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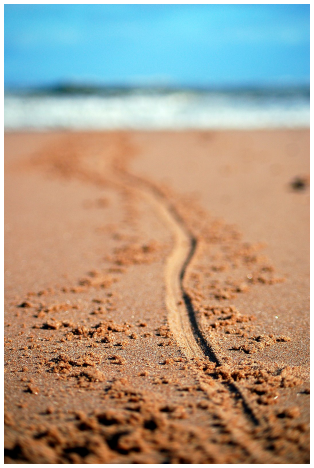
Midwest Business Group on Health



Drawing a Line in the Sand: Employers Must Rethink Pharmacy Benefit Strategies

Throughout this report, you will see commentary from health benefit professionals, speakers and others who participated in MBGH educational programming in 2017. Look for this icon

Middlemen continue to add to the cost of drugs

Health care reform continues to drag on with Washington's inability to address rising costs with rational health care policy. This lack of direction negatively impacts the market, and employers – as the largest purchasers of health care – can no longer afford to sit on the sidelines. One area of the health care value chain ripe for transformation is pharmacy benefits.

Organizations like the non-profit Midwest Business Group on Health are partnering with progressive employers, key industry leaders and employer coalitions across the country to improve the effectiveness, efficiency and value of pharmacy benefit programs to influence affordability and transparency.

This report offers a call to action on the key issues and important steps public and private employers can take to:

- Understand how today's pharmacy benefits model, with multiple parties in the middle, contributes to higher costs in the supply chain
- Identify ways to work with intermediaries to reduce unnecessary costs and drive efficiency

Employers are caught in the middle with specialty drugs

Biologic and specialty drugs have the ability to change the face of treating disease. Every year, there is an increasing number of these drugs being produced for rare and chronic diseases or previously untreated conditions. The high cost of specialty drugs has become an increasing concern for employers, as plan sponsors. In 2016, MBGH members cited "managing specialty drugs" as their #1 priority.

Although employers value the knowledge, skills and resources provided by Pharmacy Benefit Managers (PBMs), there is growing concern about their revenue streams which are increasing the costs of specialty drugs. Employers are caught in the middle unless they take action to change the paradigm. This report outlines some of these challenges and provides employers with important recommendations.

In addition, MBGH created an online employer toolkit as part of its *National Employer Initiative on Specialty Drugs* – www.specialtyrxtoolkit.org – to support health benefits professionals in making critical and informed decisions to more effectively manage specialty drug costs. The toolkit offers no cost tools and resources, including those linked to the titles below.

PBM Contract Checklist: Criteria for inclusion in a PBM contract to drive high performance and determine if your vendor is delivering results.

PBM Audit Recommendations: Types of benefit assessments/reviews commonly conducted and what elements should be included in a pharmacy benefit audit.

Checklist for Designing Specialty Drug Benefits: Key elements to address when developing a specialty drug benefit and contracting strategy.

Checklist for Site of Care: Guidance to determine if a site of care strategy is beneficial for your company.

Consumer Education Strategy: Communication strategy for employees/plan members offering tools and resources, along with strategy implementation and measurement recommendations.

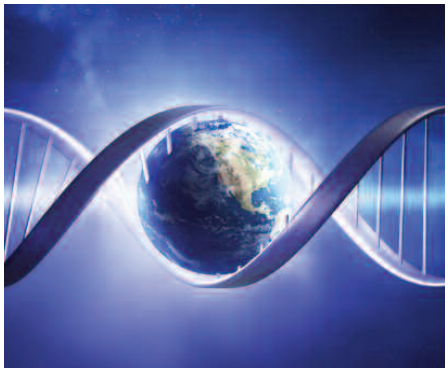
The pharmacy value chain is a complex structure that has many stakeholders, each performing different functions with different motivations. In theory, a drug should function like any other product in a rational consumer purchasing transaction, but it does not. Requirements related to the distribution of products, patient safety and clinical efficacy have pushed the industry to develop a complex chain of middlemen that deliver point solutions and are interdependent on one another, resulting in a longer and more complex channel.

