Managing Prescription Drug Benefits

NAIC PBM Regulatory Issues Subgroup
August 29, 2019

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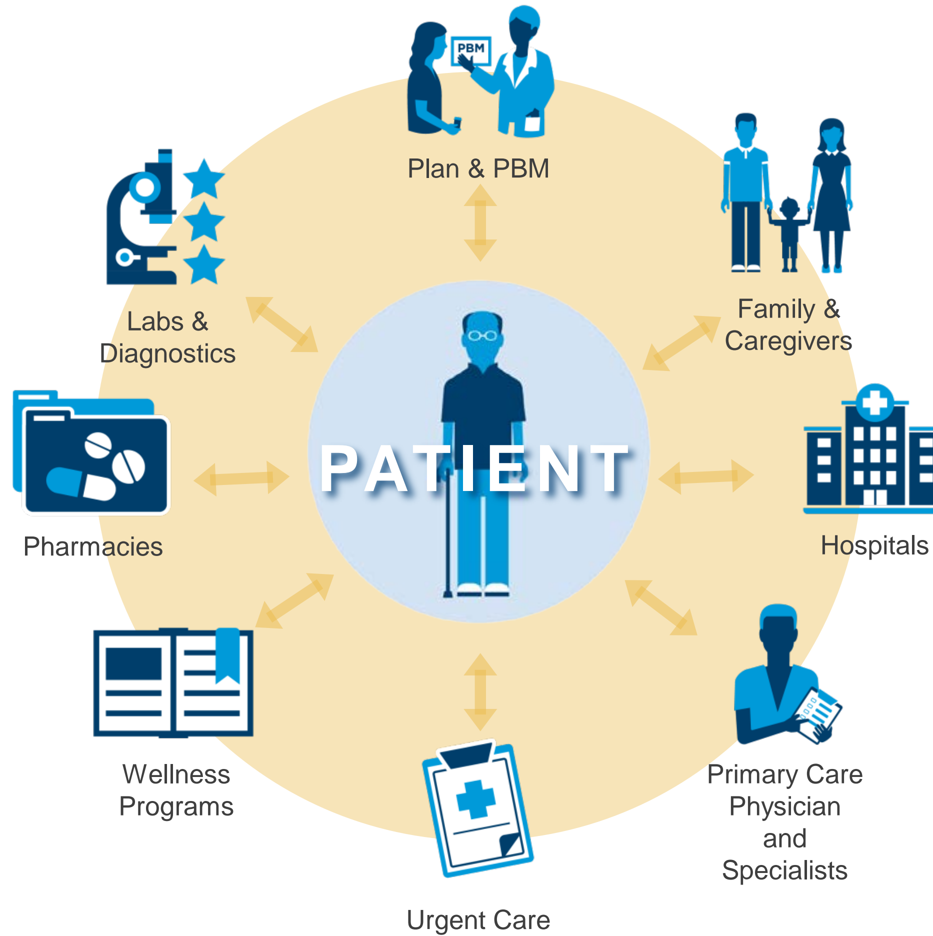
Agenda for Discussion

