Managing Prescription Drug Benefits

NAIC PBM Regulatory Issues Subgroup
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Horizon Government Affairs
Agenda for Discussion

• Introduction
• Why We Are Here
• History/Background/Snapshot of PBMs
• Why Plans Choose Pharmacy Benefit Managers
• PBM Services & How PBMs Drive Savings & Quality
• How Would The World Look Without PBMs?
• Regulation of PBM Services & NAIC Work
• Questions
Why We Are Here

Flow of Goods, Transactions & Services

1. **Pharmacy**
2. **Prescriber**
3. **Payer**
4. **PBM**
5. **Manufacturer**
6. **Wholesaler**
7. **PSAO**

**Payment**
- Green arrows

**Rebates**
- Light green dotted arrows

**Administrative Services**
- Orange arrows

**Drugs**
- Blue arrows

**Business Relationship**
- Red dotted arrows

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Who Pays for Prescription Drugs?

Source of Payment for Outpatient Prescription Drug Expenditures, 2016

1. Includes workers’ compensation and Pembroke Consulting estimates for employer share of private insurance.
2. Includes those with Medicare supplemental coverage and all individually purchased plans, including coverage purchased through the Marketplaces. Figure reflects Drug Channels Institute estimates for prescription drug spending for individually purchased private insurance.
3. Includes Children’s Health Insurance Program (Titles XIX and XXI), Department of Defense, Department of Veterans Affairs, Indian Health Service, workers’ compensation, general assistance, maternal and child health, and other federal, state, and local programs. Other federal programs include OEO, Federal General and Medical, Federal General and Medical NEC, and High Risk Pools under ASA. Other state and local programs include state and local subsidies and TDI.

Source: Drug Channels Institute analysis of National Health Expenditure Accounts, Office of the Actuary in the Centers for Medicare & Medicaid Services, December 2017. Totals may not sum due to rounding. Data exclude inpatient prescription drug spending within hospitals and nearly all provider-administered outpatient drugs.
What Role Does a PBM Serve?

- Pharmacy benefit managers (PBMs) negotiate on behalf of plan sponsors and administer the outpatient prescription drug portion of the health care benefit, in a high-quality, cost-effective manner.

- PBMs aggregate the buying clout of millions of enrollees, enabling plan sponsors and individuals to obtain lower costs for prescription drugs. PBMs are expected to save $654B in 10 years nationally.¹

- PBMs are the only check in the retail Rx drug supply chain against drug makers’ power to set and raise prices.

PBM History: Evolving Payer Strategies

- No drug coverage → pharmaceuticals as add-on benefit → mandated benefit
- Creation of Medicare Part D program – 2006PY
- Paper claims → electronic communications
- Drugs becoming unaffordable → harnessing manufacturer competition when able
- Introduction of generic drugs → now 90% of drugs dispensed
- 3.8 billion prescriptions in 2018.¹
- Ultimately, no plan is required to use a PBM.

¹ Kaiser Family Foundation, based on IQVIA data.
Snapshot of PBM Marketplace

• Competition in PBM Marketplace is strong.
  – 66 PBMs in the U.S.\(^1\)

• PBMs vary in size, geographic footprint, service offerings, expertise and focus.

• Market changes: consolidation, vertical integration, new entrants.

• PBMs’ net profit is lowest in supply chain.

\(^1\) Pharmacy Benefit Management Institute (PBMI) Data
Pharmaceutical Supply Chain Profit Margins

Source: The Flow of Money Through the Pharmaceutical Distribution System. Schaeffer Center for Health Policy & Economics, University of Southern California. June 2017
Why Do Plans Hire PBMs?

- PBMs help save plans 40-50% over unmanaged benefit, increase adherence.\(^1\)
- Reduce medication errors through use of drug utilization review programs.
  - Over next 10 years, PBMs will help prevent 1 billion medication errors.\(^2\)
  - Improve drug therapy and patient adherence, notably in the areas of diabetes and multiple sclerosis.\(^3\)
- Manage programs to address opioid use issues.

