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

Navigating Prescription Drug Pricing Complexities, Selecting PBMs and Managing the PBM Relationship, Avoiding Hidden Fees

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

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THE PBM MARKETPLACE

BIG THREE PBM's	MID- SIZED	SMALL PBM's	VERY SMALL
	PBM's		PBM's
EXPRESS SCRIPTS	PRIME THERAPIES	PRO-ACT	BENE-CARD
CVS HEALTH	MEDIMPACT	MAGELLAN	PERFORMRX
OPTUM RX (UHC)	NAVITUS	US SCRIPT	WELLDYNE
	ENVISION	SAV-RX	30+ OTHER NICHE PBM'S

June 21, 2016

PBM Market Share

- Relative Share of the Total PBM Market Share
 - In \$ Billions 2014

PBM	Total Dollars (Retail and Mail Order)
Express Scripts	\$101
CVS	\$88
Optum Rx (United)	\$54
Prime Therapeutics	\$16
Humana	\$13
MedImpact	\$9
All Other	\$26

June 21, 2016

"BIG THREE" COMPARISON

*Source: Company 10K and Segal estimates	ESI	CVS	OptumRx
Lives Covered	79M	65M	65M
Revenue	\$101B	\$88B	\$54B
Rx's	1350M	932M	963M
Mail Rx's	128M	82M	24M
Mail Rx %	9%	9%	2%
Gross Profit%	7.9%	5.4%	4.8%

PBM'S AND INSURANCE CARRIERS

Carrier	PBM	Relationship
Anthem *1	ESI	Long-Term Agreement
Aetna (Humana) *2	CVS Health	Long-Term Agreement
United Health Care	Opum Rx (Catamaran) *3	Wholly Owned
BCBS Plans *4	Prime Therapeutics	Wholly Owned Non-P

- 1. Anthem announced agreement to acquire CIGNA on 7/24/2015. Regulatory approval still pending. CIGNA currently has a long-term PBM sourcing agreement with Catamaran.
- 2. Aetna announced agreement to acquire Humana on 7/3/2015. Regulatory approval still pending.
- 3. UHC finalized acquisition of Catamaran on July 23, 2015.
- 4. Prime Therapeutics is owned by BCBS AL, FL, IL,KS, MT, NE,ND, NC, OK, TX, WY.

SPECIALTY PHARMACY OVERVIEW

- Specialty pharmacy industry is highly concentrated with three companies controlling more than half the market:
 - CVS Caremark: 26%;
 - Accredo (ESI): 9%;
 - Walgreens: 11% (only major specialty pharmacy player that is not PBM owned)
- Certain sub-agreements are in place among specialty pharmacy firms due to manufacturer limited distribution arrangements.
- NOTE: Some (*but not all*) firms are highly competent with respect to both technology and patient service and will agree to competitive terms.

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 dominant specialty pharmacies, Walgreens has shown itself to be a formidable competitor in the specialty market.

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 may 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. So, 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.

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*.
 - The latter approach could be *big* trouble.

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: SPECIALTY DRUGS

- Specialty Drugs: why is the definition important?
 - Because your plan gets a much higher rate (that is, a much lower discount) on specialty drugs than on other brand drugs. Therefore, you want to make sure your plan is not paying specialty rates for what really is just another brand-name drug.

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 First Data Bank, or another **applicable** industry standard reference on which pricing hereunder is based, for the **actual** package size dispensed.

PAYMENT BENCHMARKS: AWP

- Another contract approach:
 - "AWP" means the average wholesale price of a prescription drug as identified by a **source recognized in the retail prescription drug industry selected by PBM**. Under no circumstances will the AWP's from two pricing sources be used simultaneously. The applicable AWP shall be the **11-digit NDC for the product dispensed** on the **date 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 the WAC.
- The difference between the WAC -- 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: price a customer without insurance would pay for a prescription 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.

PAYMENT BENCHMARKS: MAC

- Possible contract approach:
 - "MAXIMUM ALLOWABLE COST" or "MAC" means the maximum unit ingredient cost payable by Plan Sponsor for a proprietary list of off-patent Brand Drugs which has been negotiated with Participating Pharmacies. The MAC list and associated drug prices are updated from time to time by PBM and are fully auditable by Plan Sponsor. Plan Sponsor will be charged the exact amount payable by PBM to Participating Pharmacies for the most current MAC list.

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.

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 CONTRACTS: TRADITIONAL PRICING

"Traditional" Pricing is based on a percentage off AWP (e.g. AWP – 22%), regardless of the PMB's actual pharmacy costs 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, 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"; 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? May include:
 - 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
- Require full disclosure of all manufacturer revenue sources, subject to confidentiality agreement
- Negotiate "Point of Sale" brand discounts that includes the value of rebates, with annual reconciliation against minimum guarantees.

CONTRACT TERMS: REBATES – BEST PRACTICES

- Pursue realigned PBM payments tied to overall lowest net cost per brand treatment with therapy class:
 - Shared savings incentive payments tied to net patient cost per year of therapy vs. non-formulary or non-covered brand products in the same class
 - Shared savings beyond rebate payment as a percentage of cost per year of therapy
 - See next slide for Example

CONTRACT TERMS: REBATES – BEST PRACTICES

• **EXAMPLE**: Current price after rebate cost per year of therapy for statins is X. PBM contract sets a target of X+2% for the next plan year, factoring in expected changes in generic utilization, future pharma rebate payments, and future AWP increases. PBM shares 50% of excess cost per year of therapy and 50% of the savings below X + 2%.

QUESTIONS?



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