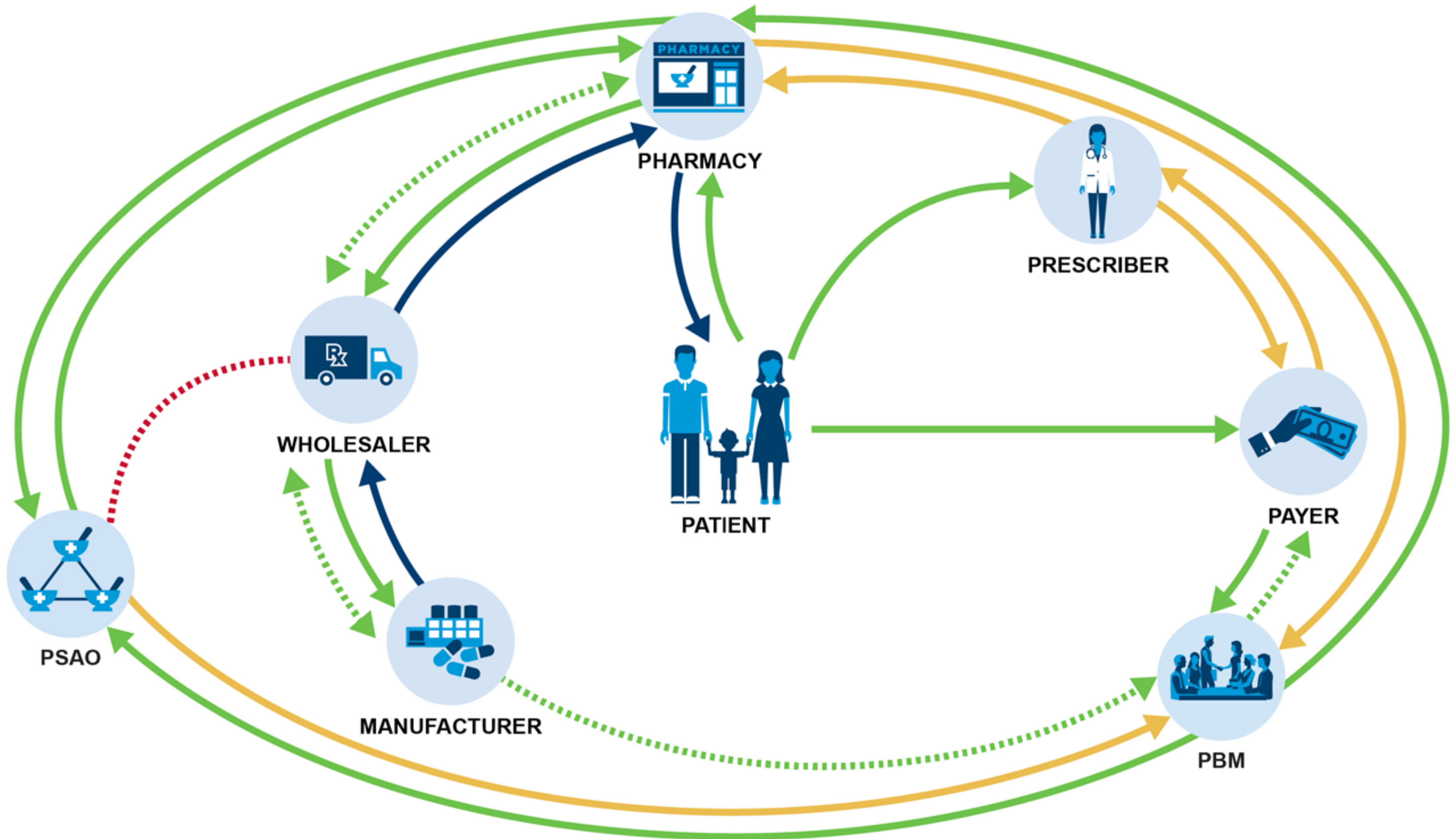
- Introduction
- Why We Are Here
- History/Background/Snapshot of PBMs
- Why Plans Choose Pharmacy Benefit Managers
- PBM Services & How PBMs Drive Savings & Quality
- How Would The World Look Without PBMs?
- Regulation of PBM Services & NAIC Work
- Questions

Why We Are Here

INTEGRATED CARE DELIVERY: Individualized. Proactive. Connected.