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1 Visante, Return on Investment on PBM Services, Nov. 2016.
2 Visante estimates based on IMS Health data and DUR programs studies.
3 Visante estimates based on CDC National Diabetes Statistics Report 2014 and studies demonstrating improved adherence by 10+%).
Pharmacy Benefit Management Services

- Claims Processing
- Price, Discount and Rebate Negotiations with Pharmaceutical Manufacturers and Drugstores
- Formulary Management
- Pharmacy Networks
- Mail-service Pharmacy
- Specialty Pharmacy
- Drug Utilization Review
- Disease Management and Adherence Initiatives
How Plans Hire PBMs: RFP Process

Plan Issues RFP
- Request for Proposal (RFP) dictates the terms and conditions of the PBM services

PBM Bids
- Multiple PBMs bid in a highly competitive environment
- PBMs offer various design models depending on plan sponsor’s specific needs

Plan Decision
- Plan sponsor may utilize benefit consultants for direction
- Decisions often reflect need of a robust pharmacy benefit that delivers cost savings

Plan Design
- PBM provides options based on the plan sponsor’s unique needs
- Plan sponsor makes the final decision about the drug benefit plan
PBM – Plan Contracts

• PBM offers various design models depending on a plan’s specific needs:
  – Plans choose how to compensate PBMs: traditional/spread, pass-through/fees, rebate share.
  – Performance guarantees and audit rights protect plans and ensure transparency.
  – On average, more than 90% of rebates negotiated by PBMs are passed through to plan sponsors.¹

• The plan sponsor always has the final say when creating a drug benefit plan.

• Things not determined by a PBM: benefit design, cost sharing levels, deductibles, etc.
### Example of Negative Spread

<table>
<thead>
<tr>
<th>Rank</th>
<th>Drug Name</th>
<th>Total MCO Reimbursed</th>
<th>Total NADAC</th>
<th>&quot;Negative Spread&quot;</th>
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<tbody>
<tr>
<td>1</td>
<td>EPI NEPHRINE 0.3 MG AUTO-INJECT</td>
<td>$528,292</td>
<td>$1,201,303</td>
<td>-$673,012</td>
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<tr>
<td>2</td>
<td>AVONEX PEN 30 MCG/0.5 ML KIT</td>
<td>$145,184</td>
<td>$577,004</td>
<td>-$431,820</td>
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<tr>
<td>3</td>
<td>AVONEX PREFILLED SYR 30 MCG KIT</td>
<td>$92,181</td>
<td>$367,066</td>
<td>-$274,885</td>
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<tr>
<td>4</td>
<td>ADDERALL XR 20 MG CAPSULE</td>
<td>$1,274,750</td>
<td>$1,438,381</td>
<td>-$163,631</td>
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<tr>
<td>5</td>
<td>ADDERALL XR 30 MG CAPSULE</td>
<td>$1,226,413</td>
<td>$1,365,301</td>
<td>-$138,888</td>
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<tr>
<td>6</td>
<td>EPI NEPHRINE 0.15 MG AUTO-INJCT</td>
<td>$241,838</td>
<td>$353,637</td>
<td>-$111,799</td>
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<tr>
<td>7</td>
<td>NEULASTA 6 MG/0.6 ML SYRINGE</td>
<td>$322,501</td>
<td>$411,054</td>
<td>-$88,553</td>
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<tr>
<td>8</td>
<td>CONCERTA ER 36 MG TABLET</td>
<td>$1,056,020</td>
<td>$1,138,317</td>
<td>-$82,298</td>
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<tr>
<td>9</td>
<td>REMICADE 100 MG VIAL</td>
<td>$555,498</td>
<td>$637,652</td>
<td>-$82,154</td>
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<tr>
<td>10</td>
<td>ADDERALL XR 10 MG CAPSULE</td>
<td>$467,401</td>
<td>$535,141</td>
<td>-$67,740</td>
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<tr>
<td>11</td>
<td>FOCALIN XR 10 MG CAPSULE</td>
<td>$368,264</td>
<td>$422,993</td>
<td>-$54,728</td>
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<td>12</td>
<td>FOCALIN XR 15 MG CAPSULE</td>
<td>$255,681</td>
<td>$308,370</td>
<td>-$52,689</td>
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<td>13</td>
<td>ADDERALL XR 15 MG CAPSULE</td>
<td>$404,040</td>
<td>$455,148</td>
<td>-$51,108</td>
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<td>14</td>
<td>CONCERTA ER 54 MG TABLET</td>
<td>$645,025</td>
<td>$693,277</td>
<td>-$48,252</td>
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<tr>
<td>15</td>
<td>CONCERTA ER 18 MG TABLET</td>
<td>$510,871</td>
<td>$550,309</td>
<td>-$39,439</td>
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<tr>
<td>16</td>
<td>ANDROGEL 1.62%(2.5G) GEL PCKT</td>
<td>$43,356</td>
<td>$82,002</td>
<td>-$38,647</td>
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<tr>
<td>17</td>
<td>ADDERALL XR 25 MG CAPSULE</td>
<td>$379,846</td>
<td>$418,286</td>
<td>-$38,440</td>
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<tr>
<td>18</td>
<td>CONCERTA ER 27 MG TABLET</td>
<td>$587,185</td>
<td>$625,486</td>
<td>-$38,301</td>
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<td>19</td>
<td>FOCALIN XR 20 MG CAPSULE</td>
<td>$316,520</td>
<td>$351,844</td>
<td>-$35,324</td>
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<tr>
<td>20</td>
<td>EPI PEN 0.3 MG AUTO-INJECTOR</td>
<td>$35,347</td>
<td>$67,797</td>
<td>-$32,450</td>
</tr>
</tbody>
</table>

| Total Top 20 | $9,456,212 | $12,000,369 | -$2,544,158 |

Brand Drug Prices Increased 58% 2013-2017

Changes in Healthcare Costs or Cost Drivers 2013-2017, Indexed (2013 Values + 100)


