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Drafting Pharmacy Benefit Manager Contracts: Controlling Costs, Avoiding Hidden Fees

Navigating Prescription Drug Pricing Complexities, Selecting PBMs, Managing the Relationship

THURSDAY, DECEMBER 14, 2017

1pm Eastern | 12pm Central | 11am Mountain | 10am Pacific

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Negotiating and Drafting Pharmacy Benefit Manager Contracts for Self-Insured Plans

ED KAPLAN

SR. VICE PRESIDENT AND NATIONAL HEALTH PRACTICE LEADER

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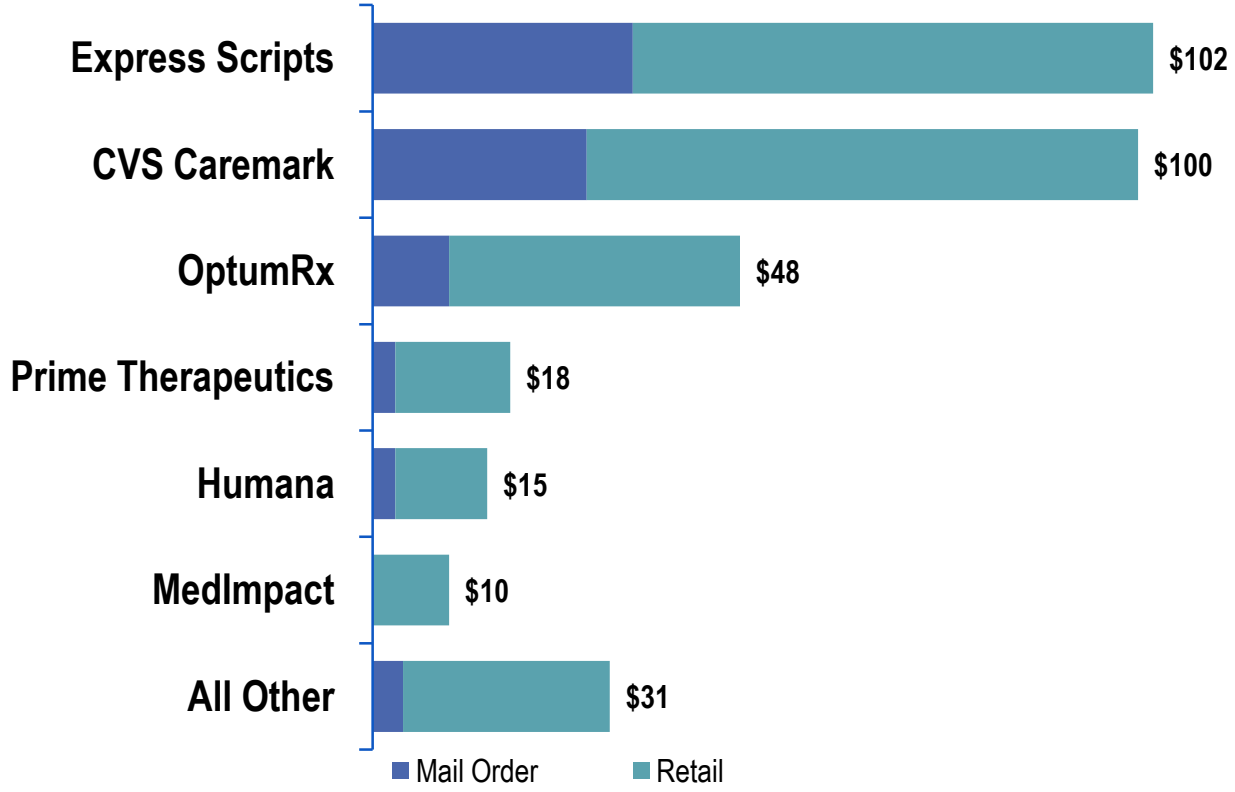
WILLIG, WILLIAMS & DAVIDSON

PBMs: WHO ARE THE PLAYERS

"Big Three"	Mid-Sized PBMs	Small PBMs	Smaller PBMs
Express Scripts	Prime Therapeutics	Envision**	BeneCard
CVS Health*	MedImpact	Magellan	ProAct
OptumRx (UHC)	Navitus	US Script	Welldyne
	Humana	Sav-Rx	30+ other niche PBMs

PBM MARKETSHARE:

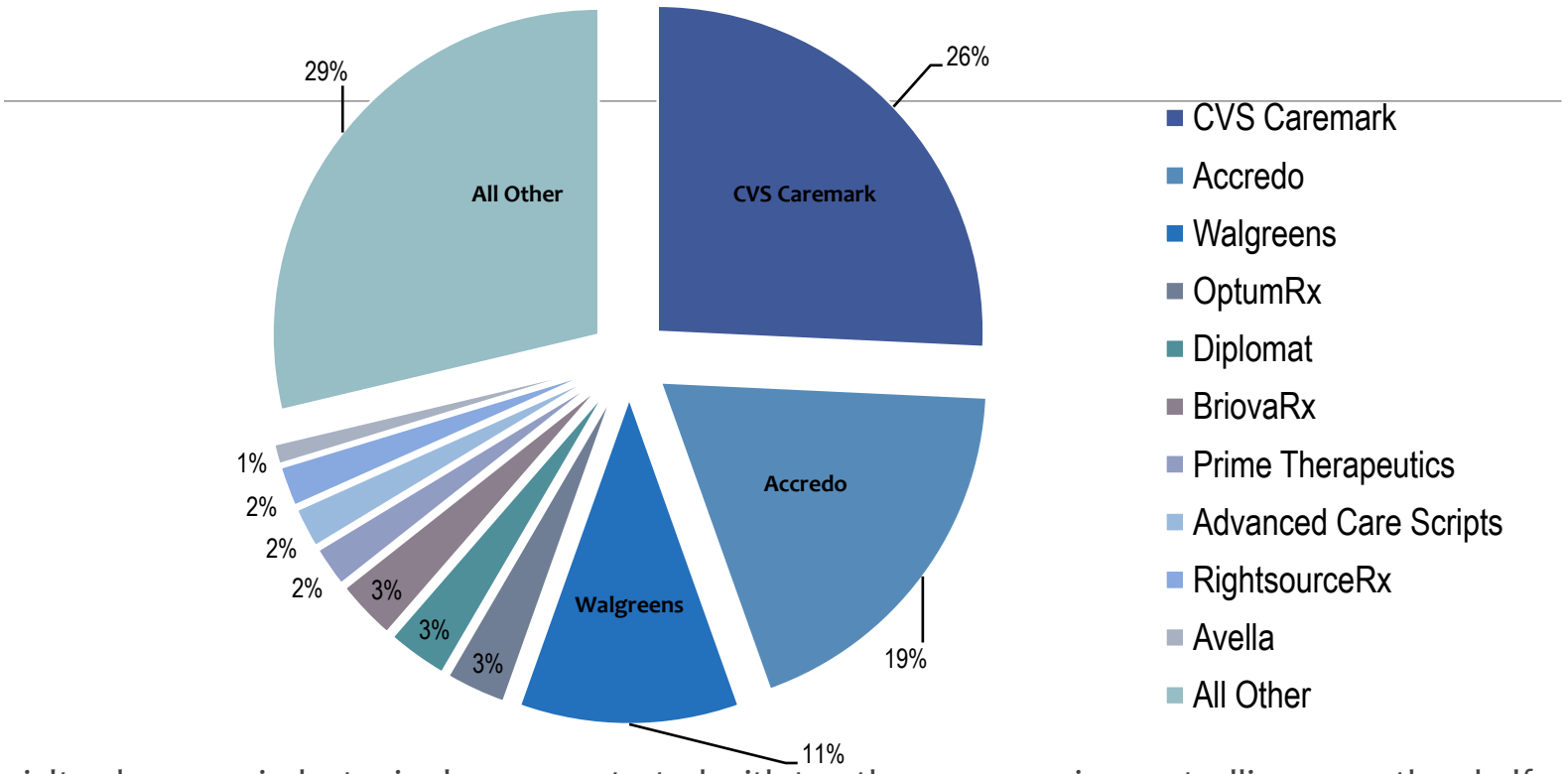
2015 In Billions



PBM's & Insurance Carriers

Carrier	PBM	Status
Aetna	CVS/Caremark	Merger Announced 12/17; Regulatory Approval Pending
Anthem	ESI	Relationship Terminated April 2017
United Healthcare	OptumRx	Wholly Owned PBM

Specialty Pharmacy Industry Overview



Specialty pharmacy industry is also concentrated with top three companies controlling more than half the market

Certain sub-agreements are in-place amongst specialty pharmacy firms due to manufacturer limited distribution arrangements

Further consolidation and realignments within the industry are expected

PBM INDUSTRY TAKE-AWAYS

- Current industry configuration is dynamic and will continue to change;
- Major health insurers, after years of out-sourcing PBM services, have started to re-enter the market;
- PBM's want to cover as many lives as possible, as scale remains critical for the PBM's if they are to negotiate effectively with pharmaceutical manufacturers and wholesalers;
- While CVS and ESI (Accredo) are important specialty pharmacies, Walgreens has shown itself to be a formidable competitor in the specialty market. Briova and Diplomat are becoming more important providers in this area.