Flow of Goods, Transactions & Services



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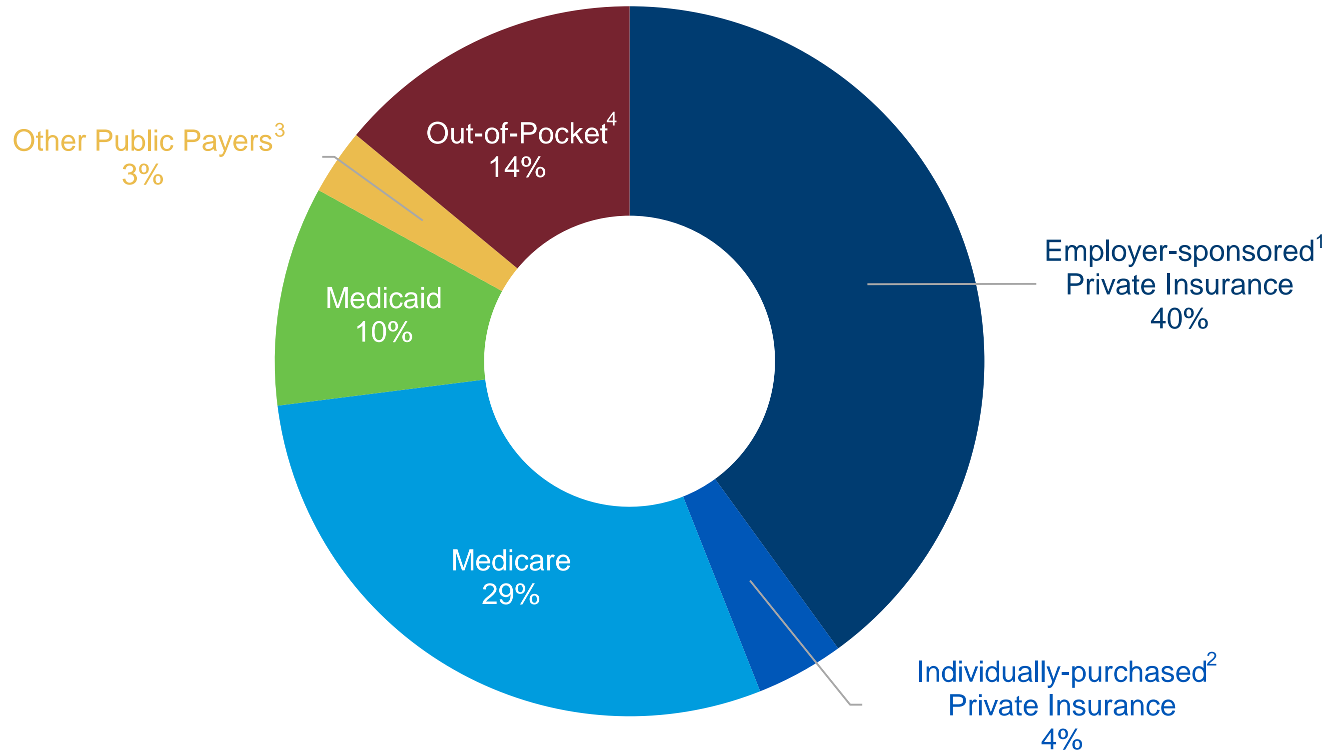
Who Pays for Prescription Drugs?



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.
4. Consumer out-of-pocket expenditures equal cash-pay prescriptions plus copayments and coinsurance.

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.

1 Visante, Generating Savings for Plan Sponsors, Feb. 2016, available at: - https://www.pcmanet.org/wp-content/uploads/2016/08/visante-pbm-savings-feb-2016.pdf

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.

