Understanding the Prescription Drug Landscape & Best Practices for Managing the Benefit

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Prescription Drugs – When did it become Fashionable?

• Early discussions to cover prescription drugs
  • When did it all start?

• Prescription drug coverage becomes mainstream
  • When did prescription drug coverage become common coverage option?

• Direct to consumer advertising
  • When did DTC start?

• Overall impact on patient experience, utilization and costs to Plan Sponsors

• What does this mean for you?
Instant Gratification Society

The Pharmaceutical Industry Does not create cures, They create customers...

True or False?
Pharmacy Landscape
The Current Landscape | A State of Change

The past few years have seen dynamic change in the pharmacy benefits landscape:

• **The beneficial “generic wave” is ending**, and pharmacy cost trend rates are now on their way back up
• **Specialty drug costs are skyrocketing**, with no easy options for effective cost containment - PBMs remain behind the curve
• **Consolidation among PBMs** has led to marketplace domination by several key players
• **Pricing and contracting remain convoluted**, and financial transparency is extremely limited
• **An unpredictable future state** creates plan management challenges for payers
Prescription Drug Trend

ESTIMATED FORCASTED DRUG TRND: COMMERCIALY INSURED

Source: Express Scripts 2016 Drug Trend Report
The End of the Generic Wave

TOTAL REVENUE FOR BRAND DRUGS LOSING PATENTS, BY YEAR OF PATENT LOSS

Source: Medco Health Solutions & Express Scripts
The Lay of the Land

- The past decade has seen dynamic change in the Pharmacy Benefit Manager (PBM) landscape.
- Extensive Merger & Acquisition activity has led to accelerated growth of several key players.
- Integration and service issues persist among the jumbo PBMs.
- Smaller PBMs find some success targeting niche markets and clients with unique demands.
- Unpredictable future state creates procurement and contracting challenges for clients.
How Do PBMs Differentiate?

• PBM size.
  • BIGGER is better! More marketplace leverage to deliver value to clients!
  • SMALLER is better! More agility to meet unique client needs!

• Integration/coordination with overall healthcare strategy.
  • Marketing keystone for captive PBMs.
  • Carve-out PBMs creating wrap-around solutions to address this.

• Delivery channel specialization (Retail, Mail, and Specialty).
• Ownership vs. outsourcing of key functionalities.
• Market segment focus (Employer, Labor, Hospital, and Health Plans).
• Business model differentiation (i.e., “Transparency”).
• Price matters!
A Rapidly Evolving Vendor Landscape

Express Scripts
- NPA (1998)
- DPS (1999)
- ValueRx (2002)
- NextRx (2009)
- Caremark Rx
- CVS/Pharmacare
- RxAmerica (2008)
- Catalyst Health Solutions
- FutureScripts (2010)
- WHI (2011)
- SxC Health Solutions
- NMHC (2008)
- HealthTrans (2011)

Medco Health Solutions (2012)

Caremark (2006)

Catalyst Health Solutions (2012)

Restat (2013)

SxC Health Solutions (2012)

OptumRx

CVS Health

Catamaran
PBM Market Share (% of Claims – 2016E)

Assuming Insourced PBM Functions at Major MCOs

- CVS/Caremark, 30%
- OptumRx, 23%
- Express Scripts, 25%
- Humana, 7%
- Medimpact, 5%
- EnvisionRx, 1%
- All Other, 3%

Source: Deutsche Bank Markets Research (March 2017)
Drug Pricing and the Impact of AWP Increases
Average Wholesale Price (AWP)

Average Wholesale Price (AWP) is the pricing benchmark used by most payers.

