>
<td>8.0%</td>
<td>-1.1%</td>
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<td>Cardinal Health (CAH)</td>
<td>15</td>
<td>$121.5</td>
<td>18.5%</td>
<td>$25.7</td>
<td>$3.3</td>
<td>1.2%</td>
<td>4.2%</td>
<td>6.4%</td>
<td>-17.7%</td>
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<tr>
<td>Express Scripts Holding (ESRX)</td>
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<td>$3.9</td>
<td>3.4%</td>
<td>6.6%</td>
<td>14.4%</td>
<td>-21.3%</td>
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<tr>
<td>Rite Aid (RAD)</td>
<td>91</td>
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<td>15.9%</td>
<td>$4.5</td>
<td>$0.4</td>
<td>0.5%</td>
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<td>4.2%</td>
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<td><strong>Average</strong></td>
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<td><strong>$126.7</strong></td>
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<td><strong>$41.6</strong></td>
<td><strong>$2.8</strong></td>
<td><strong>2.0%</strong></td>
<td><strong>4.6%</strong></td>
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<td><strong>Median</strong></td>
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<td><strong>13.4%</strong></td>
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Source: Pembroke Consulting analysis of 2017 *Fortune* 500 list
Published on Drug Channels ([http://www.DrugChannels.net](http://www.DrugChannels.net)) on June 20, 2017. *(revised)*
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<tr>
<td>Johnson &amp; Johnson (INJ)</td>
<td>35</td>
<td>$71.9</td>
<td>2.6%</td>
<td>$337.6</td>
<td>$0.6</td>
<td>23.0%</td>
<td>11.7%</td>
<td>9.0%</td>
<td>15.3%</td>
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<tr>
<td>Pfizer (PFE)</td>
<td>54</td>
<td>$52.8</td>
<td>8.1%</td>
<td>$203.7</td>
<td>$0.5</td>
<td>13.7%</td>
<td>4.2%</td>
<td>6.8%</td>
<td>4.4%</td>
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<td>Merck &amp; Co. (MRK)</td>
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<td>$39.8</td>
<td>0.8%</td>
<td>$174.5</td>
<td>$0.6</td>
<td>9.8%</td>
<td>4.1%</td>
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<td>15.1%</td>
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<td>Gilead Sciences (GILD)</td>
<td>92</td>
<td>$30.4</td>
<td>-6.9%</td>
<td>$88.8</td>
<td>$3.4</td>
<td>44.4%</td>
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<td>AbbVie (ABBV)</td>
<td>111</td>
<td>$25.6</td>
<td>12.2%</td>
<td>$103.8</td>
<td>$0.9</td>
<td>23.2%</td>
<td>9.0%</td>
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<td>Amgen (AMGN)</td>
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<td>Eli Lilly and Company (LLY)</td>
<td>132</td>
<td>$21.2</td>
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<td>Bristol-Myers Squibb Company (BMY)</td>
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<td>$89.6</td>
<td>$0.8</td>
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<td>Biogen (BIIB)</td>
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<td>$59.0</td>
<td>$1.5</td>
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<td>Celgene (CELG)</td>
<td>254</td>
<td>$11.2</td>
<td>21.3%</td>
<td>$96.8</td>
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Ideas To Improve The System

- Transparency
- Pass through of rebates - point of sale to patients – Part D proposed rule
- Fee based PBMs – not tied to list price of drugs – no conflict of interest
- Formulary based on efficacy, safety and lowest list price (>= 50% discount on list price – open formulary)
PBM Position on Transparency

Quote from Steve Miller, Chief Medical Officer, Express Scripts:

• "We love transparency for our patients. Our patients should know exactly what they're going to pay when they go to the pharmacy counter."
  ▫ We just don’t want them to know what we ultimately paid for the drug after rebate—because their coinsurance may be based on a much higher price!

• “We love transparency for our clients—they can come in. They can audit their contracts. They know exactly what they're going to be required to pay.”
  ▫ We just don’t want them to know the profit we are making on specialty rebated drugs because we don’t always pass those rebates/reclassified fees back to them.

• “What we don't want is transparency for our competitors.”
  ▫ The top 3 have nearly 80% of the market – What competition?

The Transparency Problem

“Let’s never forget that the public’s desire for transparency has to be balanced by our need for concealment.”
Adressing the Problem:  
Alliance for Transparent & Affordable Prescriptions (ATAP)

- Coalition of patient and provider groups that joined forces to address PBMs and their impact on patient care.

- ATAP Mission: Reduce drug costs and ensure patient access to affordable treatment by regulating PBMs and reforming drug industry through education and federal/state advocacy initiatives.

- ATAP Activities
  - **Federal**: Hill visits, MedPAC, CMS, educate lawmakers/agency personnel.
  - **State**: FMA Resolution, state group membership, educate state lawmakers, work with state/county medical associations.
  - **Media**: Actively engaged in media outreach/monitoring, working with media outlets to get patient/physician voice front and center.
Finally, the End!

Questions??