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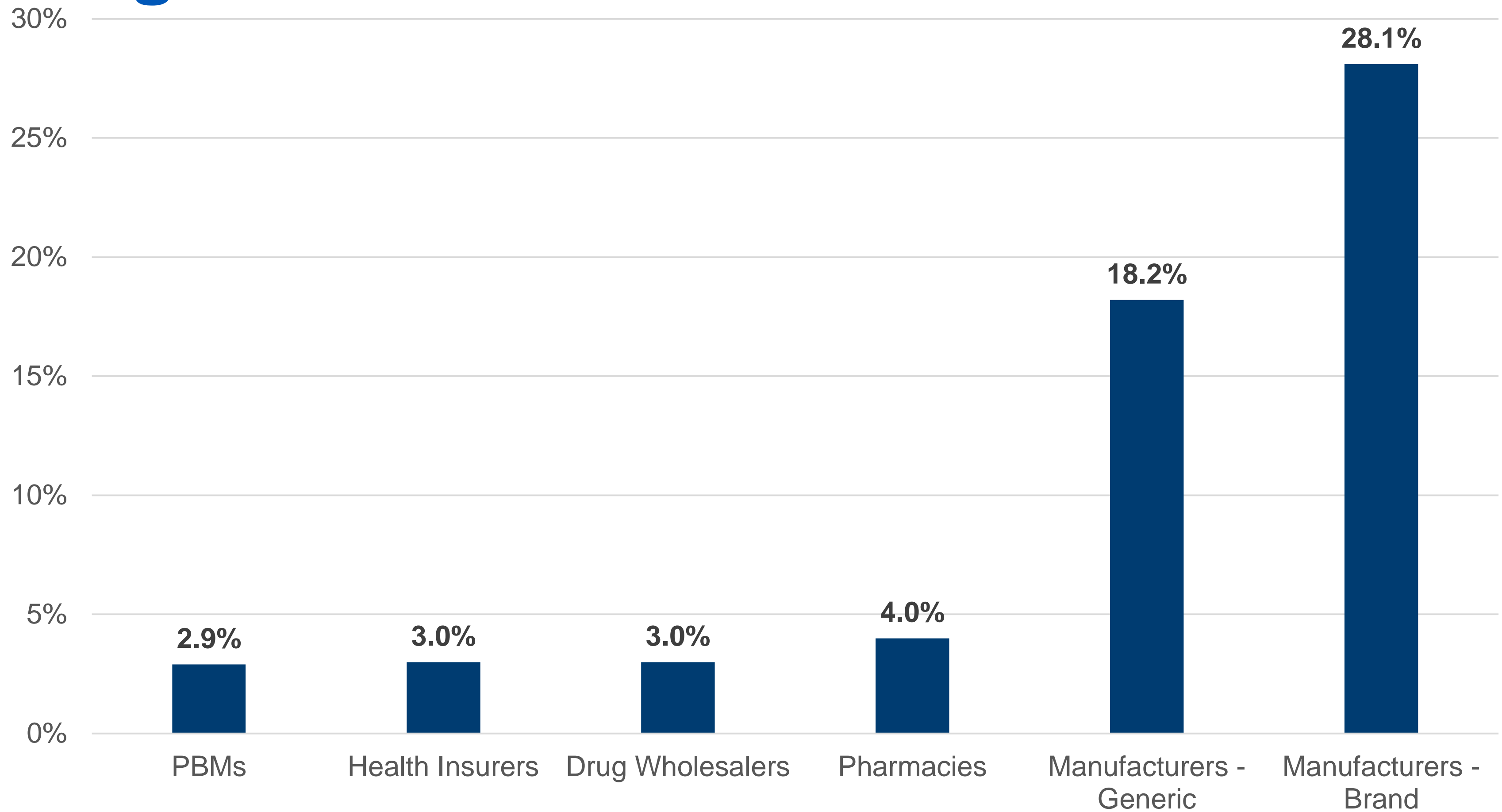
Snapshot of PBM Marketplace

- 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

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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.

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

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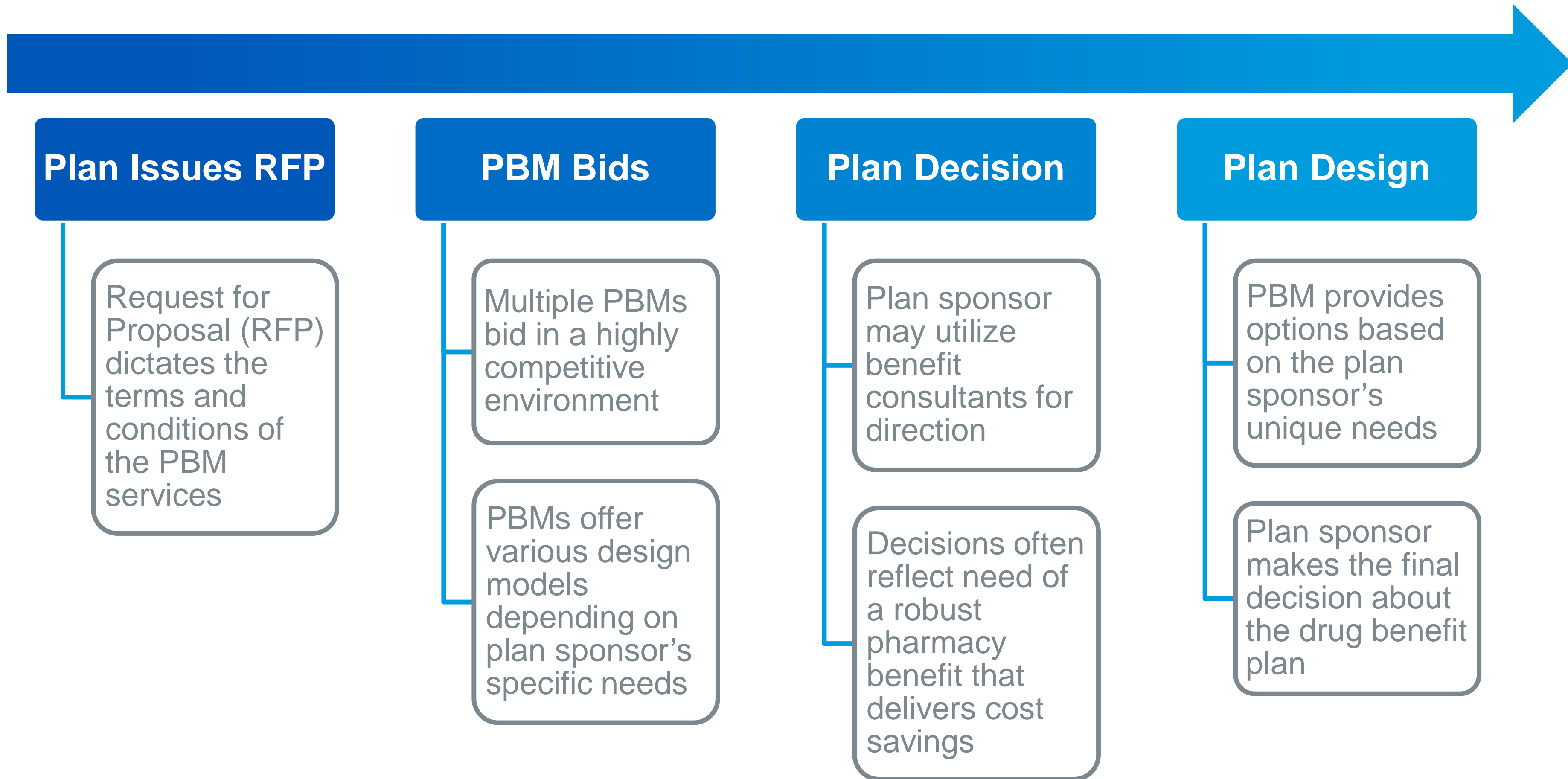
How Plans Hire PBMs: RFP Process