This is further exacerbated by current trends in the U.S. market, an aging population, continued rise of chronic disease, and leading edge scientific discoveries that drive manufacturers to accelerate the commercialization of innovative drugs. Many of the drugs in the current FDA approval pipeline are specialty or biologic drugs for rare diseases that usually come with a higher price tag. These new drugs will raise utilization and costs. In order to control the costs, employers often implement additional limits and administrative requirements, resulting in an increasingly complex benefit scheme.

Market driven changes for some players in the value chain

As costs continue to rise, players in the value chain respond by looking for ways to rationalize, cut operating expenses and increase scale to protect their market position and respond to employer demands for lower costs. Additionally, aggressive merger and acquisition activity has resulted in mega-sized PBMs, wholesalers, pharmacies and pharmaceutical manufacturers. Each player is looking for a way to maintain their negotiating power by leveraging scale and interloping into territories they see as ripe for take-over or disruption. Here is what some of them have experienced:

- Pharmacies – Declining payer reimbursements, PBM strength and mail order mandates were pressuring profits so increasing scale was the one way they could rebalance their negotiating leverage. The result is giant retail pharmacy chains that manage tens of thousands of stores across the country. As regulations increased accountability for pharmacies around managing patient safety and social responsibility, provider relationships became a priority and resulted in interesting alliances and partnerships with hospitals, further extending scale.
- Pharmaceutical manufacturers – The rising cost of discovery and liability settlements put pressure on profits and drove even more consolidation to capture a broader spectrum of therapy areas and the ability to offer a diverse portfolio of products to the market.
- PBMs – Significant growth in new cures and specialty drugs was driving utilization of more expensive therapies while reducing a PBMs ability to restrict access so some demanded more list price discounts and rebates from manufacturers.



"The majority of employers are still using HR specialists to do negotiations and manage health care plans. Formularies are mostly based off of cost savings not clinical outcomes and most employers don't know how to ask the PBM the right questions. Contracts need to be reworded. What does it really say? How is it helping my business/ member? Employers should not engage in contracts they do not understand."

The role of PBMs as middlemen

The intermediaries in the value chain that profit the most from these hidden costs are referred to as "middlemen." In addition to PBMs, wholesalers and distributors are also middlemen. They purchase, inventory and sell drug products to independent and chain drugstores, supermarkets, mass merchants, mail-order pharmacies, hospitals and physician offices. This report will focus on PBMs that have a direct relationship to the employer, as the plan sponsor.

Some PBMs have evolved into giant organizations that are sophisticated, organized, well-represented by industry groups and frequently lobby Washington to protect their position. Shareholders have come to expect high single and double-digit profits from them. PBMs can influence a significant portion of the cost of drugs. Lack of price transparency for employers in many PBM contracts has led many stakeholders to question how they function, what deals they cut, how they generate revenue and what specific services they perform.

PBM profits can be impacted if the price of a drug is not high enough because some of their revenue comes from retaining a percentage of the drug price or through a discount or rebate. Employers still believe that their PBM is managing all the costs in the value chain, yet there are significant issues with the current economic model that result in higher costs, without equivalent value for employers.

"Manufacturers can tell you what they charge the wholesaler but they can't talk about rebates with the PBM because of required confidentiality clauses between the two."

"When you pay a PBM a PMPM fee, any revenue or rebate derived by adjudicating your formulary should get passed back to you. PBMs have lots of ways to hide revenue streams so it doesn't always happen. Transparency standards have been in place for a long time but you still need to negotiate with suppliers."

"As an employer, we learned that we are only getting 70% of our rebate dollars. We need to review our PBM contract language and if necessary, change it to demand more rebates get passed through."

"Our "suppliers" don't share contracts or disclose fees. Employers are starting to notice and wondering why they are paying so much. We need to ask intermediaries what they are paying each other and how they spent the money."

PBMs began as the broker and claims payer in the middle, negotiating the best price and service on the employer's behalf. Many became pharmacies by offering mail order services and some developed relationships with retail pharmacy chains. This created a channel conflict – with some PBMs pushing patients to preferred networks, formularies and their own mandatory mail order programs, which drove their profit.

