We thank you for the opportunity to testify regarding whether the Advisory Council should ask the Department of Labor to consider imposing mandatory disclosure requirements on pharmacy benefit managers ("PBMs") pursuant to section 408(b)(2) of the Employee Retirement Income Security Act of 1974, as amended ("ERISA"). As the Advisory Council considers this question, the HR Policy Association ("HRPA") and the HRPA Pharmaceutical Coalition ("Coalition") believe we can best assist the Advisory Council by outlining the Coalition’s experience helping its members secure cost-effective pharmacy benefits in a transparent manner and discussing the issues that we have been wrestling with since 2004 when our Pharmaceutical Coalition was formed. At this time, we do not have a specific recommendation or recommendations to make regarding mandatory disclosure requirements under ERISA. At the same time, we want the Council to understand that the cost of pharmaceuticals now occupies a very large percentage of the overall health care spend for large employers, that large employers have become very frustrated by the lack of transparency in the pharmaceutical procurement process, and that as the delivery of health care moves rapidly to high-deductible Consumer Directed Healthcare Programs, there will be increased pressure by large employers as well as their employees and dependents to develop far more transparent systems around pharmaceutical purchasing.

**HR PharmaDirect and its History**

The HR Policy Association has approximately 360 members, which represent many of the Fortune 500 companies. The HR Policy Association's Pharmaceutical Coalition was initially formed in 2004 by 56 Association members against a backdrop of rapidly rising drug prices and confusing market conditions, a situation we believe still pervades the marketplace today despite ten years of efforts by the Coalition to bring more transparency to the procurement process.
Employers contract with PBMs and health plans that offer integrated PBM functions to procure a variety of important services, including administering prescription benefit plans, processing and paying claims of plan participants, and managing both mail order and retail drug distribution channels. However, complex financial arrangements between various stakeholders in the pharmaceutical supply chain has added significant complexity to ascertaining the true cost of the prescription drugs purchased on behalf of HRPA member’s employees.

To address these issues, the Coalition has pursued a variety of initiatives since 2004, all of which have ultimately led to the formation of HRPA/PharmaDirect. The Coalition's pharmaceutical initiative represents an innovative approach intended to overcome a number of issues HRPA members have encountered when contracting with the PBM industry. HRPA/PharmaDirect includes the following features:

- **Clear, Pass-Through Pricing**— A transparent contract with a PBM that can be utilized by any Association member that clearly delineates how the PBM is compensated and greatly diminishes opportunities for revenue from mark-ups or keeping “spread” between what they charge the employer and what they reimburse the retail pharmacies. It also requires the Coalition’s PBM to give the employers 100% of all revenue sources coming from drug manufacturers such as rebates, purchasing discounts, sale of data, price protections, manufacturer administrative fees etc.;

- **All-Inclusive Pricing**— Comprehensive PBM services including cost control and clinical programs, utilization management initiatives, step therapy programs, case management, disease management and clinical programs included in a single administrative fee; and

- **Deeper Discounts Through Cost Plus pricing in a Preferred Retail Network**— An exclusive preferred retail network option, whose pharmacies directly contract with the employer. It is available to HRPA members who utilize PharmaDirect and offers deeper discounts and invoice-cost plus pricing which maintains a direct link between a pharmacy’s purchasing cost and sale price. In a cost plus pricing model, if the pharmacy’s cost goes down (e.g., when multiple generics compete) the employer’s cost also goes down. Finally a preferred retail network also provides pricing neutrality between retail and mail delivery channels and offers more options to the members.
History of the HRPA Pharmaceutical Coalition

In 2004, HR Policy Association’s Board of Directors authorized the creation of the HR Policy Association Pharmaceutical Coalition. Even though Coalition members represented some of the largest pharmacy benefit purchasers in the United States, HRPA members found themselves struggling to deal with rapidly increasing drug costs. Coalition members perceived that they were at a significant bargaining disadvantage to PBMs in an environment of rapidly changing contracting and financial relationships between PBMs and their suppliers, manufacturers, and drug wholesalers, incidentally many of which are members of the Association. Certainly organizations that lack adequate commercial bargaining leverage of large employers (i.e., small and mid-size companies, as well as multiemployer welfare funds) most likely face even greater PBM contracting challenges. This fact has been borne out by the experience of Coalition members who, after having acquired smaller organizations, achieved significant cost savings incorporating the smaller organization’s prescription drug program into the larger company’s benefit structure.