Chart notes: Indices sourced from Kaiser/HRET Employer Survey include: family coverage, premiums, workers earnings, overall inflation. Brand, generic and total final out-of-pocket costs and brand pharmacy prices are for commercially insured, Medicare Part D and cash payment types sourced from IQVIA Formulary Impact Analyzer. All charted values are indexed to set their 2013 value equal to 100.
How PBMs Drive Savings and Quality: Manufacturers

- PBMs are able to bring volume to manufacturers and in some cases, obtain price concessions.

- Rebates reduce the net cost of drugs for payers, but they aren’t available on all drugs—only where there is competition.
  - 90% of drugs dispensed are generics, with little-to-no rebate in commercial programs.
  - In Medicare Part D, 64% of brands were not eligible for rebates.¹
  - PBM clients get the vast majority of the rebates.² ³

- Rebates help reduce premiums & cost-sharing, and revenue is included in MLR calculation.

- Plans have no alternative tool at this time that is as effective at forcing manufacturers to compete, bringing down the net cost of drugs.

# Reporting of Rebates – Plan MLR Filing

## Part 1 Summary of Data

<table>
<thead>
<tr>
<th>Line Description</th>
<th>SHCE</th>
<th>1 Health Insurance INDIVIDUAL Total as of 12/31/17</th>
<th>2 Health Insurance INDIVIDUAL Total as of 3/31/18</th>
<th>Health Insurance INDIVIDUAL (Included) Total as of 3/31/18</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.6 Risk revenue</td>
<td>Pt 1, Ln 1.1</td>
<td>$52,993,384</td>
<td>$56,679,321</td>
<td>$56,679,321</td>
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<tr>
<td>2. Claims</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.1 Total incurred claims (MLR Form Part 2, Line 2.16)</td>
<td></td>
<td>$52,993,384</td>
<td>$56,679,321</td>
<td>$56,679,321</td>
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<tr>
<td>2.2 Prescription drugs (informational only; already included in total incurred claims above)</td>
<td>Pt 1, Ln 2.2</td>
<td>$10,890,551</td>
<td>$10,890,551</td>
<td>$10,890,551</td>
</tr>
<tr>
<td>2.3 Pharmaceutical rebates (informational only; already excluded from total incurred claims above)</td>
<td>Pt 1, Ln 2.3</td>
<td>$1,802,023</td>
<td>$1,802,023</td>
<td>$1,802,023</td>
</tr>
<tr>
<td>2.4 State stop loss, market stabilization and claim/census based assessments (informational only; already excluded from total incurred claims above)</td>
<td>Pt 1, Ln 2.4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.5 Net assumed less ceded claims incurred (exclude amounts already reported in Line 2.1</td>
<td>Pt 1, Ln 5.1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.6 Other adjustments due to MLR calculations – claims incurred</td>
<td>Pt 1, Ln 5.2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.7 Rebates paid</td>
<td>Pt 1, Ln 5.3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.8 Estimated rebates unpaid at the end of the previous MLR reporting year</td>
<td>Pt 1, Ln 5.4</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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Study Shows No Correlation Between Drug Rebates and Price Increases

**Major Findings:**

- **No correlation** between drug prices and PBM/payer rebates.
- Cases exist of higher-than-average price increases with relatively low rebates.
- Cases exist of lower-than-average price increases with relatively high rebates.
- Drugmakers are increasing prices regardless of rebate levels.

**Study:** Top 200-self-administered, patent-protected, brand-name drugs in 23 major drug categories examined.

How PBMs Drive Savings & Quality: Pharmacy Networks

• Plans need a broad variety of pharmacies for adequate networks, and expect pharmacies to compete on both price and quality.