PBM – Plan Contracts

- PBMs offer 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.

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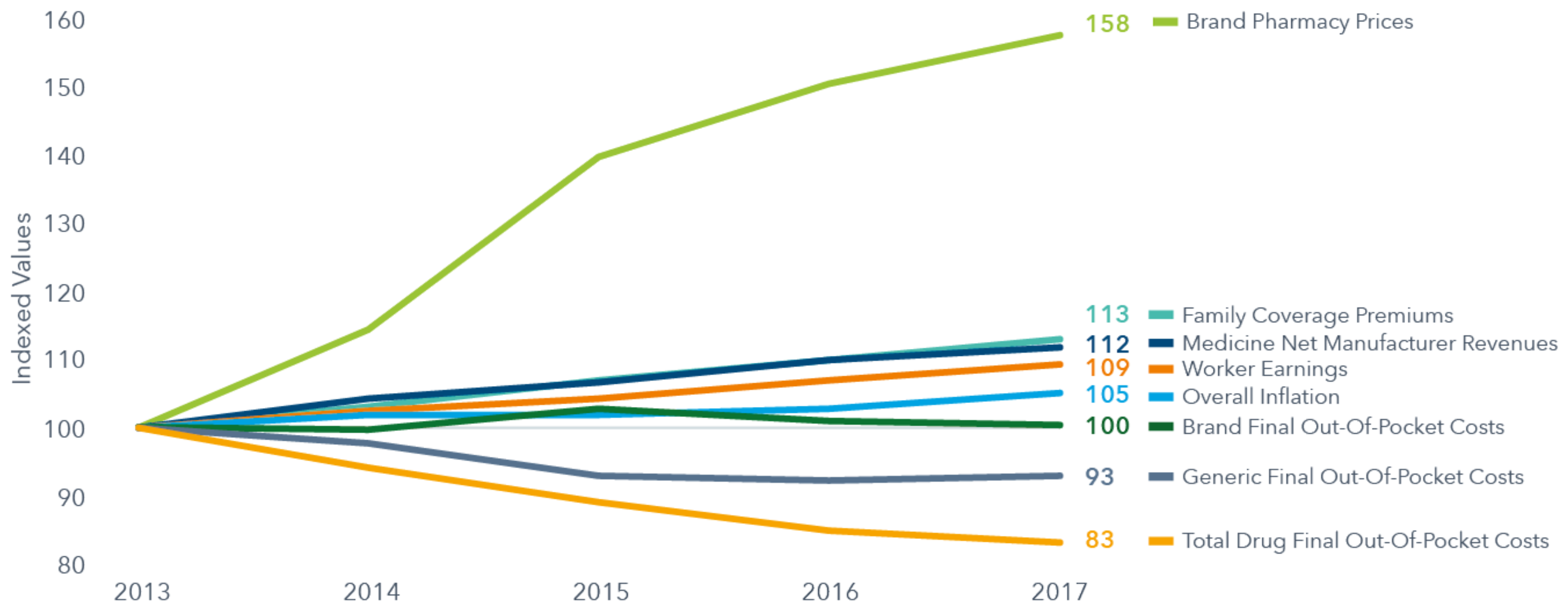
Example of Negative Spread