REQUEST FOR PROPOSAL
ESSENTIAL BEFORE SELECTING PBM

RFP allows you to:

- Review Competitive Landscape of PBM's;
- Telegraph that you will apply contracting terms that move away from inflationary PBM definitions;
- Propose pricing strategies like tying financial incentives to future cost containment;
- Tie penalties and bonuses setting price inflation benchmarks with risk sharing features for gains and losses.

REQUEST FOR PROPOSAL ESSENTIAL BEFORE SELECTING PBM

For example, in an RFP, you can communicate that the successful PBM must include in the contract a New Price Inflation Protection Provision that could include:

- Establish target market trend rate for existing brand and generic drugs for all plan years based on industry data and recent plan history;
- Establish gain and loss share that the PBM is required to accept (e.g. 50% of excess trend and 50% shared savings below target);
- Exclude new drug entrants or drug market mix changes.

REQUEST FOR PROPOSAL ESSENTIAL BEFORE SELECTING PBM

In the RFP process:

- Demand repricing with trending on **YOUR** plan's actual utilization using YOUR plan's formulary for a defined period. Otherwise, e.g. data could be skewed by conversions of highly used drugs from brand to generic).
  - **You will want to engage an independent party to do the repricing rather than relying on the PBM's to reprice your claims.**
- Ask for a model contract and make clear that the successful PBM "must have" certain provisions, e.g. YOUR definitions, performance and pricing guarantees; termination provisions, etc.

YOUR PLAN'S LEVERAGE

You must be realistic about your plan's leverage with the PBM.

- If your plan is small, (e.g. 500 lives), your leverage is limited and you will want to seek a company whose "off-the-shelf" product best meets your needs at the best price.
- If your plan is not large (e.g., at least 10,000 lives), you may wish to explore joining a coalition, which may cover several million lives. Often a coalition can leverage its size so that it can require the PBM to allow individual plans or plans to customize formulary or services.

PBM CHALLENGES FOR PLAN SPONSORS

- Significant year-over-year cost trends continue:
  - Price inflation
  - Specialty utilization
  - Generic dispensing plateau
- High-cost specialty medication pipeline

Industry consolidation may be reducing competition

- PBM's continued reliance on manufacturer revenue streams;
- Balancing cost control with participant satisfaction.

PLAN SPONSOR STRATEGIES

- **SMART PLAN DESIGN:**
  - Meaningful participant cost-sharing; incentives to chose lower cost options ;
- **COMPREHENSIVE UTILIZATION MANAGEMENT:**
  - Prior authorization; Step therapy; Drug exclusions; Quantity limits;
- **PBM CONTRACT ALIGNED WITH PLAN GOALS:**
  - Lowest net cost; Performance guarantees; Plan flexibility;
- **DECISIVE ACTION:**
  - Willingness to implement changes in a timely fashion to address emerging issues.

CONTRACT TERMS

Essential Elements:

- Financial cost & terms
- Disruption impact (formulary, network, benefit, etc.) if moving to a new PBM
- Account management (reporting, service)
- Drug channel management (mail, retail [30, 90 limited], specialty)
- Data rights including right to MAC list used for billing cycle pricing
- Customer service
- Clinical program fit
- Reporting & Trend management

KEY TERMS: BRAND vs. GENERIC

A plan is charged different rates for a drug depending on whether the drug is a **"brand" drug** or a **"generic"** drug. PBM's give payors relatively small discounts for brand name drugs but very significant discounts for generic drugs.

- If a PBM classifies a generic as a brand drug (e.g. a ***single source generic***), the PBM can charge the payor much higher prices than if the drug is classified as generic drug.
- Another potential pitfall: ***house generics.***

KEY TERMS
BRAND-NAME DRUG

The FDA defines a brand-name drug as follows:

- ***A brand name drug is a drug marketed under a proprietary, trademark-protected name.***

Brand name medications can only be produced and sold by the company that holds the patent for the drug.