There can be large variances in price when you pay cash for a drug versus using your insurance. When pharmacies, manufacturers and PBMs consolidate they have an enormous amount of buying power and the ability to control price, which can increase significantly from the point when the manufacturer issues the wholesale price to when the drug gets into the patients' hands. Some estimates indicate that almost 20% of pharmacy products in the U.S. are paid for in cash, at a much lower price than what the plan would pay. This has resulted in a growing number of class action lawsuits going after the pharmacy when in reality, many PBM contracts don't allow pharmacies to disclose to the patient that cash is an option - see "Clawing back the copay."

Ways that PBMs generate revenue

1. Retaining rebates – Manufacturers pay a PBM rebates based on the number of drugs sold as well as offering discounts to the PBM for favorable placement on the formulary. A PBM may select or exclude drugs from their formulary based on the manufacturer's discounts and rebates. Some employers require 100% of those rebates to be passed back to them so they can benefit their plan beneficiaries. However, many employers do not know they can require a pass through and in many contracts, the PBM retains a portion of the rebate to "pay for administrative expenses."
2. Keeping the "spread" – In some cases, a PBM will charge the plan sponsor more than they pay the pharmacy to fill a prescription. Because of the opaque nature of many PBM contracts, the plan sponsor is not aware of this and the PBM keeps the difference – or what is called the "spread" – a fee that is on top of other fees in the PBM contract.
3. Keeping drug distribution in house – A PBM may contract with an employer to mandate use of their mail order pharmacy (versus allow the patient to go outside the network) to keep all the revenue in house. Some PBMs also mandate use of certain generics based on the value of the spread price or permit some brand-name drugs back on formulary because there is a higher rebate.
4. Clawing back the copay – When the cost of a drug is lower than the patient copay, the pharmacy must sell the drug at the contracted rate and some PBM claw back the excess copay (but prohibits the pharmacy from telling the patient or discussing cash as an option). Pharmacies who share the cash option with the patient risk being excluded from the PBM network per their contract terms.

"Today, employers are not allied and have no common agenda (to drive change). The people you're buying benefits from know it. You have to stand up and ask (your vendors) for accountability."

"We don't talk to employers about the concept of fiduciary responsibility; in this health care environment, employers will have to make ethical decisions about which drugs to cover that will require making difficult choices."

"As a fiduciary, an employer is responsible for reviewing the quality of its vendor and its products; they need to gather information, compare data points among vendors, document the process and why they made the decision."

"Employers haven't felt there is a problem (with pharmacy benefits) and have been told by consultants and partners that everything is under control and they are getting the best deal possible. We want to trust our partners, but don't know what questions to ask or what to include in the RFP. Employers need help!"

5. Using direct and indirect remuneration (DIR) claw backs – DIR fees were originally intended to be payments or other reimbursement received by a PBM from a variety of sources that lowered the ultimate "true cost" of the medication, such as manufacturer rebates. DIR fees are being used by some PBMs as "backdoor" fees, chargebacks or other recoupments imposed by PBMs on pharmacy providers after a drug claim is submitted, adjudicated and even paid out to a pharmacy. The PBM claws back a "DIR fee" from the pharmacy, cutting the pharmacy's gross profit significantly.

6. Locking out new drugs – PBMs often refuse to adopt newly released drugs while they are negotiating with the manufacturers on pricing and the rebates. Employers are beginning to exclude new drug lockouts from their PBM contracts recognizing they may initially pay more than the final negotiated price, but they believe they are designing benefits to protect their members from receiving less than optimal care. Manufacturers claim PBMs often do this to lock out competition or to demand greater rebates for market access.

7. Requiring price protection rebates from the manufacturer – On top of the traditional drug rebate, many PBM contracts with manufacturers may require that if a drug's list price increases by more than "x" percentage, the manufacturer must provide a price protection rebate reimbursing the PBM for all increases above the stated amount. This can significantly add to the revenue a PBM receives, particularly if employers are not sharing in the price protection rebate. In certain drug categories, the price protection can exceed the value of traditional rebates.

"Include questions in your RFP that ask intermediaries what they have been paid by partners in the supply chain (and indicate they will be audited – you have a fiduciary duty)."