Rank	Drug Name	Total MCO Reimbursed	Total NADAC	Total "Negative Spread"
1	EPINEPHRINE 0.3 MG AUTO-INJECT	$528,292	$1,201,303	-$673,012
2	AVONEX PEN 30 MCG/0.5 ML KIT	$145,184	$577,004	-$431,820
3	AVONEX PREFILLED SYR 30 MCG KIT	$92,181	$367,066	-$274,885
4	ADDERALL XR 20 MG CAPSULE	$1,274,750	$1,438,381	-$163,631
5	ADDERALL XR 30 MG CAPSULE	$1,226,413	$1,365,301	-$138,888
6	EPINEPHRINE 0.15 MG AUTO-INJCT	$241,838	$353,637	-$111,799
7	NEULASTA 6 MG/0.6 ML SYRINGE	$322,501	$411,054	-$88,553
8	CONCERTA ER 36 MG TABLET	$1,056,020	$1,138,317	-$82,298
9	REMICADE 100 MG VIAL	$555,498	$637,652	-$82,154
10	ADDERALL XR 10 MG CAPSULE	$467,401	$535,141	-$67,740
11	FOCALIN XR 10 MG CAPSULE	$368,264	$422,993	-$54,728
12	FOCALIN XR 15 MG CAPSULE	$255,681	$308,370	-$52,689
13	ADDERALL XR 15 MG CAPSULE	$404,040	$455,148	-$51,108
14	CONCERTA ER 54 MG TABLET	$645,025	$693,277	-$48,252
15	CONCERTA ER 18 MG TABLET	$510,871	$550,309	-$39,439
16	ANDROGEL 1.62%(2.5G) GEL PCKT	$43,356	$82,002	-$38,647
17	ADDERALL XR 25 MG CAPSULE	$379,846	$418,286	-$38,440
18	CONCERTA ER 27 MG TABLET	$587,185	$625,486	-$38,301
19	FOCALIN XR 20 MG CAPSULE	$316,520	$351,844	-$35,324
20	EPIPEN 0.3 MG AUTO-INJECTOR	$35,347	$67,797	-$32,450
	Total Top 20	**$9,456,212**	**$12,000,369**	**-$2,544,158**

Source: Top 20 drugs with "negative spread," MassHealth MCOs 4Q2018. Visante analysis of Massachusetts HPC Report on PBM Spread, 2019.

Brand Drug Prices Increased 58% 2013-2017

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



Source: IQVIA Institute. *Medicine Use and Spending in the U.S.: A Review of 2017 and Outlook to 2022*, April 2018. Kaiser/HRET Survey of Employer-Sponsored Health Benefits, 2017; IQVIA Formulary impact Analyzer (FIA). IQVIA Institute, December 2017.

Chart notes: Indices sourced from Kaiser/HRET Employer Survey4 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.

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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.

[1]Milliman, "Prescription Drug Rebates and Part D Drug Costs." (July 2018); [2]U.S. Government Accountability Office, "Medicare Part D: Use of Pharmacy Benefit Managers and Efforts to Manage Drug Expenditures and Utilization." (July 2019); and [3]Pew Charitable Trusts, "The Prescription Drug Landscape, Explored." (March 2019).