KEY TERMS: GENERIC DRUG

The FDA defines a generic drug as follows:

A generic drug is the same as a brand name drug in dosage, safety, strength, how it is taken, quality, performance, and intended use… The FDA bases evaluations of substitutability, or "therapeutic equivalence," of generic drugs on scientific evaluations. By law, a generic drug product must contain the identical amounts of the same active ingredient(s) as the brand name product…”

KEY TERMS
GENERIC DRUG

Possible contract approaches:

- **Straight-forward:** "Generic Drug" means a drug where the Generic Indicator (GI) field in Medi-Span contains a "Y" (generic).
- **Less straight-forward:** "Generic Drug" means a prescription drug, whether identified by its chemical, proprietary, or non-proprietary name, that is therapeutically equivalent and interchangeable with drugs having an identical amount of the same active ingredient(s) and approved by the FDA. A Generic Drug determination is made using indicators from a neutral pricing service depending on its characterization under a ***brand/generic algorithm***. (Could be ***big*** trouble!).
- **House Generics**

KEY TERMS: SPECIALTY DRUGS

The FDA does not list a standard definition for "specialty drugs." However, many factors can be considered in determining if a drug is a "specialty" drug:

- Cost >$600/month
- Treats a rare condition
- Requires special handling
- Uses a limited distribution network
- Requires ongoing clinical assessment
- Licensed under a Biologic License Application

KEY TERMS: REBATES

Pharmaceutical manufacturers pay **rebates** to PBM's in an amount related to how much of the manufacturer's business the PBM can drive. PBM's accomplish generally as part of their formulary contracting agreements.

PBM's also receive **"program fees", "administrative fees," "educational fees",** etc. from manufacturers.

- The plan's interest here is in capturing at least a portion of the amount that the PBM is paid on account of the plan's utilization, whether it's called "rebate", "fee", etc.

KEY TERMS: FORMULARY

A **formulary** is a list, generally created by the PBM, of prescription drugs available to enrollees for which a plan will provide benefits coverage.

A **tiered formulary** provides financial incentives for patients to select lower-cost drugs or specified brand name drugs, for example: $10 generic; $35 "preferred brand" and $50 "non-preferred brand."

- *The copayment structure encourages participants to use the brand-name drug for which the PBM receives the most beneficial manufacturer payments.*

PAYMENT BENCHMARKS: AWP

AWP = "AVERAGE WHOLESALE PRICE"

- Sometimes called "Ain't What's Paid";
- Essentially the sticker price;
- The list prices for drugs reported by the manufacturers and reported to a data bank;
- Reported prices relate to drug, strength, dose form, package size and manufacturer;
- Doesn't reflect the real wholesale price.

PAYMENT BENCHMARKS: AWP

Possible Contract Approach:

- "Average Wholesale Price" or "AWP" shall mean the average wholesale price of a prescription medication **in effect on the date the prescription was dispensed** as listed by **Medi-Span**, or another **applicable industry standard reference** on which pricing hereunder is based, for the **actual package size dispensed**.

PAYMENT BENCHMARKS: WAC

WHOLESALE ACQUISITION COST (WAC):

- Manufacturer's "list price";
- Price that pharmaceutical manufacturers set for their medication prior to any discounts or rebates that a wholesaler or distributor would pay.

PAYMENT BENCHMARKS: AWP / WAC

The amounts that plans pay for drugs are based on AWPs. Pharmacies, on the other hand, purchase drugs based on proprietary contracting and acquisition prices.

The difference between the acquisition price -- what the pharmacy actually paid for the drug -- and the amount the plan pays the PBM for the drug, that is, AWP, is known as the **spread**.

PAYMENT BENCHMARKS: UCR and INGREDIENT COST

Usual and Customary (U&C) price: the cash price at retail.

Ingredient Cost: drug cost used for claims processing; includes discounts at retail and mail service and other plan-specific pricing rules, and usually defined as a percentage of the AWP

PAYMENT BENCHMARKS: MAC LIST

MAXIMUM ALLOWABLE COST LIST: A list, often characterized by the PBM as proprietary, of generic drugs put together by a PBM which is supposed to represent the upper limit paid by a plan sponsor for most generic drugs.

- *The benchmark for MAC is often the average wholesale price (AWP) minus a percentage discount, ranging widely from 20% to as much as 95%. However, AWPs are often inflated when compared to actual market prices.*

WHERE PURCHASED: RETAIL

Retail purchases provide the plan with lower discounts than mail order purchases. At retail, plan pays:

- **Administrative Fees** – the fee charged by the PBM for the basic electronic transaction of processing a claim.
- **The PBM's Brand and Generic Ingredient Costs**: The PBM will contract with the pharmacy to provide the drug at X while charging the plan X+.
- **Pharmacist Dispensing Fees –** ranging from $1.00 to $2.25 per script.
- **Ancillary Fees**: prior authorization fees ($50 per review), etc.