HRPA’s Board of Directors felt that it could help address this problem by asking PBMs to accept contract terms that required enhanced price disclosure and auditing rights for Coalition members. These contractual requirements became the centerpiece of the Coalition’s PBM pricing transparency initiative.

Price Transparency and Enhanced Audit Rights - The Early Days

Without question, the PBM industry has changed rapidly over the last 10 or more years. We will not go into detail regarding the services that PBMs offer, but suffice it to say that PBMs can and do provide important services that help workers maintain their health and productivity. But as service providers (in the generic – not ERISA – sense of the word), PBMs need to be accountable to their customer base (i.e., employers) from a quality, pricing and timeliness standpoint.

Most Coalition members engage the services of benefit consultants to help them understand their options in the PBM marketplace, but all too often those same consultants have preferred relationships with specific PBMs, which significantly calls into question their independence.
HRPA Coalition members are constantly reminded to consider these relationships when contracting in the PBM space.

In 2004, the Coalition approached a number of major PBMs asking them to agree to a ‘certification’ process wherein they would agree to insert specific contract terms that provided greater price transparency and enhanced audit rights for Coalition members. Highlights of the transparency standards are below:

- Client receives full pass-through of retail network pricing
- Acquisition cost basis (Average Acquisition Ingredient Cost or Wholesale Acquisition Cost) for mail order pricing
- Full pass-through of ALL categories of pharma revenue
- Specialty drugs handled with same transparent philosophy
- PBMs were required to offer tools to engage consumers at the point of sale
- PBMs were required to notify and provide client the value of improved rate schedules with pharmacies
- PBMs were required to provide Coalition members with a quarterly measure of financial guarantees on quarterly basis

Over time, the Coalition increased the contractual stipulations required for PBM certification. To help defray the Coalition’s cost to develop, maintain and revise the contractual requirements, as well as to manage the certification process, the Coalition charged PBMs an annual fee to participate in the certification process.

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1 Average Acquisition Ingredient Cost (more commonly the Average Acquisition Cost, or AAC): AAIC rate schedules are based on the premise that chemically equivalent drug products in the same strength and dosage should be reimbursed similarly. The AAIC is the cost at which pharmacies within a state purchase a drug, as defined, calculated and reported by the relevant state’s Medicaid program. Since all states do not report an AAIC, AAICs price schedules include only those states where it is available. See more at: http://www.fdbhealth.com/policies/drug-pricing-policy/#sthash.oE9Wbvf4.dpuf
Initially, PBM industry’s receptivity to the Coalition’s certification process was extremely cool with only 10 PBMs out of the 30 PBMs approached actually agreeing to the certification standards. When HRPA Coalition members went out to bid, they were free to use the PBM of their choice, but a number of Coalition members choose to exclude non-certified PBMs from their bidding process or required non-certified PBMs to become certified at the next opportunity in order to submit a bid.

It is HR Policy Association’s opinion that Pharmaceutical Coalition certification process drove the PBM marketplace (at least as to large employers). Over time, the number of PBMs increased to 15 at the high water mark. But eventually, the Coalition believed that the Coalition certification process had run its course and a new, more ground-breaking approach was needed. This lead to the development of the PharmaDirect program.

\[\text{Wholesale Acquisition Cost: Wholesale Acquisition Cost (WAC): represents the manufacturers’ (for this purpose, the term “manufacturer” includes manufacturers, repackagers, private labelers and other suppliers) published catalog or list price for a drug product to wholesalers as reported by the manufacturer. WAC does not represent actual transaction prices and does not include prompt pay or other discounts, rebates or reductions in price. Publishers of WAC price schedules typically do not do any independent investigation or analysis of the prices reported to compile the WAC price schedules, but rely solely on what manufacturers to reports. See more at: http://www.fdbhealth.com/policies/drug-pricing-policy/#sthash.oE9Wbvf4.dpuf}\]
**PharmaDirect - It’s Genesis and Purpose**

The power inherent in HRPA membership is the Association’s ability to identify and then operationalize across the entire HRPA membership the cutting-edge ideas of HRPA members. The creation of PharmaDirect is a clear example.