- Usually expressed as a discount off of AWP
  - *Example*: AWP-16% for brands and AWP-82% for generics
- Not an actual market price
- Can be reported by the manufacturer or calculated by the publisher based on a mark-up on wholesale acquisition cost (WAC)
National Health Expenditures 2014

- Inflation: 0.8%
- US Healthcare: 5.3%
- Prescription Drug: 12.2%

Source: Kaiser Family Foundation
A New Model for Drug Pricing

• The manufacturer of Daraprim
• Rx used for the treatment of toxoplasmosis and acute malaria
• Prior to the acquisition by Turing, price was $13.50 per pill
• After acquisition, price increased to $750 per pill—5,456% increase

Martin Shkreli, CEO—Turing Pharmaceuticals
Average Wholesale Price (AWP)

- Market price of brand drugs is *typically* about 16.6% less than AWP
- Market price for older generics can be significantly less than AWP
  - Up to 80% or 90% less than AWP
- As AWP prices increase, the cost of drugs to payors increases
- Manipulation of AWP prices can result in large profits for manufacturers, pharmacies and PBMs
### Inflation Monitoring

Tracking AWP inflation on an ongoing basis will showcase claims that are anomalies and outliers.

<table>
<thead>
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<th>NDC</th>
<th>Product Name</th>
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</table>
Exclusion Example - Glumetza

• In 2015, there were significant AWP increases of Glumetza of over 800%.

• Glumetza is a unique oral extended release tablet used to prevent and manage hyperglycemia in Type II diabetics.
  – There is not a substitutable generic, but Metformin is available as generic with the same clinical effectiveness.

<table>
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<tr>
<th></th>
<th>Annual Plan Cost Estimate</th>
<th>Average Drug cost per 30 DS*</th>
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<tbody>
<tr>
<td>Glumetza</td>
<td>$40,448</td>
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**GLUMETZA: AVERAGE WHOLESALE PRICE PER UNIT**

*Based on PSG’s Book of Business Utilization Summary – Post-Change (6/19/2015 – 10/26/2015)
Exclusionary vs. Open Formularies
What is a Formulary

- List of preferred medications in each drug therapeutic class
- May have varied tiers for member cost share

Preferred Drug List (PDL)

- Targeted drugs in therapy classes
- May have varied tiers for member cost share
<table>
<thead>
<tr>
<th><strong>Open Formulary</strong></th>
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<tbody>
<tr>
<td>• All drugs covered</td>
</tr>
<tr>
<td>• May have varied tiers for member cost share</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th><strong>Exclusionary Formulary</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Targeted drugs in therapy classes where multiple similar products are not covered</td>
</tr>
<tr>
<td>• Creates competitions</td>
</tr>
<tr>
<td>• May have varied tiers for member cost share</td>
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</tbody>
</table>
Exclusionary vs. Open Formularies

- Exclusionary formularies have been gaining in popularity over the past 5-7 years
  - The competition created by excluding targeted drugs has increased the rebate levels from manufacturers
    - Higher cost in covered drugs offset by rebates
  - Most PBMs will offer both open and exclusionary formularies
    - Prefer formularies with exclusions

Although the excluded drugs may be relatively higher in cost than the covered drugs, the primary driver of savings is increased rebates
Exclusionary vs. Open Formularies

Market Place Experience so far:

- Many plans have elected to implement
- Member disruption is generally minimal
  - Typical disruption levels have approximated less than 2-3% of members
- Typical difference in rebate guarantees with exclusionary formularies offered by PBMs is 25-30%
Exclusionary vs. Open Formulary

Things to Consider:

- Disruption will occur but is minimal and declines within 120 days after the initial implementation
  - Have your PBM provide a disruption report
- The formulary will change each year:
  - Additional excluded drugs are added while others are reinstated
  - Transfers some control of drug coverage to the PBM
- Primary savings is due to increased rebates however, some contracts between manufacturers & PBM include inflationary caps
  - Due to the lag in rebate payment schedules, the benefit of increased rebates is delayed
The Impact of Benefit Design On Utilization and Costs
Benefit Design Goals