WHERE PURCHASED: MAIL ORDER

At Mail Order, the PBM is essentially a giant drug store, able to negotiate aggressive deals with manufacturers – the benefit of which may not accrue to the plan.

- Mail Order Pharmacy:
  - Has professional pharmacists who review and fill the scripts (although dispensing fee);
  - No administrative fee;
  - However, pricing controls on brands and generics may not be easily applicable to the mail order facility.

PBM PROFIT SOURCES

PBM's have multiple sources of potential profit and will vary pricing terms/fees based on the unique characteristics of a client

Retail

- AWP margin "spread"
- Dispensing fee margin "spread"
- System access fees

Mail Order and Specialty

- AWP margin
- Purchase discounts
- Patient services

Pharma Revenue

- Formulary rebates
- Incentive rebates
- Administrative fees
- Patient education/ services
- Data sales
- Other

Administrative Fees

- Utilization Management
- Clinical programs
- Medicare Part D administration
- Disease and Health management

PBM CONTRACTS: TRADITIONAL PRICING

"Traditional" Pricing" is based on a percentage off AWP (e.g. AWP – 22%), regardless of the PBM's actual cost from their negotiated network discounts. If the cost is greater, the PBM absorbs the cost; if the cost is less, the plan does NOT receive the benefit.

PBM CONTRACTS: TRANSPARENT PRICING

Ideally, in a **"transparent"** arrangement, the plan pays exactly what the pharmacy benefit manager pays its network of retail pharmacies for a drug or drugs in a pass-through pricing model.

- The PBM should ***pass through*** all drug formulary rebates and manufacturer derived revenue (but they don't, really), network dispensing fees and revenue to the client.
- Plan pays an administrative fee rather than allowing PBM to earn "spread" or other manufacturer payments.

PBM CONTRACTS: Traditional v Transparent

No such thing as pure transparency:

- Even "transparent" PBMs can generate revenue beyond employer contract administrative fees, including "promotional fees"; clinical fees paid to subsidiaries; shadow deals

No evidence yet that transparent deals produce lower costs on a PMPM basis

Deals based on AWP are inflationary and upward costs are hard to contain

PBM CONTRACTS: PRICING ARRANGEMENTS

New PBM pricing arrangements require:

- Prospective price ceilings based on unit costs
- Shared savings and risk contracts tied to overall pharmacy costs by patient (lowest new cost by therapy)
- Fees tied to outcomes

CONTRACT TERMS: Prospective Unit Cost Pricing Methodology

Transition away from AWP if possible. Will lead to more transparent, predictable and equitable pricing methodology.

One method is prospective unit cost price ceilings for generic drugs:

- Allows for uniform measure of analysis across competing PBMs
- Eliminates PBM manipulation of MAC list prices
- Using actual plan utilization (units by drug) against prospective ceiling list, we can expect more predictable generic cost projections and easier audit process.

PBM CONTRACT: BEST PRACTICES

- Be strategic about RFP vendor lists

  Scrutinize definitions and payment terms that could compromise pricing guarantees

- Maintain competitive pricing throughout contract term:
  - Clear Termination Rights
  - Market Check

- Understand how pricing guarantees are calculated:
  - Single-source generics
  - Other exclusions/inclusions
  - Brand/Generic performance offsets

- Reasonable audit rights

CONTRACT TERMS: REBATES

Rebate Payment Terms:

- Flat Dollar Minimum
- Percentage of Manufacturers' Rebate

Types of Rebates:

- **Per prescription** : rebate is paid based on brand and generic utilization.
- **Brand only**: rebates paid on brand prescription use only
- **Per rebatable drug**: rebates paid only subset of brand prescriptions.

CONTRACT TERMS: REBATES

Key question : What is NOT included in the rebate pool?

- Manufacturer administrative fees
- Product discounts
- Fees related to the procurement of prescription drug inventories by or on behalf of PBM owned and operated specialty or mail order pharmacies
- Fees received for care management or other services provided in connection with the dispensing of specialty products
- Other fee-for-service arrangements performed by PBM for manufacturer, etc., etc.

CONTRACT TERMS:
REBATES – BEST PRACTICES

- Demand access to manufacturer rebate contracting terms;
- Negotiate "Point of Sale" brand discounts that includes the value of rebates, with annual reconciliation against minimum guarantees.

QUESTIONS?

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