As the saying goes: “Necessity is the mother of invention.” When faced with difficult business conditions or the struggle to simply survive, businesses have the capacity to think outside the box. Leveraging off of the successful experience of a large Midwest-based HRPA member, the Coalition started the PharmaDirect program.

While the PBM industry started as a means to assist payers in getting a handle on their drug expenses by setting up contracted retail networks and electronically processing claims to establish some consistency in drug pricing across that network, the industry quickly evolved to provide other services like formularies and rebate contracting which became a major revenue source for PBMs. PBMs offered employers the ability to aggregate purchases of brand-name drugs and provide a better financial deal than an employer could get on its own. This created a revenue stream of rebates and other manufacturer dollars for both the employer and the PBM. In the prescription drug market, it is no secret that a number of name-brand drugs were about to lose their patent protection. PBMs then started to add ancillary services (e.g., step-therapy, prior authorization programs, quantity limits, claims appeals, advanced retail network management) to their panel of services and in most cases, charged additional fees for those services.

With the loss of patent protection for many highly-used brand drugs, the PBMs have since turned their attention to the generic drug market.

The principle of HRPA’s PharmaDirect is to use PBMs for the skills they are uniquely qualified to provide, i.e., processing drug claims. Currently, large PBMs provide a completely bundled service and this is what employers buy. PBMs pay drug claims. PBMs run highly efficient mail-order facilities. They manage extensive retail pharmacy chains arrangements. They provide specialty pharmacy services and supply important clinical expertise. The PharmaDirect program essentially allows for the disaggregation of these services making it possible for large employers to select best-in-class providers for these key services, allowing them to take advantage of value in the market that is unavailable when these services are bundled.
Again, contracting in this manner reduces the PBM’s role to simply processing pharmacy claims plus those areas where they exhibit superior value to other market options (for example, they could additionally be the formulary, mail-order and specialty provider if there is a value advantage versus other providers of those services)). Since the PBM is not holding the contracts with all the retail stores and may not be the provider of other services like mail-order, the employer can have better financial and performance control over their pharmacy benefit offering. To be sure, the selected PBM is often called upon to provide many additional services (e.g., mail order fulfillment, specialty pharmacy, care management, etc.), but the PBM’s revenue is limited mainly to the administrative fee that it charges the employer. The employer collects 100% of all rebates, discounts, and other sources of manufacturer revenue etc.

In a very competitive retail market, significant savings are available to employers and employees through retail pharmacy vendors, who are looking to generate greater foot traffic. In general, employees benefit through lower prescription drug costs purchased from participating retailers whom they would visit anyway.

While this approach has yielded significant savings (i.e., 10% to 15% reductions), even HRPA members have been slow to adopt this ground-breaking approach. We believe the reason is simple. Employee benefit consultants, as sophisticated as they may be, tend to be aligned with specific PBMs. While these same benefit consulting firms say they do not derive any revenue for their PBM relationships, the consulting firms have an interest in pushing more business to their PBM partner stating that each piece of additional business gets everyone a better price. In reality, the PBM uses a number of different price schedules for the consultant’s client base. While PharmaDirect uses a PBM partner, this PBM partner has agreed to base its compensation on transparent transaction fees and allows for maximum flexibility in the selection of vendor partners across the pharmacy benefit offering, thereby providing critical additional savings to PharmaDirect members using this approach. 
As I mentioned, HRPA believes that PBMs provide an extremely valuable service to their clients. Properly administered drug therapies purchased through PBMs have saved employers significant healthcare dollars and have enabled employees to maintain their health and avoid more costly medical care. In providing these services, PBMs are clearly entitled to earn a profit. There is significant competition within the PBM industry despite the consolidation and that competition is likely to intensify.

Having said that, it is HRPA’s opinion that the PBM industry is characterized by a general lack of transparency. While employers of all sizes are willing to pay a reasonable fee for PBM services, the efforts of HRPA members have centered on understanding the various financial arrangements between the PBM, the pharmacies, the manufacturers and/or the drug wholesalers. The frustration that HRPA members have experienced centers on believing that they understand how much they are paying to provide a drug benefit to its employees only to find out that the PBM is receiving additional revenue from multiple sources that may or may not have their interests aligned with the employer.