Goals of Benefit Design

• Establish a reasonable cost share for members
• Steer members to the most cost-effective delivery channel - Mail, Retail, Specialty
• Promote utilization of cost-effective products - Brand, Generic and Specialty
Benefit Design Goals

Member Cost Share

- A common target is to attain an overall member cost share of 20%
- The actual cost share will differ amongst drug types
  - Higher for some low cost Generics
  - Significantly lower for Specialty Drugs
- Flat dollar amounts for copays will diminish in value over time as drug costs increase
- Co-insurance will adjust for inflation and requires adjusting less frequently
Benefit Design Goals

Most Cost Effective Delivery Channel

- Discounts provided by PBM’s are typically better at the Mail Channel versus Retail
  - In order for the benefit of increased discounts to be realized by the Plan Sponsor, copays for Mail need to be at least 2.5x the Retail copays
- Pricing for Specialty Drugs is typically better when filled at an exclusive specialty pharmacy than at Retail
- Mandatory Delivery Channels
  - Requiring members to utilize Mail for maintenance drugs and the Specialty Pharmacy for specialty drugs
Benefit Design Goals

Promote the utilization of the most cost-effective products

- In general, Generic drugs are less expensive than Brands
- Most Plan Sponsors are experiencing Generic Dispensing Rates (GDR) in the mid-80% range
  - Some Plan Sponsors have achieved GDR’s approaching 90%
- In order to incentivize members to use Generic drugs when available, having a minimum of $20 or 20% difference between Brand drugs and Generics is necessary
- Rules that require members to pay the difference between the Brand and the Generic if they choose a Brand when a Generic is available helps promote the use of Generic drugs
Benefit Design Goals

• Additional Tiering:
  • 4 and 5 tier plan designs have become more common
  • Feature higher tiers for specialty drugs and an additional tier for higher cost generics

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<th>Tier</th>
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<td>1</td>
<td>Low Generics</td>
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<td>2</td>
<td>High Generics</td>
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<tr>
<td>3</td>
<td>Preferred Brands</td>
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<td>4</td>
<td>Non-Preferred Brands</td>
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<tr>
<td>5</td>
<td>Specialty</td>
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Maximizing Clinical Prior Authorization & Utilization Management Tools
Questions to Ask . . .

- Are your PAs properly enforced?
- Are your current PAs effective?
- Is it check-the-box or is documentation required?
### Use of PA’s in Management of Specialty Drugs

#### Ultimate Goal: ENSURE APPROPRIATE USE

<table>
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<tr>
<th><strong>Intent of Prior Authorization</strong></th>
<th><strong>Drug Examples</strong></th>
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<td>Limit off-label use</td>
<td>Oral oncology</td>
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<tr>
<td>Limit misuse</td>
<td>Growth Hormone, Botox</td>
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<tr>
<td>Ensure appropriate use of first-line therapies</td>
<td>TNF inhibitors, OA of the knee drugs</td>
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<tr>
<td>Limit treatment duration</td>
<td>Hepatitis C</td>
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<tr>
<td>Ensure compliance with nationally recognized treatment guidelines or standards of care</td>
<td>Synagis, Hep C</td>
</tr>
<tr>
<td>Confirm Diagnosis through labs or tests</td>
<td>PAH, HAE</td>
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</table>
Real World Examples – What Have We Found?

PA process is SUB-OPTIMAL

• Solid PA criteria weakly enforced
• Weak PA criteria
• “Check the box” process for PA criteria collection
• Lack of documentation required before approval
• Lack of measurable markers required to confirm diagnosis
• Ineffective edits to manage strength, quantity, frequency or duration approved
• Lack of monitoring once PA is implemented
How Can I tell if PAs Are Effective?