Employers' call to action

With all the mergers, acquisitions and changes that have taken place in the pharmacy benefit marketplace over the past 5-7 years, how have employers fared? One could argue that the consolidation has created more consistent, relatively efficient pharmacy benefit models but it has not resulted in lower costs.

In fact, PBM economic models create incentives to drive the price up, and this consolidated power has resulted in employers quietly losing a lot of leverage because they are a highly fragmented buyer. In addition, employers cannot see the economic models between middlemen in the value chain because they are not party to these contracts. Each contract in the value chain contains a confidentiality or non-disclosure clause that precludes transparency. It may seem like pennies on the dollar but when you add up all the pennies, you realize there are a lot of dollars to be made in the middlemen space.

"Don't sign a contract until you know where every single penny is going."

What can employers do?

To start, they need to think differently about how to manage the pharmacy benefit spend, including understanding and doing something about the excess costs caused by middlemen. Ethical and philosophical decisions will arise over what a drug is worth and their ability to pay, so it's critical to make sure dollars are used efficiently.

Players in the value chain are preparing for this and many PBMs will find ways to preserve the revenue they have now. Pressure to increase prices will not change as publicly traded companies must deliver profits to shareholders.

Employer mobilization

In 2015, private health insurance coverage continued to be more prevalent than public coverage, at 67.2 percent and 37.1 percent, respectively. Employer-based insurance covered 55.7 percent of the population. Because the private sector covers more people than Medicare and Medicaid combined, employers could have a great deal of power over health care system reforms, but they need to use their market predominance to change the practices of the middlemen.

Today's pharmacy benefits environment is ripe for transformation. Employers are getting close to the tipping point and although it may take some time to experience real change, it will be worth the effort. There are many forward thinking employers who are already leading the charge with others ready to follow. These companies are:

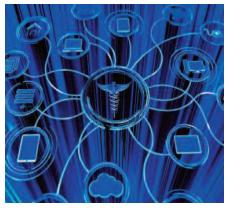
- Holding the supply chain and PBMs accountable by demanding more efficiency and transparency and less redundancy in their contracts.
- Not being complacent about the mandates some PBMs require and making sure their RFPs ask the right questions to protect their interests and the interests of their employees and beneficiaries.
- Part of a united voice that uses their collective experiences and expertise to support employers through local and regional coalitions.

Although employers may have to drag the rest of the system along with them, they need to ask for and then demand what they want – because it's the right thing to do – for our companies and especially for our employees and their family members.

Employer strategies

Use these recommended strategies to help guide your efforts to more effectively manage pharmacy benefits and specialty drug costs.

- Utilize a transparent/pass through PBM or Pharmacy Benefit Administrator (PBA). Although these models are often viewed as separate, they are similar. Different from a full-service PBM, they all remove the spread between the amount paid by the plan sponsor for drugs and the amount paid to the pharmacy. Contracts disclose all financial flows, including PBM revenue streams (e.g. margin pricing, rebates, formulary management fees, data sales). All pharmacy discounts, rebates, pharmacy spread and retail and mail-order discounts are passed onto the plan sponsor so true costs (not just price) are known. Contracts for transparent and pass through models have one source of revenue – either a flat administrative fee for per member/per month (PMPM) or per employee/per month (PEPM), or per claim. There may be other fees for additional services but they will be outlined in the contract. Unlike the PBM model, a PBA is paid on a fee-for-claim adjudication, and fee-for-service for other services (e.g. formulary and MAC lists which may be purchased separately or managed internally by the purchaser).
- Offer a value-based design such as those with no drug formulary. Cost sharing for this model is based on the value of the drug to the patient and the employer. For example: 1) Lifestyle enhancing drugs (e.g. diet aids, cosmetic, ED) are not covered; 2) Convenience drugs (e.g. acne, HRT, non-sedating



"Don't accept the status quo. There is a lack of willingness to change and employers need disruption and transformation. The easiest way to do this is through pharmacy benefits. If one PBM doesn't want to play, there are others waiting."

A properly designed, full pass through, transparent PBM/PBA is clean, audit-friendly and the best option for legal compliance, but most PBMs don't want to sell you a transparent contract. Traditional contracts are much more profitable.

antihistamines) are split 50/50; and, 3) Drugs for chronic diseases and lifesaving drugs have the lowest cost share or no cost to the patient. See "An Employer Journey" at www.specialtyrxtoolkit.org.