Reporting of Rebates – Plan MLR Filing

MLR_Template_Grand_Total

Part 1 Summary of Data

Line Description	SHCE	1 Health Insurance INDIVIDUAL Total as of 12/31/17	2 Health Insurance INDIVIDUAL Total as of 3/31/18	3 Health In[surance] INDIVI[DUAL] Dual Co[...] (Included i[n] ... of 3/3[...]
1.8 Risk revenue	Pt 1, Ln 1.11			
2. Claims				
2.1 Total incurred claims (MLR Form Part 2, Line 2.16)		$52,993,384	$56,679,321	
2.2 Prescription drugs (informational only; already included in total incurred claims above)	Pt 1, Ln 2.2	$10,890,551	$10,890,551	
2.3 Pharmaceutical rebates (informational only; already excluded from total incurred claims above)	Pt 1, Ln 2.3	$1,802,023	$1,802,023	
2.4 State stop loss, market stabilization and claim/census based assessments (informational only; already excluded from total incurred claims above)	Pt 1, Ln 2.4			
2.5 Net assumed less ceded claims incurred (exclude amounts already reported in Line 2.1)	Pt 1, Ln 5.1			
2.6 Other adjustments due to MLR calculations – claims incurred	Pt 1, Ln 5.2	Accepts input from user		
2.7 Rebates paid	Pt 1, Ln 5.3			
2.8 Estimated rebates unpaid at the end of the previous MLR reporting year	Pt 1, Ln 5.4			

Company Information | Pt 1 Summary of Data | Pt 2 Premium and Claims | Pt 3 MLR and Rebate Calculation | Pt 4 Rebate Disbursement | Pt 5 Additional Responses | Pt 6 Expense Allocati[on]

Ready 162%

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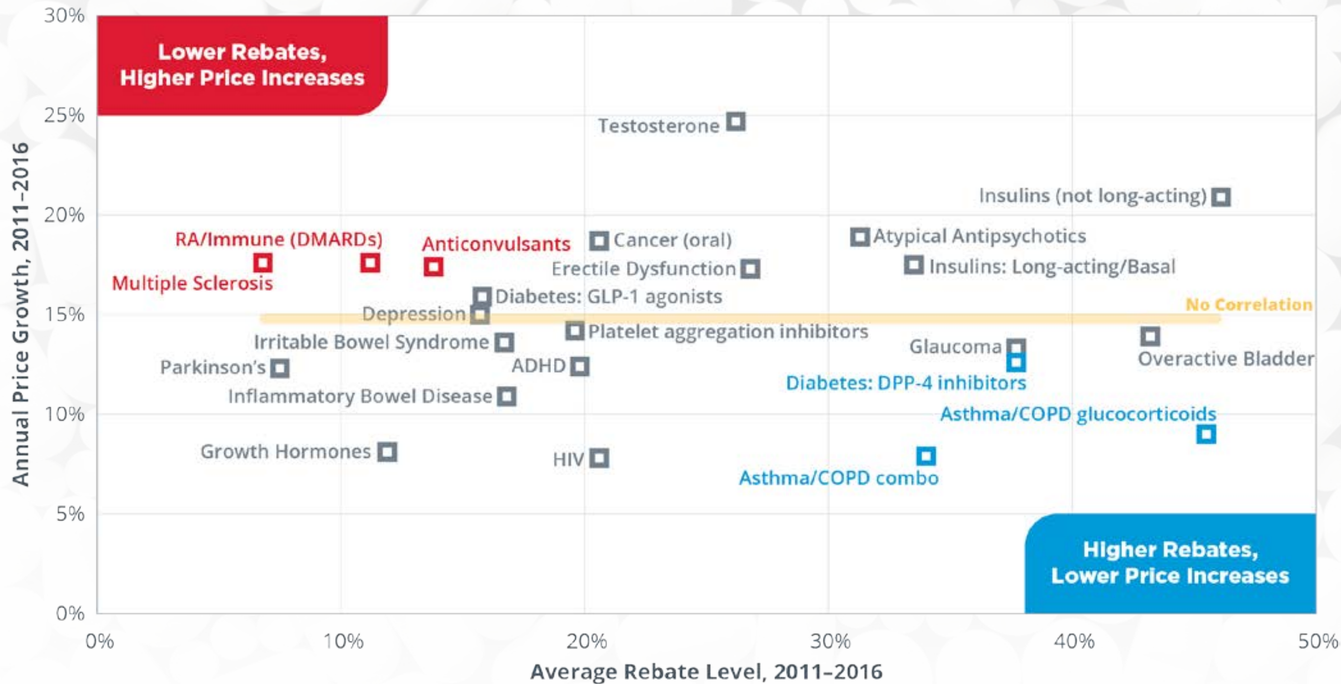
Study Shows No Correlation Between Drug Rebates and Price Increases



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.