Monitor – Monitor - Monitor

- Utilization through paid claims data
  - Appropriate diagnosis
  - Appropriate quantities
  - Appropriate treatment frequency & duration

- PA activity
  - Number of requests, approvals & denials
  - Monthly, Quarterly
Monitoring Prior Authorization Process

Many plans are managing their Prior Authorization Process to ensure appropriate use based on the following:

• Ensure guidelines
• Ensure proper administration
• Beware of conflicts
• Be diligent
  • Monitor approval rates
• Consistency across benefit pharmacy and medical benefit

CARVE-OUT OF PA IS A DEVELOPING OPTION
Need for Clinical Management and Oversight Is Growing

Key Drivers:

• Growing pipeline of marginally effective specialty drugs
• Growing direct-to-consumer ads for specialty
• Weakly written medical policies
• Poorly enforced medical policies
• Lack of monitoring and vendor accountability
Use of Prior Authorization to Manage Specialty?

Prior Authorization is used to **ensure appropriate use** but there are many different reasons to develop a PA

- Limit off-label use
  - e.g., Oral oncology
- Limit miss-use
  - e.g., Growth hormone, Botox
- Ensure appropriate use of first-line therapies
  - e.g., TNF blockers, OA of knee products
- Limit treatment duration
  - e.g., Hep C agents
- Ensure compliance with nationally recognized treatment guidelines
  - e.g., Synagis, Hep C agents
- Confirm diagnosis
  - e.g., PAH through right heart catheterization
  - e.g., specific lab values for HAE

Can approval/denial rates be used to measure effectiveness of the PA?

- Inability to measure sentinel effect
Clinical Management: Stelara Client Example

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<tr>
<th>Strength</th>
<th>Members</th>
<th>Claims</th>
<th>Plan Paid</th>
<th>Avg. Cost/Claim</th>
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<td>45mg</td>
<td>34</td>
<td>104</td>
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<td>90mg</td>
<td>32</td>
<td>100</td>
<td>$1,619,524</td>
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</table>

- Stelara is available in 2 strengths: 45 & 90mg
  - 90mg dose is indicated for patients who weigh > 100kg (220lbs)
  - According to U.S. Census Bureau 23% adult males & 11% adult females weigh > 100kg
- Client example above—49% claims were for 90mg dose
  - Client conducts biometric screenings and has documented weights for all members
  - Based on weights obtained through biometric screening, 43% or 14 patients on 90mg dose weighed < 100kg
  - PBM will notify patients and prescribers they will only be authorized for Stelara 45mg going forward
Coverage and Exclusions of Drugs

• Market change in philosophy to cover everything
• Drugs need to demonstrate value
• Different than formulary exclusions
• Plan Sponsors are doing this by:
  • Pipeline managing and reviewing drugs prospectively instead of retrospectively
  • Tracking AWP inflation for drugs
  • Assessing “Me Too” Drugs
Certain Specialty drugs have high incidences of discontinuation or dose changes due to significant side effects or lack of efficacy

- Most common with oncology drugs
- Many of these drugs can have discontinuation rates up to 30-40% in the first 3 months
- Dispensing a 30-day supply can lead to waste
Implementing a split fill program for targeted drugs can reduce waste

- Members receive a 15-day supply generally with a pro-rated copay for the first 3 months of therapy.
- Specialty pharmacy will contact the member prior to the scheduled next fill to determine if the therapy has been discontinued, changed or put on hold before sending the next 15-day supply.
- After 3 months, the member can receive a 30-day supply if tolerating and receiving the prescribed drug.
- Must require members to utilize the same specialty pharmacy for all specialty drugs to be effective.
## Client Example: Specialty Split Fill Program

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<th># MEMBERS STOPPED AFTER 2 FILLS</th>
<th># MEMBERS STOPPED AFTER 3 FILLS</th>
<th>POTENTIAL SAVINGS</th>
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<td>ZYKADIA</td>
<td></td>
<td></td>
<td>1</td>
<td>$6,855</td>
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<tr>
<td><strong>TOTAL, ALL PRODUCTS</strong></td>
<td><strong>6</strong></td>
<td><strong>7</strong></td>
<td><strong>8</strong></td>
<td><strong>$107,836</strong></td>
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- Data from a single large employer client case study.
- Savings assume that $\frac{1}{2}$ of the last fill would not be dispensed under the split fill program, and thereby $\frac{1}{2}$ the cost would be avoided (15 days of therapy for most claims).
Clinical Management: Questions to ask your PBM

• What prior authorizations/step therapy programs are available that my Plan has NOT already implemented?