One party important to the PBM supply chain is drug wholesalers. Drug wholesalers take delivery of product from manufacturers and then distribute them throughout the delivery channel including to the PBMs mailorder and specialty drug facilities. Essentially, drug wholesalers act as an inventory buffer for the PBM’s mail-order facilities. To run efficiently, the PBMs do not stock all drugs that could possibly be dispensed. PBMs will use a drug wholesaler to fill-in inventory on an as-needed basis. As a result of their arrangements with wholesalers, PBM owned mail order and specialty pharmacies are often entitled to certain contractual benefits with the wholesaler and/or manufacturers such as volume purchase discounts or early payment discounts just like other retail establishments, all of which ultimately lower the cost of a drug product, but may or may not be shared with the employer payer.
Retailers are another important player in the PBM’s supply chain. PBMs stand-up contractual relationships with a wide variety of retail providers. Some retailers have stood-up PBM services (mail-order services) in order to enhance their business offering and compete with traditional PBMs. Retailers have an additional incentive not available to traditional PBMs - increasing foot traffic through their retail establishments. There is significant complexity in the PBMs contractual relationships with retailers and payment terms vary widely across the spectrum of payers.

**The PBM Industry - Financial Incentives**

Drug manufacturers make significant financial investments in developing a drug and receiving Federal Drug Administration (FDA) approval often spending significant dollars that are never recovered - but once a drug is developed and licensed the drug’s manufacturer has a strong financial incentive to see the drug actually sold. To that end the cost to actually manufacture the approved drug is often miniscule to the drug’s sales price. This leaves a significant financial margin to share with the drug’s supply chain in order to encourage usage. The drug manufacturer can use the significant gross profit margin available to it to financially incentivize the drug supply chain (from wholesaler to PBM to consumer (via television advertising) to purchase the approved drug. The primary financial incentive used is rebates.

Drug manufacturers will pay rebates to a PBM provided the PBM meets certain tightly managed requirements:

- First, the PBM must submit a listing of all PAID CLAIMS to the drug manufacturer showing the total quantity of the drug actually sold;

- Second, the PBM must provide the drug’s manufacturer with the PBM’s formulary showing that the specific drug is on the formulary for the intended therapeutic class; and

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1 A formulary is a listing of preferred drugs (brand and generic) available to patients for each therapeutic class. For example, if a patient needs a drug to control his or her level of cholesterol, the dispensed brand-name drug used will be pre-designated as Crestor. The PBM could have picked any one of a number of statins (which is what Crestor is), but since the PBM picked Crestor, Crestor’s drug manufacturer will give the PBM a financial incentive (i.e., rebate) for actually selling Crestor as the PBM’s formulary statin.
Third, the PBM will be required to submit other documentation demonstrating that the PBM does not have any protocols in place that would act to 'disadvantage' the drug's sale to patients (e.g., application of a step-therapy\textsuperscript{2}).

Drug manufacturers will not pay the PBM rebate dollars unless the drug manufacturer can verify that the PBM dispensed the drug in question. Drug manufacturers don’t normally pay rebates to retail pharmacy vendors because the drug manufacturers do not perceive that retail chains can effectively steer patients to the drug in question. The same is true for drug wholesalers. Rebates tend to only be available to PBM’s because only PBM’s can demonstrate some ability to steer patient utilization. For this reason, some retailers have set-up PBM services in order to capture rebate dollars such as preferred formularies and clinical programs that drive specific brands.

\textsuperscript{2} A step-therapy is a utilization management protocol. Some step-therapies are clinically-based for patient safety (i.e., requiring a patient to use a less potent or less dangerous drug before trying a higher dosage or more inherently dangerous drug). Other step-therapies are financially-based (i.e., limits patient access to certain more expensive medications before they have tried equally effective lower cost alternatives).
PBM Contracting Challenges

When it comes to contracting, even the most sophisticated employer stands at a disadvantage to PBMs because only the PBM understands the whole range of the financial opportunities available in the supply chain. The short answer for employers in this situation is to re-compete their PBM services frequently, but even with the smoothest of implementations, there is significant employee disruption in moving from one PBM to another. This fact gives employers pause when they consider changing PBMs.