Source: Visante, *No Correlation Between Increasing Drug Prices and Manufacturer Rebates in Major Drug Categories.* (April 2017).

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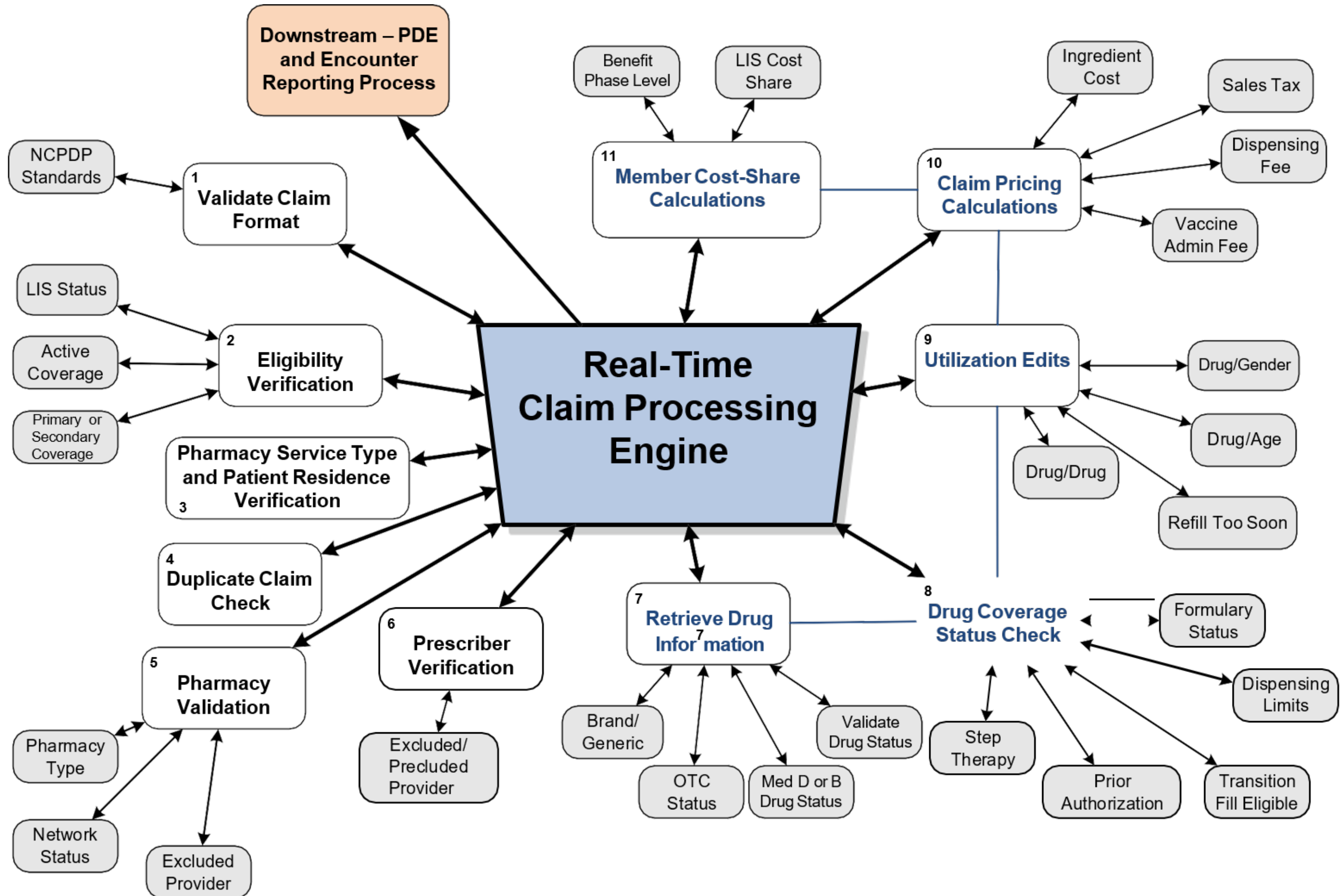
How PBMs Drive Savings & Quality: Pharmacy Networks

- 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



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

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

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

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

- PBMs 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.
- PBMs 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 PBMs play a central role in **driving adherence**, **holding down costs**, and **increasing quality.**

Questions?