• What are my savings from my current PA/Step programs?
  • Ask for a detailed report and review it

• Are you requiring documentation submission to approve prior authorizations?
The Benefit of Generics and the Patent Cliff
Benefits of Generics

• Over the past decade a wave of highly utilized Brand drugs have lost patent protection on a regular basis

  • The continued availability of new Generic drugs has provided savings opportunities for Plan Sponsors and helped keep trends down
  • Generic Dispensing Rates (GDR) have risen consistently year over year
  • Generic Dispense Rates of 85-90% are now attainable
Rx Pipeline
Top Brand Drugs Going Generic (2017 – 2019)

Estimated Dates of Possible First-Time Generic or Rx → OTC Market Entry
Benefits of Generics

The trend of Brand drugs losing patent and being available as Generics is coming to an end

• Fewer traditional Brand drugs will be utilized as the majority of claims will be for Generics and Specialty drugs will continue to increase in importance
• Specialty drugs are not available as Generics when they lose patent protection
Benefits of Generics

• Plan Sponsors will no longer be able to count on new Generics in the market to help keep trend down

• Plan Sponsors will need to look to other utilization management techniques to help contain costs
  
  • Prior Authorization, Step Therapy, Quantity Limits, Drug Exclusions
Are Biosimilars the Same as Generics for Small Molecule Drugs?

• Similar to generics for small molecule brand drugs but biosimilars
  • Are not exactly identical to the brand name innovator product
  • Should be highly similar to the brand name innovator product
  • Should have no clinically meaningful differences from the brand name innovator product in terms of safety, purity and potency
## Challenges to Entry and Uptake of Biosimilars

| **Naming** | • Same International Non-proprietary Name (INN) as originator product **OR**  
|           | • Distinguishable names based on biologic structure |
| **Interchangeability** | • FDA determines interchangeability/substitution  
|           | • Lack of clarity in the FDA’s requirements in interchangeability, may impact uptake |
| **Indication Extrapolation** | • Biologics with multiple indications may conduct studies & obtain approval for one not all  
|           | • Prescriber reluctance for use outside of approved indication |
Challenges to Entry and Uptake of Biosimilars

Patent Challenges
- Patents continuously challenged based on identity issues
- Impose significant delays to market entry

Manufacturer Reluctance
- Delays in submitting applications for biosimilars due to lack of finalized guidelines from the FDA
Unclear What Payers Should Expect

• Biosimilar entrance to the market will not be the same as when a generic enters the market for a small molecule drug
• Market share will not be driven by automatic substitution at the retail pharmacy level
• Costs are expected to be 10-30% lower but biosimilars may not end up being the lowest net cost product
• Brand name innovator products will continue to be marketed
• Brand name companies may offer rebate contracting to maintain preferred status for the brand name innovator products
• Prescribers may not be comfortable prescribing biosimilars
  • Indication extrapolation
  • Lack of interchangeability
  • ASP reimbursement lowers margin
What’s a Specialty Drug?

- High-cost
- Treats a complex and/or rare disease
- Requires special handling and administration
- Includes additional patient education or monitoring

Average Annual Retail Cost of a Specialty Drug

Source: AARP Public Policy Institute
FDA Drug Approvals

- **2013**: Total 28, Specialty 19
- **2014**: Total 39, Specialty 19
- **2015**: Total 51, Specialty 38
Specialty Drug Forecast

Growth Drivers

- Pipeline
- DTC ads
- Hospitals buying MD practices
- Drug Inflation
- Weak clinical policies

Forecasted PMPY Net Drug Spend Across the Pharmacy and Medical Benefit for Commercial Plan Sponsors

Source: Artemetrx Specialty Drug Trend Study, 2013
Why Manage Specialty Drugs?