As a general rule, it has been the experience of HRPA members that PBMs are extremely tough negotiators. PBM contracts tend to be one-sided and include sharp limitations on client access to data (even claims data that documents what the PBM is asking the employer to reimburse); unclear definitions (or silence) for important terms; sharp limits on audit rights and stringent approval process for audit firms (including excluding some audit firms from the ability to act on behalf of a client); a lack of clarity in the PBM’s drug pricing algorithm; a lack of transparency in the PBM’s retail network contracts; a lack of disclosure as to the financial incentives the PBM may receive from manufacturers and/or wholesalers; pricing disparities between retail dispensed drugs versus the cost of the same drug dispensed by the PBM’s mail order facility; definitional issues between generic versus brand drugs; and a habit of directing patients to higher cost therapies just prior to the therapy losing patent protection. While there are additional areas that an employer needs to concern itself with in PBM contracting, the above list gives a flavor for the sophistication needed when contracting with and effectively monitoring a PBM.

Below are some examples of challenges that employers face in PBM contracting.

- **Package Size Pricing:** Typically, a PBM promises an employer a certain percentage discount to the Average Wholesale Price (AWP), e.g., 16% off AWP for brand-named drugs. What is not readily apparent is that the AWP price is based heavily on the package size. For example, the employer’s price guarantee may be measured as some percentage discount off of AWP for a package size of 100 (or in some cases, less) pills, whereas the PBM might actually be purchasing the drug in lots of 50,000 plus at a substantially lower price. Structuring the PBM contract in this manner (which is often
silent) allows the PBM to say it saved the employer XX% off of AWP, when in fact the actually drug acquisition cost was significantly less.

- **Pass-through Pricing and Wholesalers:** Some employers realize that there are significant financial incentives for PBMs and have switched to ‘pass-through’ pricing models. In doing so, the employer (and their consultant) wants to capture the financial incentives previously captured by the PBM. What employers need to be careful about is that the PBM doesn’t simply assign less effective contract pricing to the employer’s drug purchases. Yes, the employer is paying the exact cost the PBM paid the pharmacy, but the price the PBM paid could be significantly higher than what the PBM would have paid had it exercised greater diligence. Often, this is driven by the fact that the PBM has a complex financial arrangement with the retail pharmacies. In allowing higher pharmacy reimbursement and drug prices to flow-through to the employer with certain pass-through pricing arrangements, it allows the PBM discount this same retail store much deeper for a separate employer contract. Since the PBM has an aggregate financial obligation to the retailer, reimbursing the retailer more significantly (and passing it through to the employer) in one case allows deeper discounting in another.

- **Retail Network Management:** In addition to mail-order pharmacy services, PBMs contract with broad retail networks. What is not apparent to most employers (or their consultants) is that the PBM will often have multiple contracts (with varying financial arrangements) with the exact same retail pharmacy networks. So employers believing that they have secured a fully-transparent PBM contract may well be subsidizing a separate contract as previously stated. The question then arises as to what would drive a PBM to act in this manner? Again, the reason is that the PBM is trying to manage its aggregate contractual relationship with the retailer to make sure that PBM is delivering on its financial commitments to the retail chain. In doing this, some employers win, while others lose. Who wins and who loses is typically based on the bargaining power with small and medium size companies (and multiemployer health & welfare funds) paying substantially more. All PBM clients do not get the same economic advantage with bigger clients getting bigger (better) deals and smaller clients get smaller (less lucrative) deals – said differently, the size of the relationship does matter.
PBM Formulary Management: PBM's have an incentive to tightly manage their formularies. As such, it would not be unusual for a PBM to reshuffle their formulary within a year of an important drug losing its patent protection. The PBM would do this to continue to secure rebate dollars from the manufacturers. For example, within a year of Lipitor losing patent protection, it would not be unheard of for a PBM to change its formulary to remove Lipitor as the designated brand-name drug for that therapeutic class and replace it with Crestor, which was not losing patent protection for some time. By doing so, the PBM can maintain its rebate dollars from Crestor’s manufacturer.

Inability to Access Claims Data: HRPA members who have wanted to bid their PBM contracts have been told by their existing PBM that they will not give the employer their own data - data that is needed to bid PBM services. PBMs have refused to turnover this information citing privacy and contractual constraints. Part of the HRPA transparency standards was that a certified PBM agreed to provide the employer with all necessary data.