- Require price protection rebates currently collected by the PBM from the manufacturer are disclosed and that employers receive 100% of these earned rebates.
- Use an independent Pharmacy & Therapeutics (P&T) committee to do an inclusive analysis based on formulary, quality and cost. Many PBM formularies are constructed with a list of drugs that provide them with the greatest discounts or rebates to ensure PBM revenue growth. The retained profits of PBMs make up a significant portion of drug costs.
- Exercise full auditing rights in PBM contracts. Most of these contracts do not have provisions allowing the employer to audit the operational and financial performance of the PBM. As a result, it is important to use full-audit authority to review all PBM practices, including the handoff between supply chain partners and how they get paid between contracts (what employers can't see now).
- Require PBMs to be at risk. Use performance-based contracting with penalties for not meeting goals and to incentivize for improved outcomes for drugs and related treatments.
- Require PBM contracts exclude use of copay claw backs at the pharmacy, which impact the legally required pharmaceutical care that benefits the patient and employer, as plan sponsor.
- Negotiate directly with retail pharmacy networks for dispensing and patient care services. For larger employers, this approach could be extended to the point where they become their own prescription coordinators.
- Contract directly with manufacturers for drugs on formulary that don't require special handling or are most commonly prescribed. Offer solutions that help employers know the price they are paying is consistent with the price charged by the manufacturer.

The future of pharmacy benefits

There are economic and clinical needs to move beyond traditional PBM management tactics to more effective administrative options that include forward-looking solutions to address today's underlying issues. Manufacturers are starting to listen with a few bringing new products to the market at net cost, and/or lower cost than existing drugs in the same category on the market. MBGH and the authors and contributors of this report believe a new world of pharmacy benefits should include the following elements:

- Drugs are net cost based off list price at the time of dispensing with no rebates or discounts hidden from the purchaser or patient.
- Drug costs and clinical outcomes are balanced to maximize outcomes for total cost of care savings.
- Formularies are based on clinical efficacy, not rebates, discounts, exclusive contracts or narrow networks.

"We need a strategic thought leadership platform based on the net cost plus model that includes collaborative partners who have had success and are the right partners."

- Dispensing, claims processing and basic required drug utilization review services are included in the claims administrative fees.
- Advanced clinical support and case management program fees are separate from drug dispensing fees.
- Smart RFP and plan designs address transparency issues and are simplified for minimal customization with a focus on member outcomes and plan performance.
- Mail order is not mandatory through PBM owned pharmacies.
- Real-time claims adjudication is independent from other services.
- Appropriate alternative drugs are used versus mandatory exclusion lists.
- Manufacturer contracts are at shared risk for product related outcomes (TBD based on drug category or condition) using meaningful metrics.

For employers as plan sponsors, doing nothing is no longer an option.

The information provided in this paper is based on the author's and contributors' experiences working in the health benefits and health care industry. For more information on any aspect of this paper, please contact info@mbgh.org.

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About the Midwest Business Group on Health

Midwest Business Group on Health is one of the nation's leading non-profit employer coalitions of 130 mid, large and jumbo self-funded public and private employers. Members consist of leading health benefit professionals, with activities focused on education, research, benchmarking and community-based initiatives that increase the value of health benefits and health care services. Members represent over 4 million lives and annually spend over $4 billion on health care. MBGH is a founding member of the National Alliance of Healthcare Purchaser Coalitions (formerly NBCH).
www.mbgh.org

National Employer Initiative on Specialty Drugs
Employer Focused, Employer Driven
MBGH Midwest Business Group on Health

In 2010, MBGH embarked on a multi-year, employer-led project to address their concerns about the rising costs of biologic and specialty drugs. Project activities offer all employers access to knowledge, benchmarking, best practices and tools and resources at no cost through an online employer toolkit – www.specialtyrxtoolkit.org. The toolkit offers guidance to support employer plan performance and cost management efforts, ways to optimize specialty drug use in the medical and pharmacy benefit, make informed decisions on benefit coverage approaches and address PBM transparency issues.