• PBMs:
  – Contract with a variety of pharmacies (typically through PSAOs) to ensure a robust network for health plan enrollees to access.
  – Efficiently process claims, provide real-time reimbursement information and timely payment.
  – Audit pharmacies for fraud, waste and abuse.
Pharmacy Claims Adjudication Process

1. Validate Claim Format
2. Eligibility Verification
3. Pharmacy Service Type and Patient Residence Verification
4. Duplicate Claim Check
5. Pharmacy Validation
6. Prescriber Verification
7. Retrieve Drug Information
8. Drug Coverage Status Check
9. Utilization Edits
10. Claim Pricing Calculations
11. Member Cost-Share Calculations

- NCPDP Standards
- LIS Status
- Active Coverage
- Primary or Secondary Coverage
- Excluded/Precluded Provider
- Excluded Provider
- Network Status
- Brand/Generic
- OTC Status
- Med D or B Drug Status
- Validate Drug Status
- Step Therapy
- Prior Authorization
- Transition Fill Eligible
- Dispensing Limits
- Formulary Status
- Drug/Drug
- Drug/Age
- Drug/Gender
- Refill Too Soon
- Dispensing Fee
- Vaccine Admin Fee
- Sales Tax
- Ingredient Cost
- Dispensing Fee
Independent Pharmacies & PSAOs

- 80% of independent pharmacies in the U.S. are represented by Pharmacy Services Administrative Organizations (PSAOs).
- PSAOs pool purchasing power of many pharmacies to leverage strength and contracting strategies with payers.
- PSAOs negotiate & enter into contracts with payers on behalf of independent pharmacies, including reimbursement rates, payment term, and audit terms.
- PSAOs also provide inventory and back-office functions to pharmacies.
- The largest PSAOs are owned by the three major drug wholesalers.
- PBMs have no insight into private contract terms between PSAOs and pharmacies.
- Independent pharmacies are doing well & national numbers have been flat or trending up since 2010 – 37% of all pharmacies in US are small, independent pharmacies.¹

¹ Quest Analytics of NCPDP Data, Jan. 2019.
Drug Wholesalers Own 3 Largest PSAOs

- Over 80% of independent pharmacies belong to pharmacy services administrative organizations (PSAOs), which provide a range of services, including: negotiating third-party payer contracts, providing access to pooled purchasing power/inventory, and back-office functions.

- PSAOs give independent pharmacies significant bargaining clout in negotiations with payers.

Pharmacy Franchise and Marketing Programs, 2016

<table>
<thead>
<tr>
<th>PROGRAM</th>
<th>Ownership</th>
<th># of Participating Pharmacies</th>
<th>2016 Prescription Revenues (billions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health Mart</td>
<td>McKesson</td>
<td>4,800</td>
<td>$10.2</td>
</tr>
<tr>
<td>Good Neighbor Pharmacy</td>
<td>AmerisourceBergen</td>
<td>2,800</td>
<td>$7.3</td>
</tr>
<tr>
<td>Medicine Shoppe/Medicap</td>
<td>Cardinal Health</td>
<td>515</td>
<td>$1.9</td>
</tr>
<tr>
<td>CARE Pharmacies</td>
<td>Independent</td>
<td>82</td>
<td>$.07</td>
</tr>
<tr>
<td>Sav-Mor Drugstores</td>
<td>Independent</td>
<td>65</td>
<td>$.03</td>
</tr>
<tr>
<td>Benzer Pharmacy</td>
<td>Independent</td>
<td>71</td>
<td>$.02</td>
</tr>
</tbody>
</table>

Source: Drug Channels Institute estimates; company reports; Drug Store News.
How Would the World Look Without PBMs?

• Without management of benefit, 40-50% more in costs\(^1\)
  – No one to make drug manufacturers compete with each other
  – No competition on price or quality in the pharmacy space
  – No auditing of pharmacies for fraud, waste, and abuse
  – No utilization controls that reduce waste and increase adherence
  – Paper claims, longer claims processing times, inability to have real-time reimbursement and coverage information for consumers at the pharmacy counter
  – Less utilization of generic drugs

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\(^1\) Visante, *The Return on Investment (ROI) on PBM Services.* (November 2016).
State Regulations & NAIC Work

- Direct: TPA or PBM licensure/registration laws
- Indirect: Health plan has direct relationship with the consumer and is the regulated entity.
  - PBM requirements flow through plan contract, based on types of services are performed on behalf of the plan and which type of product is being served—employer, Medicaid, Medicare, etc.
  - PBMs cannot cause plans to fall out of compliance with their regulators.

- Recent NAIC Models
  - Network Adequacy Model (#74)
  - Rx Benefit Management Model (#22)
Conclusion

- PBM\(s\) have developed as a way to streamline access to prescription drug benefits and help put downward pressure on net cost.

- There are significant cost pressures through high pharmaceutical list prices, for both brands and generics.

- PBM\(s\) harness competition in the manufacturer and pharmacy markets when competition exists, aiming for both affordability and quality.

- While no plan is required to use a PBM, most do, because PBM\(s\) play a central role in driving adherence, holding down costs, and increasing quality.
Questions?