Auditor Selection and Approval: PBMs jealously guard their propriety information. PBM contracts often give the PBM the right to veto the employer’s choice of auditor assigned to validate the financial guarantees embedded in a PBM contract. In addition, PBM contracts often limit the length of time the employer has the right to audit (the audit can only look back over the last two years). Part of the HRPA transparency standards was that a certified PBM agreed to use the employer’s auditor of choice.

PBM Pricing Algorithms: PBMs use complex pricing algorithms to derive the employer’s ‘cost’ or to show that the PBM met an agreed-to price guarantees. For example, the PBM may guarantee that the employer will pay no more than 16% off of Average Wholesale Price (AWP). The percentage savings (16%) is determined by dividing the total ingredient costs for all drugs purchased by the total AWP for all drugs purchased. A achievement of the savings target is determined on an aggregate basis. If the savings the PBM promised are not achieved, the PBM will pay the employer the difference. However, in determining whether the percentage off of AWP was actually achieved, some PBMs will exclude certain claim types from the calculation that would hurt the PBMs performance and include others that alter the performance calculation. In
addition, some PBMs may use an artificially low ingredient cost that allows them to achieve the aggregate savings guarantee. For example, in cases where the employee pays the entire cost of the drug (because the cost of the drug is less than the employee’s copay), the PBM may stick in a minimal cost figure (e.g., $0.05) for the ingredient cost to allow the PBM to book a large discount to the AWP.

• Contractual Over-charging: There have been some instances of PBMs deliberately failing to meet contractually-required price guarantees by over-charging the employer more money throughout the year. When the guarantee calculation is run some time after the close of the year, it turns out that the PBM owes the employer a sizable refund. By over-charging the employer throughout the year and settling up some time after the year has closed, the PBM essentially was able to use used the employer’s money for free. If the frustrated employer decides to go out to bid, the PBM will often simply pocket the money if the PBM loses the business or will hold the employer hostage to the refund during the PBM bidding process.

• Rebates verses Purchase Order Discounts: PBMs are paid rebates because the PBMs run clinical programs that steer employees to certain medications. Given the fact that many employers understand that the PBM is securing rebates, the employers have asked the PBM for ‘transparent’ pricing. So what the industry has moved to in response is to ‘reclassify’ the rebate dollars as “purchase order discounts’ or administrative fees. Since the employer is often only contractually entitled to those things labeled “rebates,” the PBM pockets the purchase order discounts. Thus, while an employer may believe that is has a fully ‘transparent’ PBM deal (receiving 100% of the revenue coming from the manufacturer), what they don’t realize is that some portion of the rebates have been carved-off and paid to the PBM as a purchase order discounts or admin fee etc.
• Definitions - Brand verses Generic: The way a drug is defined (i.e., whether generic vs. brand) drives which aggregate discount the drug contributes to (i.e., the generic discount or the brand discount). PBMs exercise great discretion in determining when a drug has actually moved from ‘brand’ to ‘generic.’ The timing may have a great impact on the pricing guarantees the PBM has contractually obligated itself to supply. For example, even after a drug has generic equivalent available, PBMs may not consider the drug as a generic (and include in the drug in the generic pricing guarantees) until the PBM has determined (in its sole discretion) that there is a sufficient supply in the marketplace, which could be months or years after the drug has gone generic.

• Reimbursements Differences between Retail and Mail-Order: Finally, it is not unusual to find a PBM reimbursing a retail pharmacy network less than the cost the employer is being charged for the same drug through the PBM’s mail order service. This fact was the primary motivation for the creation of the HRPA PharmaDirect program.

Conclusions

HRPA and its members have made a significant effort to understand the PBM industry and add higher levels of transparency and accountability to this important benefit area. Clearly, PBMs provide an important role in helping keep employees healthy and productive, but the industry is beset with a lack of transparency that is difficult to deal with even for the largest employers. Unfortunately, benefit consultants, who are often relied upon to help employers with complex situations, are often aligned with specific PBMs thereby limiting their independence. While HRPA does not have a specific recommendation to make at this time regarding mandatory disclosure requirements, we are very pleased to see that the Council is focusing on this critically important issue, and we would encourage it to continue holding hearings and conducting a review of the pharmaceutical procurement process. As discussed above, HRPA’s experience shows that the PBM supply chain is a constantly changing environment. Employers have a common objective, to remain vigilant to make sure that they are getting the most for the dollars being spent on pharmaceuticals by themselves, their employees and dependents, and their retirees.