**HIGH COST**
- Average cost $2,500/month
- Increasing trend continues

**UTILIZATION**
- Small number members driving large percentage of costs

**PIPELINE**
- Robust pipeline continues to represent significant advances in treatment
Benefit Strategy: Specialty

Breakdown of Pipeline by Disease State

- Cancer: 35%
- Orphan: 27%
- Inflammatory: 12%
- Other: 9%
- Hep-C: 7%
- HIV: 6%
- MS: 4%

Specialty Pipeline Is Full
Why Focus on Specialty Drugs?

• High Cost
  • $2,500 – average cost of a specialty drug/month
  • $150,000 – average annual cost of a specialty drug for the treatment of a rare disease

• Increasing Trend
  • Fastest growing increasing at double digit trends annually (15-20%)
  • Expected to continue at same rate

• Utilization
  • Used by a small percentage of members but responsible for a large percentage of cost
  • Often used in the treatment of complex, chronic or rare conditions

• Pipeline
  • Robust specialty drug pipeline contributes to increasing costs
  • Represents significant advances in the treatment of chronic, complex, rare & even previously untreated diseases
Affordability Strategies for Specialty Drugs

Must manage both UTILIZATION + COST

1. Use preferred specialty pharmacy
   • Eliminate first fills at retail - require dispensing of specialty drug from specialty pharmacy once specialty drug is prescribed
   • Maximize contracted rates specific to each drug
   • Set reasonable default contract rate for newly approved specialty drugs and minimum timeframe to establish a contracted rate

2. Select preferred therapies in therapeutic classes with sufficient specialty drug therapy options
   • Maximize manufacturer rebates for preferred products
   • Utilize specialty pharmacy for patient and provider communication for pull through to maximize rebate contracts

3. Limit dispense quantity to max 30-day supply, consider split-fill for therapeutic categories such as oral oncology
   • Require patient outreach to confirm patient needs drug, ensure there are not side effects or any issues/concerns and that patient is supposed to continue on therapy, before specialty drugs are dispensed

4. Ensure appropriate use through evidence-based Prior Auth policies as well as quantity limits
   • Require collection of documentation for criteria requirements
   • Limit duration of auth to allow for assessment that patient’s condition is benefiting from drug therapy
   • Implement quantity limits based on FDA approved dosing and package sizes
Key Takeaways

• Promote use of safe, effective, low-cost medications.
• Steer utilization to the most cost-effective delivery channel.
• Manage specialty drug spend with split fill program, preferred specialty pharmacy, preferred products by specialty class, and rigorous prior authorization rules.
• Partner with other plan sponsors or entities to leverage negotiating power.
• Engage a PBM consultant, physician or pharmacist for clinical review program.
Oversight for Financial Optimization
Market Place Problem

- Double-digit trends are back
- PBM not incented to manage the Plan Sponsor spend
- Medical drugs/channels - driving trend

Challenges

- Inflation with generics, specialty drugs and oncology drugs
- Misalignment between PBM, Provider and Payer
- PBM are like the “fox guarding the hen house”
Vendor Procurement

1. Identify Pharmacy Benefit Needs & Issues
2. Select Bidders & Develop Custom RFP
3. Solicit Proposals & Measure Results
4. Interview & Select PBM
5. Finalize Agreement & Implement Program

Your Request for Proposal (RFP) Paves the Path to an Optimal Service Agreement
Contract: Audit & Oversight

MONITOR YOUR PROGRAM

Financial Operations:
• Annual audit(s) your Plan’s PBM contract
  • Contract rates | plan design
• Adherence to financial guarantees
  • Financial Guarantee true up, as necessary
• Annual rebate reconciliation

Service Operations:
• Service Financial Guarantees